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Appendix
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Research Involving Prisoners

The National Commission
for the Protection of
Human Subjects
of Biomedical and
Behavioral Research

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This Appendix contains the papers, reports and certain other materials that were reviewed by the Commission during its deliberations on research involving prisoners.

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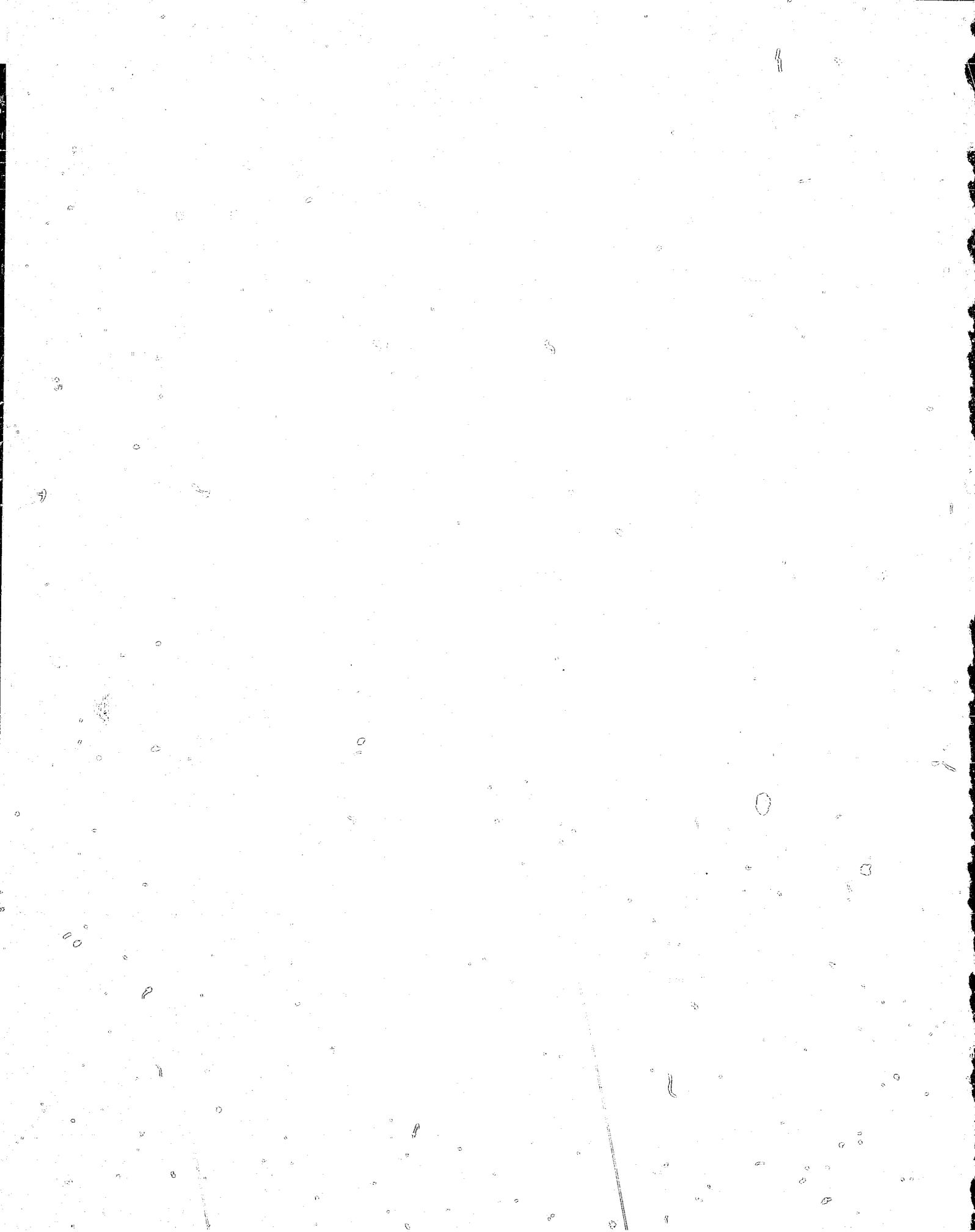
Part I

PAPERS AND REPORTS PREPARED
FOR THE COMMISSION

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PHILOSOPHICAL PERSPECTIVES ON EXPERIMENTATION
WITH PRISONERS

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OUTLINE

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Philosophical perspectives on experimentation with prisoners have implications for policy. The first and longer part of this essay reviews a variety of ethical principles bearing on prisoner experimentation. It concludes that the requirements of informed consent and justice must be met by any policy governing prisoner experimentation. The second part of the essay explores the significance of the ethical principles for various policy options. Considering the demands of the principles and the available empirical data, a moratorium on experimentation with prisoners is recommended.

The review of ethical principles begins with the arguments of those who sanction the use of prisoners and then moves to the arguments of those in opposition. On both sides of the debate the issue of free and informed consent has been a principal focus of attention, and a considerable portion of the essay examines both sides of that issue. But the essay will also reflect the fact that defenders and critics of prisoner experimentation rely on a variety of other principles.

A clarification of terms at the outset may be helpful. Experimentation and research are used synonymously. Prisoner experimentation is equated with experimentation using prisoners, not research about prisoners or prison life. Much of the debate surveyed in this essay refers to non-therapeutic, biomedical experimentation, but since the latter section of the essay, dealing with policy, suggests why the term experimentation should include therapeutic and behavioral experimentation as well, precise definition of these terms will await that discussion. As used in this essay, consequentialism decides whether an act, policy or rule is right

by calculating whether it will result in consequences producing a greater balance of good over evil than any available alternative. Non-consequentialism decides whether an act is right by considering factors other than consequences; for example, such features of an act, policy or rule itself, as whether it keeps a promise or is inherently just.

I. Principles

Approval of Experimentation

Social Good

A major justification of the use of prisoners in experimentation is the consequentialist argument that prisoner experimentation contributes to the good of society. It is suggested that prisons and prisoners are part of the society that benefit directly. An inherently closed penal system is improved by having experimenters not employed by the prisons going in and coming out of the institutions. Prisoners themselves gain a wide variety of benefits from participating in experiments: much greater financial rewards than otherwise obtainable in prison, improved physical surroundings, particularly comfort and safety, relief from boredom, and the satisfaction of acting altruistically.

Distinct from benefits to prisoners as a particular class, it is said that society as a whole gains from the increased scientific knowledge obtained in prison experimentation. Mr. Stetler, President of the Pharmaceutical Manufacturer's Association, representing 131 drug companies, whose research develops most of the prescription drugs in the United States, testified regarding the use of prisoners in experimentation before a subcommittee of the U.S. House Judiciary Committee and the National Commission for the Protection of Human Subjects. In a statement given to both groups,

he insisted that prisoners were needed, "given the kinds and amounts of biomedical data required by current standards of research as reflected in FDA new drug regulations. There are few practical alternatives." Prohibitions on the use of prisoners, he said, "may also delay development of new drugs which will benefit all people, including the prisoners themselves."⁶ One arrives at the conclusion that using prisoners in experimentation is right by assuming the importance and value of scientific research for the human community, accepting as fact the necessity of using prisoners to carry on at least certain kinds of scientific research, and following the principle, as consequentialists do, that the right act or policy is one that produces a greater balance of good over evil than any available alternative.

Reparative Justice

Another justification for prisoner experimentation, having nothing to do with informed consent, is the non-consequentialist argument that quite apart from future benefits it is inherently appropriate, as an act of reparation for previous crimes, for prisoners to be used in research. As Hans Jonas puts it, "If we hold to some idea of guilt, and to the supposition that our judicial system is not entirely at fault, they [prison inmates] may be held to stand in a special debt to society, and their offer to serve--from whatever motive--may be accepted with a minimum of qualms as a means of reparation."⁷ Agreement with this position might be inferred from governmental regulations excluding prisoners-of-war and detainees awaiting trial from any participation⁸ in experimentation. Prudential considerations may lead the army to refrain from using prisoners-of-war so that belligerent nations will

similarly exempt U.S. citizens. The DHEW Guidelines raise the question of whether detainees in U.S. jails must be exempt because it is assumed that for an inmate of a correctional institution to participate in experimentation he ought legally to be guilty of a crime.

Informed Consent

While it is true that the principle of free and informed consent has been defended on consequentialist grounds, it is usually invoked as a guide to how human beings in particular medical settings ought to relate to each other, regardless of the good which might result from the relationship.⁹ An eloquent statement of the non-consequentialist bases for informed consent is that of Paul Ramsey.

The principle of informed consent is a statement of the fidelity between the man who performs medical procedures and the man on whom they are performed... the fidelity is the bond between consenting man and consenting man in these procedures. The principle of an informed consent is the cardinal canon of loyalty joining men together in medical practice and investigation. In this requirement faithfulness among men--the faithfulness that is normative for all the covenants or moral bonds of life with life--gains specification for the primary relations peculiar to medical practice.¹⁰

This statement holds that quite apart from their varying merits, capacities or natural circumstances, and the uses to which they can be put, persons ought to respect each other's equal intrinsic dignity by not invading another's body with the other's free and informed consent.¹¹

Such non-consequentialist considerations often lead to discussion of interests, claims, duties and rights, and how they should be protected or recognized. Benjamin Freedman, appealing to the "duty which all of us have, to have respect for persons, to treat a person as such, and not as an object," insists that "there does seem to exist a positive right of informed consent, which exists in both therapeutic and experimental settings."

A person who has the capacity to give consent "has a right as against the world," as well as his physician, says Freedman, "to have it recognized that valid consent has been given."¹³

Mr. Stetler, of the Pharmaceutical Manufacturer's Association, insists that prisoners possess such a right and should not be prevented from exercising it. "If we eliminate the prisoner as someone eligible to take part in these carefully controlled trials, we also remove another right of choice from his or her already restricted life."¹³

It has been pointed out that criminal conviction itself presupposes that the citizen has been assumed to be competent to be held accountable for his acts, indicating that he is presumed to be sufficiently competent to make the choice to volunteer for experimentation unless incarceration itself erodes that competence.¹⁴ Inside prison, prisoners have had certain rights legally recognized, such as the right to sue for freedom of worship and even compensation for injuries sustained in prison jobs.¹⁵ Indeed, the Court of Appeals for the Sixth Circuit in Coffin v. Reichard stated that "a prisoner retains all the rights of an ordinary citizen except those expressly, or by necessary implication, taken away from him by law."¹⁶ According to this line of reasoning, whether or not free-living citizens or prisoners have a right to consent to participation in experimentation, prisoners, who enjoy the rights of an ordinary citizen, must be presumed to have the same capacity or competence to volunteer as do other citizens.

Furthermore, no one expects completely free and totally informed consent. "Sufficiently" or "reasonably" free and "adequately" or "reasonably" informed consent is all that is demanded.¹⁷ Unless prison conditions make it impossible for prisoners to choose to participate in activities lawfully available within the prison that they would involve themselves outside the

prison, prisoners, quite apart from any beneficial consequences, ought to be allowed to volunteer for medical experiments.

At this point an empirical fact is often cited. Prisoners participate in occupations with prisons which put them at some risk for which they receive wages. No one challenges the competence of prisoners to choose to work in these jobs (for example, stamping license plates in prison factories). Why should there be moral outrage at prisoners choosing to participate in experiments that admittedly provide financial inducements, but also may do less physical harm to prisoners?

Disapproval of Experimentation

Informed Consent

Opponents, as well as proponents of experimentation with prisoners, appeal to the principle of informed consent. A fundamental factual assumption of opponents directly contradicts assertions that experimentation is equivalent to other occupations. They believe that experimentation is different in kind from other jobs--inside and outside of prison.

Charles Fried provides several reasons for making such a distinction. Given the importance of this point for those appealing to free and informed consent on each side of the debate, considerable space is devoted to his comments. First, he regards the body as not merely one capability among others possessed by a person; he identifies the body with the person.

Caring for the body,

relates to the maintenance of the integrity, of the coherence of the human person, with specific reference to the physical substrata of that integrity. The human person identifies himself with his body; he knows that he is his body....A person's relationship to his body to his health, is not his relation to his productive goods. Instead it is a person's relation to himself. Although a person may properly be conceived as allocating his life resource to best realize his plan and

projects, underlying that conception is the conception of a person who has projects. The person comes logically and morally before the various ends he pursues. And so the doctor does not just help provide the means to get the person where he is going; he ministers to the person who has those ends. The doctor stands in a special relation to his patient because he ministers to the basic unit which is the person, rather than to the attributes and creations which that person gathers around him in pursuit of his purposes. For the person is his body, and the body's health is the integrity of the person.¹⁸

Secondly, Fried assumes a distinction between activities where "the actor is pursuing some other goal and the impingement on a person's body is an accidental or unavoidable concomitant of that pursuit," from those activities "where, as in medical practice and medical experimentation, that impingement just is the purpose of the conduct."¹⁹

Finally, in discussing experimentation with prisoners directly, he acknowledges that he is "of course, assuming that subjecting oneself to hazardous medical experiments is different from many occupations that may involve similar levels of risk." Incorporating a point made by Hans Jonas concerning the passivity of the experimental subject, he argues that the volunteer risks the integrity of his person. To illustrate his point, he contrasts a mountain climber to an experimental volunteer.

A mountain climber may expose himself to risk, but he does so actively, by exercising his capacities to attain a goal that he can understand and attain. The experimental subject does not hazard his physical capacities by using them. Rather by abstracting his purposes from those in which his body is risked he makes his body into a separate thing which he sells or gives away, so that others may pursue their purposes with it. It is only incidentally that the body so used belongs to a human being who has invested this body with his own personal identity and for whom it is the locus of purposes and integrity.²⁰

As for the sale of blood, he dismisses the comparison since "the infringement is minimal, indeed insignificant." He concludes that "to see the commercial traffic in human experimental subjects as simply another way of earning one's living is an extreme example of pressing certain kinds of economic arguments into areas where they do not belong and past limits of which they do not take account."²¹

One way of pressing the point would be to ask if selling organs would be considered to be a way of earning money comparable to receiving payment for the exercise of one's skills and talents. The National Kidney Foundation reports at least 100 recent calls from people offering their kidneys for sale. One unemployed man advertised in a newspaper that his kidney was for sale for \$5,000.²² Since the issue is put in occupational terms, one could also ask if a woman renting her womb for the purposes of artificial insemination would be engaged in an occupation equivalent to her receiving wages as a housekeeper?

Among those who cite the principle of free and informed consent in support of their opposition to the use of prisoners in experimentation, some argue that prisoners cannot in principle give a sufficiently free consent. It should be made clear that opponents of prisoner experimentation are not denying the prisoner's capacity for altruism. They can agree with sociologists who find some evidence that altruism is a motivation for prisoners' involvement in experimentation and still insist that the expression of that altruism through participation in research is insufficiently voluntary.²³ Also, it is worth noting that in current debates prisoners are seldom, if ever, said to be insufficiently informed. What is at issue is a sufficient degree of voluntariness.²⁴

In settling the suit of Gabe Kaimowitz v. the Mental Health Department of the State of Michigan, the court decided that a "criminal sexual psychopath" confined to a maximum security hospital could not freely consent to an experiment even if it were therapeutic. The court cited the invasive and irreversible nature of psycho-surgical experimentation, but also the powerful effect incarceration has on a person who otherwise has the capacity to give voluntary consent.

Although an involuntarily detained mental patient may have a sufficient I.Q. to intellectually comprehend his circumstances...the very nature of his incarceration diminishes the capacity to consent to psychosurgery...The fact of institutional confinement has special force in undermining the capacity of the mental patient to make a competent decision on this issue, even though he be intellectually competent to do so...Involuntarily confined mental patients live in an inherently coercive institutional environment... They are not able to voluntarily give informed consent because of the inherent inequality in their position.²⁵

The American Civil Liberties Union, National Prison Project makes the same argument regarding non-therapeutic experimentation. Its complaint to the U.S. District Court for the District of Maryland on behalf of seven prisoners involved in viral diarrhea, malaria, shigella and typhoid experiments asks the court to declare that "the use of prisoners in non-therapeutic biomedical experimentation of this type is unconstitutional per se because of the impossibility of truly voluntary consent."²⁶

It is possible for those who oppose the use of prisoners in experimentation to admit that prisoners can consent to many sorts of action while in prison. They can further admit with reference to experimentation specifically that in principle it might theoretically be possible for an inmate in some ideal correctional institution to give a sufficiently free and informed consent. What they do reject is that in fact either the

structure or administration of the penal system in the United States makes possible sufficiently free consent to experimentation.

The impossibility of in fact obtaining a sufficiently free consent within American prisons utilizes analyses of the basic structure of American prisons made by historians and sociologists. Historians, especially David Rothman, with coinciding studies by Gerald Grob and others, show that the coercive structure of the American prison and its powerful impact on the attitudes of prisoners is not accidental. ²⁷ The architecture of the new institutions established by American correctional reformers in Auburn (1819-1823), Sing Sing (1825) and Philadelphia (1829), with their massive gates and thick walls, was designed to isolate the prisoner from his corrupting environment within society. Cutting the prisoner off from evil influences outside the prison and organizing his entire life within, reformers aimed at changing the character of the prisoner. He was forced to acknowledge authority by engaging in forced labor, wearing uniforms and moving in a shuffling parody of a military march. During the 1830's official observers from England, Prussia and France came to New York and Pennsylvania to learn from America's experiment in altering the behavior and personalities of prisoners. One hundred and fifty years of attempting to rehabilitate or alter the consciousness of prisoners is seen to undergird the structure of the American prison system.

If these historians are accurate, it is not surprising that when sociologists began studying American prisons, culminating in Erving Goffman's work, they found what Goffman calls a "total institution." Since his term is central to the empirical analysis of those saying consent in American prisons is impossible, it is worth looking again at this definition. The prison as a total institution is "a place of residence and work where a

large number of like-situated individuals, cut off from the wider society for an appreciable period of time, together lead an enclosed, formally administered round of life." All activities are designed to make the prisoner subservient and dependent on authority.

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First, all aspects of life are conducted in the same place and under the same single authority. Second, each phase of the member's daily activity is carried on in the immediate company of a large batch of others, all of whom are treated alike and required to do the same thing together. Third, all phases of the day's activities are tightly scheduled.²⁹

External constraints, such as the physical coercion of gates, walls, and guards, are designed to coincide with internal constraints by which prisoners' inner desires conform to an imposed pattern. Goffman describes a variety of procedures by which the inmate of a total institution "begins a series of abasements, degradations, humiliations, and profanations of self," planned to fashion the inmate's conversion or conformity to the total environment: "The inmate appears to take over the official or staff view of himself and tries to act out the role of the perfect inmate."³⁰

Those opposing prisoner participation argue that particular practices, such as conducting medical experiments, cannot remain unaffected by the surrounding environment. Whatever the inevitable constraints may be on volunteers from the free-living population, medical experiments in prison are carried on in a decisively different context. They are conducted within what Gresham Sykes has called "a social system in which an attempt is made to create and maintain total or almost total social control."³¹ It is argued that in such total institutions precisely the attractive and beneficial features of experimentation can overcome the inmate's ability to give sufficiently free consent. After studying in depth the New Jersey

Maximum Security Prison, Sykes observed that "it may be that when men are chronically deprived of liberty, material goods and services, recreational opportunities and so on, the few pleasures that are granted take on a new importance and the threat of their withdrawal is a more powerful motive for conformity than those of us in the free community can realize."³²

Those convinced that the structure of prisons means that consent actually cannot be given in prison are not surprised by reports from Dr. John D. Arnold and his associates after conducting experiments using prisoners that a

factor that plays a major role in volunteerism is the factor of the substitute parent....There developed by the volunteer an almost parental view of the research physician. In part the research team has replaced the real family. Many prisoners would say 'I would do anything the doctor tells me to.' This sometimes continued after prison.³³

The conviction that sufficiently free consent to experimentation cannot, in fact be given, rests not only on the structure of American prisons, but also on their administration. Lack of certainty is a constraint. Sentences for indeterminate terms, with non-objective or unknown conditions for release make rational choices difficult for prisoners. Another uncertainty is whether or not hopes are well-founded for earlier release or parole because of participation in experiments.³⁴

Limited alternatives to experimentation among prison activities is a further constraint. No other prison activity pays comparably, with differentials between experimentation and other prison activities of well over ten to one.³⁵ Other activities are not conducted in comparably secure surroundings, and there appears to be a paucity of meaningful alternative ways for prisoners to express their altruism.³⁶

Before continuing on to other principles it may be helpful to summarize the position of those who admit that prisoners in some ideal prison might be able to give a sufficiently free consent, but who do not believe the evidence supports the assumption that prisoners in the United States can in fact do so. They take as their point of comparison for sufficiently free consent, not the freedom of consent prisoners exhibit when they enter into other prison activities, but the consent free persons demonstrate when they consent to experimentation.

Those who oppose prisoner experimentation can feely admit that sufficiently free and informed consent does not mean fully free consent, either in or out of prisons. They can also admit that prisoners have the capacity to consent to some activities in prison. But acknowledging that prisoners can give sufficiently free consent to other activities in prison or to reject experimentation is not a commitment to believing that prisoners can give sufficiently free consent to experimentation. As we have seen, consent to experimentation is considered to be significantly different from choosing a job, in or out of prison. The difference means that there must be greater assurance of a sufficiently free consent to experimentation than to other prison activities. Also, refusal to participate in experimentation does not demand as great assurance of capacity for free choice as does consent, because a refusal can more easily be reversed than can participation in experiments whose effects can be enduring or permanent.

Opponents of prisoner experimentation could still leave open the possibility that prisoners might not be sufficiently free to give consent even to other prison activities that put them at significant risk, and that at some point the justifiability of those activities should be examined.

They could also say that even if it were shown that there is no need for greater assurance of a prisoner's capacity to consent than to refuse participation in experimentation, the evidence still leaves them doubtful that prisoners can make a sufficiently free decision, either for or against experimentation.

That some prisoners themselves are satisfied with the opportunity to be involved in experimentation is not conclusive evidence that they actually have sufficient freedom to consent. To be sufficiently free it is not enough that one is free from feeling he is coerced. A more accurate account of our ordinary understanding of what it means to be free includes what Feinberg calls "the presence of genuine alternatives."

Two different ideals of liberty are involved: minimizing frustration versus maximizing the number of genuine alternatives open to a person, whatever the effect on his states of mind. According to the first conception, a person is free only to the extent that he can do what he wants to do when he wants to do it; according to the second, a person is free only if he can do considerably more than what he wants to do.³⁷

Of course, whether or not prisoners have genuine alternatives to involvement in experimentation is one point at issue in the empirical analysis of the freedom of prisoners. Opponents of prison experimentation, in the face of other, contrary evidence, may well feel that the absence of frustration with experimentation and the desire to participate in it shown by some prisoners is not conclusive evidence that their consent to experimentation--or those of other prisoners--is sufficiently free. The freedom of the satisfied prisoners may be significantly different in both degree and kind from that of non-prisoners.

As we turn from free and informed consent to other principles invoked by opponents of prisoner experimentation, the focus of the essay will move

from principles particularly concerned with protecting individuals from harm and injury to those primarily concerned with society as a whole. It will become clear that inherently right treatment of individuals and appropriate relationships among groups in society involve considerations of justice.

Injury

Those who are not certain whether informed consent by prisoners is or is not sufficiently voluntary, and want prisoners restrained from volunteering until some determination can be made, might rely on the principle of paternalism. As defined by Gerald Dworkin, paternalism is "the interference with a person's liberty of action justified by reasons referring exclusively to the welfare, good, happiness, needs, interests or values of the person being coerced."³⁸ He adds that "the easiest cases to handle are those which can be argued about in the terms...not just for the happiness or welfare in some broad sense of the individual, but rather a concern for the autonomy and freedom of the person."³⁹

Opponents of prisoner experimentation would not need to appeal to what Feinberg calls "extreme paternalism," or the rather open-ended justification of state coercion to benefit individual persons. They could limit themselves to "legal paternalism," that is, the justification of "state coercion to protect individuals from self-inflicted harm."⁴⁰ If their concern was simply that prisoners' consents might be substantially nonvoluntary and they wanted a moratorium to determine whether or not their suspicions were correct, they could appeal to what Feinberg calls "weak paternalism," which allows that "the state has the right to prevent self-regarding harmful conduct only when it is substantially nonvoluntary, or when temporary intervention is necessary to establish whether it is voluntary or not."⁴¹

Feinberg believes this form of paternalism so "innocuous" that even Mill, the determined opponent of paternalism, could have approved of it. Only if opponents of experimentation were willing to advocate an outright ban, whether or not prisoners can give informed and voluntary consent, would a "strong paternalism" have been invoked.

Those who disapproved of using prisoners in experimentation out of respect for the inherent dignity of prisoners might feel uneasy with a moral principle that approved of coercive intervention because of presumed beneficial consequences for the prisoner. This would be particularly likely if it were established that prisoners indeed have the capacity for consent, and strong paternalism would have to be invoked.

The principle of injury, presented as an alternative to paternalism, puts limits on coercive intervention by appeals to justice. It can, on occasion, however, justify intervention in a person's action even if the person has the capacity to make free and informed choices.

As articulated by Tom L. Beauchamp, the principle of injury is not inconsistent with weak paternalism. It would allow intervention if "there exists supportable grounds for believing that an individual or group of individuals has been or will be physically or mentally harmed by some cause or condition which is to that party not known or not within its control or both." Harm here is used purely descriptively to mean physical or mental damage. Injury, on the other hand, "is accepted as having a normative component and as meaning injustice resulting in harm." The principle of injury, then, relying on justice, would approve of intervention if "there exist supportable grounds for believing that an individual or group or institution serving the public interest has been or will be injured (wrongfully harmed) by the actions or negligence of others."

Though not the sole instances, cases of exploitation are typical examples of injury or unjustified harm.

Even a person with the capacity to consent may be justifiably restrained from agreeing to certain actions if the person is placed in a position to be wrongfully or unjustly harmed. The hypothetical example is given of a Mr. Brown, a rational, mature, highly informed man who wishes to sell himself into slavery, but is justifiably prevented from doing so. Although his potential master is benevolent, kind and skillful at sensitive consequentialist calculation, "we do not allow Mr. Brown to barter himself because to do so would be to legalize an institution virtually certain to produce unpoliceable injuries." The institution of slavery is such that other potential masters will injure other slaves, "and we know that slavery at their hands is inherently exploitative." So, "while Mr. Brown is adequately informable of the dangers that might befall him, and is fully capable of consenting, we are justified in more than merely temporary intervention because of the need to protect non-consenting individuals who would be harmed by the institution." ⁴³

Of course, whether the principle of injury were relevant to prisoner experimentation depends on the facts. The relevant information would not be solely the immediate circumstances of a prisoner's giving consent, such as whether the prisoner fully understood the scientific purpose of the experiment, the nature of his participation, and the possible risks he would sustain. More pertinent would be information concerning the pattern of actions into which his participation fits. For instance; the fact that because of governmental regulations phase-one drug tests are required to test the safety of dosages and their side-effects; that drug companies arrange with prison administrators to perform experiments on prison compounds,

and that, as a result, estimates indicate that 85% to "virtually all" of the initial, riskiest experiments of drugs on humans in the United States are performed on prisoners; but that prisoners typically receive a tenth (\$2.00 per day) of what free volunteers receive (\$20.00 per day).⁴⁴

Also relevant would be the degree to which allegations are accurate concerning the benefits and profits flowing to physicians, prisons and drug companies from high-risk research that is not therapeutic for prisoners.⁴⁵

Comparative Justice

The principle of injury directs attention to injustice and in one example institutionalized exploitation. The requirements of distributive or comparative justice are relevant to situations involving the relationship of groups or classes of individuals within society. Comparative justice is "the creation or modification of a relation between parties."⁴⁶ Equality of treatment is central to comparative justice. "The basic principle of comparative justice is that like cases are to be treated alike and different cases to be treated differently."⁴⁷ What is difficult is to match this formal principle with material principles that indicate in which relevant respects classes are similar and different.

Those who feel that prisoners should not, as a class, be excluded from experimentation stress the similarity in capacity for consent between prisoners and other groups in society. Similarity is also stressed by those who urge that prisoners should never be asked to volunteer for experiments that would not be tested on free-living populations. On the same grounds LeRoy Walters has urged that the risks and benefits of non-therapeutic experimentation in particular should be distributed proportionally among economic classes and groups.⁴⁸ Certainly, taking account

of the equality between prisoners and the free-living population would call for a major shift in at least Phase I drug testing.

However, injustice can be done when individuals or classes who are different in some relevant respect are treated alike. While the presumption in favor of equal treatment holds when the classes are alike, it must also be remembered that the basic principle of comparative justice also refers to differences, and "the presumption in favor of unequal treatment holds when the individuals involved are expected to be different in the relevant respects." Indeed, "sometimes the 'burden of proof' is on those who advocate equality of treatment."⁴⁹

One difference between prisoners and free persons is that prisoners have committed a crime and been convicted. Because of that significant difference prisoners are already treated differently from free persons. They must serve time in prison. But few today urge that conviction of a crime is in itself relevant to the differences or similarities between free-living and prisoner volunteers.⁵⁰ The legally imposed sentence sufficiently guarantees that guilt of committing a crime results in unequal treatment. Society, through its legal institutions at least, has not decided that participation in experimentation is punishment.

A difference that is relevant to the issue of participation in experimentation is that prisoners have been forcibly placed in total institutions, where experimentation is part of a set of institutional arrangements that result in prisoners carrying the burden of physical risks and harms for the medical benefit of society, and sustaining financial sacrifice (compared to the remuneration received by the free-living population) that some, at least, claim contributes to the economic benefit

of the institutions involved. That is an example of the greater vulnerability to possible exploitation inherent in a total institution, as compared to the free-living society. If, in addition, there is a difference between the capacity of the prisoner and the nonprisoner to sufficiently freely consent to experimentation, that would be a further relevant difference between prisoners as a class and other groups living outside the prison. If, empirically, prisoners are relevantly different from the free population in ways that make them unequal, one might conclude, according to the principle of comparative justice, that prisoners should bear a disproportionately smaller burden of experimentation, compared to the free population. The inequality of prisoners would justify a variety of solutions, up to and including a ban on prisoner experimentation.

Social Good

Another argument that is more interested in society-wide concerns than whether individuals can give a free and informed consent is the consequentialist argument that if prisoners are not allowed to participate in experimentation the good of society will be served. While others insist that experimentation leads to scientific knowledge that contributes to the good of society, Robert Burt, a University of Michigan Professor of Law who helped argue the Kaimowitz Michigan psychosurgery case, believes that at least some kinds of experimentation with prisoners contributes to social conflict that is harmful to society.

Burt first contends that the physical and psychological separation of prisoners from other citizens already defines some humans into a different order, what Erik Erikson calls a "pseudo-species." Adding to imprisonment the performance of experimental psychosurgery would be another step in the

process of dividing "us" from "them." Burt then gives his consequentialist assessment of the implications of such a division.

The central danger, of course, is not simply the fact that we choose to define some people as different species of mankind from others. But such definition provides justification for, and impulse toward, increasing and mutually destructive action by one "pseudo-species" against another.⁵¹

Burt refers to the suspicion and fear of not only those being separated, but those in charge of the separation. "When we do that to him, what will we think of ourselves? What will others think of us?...This is the cycle of violence, punitive repression, and increased violence. These are the dark, atavistic fears that afflict us all whenever we treat one group of men as radically different, radically inferior, less human than the rest of us."⁵²

Burt reminds us that he is not arguing that the prisoner in the case referred to as John Doe "lacked 'capacity for rational consent' or that his consent was not 'adequately informed' by any sensible legal standard...experimental psychosurgery was a rational, productive course for Doe in confinement." Rather, Burt is arguing that

Since this new biotechnology threatens such excacerbative social consequences, it would be wrong to rely on Doe's consent as adequate indication that we may proceed in good conscience with experimental psychosurgery in prisons. By withholding the possibility of legally consented psychosurgery from John Doe, we are thus protecting ourselves more than him.⁵³

Burt explicitly acknowledges that he is proposing a quantitative balancing of a prisoner's interests with that of society. "I am content to say that the risks I have described affect so many people so far in the future that prisoners' current interests in obtaining the surgery are outweighed."⁵⁴

As with the other principles, changed empirical conditions could mean that appeal to the same principle would lead to different conclusions.

That is, "if the social ethos clearly accepts that psychosurgery is an appropriate response to a 'brain disease,'" that it is "a widely accepted medical technology used with free populations," psychosurgery performed on prisoners might be justified as serving the social good.

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In the meantime, however, Burt agrees that psychosurgery should be banned. Others, who believed that any experimentation involving prisoners created antagonistic groups in society, could make the same argument for all experimentation.

Social Character

Robert Burt, in opposing prisoner involvement in at least psychosurgery experiments, could have rested his case at the point of his statement of how psychosurgery on captive populations redefines our understanding of each other as fellow human beings. If he had, he would have called on an ethical consideration different from (though not incompatible with) the others we have considered so far. He would have been appealing not to obligations understood in either consequentialist or non-consequentialist terms, but to some sense of what we are as a society; what our character is.

Laurence Tribe, discussing the fundamental problems posed for society by scientific technology, calls for a response that is more than instrumental analysis. Instead, "Imagine asking, for example, 'what kind of society do I want this to be,' or 'what sort of person would I wish to become?'" He is certain that "in choosing whether or what to build--in deciding what technologies to adopt--the community does more than generate a distribution of payoffs and penalties to its members: it also alters... its character as a society of persons."

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The decision about whether or not prisoners should be used in experimentation can be understood as that kind of social choice. What

purposes we decide for our prisons and prisoners is a societal one, and our choice reflects and expresses our character. Debates continue over the final purpose of correctional systems, but society has agreed that the minimal function of its prisons is coerced confinement of criminals. Whatever else society uses prisons for should not be the result of inattention, but thoughtful reflection and conscious choice. How society treats the bodies and minds it directly controls through its laws and police power is the responsibility of society: whether individuals in prisons are treated justly, whether they are injured, whether or not those institutions contribute to the common good.

If any of the previous analyses that prisoners should not be used in experimentation are correct--because prisoners are insufficiently free to give consent, because they run the risk of being exploited, or because prisoners unjustly bear the major brunt of drug experimentation--then it may well be that using prisoners in experimentation violates our character as a society. Using prisoners in experimentation does not express the kind of society we are, or wish to be.

Summary of Discussion of Principles

A National Commission trying to determine which principles should guide its decisions regarding experimentation with prisoners and concerned to know what policies these principles suggest, might well share a basic assumption articulated by Charles Fried. Society is, or ought to be, comprised of individuals committed to respecting others as ends in themselves where each individual sees

himself bound to a whole network of other individuals....And one must acknowledge that those to whom one is bound through this network are, like oneself, human persons, with equal autonomy, and an equal call on our respect and consideration. The point then becomes to design that network of impingements in such a

way that the fabric of this network itself expresses the moral equality, the autonomy and mutual respect of the persons within it.⁵⁸

Social Good

In trying to decide policy in accord with respect for the equal, inherent worth of individuals, decisions about what is morally right should not be determined solely by calculating how the consequences of a policy will strike the greatest balance of good over evil. Conformity of the policy to inherently just relationships among persons is at least as important, if not more important. Of course, consequentialist and non-consequentialist arguments are not necessarily mutually exclusive.

With respect to experimentation with prisoners, the consequentialist arguments run in different directions. It is difficult to know how one could weigh whether increasing medical knowledge or avoiding social conflict might better contribute in the long run to social good.

However, a lack of necessity to use prisoners in experiments lessens the urgency of consequentialist arguments that prisoners are needed for the increase of scientific knowledge. Prisoners are not biologically unique, and therefore are not in principle necessary for biomedical experiments. What is unique about prison conditions could, to a large degree, be simulated for behavioral research purposes, using volunteers from the free-living population.

Much of the present use of prisoners in research takes place in phase-one drug tests which require relatively small groups for short periods of time, factors which should contribute to making it possible to use persons other than prisoners in experimentation. In fact, alternatives to prison populations have already been successfully used in biomedical research.⁵⁹ As use of alternative populations extends to more hazardous experiments it may be more difficult to recruit from the

free-living population. But it has been suggested that if society were not willing to participate in an experiment, after attempts at educating them to its importance had been made, their reluctance would call into question the assumption that increased medical knowledge gained from this particular research was necessary for the public good.

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Informed Consent

Since informed consent is designed to ensure that individuals will be treated by physicians and scientists with the respect due them as rational and free persons, invocations of the principle in favor of prisoners participating in experimentation must be taken seriously. If prisoners possessing the capacity to give free and informed consent volunteer, how can their participation be prohibited?

Prisoners should, in principle, be able to consent to experimentation. They are not devoid of legal standing to make agreements that citizens outside prison can make. The question is, do prisoners, in fact, have the capacity to give sufficiently free consent? After all, attribution of rights to a class of citizens does not necessarily indicate a sufficient capacity to exercise those rights. Crucial to answering the empirical question as to whether prisoners' consent is sufficiently free is whether the standard used to judge sufficiency is the freedom of consent prisoners have for entering into other prison activities or the freedom of consent free-living persons have when they consent to experimentation. Surely, insisting that free consent to experimentation in prisons must be sufficiently equivalent (not necessarily identical) to that in the free-living population is itself a mark of respect for prisoners. Bringing such a standard to the empirical facts concerning the paucity of alternatives

(financially or otherwise), and to the ability of total institutions to coerce behavior and attitudes, justifies a serious and reasonable doubt that, in fact, inmates of American prisons can give sufficiently free consent to experimentation.

Justice

Dissatisfaction with consequentialist arguments as at least insufficient, accompanied by inquiry into whether other principles independent of free and informed consent bear on the issue of experimentation of prisoners, leads to a consideration of justice. A weak paternalism would approve of coercive intervention if prisoners did not have the capacity to consent and volunteered for activities that could be shown to be physically or mentally harmful. The principle of injury would approve of interventions in the actions of even those who had the capacity to consent, if the activities for which they volunteered were shown to be unjustifiably harmful. The evidence that prisoners are part of an institutional framework that leads them to bear a disproportionately high share of the risks and harms of experimentation, with a disproportionately low share of the financial benefits, particularly as compared to the financial rewards of participating institutions, leads to the conclusion that experimentation with prisoners is impermissible because of the likelihood that prisoners would be unjustly treated.

The requirements of not only injury but comparative justice are pertinent. Since prisoners are in relevant respects equal to free persons it seems reasonable that the burdens of risk and harm in experimentation should be proportional to those of free-living citizens. Achieving proportionality would entail significant reduction in the levels of prisoner participation in at least phase-one drug trials. But if prisoners are considered to be in relevant respects different from, and unequal to, the rest

of the population it would be justified to treat them differently. There is sufficient evidence that the fact of incarceration forcibly places prisoners in a position where participation in an experiment means participating in a system where the risks of physical harm are much greater and the financial benefits from experimentation much less than they are for the free-living population. If, because of incarceration, prisoners have unequal capacities to consent there is an additional, significant difference between prisoners and free-living persons. The similarities of prisoners to free persons require that the proportion of experimentation utilizing prisoners should be reduced. The differences between experiments in prison and those conducted outside of prisons require that they be stopped--at least until prison conditions change.

Experimentation with prisoners is not scientifically necessary for the good of society. For the National Commission to approve of prisoner experimentation, the empirical conditions of experimentation should conform to the non-consequentialist requirements of both informed consent and justice. Although consequentialist arguments may lead to similar recommendations, policies must conform to the requirements of both informed consent and justice. Empirical evidence that experimentation, as currently conducted, fails to meet either standard requires that experimentation with prisoners, as presently organized, be stopped, at least until it meets the demands of both informed consent and justice. To continue experimentation with prisoners under the present circumstances would violate and erode our sense of what we are as a society; a community constituted by mutual regard for each other's equal, intrinsic dignity.

II. POLICIES

The ethical principles outlined above could lead to a wide range of possible policies. Two opposite poles immediately come to mind. Beginning with the most permissive policy, one could approve continuing prisoner experimentation under present guidelines. Such a policy might be justified by a consequentialist calculus that experimentation with prisoners was a necessary way of gaining needed scientific knowledge for the good of society. Even if one were to accept the two criteria suggested of sufficiently free and informed consent and justice, certain empirical analyses could conceivably lead to the conclusion that present policies should continue.

At the other extreme, one could approve an outright ban. Such a policy might be approved if one were a consequentialist and convinced that there were no conceivable circumstances in which the good consequences of experimenting with prisoners could outweigh the evil, or if one were convinced that in principle prisoners could not give sufficiently free consent to experimentation or avoid being treated unjustly.

Between these polar opposites several alternative policies could be found by a person committed to the necessity of adhering to at least the principles of informed consent and justice, and doubtful that their requirements can in fact be satisfied in American prisons.

Guidelines for Experimental Review

One possibility would be to improve the review procedures for experiments using prisoners. A basic protection of at least legal liberties among citizens in the free-living population is the U.S.

system of checks and balances among governmental institutions and the myriad private groups in society. Attempts to institutionalize some legitimate checks and balances might lead to requirements that a prisoner protection (or review) committee be formed in prisons where experiments were to take place. This prisoner protection committee would be empowered to reject or approve experiments and the procedures to be used in obtaining consent from individual prisoners. It would also monitor the actual gaining of consent from prisoners.

Since this committee needs scientific information and counsel, as well as the cooperation of the prison administrators, but is primarily concerned to protect the interests of prisoners, the committee could be comprised of five prisoners, one scientist, one prison official, and one non-voting representative of the media. Election of all members, including the scientist, prison official and media representative, would be by secret ballot of the prison population. Terms would be for limited periods of time--perhaps six months--with a limit of two consecutive terms. Minority views and reports would be available to prisoners as well as the public. Prisoner participants would not receive special consideration by parole boards and the prisoners would be so notified before election. Remuneration of the prisoners on the committee would be equivalent to other prison jobs.

The prisoner protection committee would be a safeguard for free and informed consent, but problems of injustice would remain. A crucial practical dilemma of experimentation with prisoners is devising remuneration rates that simultaneously satisfy the consent and the justice re-

quirements. According to the demands of justice whatever is done about the proportionate or disproportionate amounts of experimentation performed in prisons compared to the free-living society, prisoners should receive at least the same money as free-living volunteers for experimentation-- typically \$20 per day. But the difficulties of obtaining sufficiently free consent dictate that prisoners receive the same remuneration for experimentation as they do for other prison activities-- \$.65 per day is one example.⁶¹

One suggestion for solving this practical problem is for research groups to pay sums equivalent to that which would be paid to free-living volunteers (and laboratory aides) into a fund for the benefit of prisoners generally in the institution. Individual prisoners would receive amounts equivalent to what they would receive from other prison jobs. To create further protection, a separate prisoner finance committee composed and elected in the manner of the prisoner protection committee, but with different individuals serving, would be empowered to decide for what purposes the money should be spent beyond the small sums going to volunteers and laboratory aides.⁶²

Another possibility would be for non-prisoners, as well as prisoners, to receive the same amount for participation in experiments as prisoners receive for other prison jobs. An even more sweeping suggestion would be to follow the arguments of Richard Titmuss concerning blood donation, and make all participation in experimentation purely voluntary, both in and out of prison. That is, pay no one for participating in any experimentation.⁶³ Of course not all rewards to prisoners are financial. Even if one solved the problem of financial payment, non-financial rewards of

experimentation peculiar to prison settings such as early parole or relief from boredom, might still cause problems for the consent requirement.

A consensus seems to have emerged that justice demands that any guidelines should include compensation of prisoners harmed in non-therapeutic experimentation.⁶⁴

Accreditation of Penal Institutions

Recognition that consent takes place inside a total institution has led to accreditation proposals. One of the most elaborate to date is a plan for "inverse risk-rating." It assumes that there are predictable variations in risk among experiments and relevant differences in the approximation of prisons to free-living conditions. Looking at the amount of voluntarism permitted by the objective characteristics of a "correctional modality," accreditation would compare the "risk of ethical impairment" a correctional setting exhibited (from maximum security prison to half-way house) with the risk of physical harm likely from an experiment.

As the physical risk inherent in the research increases, a greater approximation of freedom and knowledge would be demanded of institutions conducting such research. Some correctional modalities might be determined too coercive to allow experiments of even the lowest risks; others, like halfway houses, might be found to require no special safeguards beyond those employed in the free world.⁶⁵

Another suggestion, concerned primarily with informed consent, is accreditation not of prisons, but of new institutions physically outside the prison (though presumably reasonably proximate to it) created expressly to conduct experimentation utilizing both prisoners and non-prisoners.⁶⁶ Neither accreditation plan includes suggestions concerning remuneration rates.

Having assumed that in principle prisoners can give free and informed consent in an ideal prison, these various proposals try to reform present prisons in that direction. Unfortunately, one can see problems with each of the suggestions.

Revising procedures for reviewing experiments and changing administrative practices for paying prisoners overlooks the basic structure of prisons. Developing new, prisoner-dominated organizations as checks to supervisory authority may well be considered unfeasible by prison officials whose essential (if minimum) assignment from society is to keep prisoners secure. Even if prisoner protection and finance committees were organized, the presence of prison officials on the committees might well lead prisoners out of fear or cunning to defer to the dominant power in a total institution, even to the detriment of the interests of other prisoners. On the other hand, eliminating non-prisoners from the committee would heighten the risk of what might happen in any case: exploitation of individual prisoners by committees of prisoners acting within the coercive forces of a total institution.

Devising accrediting plans for correctional modalities that might have an acceptable inverse risk-ratio also runs into several difficulties. First, it assumes that measurement of external, objective constraints on a prisoner's freedom of action, while admittedly incomplete, is adequate for judging a prisoner's ability to volunteer. While one might agree that measuring such factors as the number and nature of security precautions and evaluating the number of options for meaningful, paid

activity in a prison is necessary, is it sufficient? Some prisoners might find minimum security facilities more intimidating or boring than other prisoners would find maximum security prisons. Such prisoners, perhaps younger and/or not accustomed to incarceration, might well find the inducement overwhelming to participate in experiments with high levels of authorized risk.

Second, implementation of such an accreditation system would be different administratively. The known difficulties of setting up procedures for reviewing the form by which experimenters gain consent from individuals, in or out of prison, let alone the continued monitoring of experimenters' actually obtaining consent, would surely be simple compared to the complexities of devising and monitoring accreditation guidelines for entire institutions. The time and personnel needed to inspect federal, state, county and municipal correctional institutions, not just initially but on a sustained basis, would be immense.

In addition, it has been pointed out that weighing risks of physical harm against ability to give sufficiently free consent assumes that consent is required only to protect individuals against physical risks. If, on the other hand, obtaining a person's consent before experimenting on him is a duty we owe him - a necessary mark of respect whatever the risk - then a plan based on weighing levels of ability to consent against levels of physical risk is suspect, conceptually as well as practically.⁶⁷

The proposal to avoid consent problems by developing experimental facilities outside prisons which would use both prisoners and non-prisoners misplaces the locus of the problem. While the treatment of prisoners

during an experiment would conceivably be more open to scrutiny, it is not the isolation of the experimental facilities inside a prison that is primarily at issue. Subjects used for extended periods of time to test toxic agents are taken from their cells in any case and placed in isolated wards (sometimes especially built for the purpose) within the prison compound, which are not significantly different from isolated wards in medical facilities outside prisons. Primarily at issue are the non-medical conditions and characteristics of total institutions within which prisoners consent to experimentation. The problems of consent and remuneration continue whether the prisoner's choice leads him to a restricted environment inside or outside the prison gates.

Moratorium

The Commission might accept the thesis that prisoners, in principle, can give sufficiently free consent in ideal conditions and therefore judge that an outright ban on experimentation was inappropriate. The Commission might also believe that in fact prisons create insurmountable problems for voluntary consent and justice which neither revised review procedures nor institutional accreditation proposals adequately deal with. The Commission still has an alternative. It could adopt the alternative policy of declaring a moratorium on experimentation with prisoners. A moratorium would admit that future developments might make experimentation possible but would assert that the present situation makes experimentation with prisoners impermissible.

If the Commission believed that alteration of conditions within the present structure of prisons would be a sufficient change, then the

Commission might accompany the moratorium with proposed guidelines or accreditation plans. If the structure of prisons themselves were thought to be the problem, then it might be more appropriate to accompany the declaration of a moratorium with a statement of basic principles to guide the shaping of alternative institutions within which subjects for experimentation might volunteer. Given the complexity of penal theory the wisest course would seem to be for the Commission to fulfill its mandate by declaring a moratorium accompanied by its reasons for doing so. The shock of a moratorium might itself be a considerable impetus for experts in correctional theory and practice to implement reforms in the American prison system.

Whether the duration of the moratorium would be for a specified period of time or would be indefinite in length would depend on whether one wanted to place the burden of proof on those who support or those who oppose experimentation. Since the evidence indicates that prisoner experimentation fails to meet the requirements of both informed consent and justice, placing the burden on those who wish to experiment with prisoners is appropriate. An indefinite moratorium is the best policy. If evidence develops that conditions have decisively changed, it can be presented and the lifting of the moratorium considered.

If it is important to protect prisoners and to make clear to them and others that they are protected, the scope of the moratorium must observe distinctions that are as clear and understandable as possible. In recent literature several categories have been developed, five of which

appear to spread across a continuum, from experimentation designed purely to gain knowledge to treatment prescribed solely to alleviate or cure the illness of a particular patient. The five categories are: non-therapeutic experimentation (or research), mixed experimentation, therapeutic experimentation, innovative therapy (or practice), and standard therapy.

Everyone writing on the topic is acutely aware that the analytic terms describe activities that often cannot be restricted to such categories.

It is also obvious that varying definitions of the categories lead to overlapping among terms. For example, Robert J. Levine's use of the term innovative therapy--"Innovative therapy is a term applied to a simple activity that is ordinarily conducted by the physician with either pure practice intent or varying degrees of mixed research and practice intent,"--would appear to allow more use of the patient to gain scientific knowledge than Charles Fried's definition of therapeutic experimentation: "Experimentation is therapeutic when a therapy is tried with the sole view of determining the best way of treating that patient."⁶⁸ The various definitions do agree, however, that there is a significant difference between experimentation and therapy.

Surely the Commission would not want a moratorium to be so strictly understood that it would preclude prisoners receiving the benefit of new procedures or agents that had exhibited some chance of success, but had not yet become a part of standard medical practice. If the term therapy could include innovative therapy understood in Levine's terms as "conducted with pure practice intent," the moratorium could extend to all

experimentation, not simply "non-therapeutic experimentation," and still allow for prisoners to benefit from new medical techniques.

Within the context of a prison it appears more practical to say that prisoners may be asked to consent to therapy (including innovative therapy carefully defined), but not experimentation, than to say that prisoners may consent to one kind of experimentation--therapeutic--but not to another--non-therapeutic. The distinction between therapy and experimentation would be less likely to confuse researchers, prisoners and correctional authorities and thereby provide greater protection for the prisoner.

There are other substantial reasons for drawing the line of the moratorium along the more familiar distinctions of experimentation and therapy. It is generally expected that greater knowledge is available to the physician about therapy than experimentation and that therefore there is a greater chance that the physician will be able to communicate enough knowledge to the prisoner for him to give a sufficiently informed consent. It is also assumed that since the entire purpose of the therapy is to benefit the patient by ameliorating or curing his illness, it can be assumed with greater assurance than with experimentation that his consent is sufficiently voluntary. Even if doubt persisted about a prisoner's capacity to consent, it would be assumed that a reasonable person similarly afflicted would consent to therapy performed solely on his own behalf.

Furthermore, if the procedure is therapy, there is greater assurance than with experimentation that it has been tried before on non-prisoners, even if it has not become standard practice. Finally, more than for experimentation, there is a tradition of professional and legal sanctions against those who engage in malpractice. Prisoners would have more precedent allowing them to bring suit against harmful therapy than against injurious experimentation.

Behavioral Experimentation

An indefinite moratorium on all experimentation or research using prisoners should extend to behavioral experimentation. The fact that it may be more difficult to distinguish between experimentation and therapy among behavioral techniques does not weaken the necessity for declaring a moratorium on such experiments. Rather, it strengthens the need for caution in considering consent to procedures modifying behavior, even when they are called therapeutic. The Kaimowitz psychosurgery decision objects to the proposed surgery for a variety of reasons, including the fact that it had not been sufficiently tested and was "clearly experimental."⁶⁹

The arguments concerning biomedical experimentation apply also to behavioral experimentation. The question raised by the administration and structure of prisons about the capacity of prisoners to give consent persist, particularly for behavioral experiments that may be even more intrusive and irreversible than biomedical experimentation. Past practices using prisoners for surgical procedures profoundly altering behavior, raise real if sometimes overly lurid fears, that other behavior-altering tech-

niques will violate the requirements of justice. Furthermore, as with biomedical experiments, it is not necessary to use prisoners in behavioral research. Experimentation with free-living volunteers who consent to live in simulated prison environments, however difficult in practice, could in principle provide sufficient knowledge about the safety and efficacy of behavioral techniques that could later be used therapeutically with prisoners.

Clearly, a moratorium on behavioral experimentation would be less restrictive if there could be agreement about more precise definitions of the word behavioral. The moratorium would not extend to certain activities if they were found to be not behavioral but educational; for example, programmed instruction, including, perhaps, its "constructional" form.⁷⁰ Experiments that did not manipulate, or even alter behavior, but only observed it might be called social rather than behavioral research. Of course, ethical questions can be raised about observational studies--particularly concerning breaches of privacy or confidentiality--but they might not justify excluding such social research from prisons. In any case, careful definition of the word behavior might lead to certain questions being settled apart from voting a moratorium on biomedical and behavioral experimentation.

Greater agreement of what is included within behavior techniques might mean that while a moratorium was declared on using prisoners in behavior experimentation behavioral therapy on prisoners could proceed. On the other hand, a moratorium on experimentation that allowed innovative biomedical or behavioral therapy might still be too permissive and guidelines for the use of innovative therapies with prisoners would need to be drawn up; but that would be another, separate enterprise.

Conclusion

It has been suggested by some that beyond the sick prisoner there are classes of non-prisoners who would remain untouched by any guidelines concerning prisoner experimentation, classes who are also vulnerable to coercion. Indeed, sometimes it is argued that even though classes of non-prisoners are also coerced, economically and otherwise, there is no sense of the urgent need to exclude them from experimentation. Why should society isolate prisoners as a class from experimentation? But surely, if groups in American society were placed on a scale of vulnerability to coercion, prisoners would be placed at the higher end of the scale. In bioethical discussions it has become common for practices or policies to be disapproved because they might lead to worse practices. With prisoner experimentation we are already at the thick edge of the wedge. If other populations are vulnerable, their cases may also need to be examined. Inaction in other areas is not a sufficient reason for avoiding action now concerning research on prisoners.

FOOTNOTES

1

I wish to thank my colleagues at the Kennedy Institute for their comments and criticisms. Kenneth Casebeer and LeRoy Walters have been particularly generous with their time.

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Fried, pp. 95,96.

19

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21

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22

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23

Wells, op. cit.

24

The possibility that prisoners have special problems giving an adequately informed consent should be more carefully explored. Almost all the initial prescription drug tests are first performed on prisoners, at a point when there is presumably less information that can be given anyone, including prisoners, than at any other stage of drug testing on humans. What information is available is communicated to a prisoner who may have spent much of his life, through long-term sentencing or recidivism, within the prison culture. The experience may have strongly affected his perceptions. What non-prisoners, or even some prisoners, regard as a possibility of becoming "a joint adventurer in an experiment for the sake of the knowledge and good to come," (Ramsey, p. 42) may be perceived by other prisoners as a money-making proposition. It may be very difficult for some prisoners to see the experiment as a scientific enterprise and therefore to be genuinely informed. The discussions concerning capacity for sufficiently free consent do not depend on what the prisoner perceives an experiment to be, but future empirical studies should not ignore data bearing on a prisoner's capacity to be adequately informed. (Kenneth Casebeer's comments have been useful on this point.)

25 Gabe Kaimowitz v. Department of Mental Health for the State of
Michigan, pp. 25-29.

26 Complaint, paragraph 60.

27 David J. Rothman, The Discovery of the Asylum: Social Order and
Disorder in the New Republic, Little, Brown and Co., Boston, 1971;
Gerald H. Grob, Mental Institutions in America: Social Policy to
1875, The Free Press, New York, 1975.

28 Erving Goffman, Asylums, Aldine Publishing Co., Chicago, 1962, p. xiii.

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33 Arnold, et al, pp. 463-469.

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Staff Paper, "Prisoners as Research Subjects," National Commission for
the Protection of Human Subjects of Biomedical and Behavioral Research,
October 31, 1975, p. 14.

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38 Gerald Dworkin, "Paternalism," The Monist, vol. 56, January, 1972, p. 65.

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forthcoming, 1976, pp. 11,12 in typescript.

43 Ibid., p. 16.

44 ACLU, National Prison Project Complaint, paragraphs 41 & 51; cf.
Bronstein, pp. 130-135; cf. Aileen Adams and Geoffrey Cowan, "The
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45

Peter B. Meyer, Medical Experimentation on Prisoners: Some Economic Considerations, American Bar Association, Washington, D.C., June 1975; cf. Jessica Mitford, "Experiments Behind Bars," Atlantic Monthly, January, 1973, pp. 64-73.

46

Feinberg, p. 98; cf. p. 107, "The term 'distributive justice' traditionally applied to burdens and benefits directly distributed by political authorities...in most recent literature the term is reserved for economic distribution."

47

Ibid., p. 99; cf. p. 100, "Our formal principle (which derives from Aristotle) would have us: (1) treat alike (equally) those who are the same (equal) in relevant respects, and (2) treat unlike (unequally) those who are unlike (unequal) in relevant respects, in direct proportion to the differences (inequalities) between them."

48

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49

Feinberg, p. 101.

50

"Resolved that the House of Delegates of the American Medical Association express its disapproval of the participation in scientific experiments of persons convicted of murder, rape, arson, kidnapping, treason, or other heinous crimes, and also urges individuals who have lost their citizenship by due process of law be considered ineligible for meritorious or commendatory citation." House of Delegates of the American Medical Association, Resolution on Disapproval of Participation in Scientific Experiments by Inmates of a Penal Institution (1952), cited in Jay Katz, Experimentation with Human Subjects, Braziller, New York, 1970, p. 1025.

51

Robert Burt, "Why We Should Keep Prisoners from the Doctors," Hastings Center Report, vol. v., no. 1, February, 1975, p. 33.

52

Ibid., p. 34.

53

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54

Ibid.

55

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56

Laurence H. Tribe, "Technology Assessment and the Fourth Discontinuity: The Limits of Instrumental Rationality," Southern California Law Review, vol. 46, no. 3, June, 1973, p. 654. James Childress' comments on the topic of this section have been particularly helpful.

57

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58

Fried, p. 111.

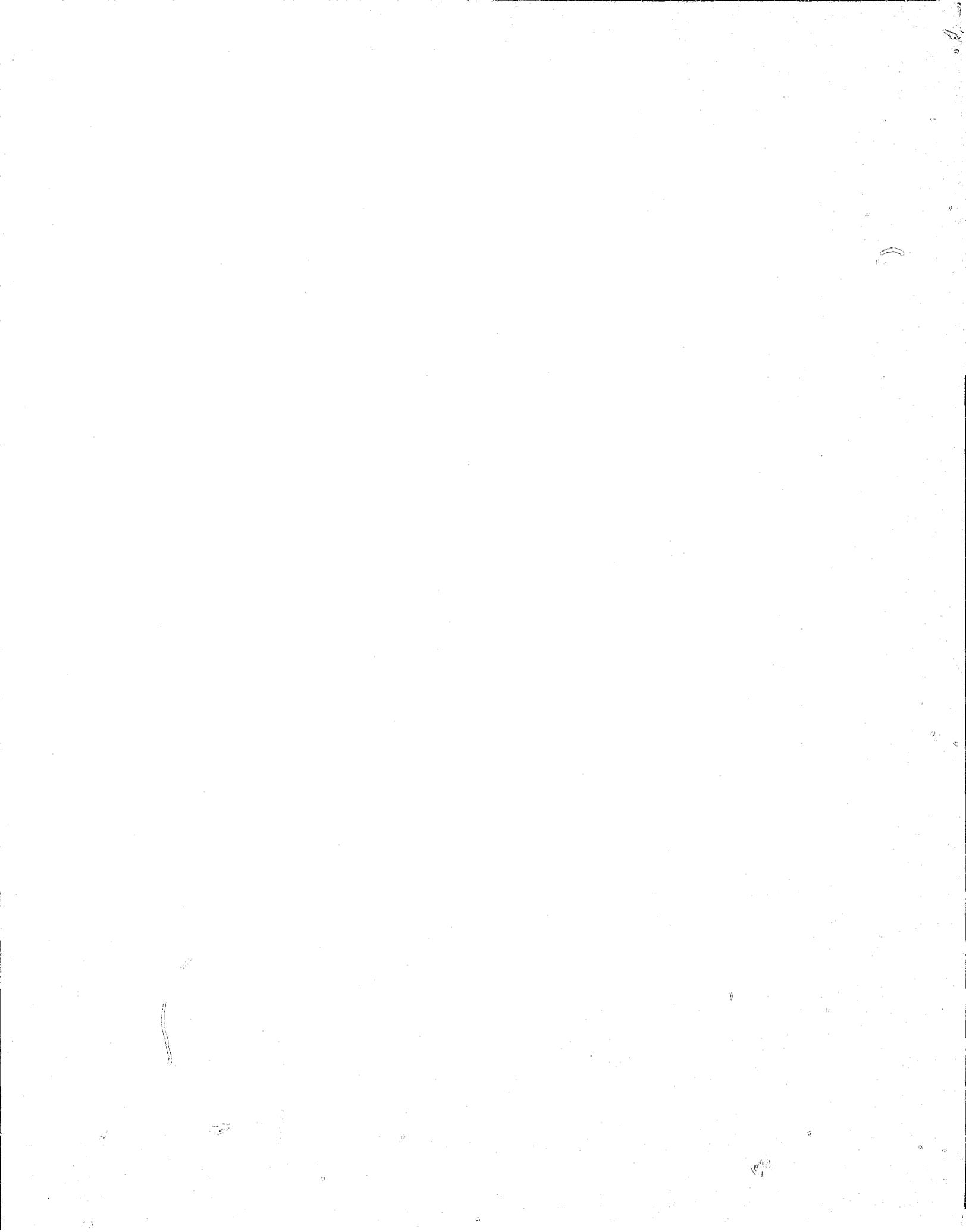
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Fried, p. 170.

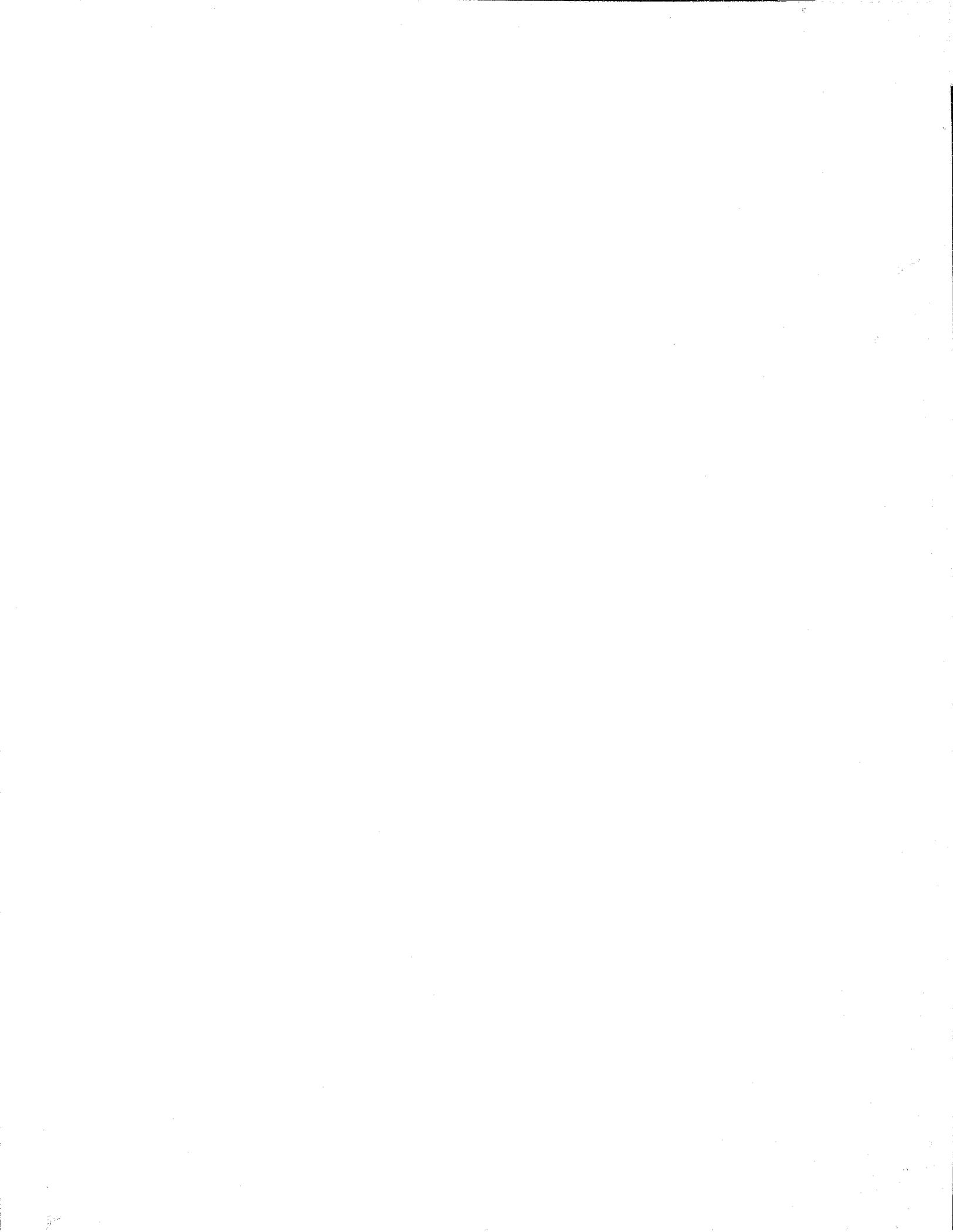
- 61 ACLU, National Prison Project Complaint, paragraphs 32,41.
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- 63 Richard M. Titmuss, The Gift Relationship, Pantheon Books, a Division of Random House, New York, 1971.
- 64 Walters, pp. 22-24; Fried, pp. 171,172; Norval Morris and Michael Mills, "Prisoners as Laboratory Subjects," Wall Street Journal, April 2, 1974.
- 65 Albert R. Jonsen, Michael L. Parker, Rick J. Carlson, Carol B. Emmott, Biomedical Experimentation on Prisoners: REview of Practices and Problems and Proposal of a New Regulatory Approach, Health Policy Program Discussion Paper, September, 1975, p. 35.
- 66 Transcript of National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Meeting, January 10, 1976, pp. 377-401.
- 67 Robert M. Veatch, personal communication.
- 68 Robert J. Levine, "The Accepted and Routine Practice of Medicine," Paper for the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, December, 1975, p. 14; cf. Fried, p. 25.
- 69 Kaimowitz v. Department of Mental Health for the State of Michigan, p. 16.
- 70 Michael H. Shapiro, "Legislating the Control of Behavior Control: Autonomy and the Coercive Use of Organic Therapies," Southern California Law Review, vol. 47, no. 2, pp. 300-301; Israel Goldiamond, "Toward a Constructional Approach to Social Problems," Behaviorism, vol. 2, no. 1, Spring, 1974, pp. 1-84.

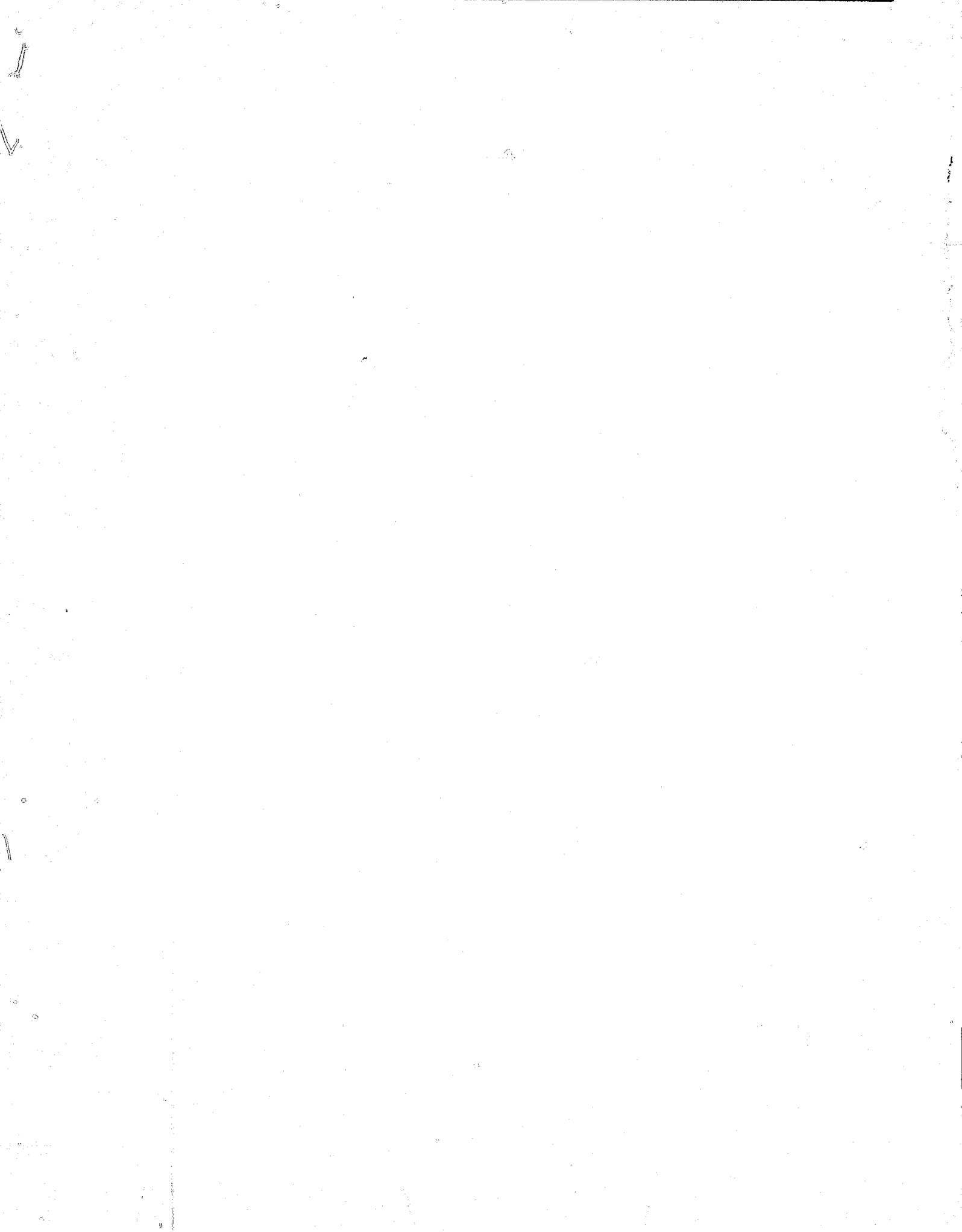


PHILOSOPHICAL PERSPECTIVE ON THE PARTICIPATION
OF PRISONERS IN EXPERIMENTAL RESEARCH

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INTRODUCTION

This essay will attempt to present some philosophical guidelines for public policy in regard to the involvement of prisoners in biomedical and behavioral experimentation. These guidelines consist of certain specifiable conditions which must be satisfied if the participation of prisoners in experimentation is to be legitimate. A clear formulation of these conditions is aided by an acute analysis of the notions of coercion, bribery and consent (informed and tacit); the conditions are rendered applicable by a close adherence to reliable empirical facts.

PHILOSOPHICAL INQUIRY: EXPERIMENTATION IN GENERAL

Prior to distinguishing the issues involved in the participation of prisoners in nontherapeutic biomedical research from those of therapeutic behavioral research, our inquiry will present the principles of justice which govern the prescription of human rights to persons (including those in penal institutions). These principles embody a particular ideal of the person; they are addressed to the legitimate conditions under which the participation of prisoners in experimentation (in general) may occur.

In America, the ideal of the person is manifest in the philosophical formulations (i.e. the Declaration of Independence) of the Founding Fathers. This formulation exalts the values of freedom, equality and rationality. The fundamental principles of the American Republic conceive of persons as free, equal and rational beings. Human rights are assigned and governed by these philosophical principles; these rights play a crucial role in formulating the legitimate conditions for the participation of prisoners in experimentation.

Following the highly sophisticated argument of John Rawls, in his celebrated work A Theory of Justice, I shall argue that the acceptance of the aforementioned ideal of the person entails the acceptance of the principles free, rational persons would choose under conditions of equality and fairness.¹ These principles, which should regulate human participation in experimentation, constitute the legitimate conditions for such participation. They are:

- 1) Persons must be fully informed of the consequences of experimentation (i.e. persons possess the human right to know).

- 2) Persons must openly consent to participation by signing a contract with group conducting experimentation (i.e. the human right to choose).
- 3) Persons must decide to participate in experimentation based on rational grounds under conditions of equality and fairness (i.e. the human right to rationally and fairly decide).

The first condition requires that the person be informed about the positive and negative consequences of their participation in experimentation; these consequences include the effects such experimentation will have on the person involved as well as those on society. This information is required for ethical reasons. As Hans Jonas cleverly writes, "if the prisoner is not informed he (or she) is definitely wronged even when not harmed"². Hence, if persons are not informed fully as to the consequences of experimentation, their human right to know has been violated.

The second condition fulfills the requirement of freedom; that is, it insures that the decision is the free choice of the prisoner. This choice is possible only under non-coercive conditions. The philosophical justification of condition two is that our ideal of the person demands that our agent be a free agent i.e. one who acts on one's own will. Hence, if persons are coerced into participating in experimentation, then their human right to choose has been violated.

The last condition insures that the decision is the rational choice of the prisoner under conditions of fairness and equality. This decision is possible only in non-manipulative relations. It cannot be made under bargaining conditions of domination and control. Hence, if persons are manipulated into participating in experimentation, then their human right to rationally and fairly decide has been violated.

The existence of penal institutions can be justified on libertarian grounds; that is, they are needed for the sake of liberty. Criminal laws and prisons serve as persons' security to one another.³ They are justifiable only if they protect the liberties of persons in society and preserve the fundamental human rights of persons within the penal institutions.

The human rights of persons are inviolable. They are violated only if the aforementioned ideal of the person is no long cherished. If this ideal of the person is no longer cherished, then the fundamental principles of the American Republic are no longer respected.

II

The most important task of our philosophical inquiry into the participation of prisoners in experimentation (for scientific research) is providing a clear analysis of the notion of coercion. This elusive concept holds primacy over the notion of consent, for legitimate consent presupposes non-coercive conditions.

In light of our justification of the human rights of persons (and prisoners, of course), we shall claim that non-coercive conditions are necessary, though not sufficient, conditions for the legitimate participation of prisoners in any kind of experimentation. This claim follows logically from our ideal of the person because the consent of persons under coercive conditions clearly violates the human right to freely choose (condition two).

The crucial question becomes "What are coercive conditions?" Following the highly rigorous argument of Robert Nozick⁴, I shall define

coercion as the performance of an action if one does that action because of a threat that has been made against one not doing that action. For example:

P is Q's usual supplier of drugs, and today when he comes to Q he says that he will not sell them to Q, as he normally does, for \$20, but rather will give them to Q if and only if Q beats up a certain person.⁵

In this example of coercion, P is threatening not to give Q the drugs. In the normal course of events, P does supply Q with drugs for money. P is threatening to withhold the supply, to deprive Q of his drugs if Q doesn't beat up a certain person. Hence, P coerced Q into beating up the person.

Coercion always involves a threat, which is understood by the person coerced and is intended to alter that person's behavior. A threat makes the consequences of one's action worse than they would have been in the normal, expected course of events.

So coercive conditions are those under which A does x owing to a threat made against A for not doing x and which worsens the consequences of not doing x relative to the normal, expected course of events. We should note also that coercive behavior is unwilling behavior; that is, a person who does something because of threats does not perform a voluntary action.⁶

In juxtaposition to the notion of coercion, we shall examine the notion of bribery. This latter notion shall be defined as the manipulation of incentives to get persons to perform a certain action. Bribery is not coercion; it does not involve a threat (as characterized above). A person is not coerced into performing an action if he performs it because someone

has offered him something. For example:

P is a stranger who has been observing Q, and knows that Q is a drug addict. Both know that Q's usual supplier of drugs was arrested this morning and that P had nothing to do with his arrest. P approaches Q and says that he will give Q drugs if and only if Q beats up a certain person.⁷

In this case, where P is a stranger to Q, P is not threatening not to supply Q with drugs because P does not do so in the normal, expected course of events. If P does not give Q the drugs he is not withholding drugs or depriving Q of drugs, rather P is offering Q drugs as an incentive to beat up a certain person. Hence, P does not coerce Q into beating up the person, since P does not threaten Q.

Where offers rather than threats are used to induce the alteration of conduct, we have the manipulation of incentives without coercion. The notion of bribery involves offers or incentives; they make the consequences of one's action better than they would have been in the normal, expected course of events. Bribed behavior is willing behavior; that is, when a person does something because of offers, it is one's own choice.⁸

The distinction between offers and threats is subtle, yet crucial. It demarcates the notions of coercion and bribery, unwilling and willing behavior. We intuitively can grasp the distinction by noting that we willingly accept offers, whereas we unwillingly go along with threats. The important observation is that the notion of coercion does not encompass all examples of "getting one to do something". Without an acute analysis of this vague phrase, almost all alterations of human behavior becomes coercive.

III

The participation of prisoners in experimentation (in general) falls under the rubric of bribery, not coercion. Participation is not induced by threats, but rather by offers e.g. money, pardons, prestige, relief from loneliness. So this participation occurs under non-coercive conditions; the free choice of prisoners is at play.

The central question now becomes "Does the promise of more comfortable quarters, better food, additional contact with outsiders, relief from fear and boredom all constitute coercion?"

In our analysis, we have defined coercion as involving a threat which makes the consequences of one's action worse than they would have been in the normal, expected course of events. The crucial question above asks whether the normal or expected course of events itself can be viewed as coercive. For example:

Suppose that usually a slave owner beats his slave each morning, for no reason connected with the slave's behavior. Today he says to his slave, "Tomorrow I will not beat you if and only if you now do A".⁹

One is tempted to view this as either a threat or an offer. Nozick suggests that it is to be viewed as a threat: in this case the standard for assessing an action (as to whether it is a threat or offer) is not the normal course of events, in which the slave is beaten daily, but rather the expected course of events (which the slave prefers) in which he is not beaten daily. Hence, the slave owner performs an action which makes the consequences of the slave's action worse than they would have been in the expected, preferred course of events.¹⁰ This example cannot be a situation of bribery because the best consequences of the offer cannot be better than the expected, preferred course

of events. So the normal course of events (in which the slave is beaten) is itself coercive.

We must now ask the question, "Are present prison conditions analogous to the slave example?" In other words, "Do present prison conditions constitute coercion in regard to the participation of prisoners in experimentation in general?"

I suggest that the slave example is not analogous to prisoners' participation in experimentation. The slave receives beatings from the slave owner for no reason connected with the behavior of the slave; the beatings are attributable to the capricious whims of the slave owner. This is the normal course of events. The expected and preferred course of events involves the slave not being beaten¹¹; yet, given his situation, he must go along with the threat i.e. do A. Prisoners indeed must put up with excruciating conditions (many unnecessary and unjustifiable on merely sanitary grounds)¹² but the basic reason for being incarcerated is connected with some behavior of the prisoner in society.

The alteration of the slave's conduct i.e. "do A" from the unwarranted beating of the slave is coercive because the standard of assessing whether the action of the slave is attributable to a threat or offer is the course of events the slave prefers. The alteration of the prisoners' conduct (i.e. freely participate in experimentation) from the warranted incarceration of the prisoner is not coercive because the standard for assessing whether the participation in experimentation is attributable to a threat or offer is not the course of events the prisoner prefers but rather the normal course of events of the prison.

This argument assumes that the legal system which feeds into the prison system approximates justice i.e. usually prosecutes the responsible person. If the legal system approximates injustice (or arbitrarily sends persons to prison) then the whole penal system is unjustifiable.

My argument also assumes that persons (of normal mental capacity) are responsible for criminal actions they commit. This assumption may sound simplistic, but it runs counter to certain deterministic, environmentalist claims that most prisoners who commit crimes are not really guilty of their actions since he or she grew up in social conditions which facilitated or forced them to commit a crime. According to this view, prisoners are symbols of oppression and mere objects of circumstance.¹³ It is pathetic and undeniable that most prisoners are poverty-ridden minority males; it is important to note the oppressive conditions against which they combatted. But this observation is related to the issue of social reform; it cannot be the basis of an analysis of coercion in prisons.

We have found that the promise of better food, more comfortable quarters, relief from fear and boredom, etc. does not constitute coercion. So such enticements, in addition to full information of the consequences, do not -- as of yet in our analysis -- violate the human rights of prisoners. The first and second conditions have been fulfilled. We must now see whether the last condition for the legitimate participation of prisoners in experimentation can be fulfilled.

The participation of prisoners in experimentation falls under the rubric of bribery. As we noted earlier, the notion of bribery involves the alteration

of one's conduct by the manipulation of incentives. It does not involve threats (as does coercion) but rather offers: an offer makes the consequences of one's action better than they would have been in the normal, expected course of events.

I now claim that offers and incentives used in the participation of prisoners in experimentation constitute bribery. These enticements occur in manipulative relations under bargaining conditions of domination and control. These relations indeed allow for the free choice or voluntary consent of the prisoner (required by condition two), yet it undermines the rational basis of such consent or choice. The evidence shows that over half of prison volunteers do so out of a desire for better living conditions.¹⁴ These conditions can be obtained solely by volunteering, so prisoners volunteer to participate in experimentation. I claim that this kind of reasoning, given the circumstances, is irrational. The prisoners voluntarily consent but the alternatives are too narrow for their choices to be philosophically justified. It is a cheap decision based solely (or primarily) on the manipulation of incentives by those who offer the once in a "term-time" opportunity.¹⁵ Following Bernard Williams, I would characterize such prisoners' participation in experimentation as an "irrational situation":

What is meant is that it is a situation in which reasons are insufficiently operative; it is a situation insufficiently controlled by reasons -- and hence by reason itself.¹⁶

The notion of bribery involves the free choice (or voluntary consent) of the prisoner but the choice itself is based on irrational grounds. It is similar to voluntarily consenting (i.e. freely accepting an offer) to live in a more

sanitary hotel room when it's the only room available other than your present nasty one. The choice itself is not irrational (but rather the best opportunistic action to take given the circumstances), though the choice has an irrational basis upon which it is made.

A choice has a rational basis if and only if a variety of alternatives are available and relevant reasons of the agent are operative. In prisoners' participation in experimentation, there is a paucity of alternatives, thus certain pertinent reasons are suppressed i.e. are insufficiently operative. For example, if that half of the prisoners who volunteered to participate in experimentation for reasons of better living conditions already had decent living conditions, then undoubtedly certain reasons for volunteering would be operative which are not under the present circumstances. Likewise holds for other attractive enticements e.g. wages which far exceed the normal levels in prisons.

So informed and voluntary consent in manipulative relations under conditions of domination and control leads to our rejection of our ideal of the person as a free, equal and rational being. This kind of ("cheap") consent violates the human right of persons (and prisoners included, of course) to rationally and fairly decide whether to participate in experimentation.

A reasonable objection to my reasoning and conclusion may be that, even though prisoners do reside under conditions of domination and control, these conditions are warranted. Therefore they cannot serve as grounds for disallowing the participation of prisoners in experimentation.

I noted earlier in this paper that some form of incarceration (not necessarily the present: excruciating conditions of prisons) is warranted assuming the legal system on which it feeds approximates justice. This warrant indeed justifies a certain degree of domination and control in penal institutions. But penal institutions should not violate the basic human rights involved in the participation of prisoners in experimentation. So the conditions of domination and control in some form of incarceration may be justified; and it is precisely this reason penal institutions are undesirable for experimentation. The human rights of prisoners are more easily violated precisely because the prisoners are more easily manipulated. Basic human rights guarantee that prisoners are not manipulated in research requiring human experimentation; basic human rights do not guarantee that some form of domination and control will be absent in warranted penal institutions. My arguments pertain solely to the former.

Prisoners should have the right to participate in the sustenance and improvement of society and mankind¹⁷, through the joint cooperation with the medical and social science professions, respectively. But this right is a prima facie right; that is, persons are entitled to it if it is not overridden by other more important moral considerations. I have claimed that prisoners are entitled to this right if and only if their more basic human rights are not violated. These basic human rights are respected only if the three conditions for legitimate participation are met.

PHILOSOPHICAL INQUIRY: THERAPEUTIC EXPERIMENTATION

Although the previous section applies to the participation of prisoners in experimentation in general, participation of prisoners in therapeutic experimentation deserves additional attention. Since the turn of the century, the stated objective of the penal system in this country has been the rehabilitation of its inhabitants. Therapeutic research on prisoners can easily be construed consistent with the rehabilitative objective.

The central questions in this inquiry are, "What is the demarcative line between research qua rehabilitation and research qua experimentation?" and "What is the extent to which a prisoner retains the right to refuse rehabilitative therapy?" The former question is an empirical one; that is, we must see whether the present state of the scientific enterprise views current behavioral and biomedical therapy as rehabilitative or experimental. The latter question is a philosophical one; that is, we must define those rights a prisoner retains or forfeits as a result of conviction.

In any stage in the ever-ongoing, self-correcting process of science, conflicting theories exist as to the explanation of certain phenomena. For example, the effectiveness or ineffectiveness of behavioral modification techniques in reducing recidivism in prisoners is hotly contested on both sides of the issue.

In any scientific controversy which involves human experimentation, we must never lose sight of the fact that real, live human beings constitute the domain of data. Only a crude utilitarianism could justify continual human experimentation in the face of experimental failure.

Recent literature in the area of therapeutic research strongly avers that such research is primarily ineffective in rehabilitating prisoners; at this point in its development, it is highly experimental.¹⁸ In fact, there is some laboratory evidence to support the claim that the rate of undesirable behavior is increased by aversive conditioning owing to a "paradoxical effect", among other things.¹⁹ After viewing the evidence, it seems to me that the current state of therapeutic research on prisoners is experimental; it has not shown to contribute significantly to the rehabilitation of prisoners.

Hence, the argument presented in the previous section answers our second question. This argument was presented in order to justify the legitimate conditions under which prisoners could participate in experimentation in general. It holds for "therapeutic" experimentation in that such experimentation does not rehabilitate. So "therapeutic" experimentation is literally nontherapeutic experimentation; it is not therapeutic i.e. it does not rehabilitate.

A reasonable counter-argument can claim that experimentation will never become therapeutic i.e. rehabilitative, if it is not allowed to proceed and develop; I agree. But, as the previous section attempts to show, experimentation can proceed and develop with prisoners as their data only if the three conditions are met. I do not foster an anti-science view; I merely claim that certain ethical constraints be observed. Scientific progress is grand, but even it must bow before the altar of human rights; scientific progress is progress only if it legitimately respects the value and dignity of persons. Such progress is guaranteed if the gusto for it is proportionate

to the willingness to satisfy the three conditions for justifiable human experimentation.

I should add that if such conditions are met and the resumed research yields rehabilitative results, new problems would arise concerning the second question above. This new influx of complexity is attributable to the rehabilitative policy of penal institutions and the rehabilitative results from legitimate human experimentation. Our three conditions would remain, but the notions of coercion and bribery would have to be redefined. For example, the very standard of assessing whether an action is a threat or offer (in our analysis this standard was the normal, expected course of events) would be altered. Prisoners would now expect to be involved with some form of therapy; given the rehabilitative objective of prisons and effective rehabilitative therapy, some form of therapy would now be part of the normal, expected course of events. Hence, effective rehabilitative therapy would not fall under the rubric of bribery, for it would no longer be experimental. The important point is that the human rights of prisoners would be observed, irregardless of the state of science.

ALTERNATIVES

In light of my refusal to allow the participation of prisoners in experimentation unless the relevant conditions are satisfied, we may ask, "Are there other possible populations available who could more easily meet the legitimate conditions for human experimentation?" The answer is emphatically affirmative. The claim that prisoners are the sole population available to demonstrate the efficiency and safety of new drugs is inane. This claim, most likely, is but a facade or weak rationalization of research activity on behalf of profit-hungry firms and knowledge-thirsty psychologists who don't want their pleasant situation to be disturbed.

It is reasonable to expect human experimentation in scientific research to shift from prisons to Third World countries. I suggest that this shift would be unjustifiable, for it is highly unlikely that the conditions under which human experimentation occurs there, would violate the legitimate conditions which protect human rights.

The legitimate conditions are met most easily (and possibly only) by normal volunteers. Full information would be available to the volunteer; overt consent would be freely displayed; and, most importantly, consent would be based on rational grounds under conditions of equality and fairness.²⁰ The manipulation of incentives under conditions of domination and control is severely minimized.

It is significant that this viewpoint is advocated by John Arnold, former director of the Truman Research Laboratory in Missouri, who has conducted

malaria research for twenty-seven years. He even notes that there are certain positive benefits for the research itself (e.g. better systems for follow-up care, better research staff, etc.) over and above the humanistic considerations.²¹

POLICY RECOMMENDATIONS

The preceding philosophical inquiry has lead to the following reasoning for the basis of public policy concerning the participation of prisoners in experimentation for scientific research:

- 1) The participation of prisoners in experimentation should be regulated by philosophically justifiable principles. These principles should embody the ideal of the person found in the fundamental philosophical formulations of the land. These principles govern the assignment of human rights to persons in general (and for our purposes to prisoners in particular).
- 2) Within a society whose legal system approximates justice, prisoners rightfully forfeit certain liberties in lieu of incarceration, yet they retain their basic human rights as defined by the aforementioned principles.
- 3) Coercion is a sufficient, though not a necessary, condition for the termination (or disallowance) of human participation in experimentation. Incarceration in addition to the offers of researching firms do not constitute coercion.
- 4) Bribery is a sufficient, though not a necessary, condition for the termination (or disallowance) of human participation in experimentation. Incarceration in addition to the offers of researching firms do constitute bribery. So prisoners' participation in experimentation under briborous conditions is not philosophically justifiable i.e. it violates at least one human right of the prisoner.
- 5) The reasoning in 1-4 applies to research qua nontherapeutic experimentation; yet research qua therapy has not proven to be therapeutic i.e. rehabilitative, so present research qua therapy remains research qua nontherapeutic experimentation. Hence, the reasoning in 1-4 applies to all prisoners' participation in experimentation at present. A significant scientific advance in research qua therapy would present complexities, assuming the objective of the penal system remains that of rehabilitation.
- 6) The reasoning in 1-4 applies to pertinent alternative populations e.g. Third World countries, domestic unemployed poor, et. al. The best alternative (or that which most easily meets the legitimate conditions) population is normal volunteers.

My policy recommendations are:

- 1) The immediate termination of prisoners' participation in experimentation in nontherapeutic biomedical and "therapeutic" behavioral research.
- 2) Participation can be resumed if and only if the legitimate conditions for participation of persons in experimentation is fulfilled. This fulfillment within penal institutions entails vast prison reform, an issue untouched in this essay.
- 3) Human participation in experimentation should involve primarily (and at the present time only) normal volunteers, provided that legitimate conditions are fulfilled.

FOOTNOTES AND COMMENTS

- ¹The philosophical justification of this neo-Kantian methodology is forcefully argued by Rawls, A Theory of Justice (Cambridge, 1971) Chap. I, esp. Sect.9, Chap. III and Chap. IX, Sect. 87. I do not offer an analytic argument for the derivation of the three principles that regulate human participation in experimentation; this paper is primarily an attempt to provide guidelines for policy, thus a purely deductive argument based on neo-Kantian (or Rawlsian) methodology would be a bit out of place. I do hope that one does intuitively grasp the relationship between the American ideal of the person and the three principles based thereon.
- ²Hans Jonas, "Philosophical Reflections on Experimenting with Human Subjects", Experimentation with Human Subjects, ed. Paul Freund (New York, 1970), p.23.
- ³For an elaboration on the reasoning underlying this conception of penal institutions, see Rawls, A Theory of Justice, Chap. IV, Sect. 38, esp. pp. 240-241.
- ⁴Robert Nozick, "Coercion", Philosophy, Science, and Method: Essays in Honor of Ernest Nagel, ed. S. Morgenbesser, P. Suppes and M. White (St. Martin's Press, New York, 1969), pp. 440-472.
- ⁵Ibid., p. 447.
- ⁶Ibid., p. 459.
- ⁷Ibid., p. 447.
- ⁸Ibid., p. 459.
- ⁹Ibid., p. 450.
- ¹⁰Nozick argues for his suggestion on pages 450-451 in his article. This example is analogous to the researcher threatening the prisoner by saying "Either you participate or you get tortured by the Tucker Telephone or the teeter board". In this case, the preferred course of events (in which the prisoner is not tortured) becomes the standard of assessment as to whether a particular action is a threat or offer. I should add that the 'Tucker Telephone' and the 'teeter board' were forms of torture in Arkansas prisons prior to court cases outlawing them. For further information, see Criminal Law and Procedure; Cases and Materials, James Vorenberg (St. Paul, 1975), Part II, Sect. 29B, "Prisoners' Rights", esp. p. 893.
- ¹¹The slave may prefer, of course, to be free; but if our point is to be cogent, we must stay within the perimeters of our example.

- 12 It is important to make a distinction between incarceration and prison conditions; that is, between the warranted removal of one from society and the conditions inside the penal institutions. I address myself only to the former. I am not asserting that the present prison conditions are warranted. In fact, present prison conditions can be rightfully condemned on other moral grounds; but this is a subject for another paper. The present conditions of prison are important here only in so far as they serve as a background for coercion or bribery in the participation of prisoners in experimentation. For a recent legal condemnation of prison conditions, see the description of U.S. District Judge Frank Johnson's decision in Alabama in Newsweek, Jan. 26, 1976, p. 43.
- 13 I suggest that this deterministic view stultifies the self-image of the poor as well as dehumanizes them. It's obvious that the poor need help, but it doesn't follow that the poor are helpless. Ironically, the Left have pushed this view, which views the poor as mere objects, only worthy of manipulation. I believe that if one views others as not responsible for their actions (while admitting that there are some people who are responsible for their actions), one is presupposing the inferiority of the former. To hold a person or group of people responsible for their actions means to treat them as equal moral agents as oneself; if persons are not treated as equally responsible, there is not much left to their equality as moral agents. My view does not entail victimology or "blaming the victim", but rather recognizes the free will of the victim i.e. respecting him or her as a person. For further elaboration, see Bernard Williams, "The Idea of Equality", Moral Concepts, ed. (Oxford, 1970), p. 159.
- 14 John D. Arnold, Daniel C. Martin and Sarah E. Boyer, "A Study of One Prison Population and its Response to Medical Research", 169 Annals of the New York Academy of Science, Jan. 21, 1970 pp.463-470. There is further evidence in John C. McDonald's article in the Journal of the American Medical Association, No. 6, 202, Nov. 6, 1967 "Why Prisoners Volunteer to be Experimental Subjects", p. 175.
- 15 In a Trenton newspaper article entitled, "WILLING 'VICTIMS': Inmates oppose efforts to halt drug testing", one prisoner states in reference to participation in experimentation, "It's like going to the Bahamas". This statement says as much about present prison conditions as it does about the motivations for prisoners' participation in experimentation. For the article, see The Star-Ledger, Nov. 19, 1975, p. 38
- 16 Bernard Williams, "The Idea of Equality", Moral Concepts, ed. Feinberg (Oxford, 1970), p. 164.
- 17 I think this right is crucial and should not be overlooked. Although it can be overridden by other moral considerations, it is often ignored by overly eager libertarians. Paul Ramsey and Paul Freund as well as Margaret Mead and Talcott Parsons have caught note of this important right. For further elaboration, see Paul Ramsey, The Patient as Person, (New Haven, 1970), esp. p. 42f; Paul Freund, "Introduction", esp. p. xvi, Margaret Mead

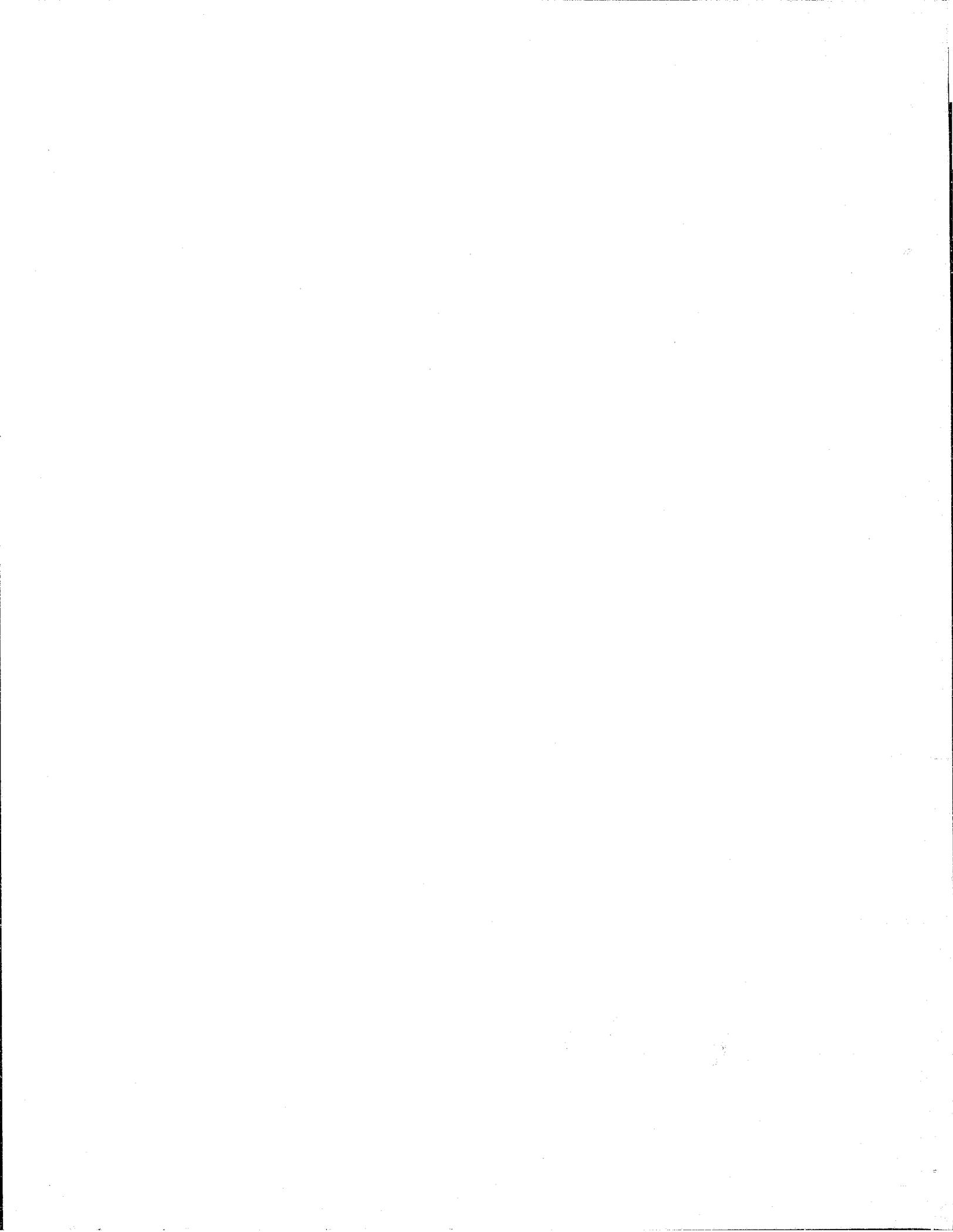
"Research with Human Beings: A Model Derived from Anthropological Field Practice", esp. the beginning of the essay pp. 152-157, Talcott Parsons, "Research with Human Subjects and the 'Professional Complex'" pp. 116-151. All of the last four articles mentioned can be found in the anthology edited by Paul Freund, Experimentation with Human Subjects op. cit.

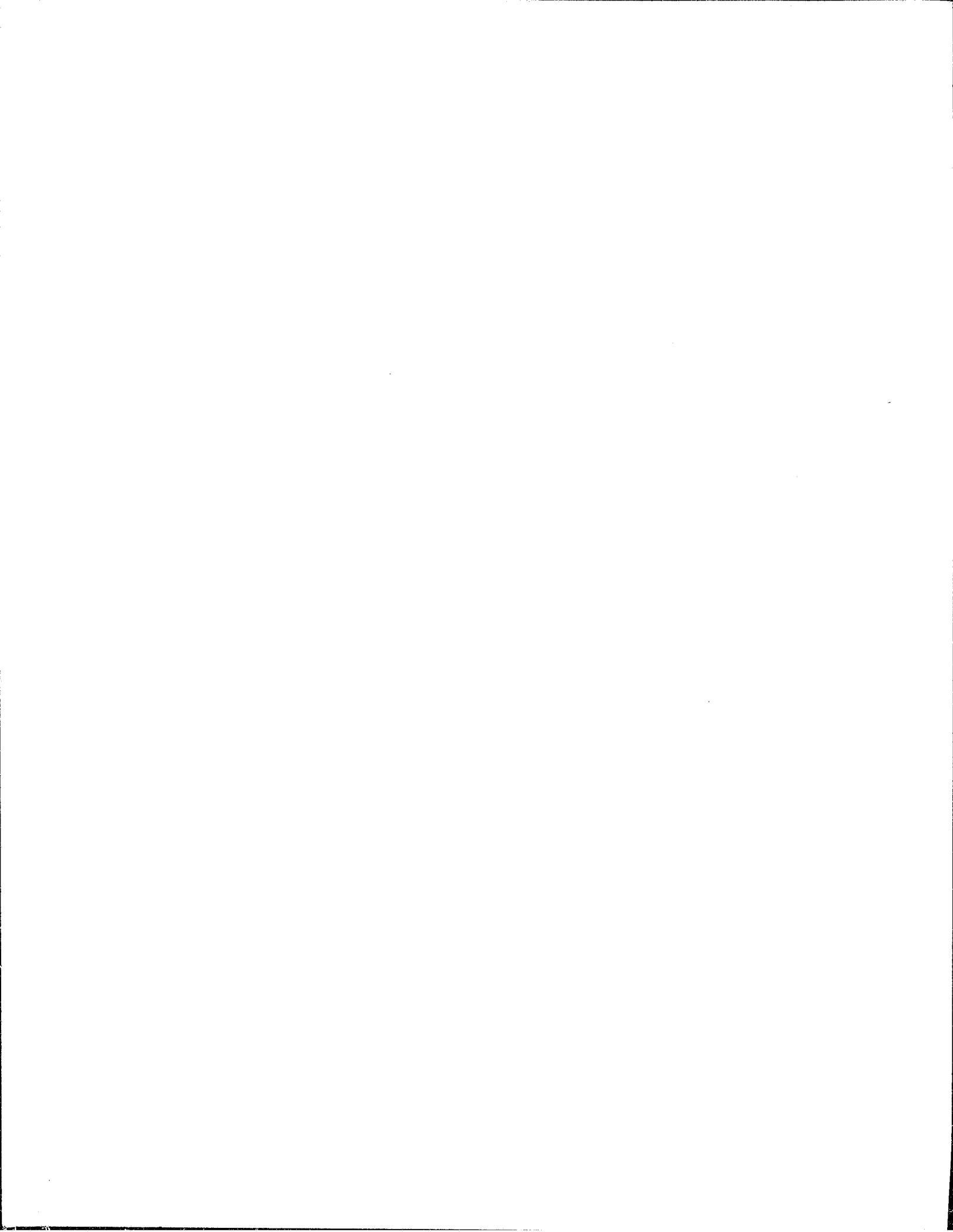
18 This conclusion is supported by many studies, but most importantly the crucial article by C. R. and Ina A. Jeffery, "Psychosurgery and Behavior Modification", American Behavioral Scientist, Vol. 18, No. 5, May/June 1975, pp. 685-722. They explicitly state on pages 714-715, ". . . at this point in history we do not possess the necessary knowledge to alter criminal behavior". They also quote the conclusion of the President's Crime Commission on page 692, ". . . there is probably no subject of comparable concern to which the nation is devoting so much effort with little knowledge of what it is doing".

19 Ralph K. Schwitzgebel, Development and Legal Regulation of Coercive Behavior Modification Techniques with Offenders, NIMH, Center for Studies of Crime and Delinquency, DHEW Publication No. (ADM) 74-102, 1974, p. 15.

20 These rational grounds would be the most rational ones our economic system allows. There will still be pecuniary incentives, but also a variety of alternatives which will allow the person to negotiate under more egalitarian bargaining conditions. It seems to me that the chronically unemployed may still be at a disadvantage, similar but not to the same degree as prisoners. For reasons I cannot fully delineate at the moment, I would oppose the participation of the chronically unemployed in experimentation. I am not convinced that their social conditions would satisfy the third condition; they would be easy bait for the manipulation of incentives under conditions of domination and control. But I cannot adequately make my argument now, for it is not the issue at hand. It indeed deserves some kind of treatment in future papers on human experimentation in general.

21 John Arnold, Statement before the Subcommittee on Courts, Civil Liberties and the Administration of Justice, House Judiciary Committee, Sept. 29, 1975. In this testimony, he states succinctly, "The prediction that alternate populations were not available has been wrong . . . We no longer need to propose that important programs be dismantled if we discontinue use of prison volunteers."

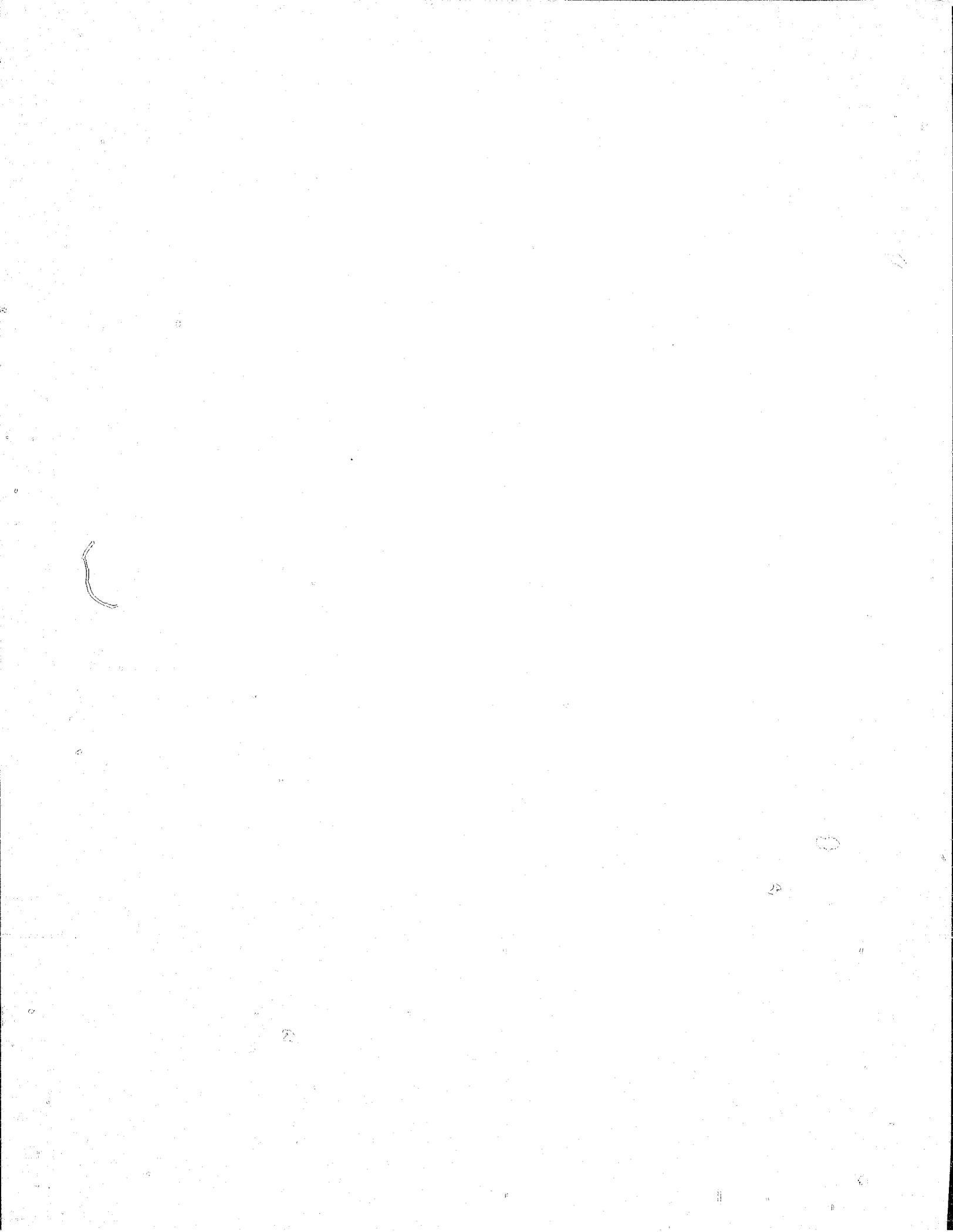




ON DOING IT FOR MONEY

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ON DOING IT FOR MONEY

In this brief paper, I will consider the ethical contexts of selling the disposition over the use of one's body for purposes of biomedical or behavioral experimentation. The aim of these considerations is to answer the question of whether there are any well-founded ethical objections to such participation in human experimentation for monetary reward. I will deal with the question in the following contexts:

- (1) What is it that is being sold (and bought)? In the context of an economic exchange, what rights does the seller have over what is being sold? What rights does the buyer have to buy, and what rights does he have over what is bought? What constraints, limits, and obligations are entailed by such an exchange, for the seller and the buyer? Obviously, what is at issue here is whether participation in human experimentation for monetary reward can be defined as a job, and whether the model of wage labor is appropriate to this context.
- (2) Does the motivation of the research subject bear on the ethical questions raised in the exchange? Similarly, does the motivation of the researcher, or the purpose of the research project have bearing here? Beyond this, do the anticipated consequences of the experiment (a) upon the research subject (b) with respect to potential benefits in the advancement of medical knowledge or therapeutic effectiveness bear on the ethical character of the exchange?
- (3) Does the sale of the disposition over the use of one's body for experimentation necessarily entail some degree of coercion or constraint, or can it be a free and voluntary act?¹

(4) What ethical considerations, if any, enter into making government policy in these matters? What does the government have the right to regulate? Would regulation or prohibition of the right to sell disposition over one's body for experimentation be in restraint of trade?

In short, then, the considerations here concern a persons's rights and obligations, with respect to his or her body, or with respect to the body of another; motives and consequences; coercion; and the rights and limits on governmental regulation. I am not concerned here with the legal contexts, concerning property-right, nor with the legal contexts of motive, nor with the question of compliance with existing laws, nor with the regulatory contexts of business law. Rather, the discussion will focus on ethical questions, including those concerning the law.

First then: what exactly is involved in participating in human experimentation for monetary reward? The frequently used description of "selling one's body for research" confuses the issue, and needs initial clarification. Only in the condition of slavery is one's body as such sold; and then, not by oneself but by another who has obtained control over it by force, or by custom (i.e., in slave societies). The moral force of the abolition of slavery is precisely the principle that one's life and liberty are inalienable rights, that is, that they cannot be separated from one's person and sold. The notion of alienable rights is a property notion, i.e., it ascribes as alienable those things, aspects or products of one's person which he or she can be said to possess and which can be sold as property. Thus, one doesn't have the right (nor does any other person have the right) to sell (or buy) one's body, as such. What is at issue, rather, is the sale of the disposition over the use of one's

body for stated purposes, and usually, for a stated time and under specific conditions. Such a sale characterizes indentured servitude, for example. But, like slavery, this too is outlawed as morally and legally repugnant, since the sale involves one's liberty during the period of indenture, and the contract is not revocable except by payment, i.e., by compensatory redemption for the services contracted. What is at issue, then, is not the sale of one's body for research but rather the sale of the disposition over the use of one's body for specified purposes, for a specified time and under specified conditions. The ethical question concerns what is and what is not alienable under these conditions, not simply as a question of defining property, but as a question of what the relation is between person and property, i.e., whether and under what conditions there are aspects of one's own person which are alienable.

My own premise here is that person and body are coextensive, as a whole, though parts and products of one's body are not necessarily parts and products of one's person.²

Thus, the changes in one's body which may be said to affect and change the person one is, are the ones which are relevant here. Where a change in a part of the body does affect such a change in the body as a whole, i.e., affects the whole organism, and thereby the state of health, well-being, or prospective longevity of the person, or effects a psychological change (in "personality"), then it is difficult to separate part from whole, functionally. However, taking of urine or blood specimens, or tissue, or even organs, under certain circumstances, may have no such effect on the person, or only a minimal effect.

In general, then, the question of what is alienable, or what a person may permit to be separated from himself or herself, and sold, may initially be considered in terms of some criterion of whether the change affects the health, well-being or prospective longevity of the whole organism, i.e., of the body insofar as it is coextensive with the person.

Here, let me state what is, I believe, an accepted ethical principle, namely: that no one has the right (including the person himself or herself) to alienate one's own person as such; and by the definition of person as co-extensive with the (living) body, no one may alienate one's body as such. Thus, one cannot sell one's life (or body) or buy another's; for this would be tantamount to slavery. For example, the taking of another's life, in the case of murder, is a case of taking what is not alienable property, on this view. Short of this, however, questions arise as to what, then, is alienable; and what exactly it is that is sold by paid research subjects, and bought by researchers. We need some viable models of alienable rights, or alienable possessions, where such sale or purchase is countenanced.

The major context in which the alienability of one's person arises, in modern societies, is that of wage labor. The relevance of this context to the present issue is clear, since what is at stake is whether research subjects who do it for money may be categorized as engaging in a job, i.e., in selling one's capacities or services for a wage, or an equivalent form of monetary compensation (e.g., a fee). Here, the ethical question is, in one sense, settled, and in another, not. On the one hand, since, in a capitalist economic system, or a free-market system, the exchange of one's capacity to work for wages is the very basis of social and economic life, and is not considered ethically

objectionable or repugnant, then, insofar as research subjects and researchers may be said to engage in such an exchange, they are in as ethically acceptable a context as anyone who works at a job for money or employs another to do so. On the other hand, if there are ethical objections to wage labor, or to the capitalist system of exchange, then these will bear equally on the exchange which takes place in experimental research with human beings. A socialist may adduce ethical objections to wage labor in any form, but that is not a question to be resolved here. Instead, it may be useful to reconstruct the model of wage labor to see how and to what extent it is analogous to the situation of the paid research subject, and where the analogy breaks down.

In wage labor, what is being sold is one's capacity or service for a certain time, under certain conditions. The product of one's labor, or the benefit of one's services then belongs as property to the employer. Such a product or service is plainly alienable, then, and presumably, one has a right to sell it, or rather, to sell the disposition over the labor or skill which produces it. Only in handicraft or in personal production or service industry, where the entrepreneur is also the craftsman, is the product or service as such sold. In wage labor, it is the capacity to produce the product or to render the service which is sold, usually at a time-rate, or hourly wage or fee. Thus, in wage labor, it is the disposition over the use of one's body, at work, or with a certain skill, which is sold.

In classical economic theory, the value of products was seen to derive from the human labor embodied in these products. This "labor theory of value," in all its historical variants (e.g., William Petty, John Locke, Adam Smith, David Ricardo, G. W. F. Hegel, Karl Marx) presupposes that one's capacity to

work is alienable -- i.e., that there is "free labor" -- and that this capacity is the origin of economic value, and may be sold in the market as itself a commodity, in exchange for monetary payment. Thus, John Locke proposes that the value of cultivated land, (or of any product of labor) derives from the fact that a person has "mixed" some of his labor with the raw material, and has thus "mixed" part of himself, or his person (his proprium) with it. Property right derives from this embodiment of part of one's person in the commodity, according to Locke.

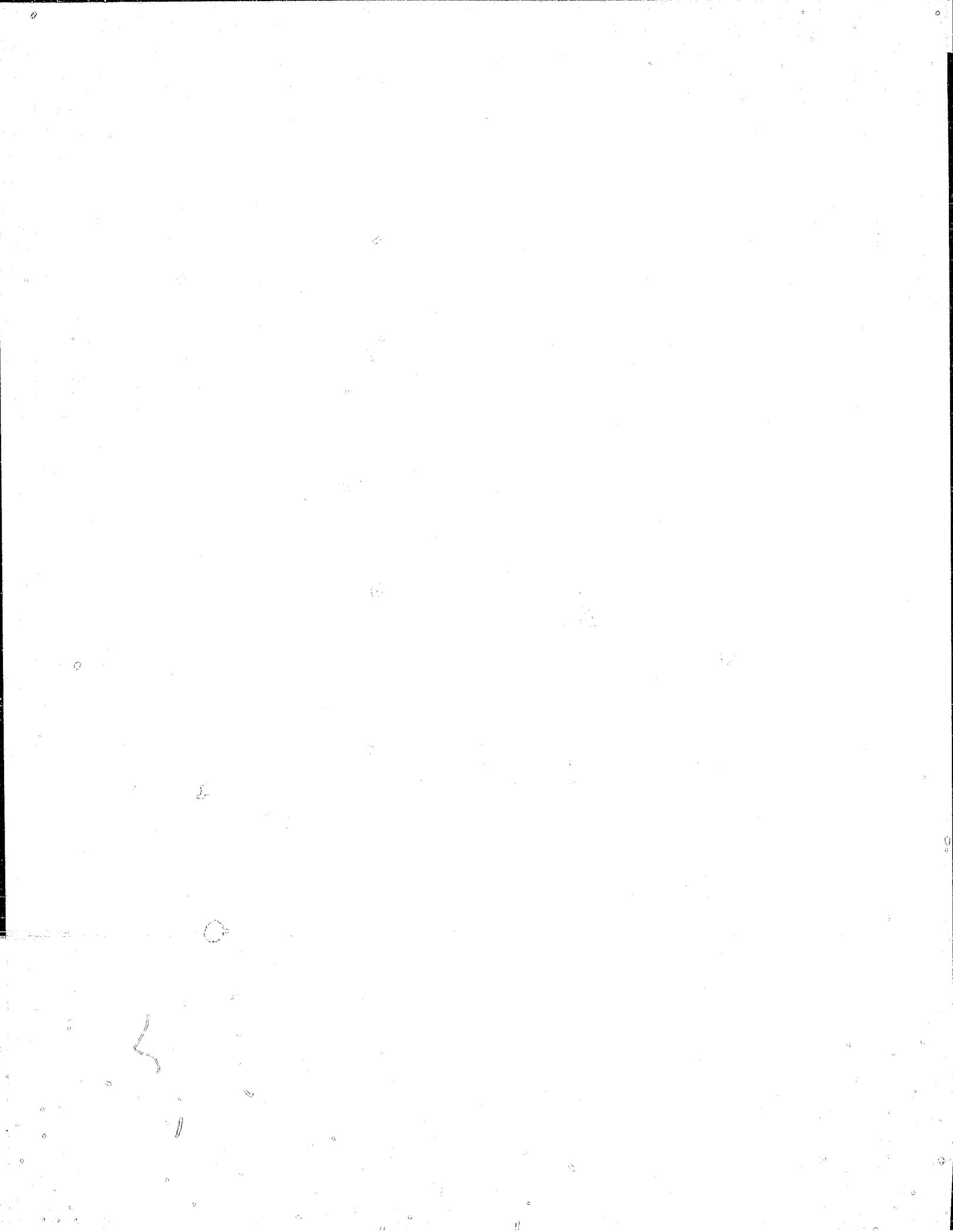
In effect, then, the wage worker does not sell the products of his or her labor, but only the capacity to work, i.e., disposition over his or her ability to produce goods or services. And since the practice of this capacity involves the use of one's body, wage labor may be seen as the sale of the disposition over the use of one's body for certain purposes, and for a certain time, in exchange for money, at a specified time-rate. Presumably, also, since this is regarded as a free market exchange, it is voluntarily entered into by both seller and buyer, and may be terminated. One may always quit one's job; and one may always be fired, on this ideal model of free exchange. So too, one may always refuse an offer of employment; or refuse to hire an employee. This relation is therefore one of contract, in which both parties are regarded as free and voluntary agents in the agreement.

The virtue of such a displacement of the ethical questions concerning rights over the uses of one's body, is that all of the ethical considerations and objections are resolved into legal considerations regarding relations of contract. The ethical question is presumably taken care of by the presupposition that persons are essentially free, rational agents, and that a valid

contract is one in which the parties agree as free, rational agents. What conditions or constraints there may be on the freedom or the rationality of such agents is not taken into account on this ideal model. But presumably, if there is deficiency in the rationality of the agent (e.g., incomplete knowledge, or deceit and fraud) or in the freedom of the agent (coercion of any sort), then the ideal conditions of contract are not met.

This digression into the question of wage labor is for the sake of examining how far the analogy holds to participation in experimentation for monetary reward. Let us examine the case, then.

Is the sale of the disposition over the use of one's body for research purposes conformable to the model of wage labor? For example, does the subject have the right to sell (and does the researcher have the right to buy) such disposition, in research contexts? Is the relation simply one of contract? i.e., are the ethical questions dissolved into the legal relations of contract? The attempt to specify the rights of research subjects (monetary or otherwise) in the recent moves for the protection of such subjects is just the attempt to resolve the ethical question into a legal one, by defining the terms under which such a research arrangement will have the form of a viable contract, namely an agreement entered into by the free consent of both parties. The definition of "informed consent," for example, is part of such an attempt. It proposes, in effect, that if the terms of "informed consent" are met, then the relation does constitute a contract entered into with "free power of choice without undue inducement or any element of . . . constraint or coercion." This, in fact, bears on the ethical question of free choice based on adequate knowledge of risks and benefits. So too, the requirements on the researcher --



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e.g., to provide a project of potentially significant benefit, and of competent research design, and the requirement for protection of the rights and welfare of the subject, and protection from unnecessary risk -- all address the question of moral justification of putting the subject at risk. The law, in effect, attempts to specify what the ethically acceptable conditions are, so that compliance with such conditions will connote not only that legal requirements have been met but ethical ones as well. That is to say, the conditions of a free contract are stipulated to be the knowledgeable and free consent of the research subject, his or her right to withdraw from the experiment at any time, etc. The connotation here is that without adequate information, the contract involves deceit and is therefore morally repugnant. This moral repugnance of deceit or fraud is translated into legal constraints upon such practices. Since the paid research subject is undertaking a risk, one may say that this risk-taking capacity is what is being sold (and bought) and that proper information in effect defines this "commodity." If it is not truthfully defined, then the buyer is in fact deceitfully buying something which the seller isn't selling freely or knowingly, and therefore there is fraud involved, and no proper contract.

Since the conditions of informed consent, quality of the research project, competence of the researcher, review by a board, etc. apply equally to voluntary unpaid research subjects as well as to paid research subjects (hereafter, PRS's), this doesn't yet touch on the specific contexts of monetary reward. Whatever ethical objections there may be to the specific case of PRS's must relate directly to the matter of payment. Further, as will be seen, it is this context of payment which opens up questions of motivation and coercion, and questions of regulations, in a specific way.

If paid research subjects are analogous to wage workers, in selling disposition over specified uses of their bodies, then only those ethical objections which bear on wage labor in general will bear on this special case. But now we have to determine further whether the situation of a market exchange is in fact comparable. What is being sold by the PRS is his or her risk-taking capacity, though of course in the specific sense of risk to the (normal) subject's biological (or psychological) functioning. The subject agrees to put his or her body at risk, to one degree or another.³ But this is comparable to risk-taking in other occupations as well; and in this sense, the PRS may simply be regarded as engaged in one of the dangerous occupations, and whatever ethical objections there are would pertain to all of these, without differentiation. The distinction between PRS's and other paid workers in dangerous occupations must be made on other grounds than calculation of risk, therefore. In many occupations where there is risk of life, limb or health, the moral justification is that the social benefits or the needs of society override the risks (e.g., in coal mining, structural steel construction, chemical and petroleum industry occupations, technology involving radioactive materials, etc.). Appropriate concern for the regulation and minimizing of such occupational hazards is regarded as the obligation of society and usually imposed upon the employer). Thus, regulation of risk, adequate compensation, insurance, and regulatory inspection are characteristic ways in which society copes with such hazardous occupations, and recognizes the responsibility for avoiding "unnecessary risk." In general, no ethical objection is raised to such occupations on the grounds that the worker is seen as having free choice in undertaking or refusing such a job; and society is content, therefore, that no "undue inducement or coercion" is being practised. There is, however, a

shady side to this claim; for in high-risk jobs, especially those of a more exotic nature -- e.g., test-pilot, stunt-man, bodyguard -- the monetary compensation is sometimes pegged at a rate which constitutes an extraordinary inducement, and may be conceived of as a kind of coercion. ("Making an offer they can't refuse," so to speak.) But I will reserve discussion of this context to the subsequent sections on motivation and coercion.

If the PRS is to be distinguished from the worker in hazardous occupations, it must be because the nature of the risk is different, since the degree of risk is, in most cases, considerably smaller for the PRS. What is of ethical concern, is whether one can willfully and knowingly subject one's body to disease, or to biological harm -- i.e., whether one may put one's health at risk for money. The intimacy of the relation between one's person and one's health or biomedical or psychological well-being is what is disturbing here. One cannot "sell" one's health, but one may sell the ability or capacity to put one's health or well-being at risk. In effect, the experimental situation is precisely one where the effects are not known and are to be discovered; and so risk is necessarily involved, as a concomitant of this ignorance. Thus, what the PRS is selling is just this capacity to put the body at risk deliberately and knowingly. This seems to me an important distinction, because it makes clear that it is not the body which is sold and bought, nor any part or product of the body. Rather it is disposition over the use of one's body for the purposes of putting it at necessary risk in an experimental situation, which is sold by the PRS and purchased by the researcher. And nothing less.

The question at issue then becomes: "Is the capacity to risk one's health or well-being an alienable property of the person?" Whatever ethical objections

there may be must relate to this question, if in fact the participation in experimental research for monetary reward is to be seen in the context of a paid job, or on the model of wage labor.

It is true that one may raise the same question with regard to hazardous occupations; and therefore it is interesting to consider why it doesn't seem quite right to put the two in the same category. A hazardous occupation also puts one's health, and even one's life or longevity at risk, often more so than does biomedical experimentation with human subjects. But it does so as a by-product of the purposes of the work. The test-pilot is testing the plane, and not his own reactions. (To the extent, however, that his own reactions in the test are monitored, he is an experimental research subject as well.) The coal miner is paid to mine coal; the structural steel worker is paid to build bridges or skyscrapers. Neither is paid to put himself at risk in order to see what the effects will be on his body or his health. Thus, though the hazards may be the same or greater than those which the PRS undergoes, what is being paid for and what is being sold is distinctive in the case of experimental research. Ethical objections which may arise in this context concern whether this more intimate aspect of one's person -- one's health or well-being -- can deliberately be put at risk rationally, i.e., freely and knowingly. Or whether the conditions for such rational risk-taking can be met, in the case of paid experimental research subjects. There is, it seems to me, no general question as to whether human beings have a right to put themselves at risk in this way. Human beings have a right to do whatever is necessary to preserve and improve human life. The argument that social benefits to humankind at large may override individual risks is also no general argument here; for one of the social benefits to humankind at large which perhaps outweighs most others

is the social benefit which accrues from respect for the life and well-being of each individual person. Thus, since I believe it may be argued that human experimentation is necessary if it preserves and improves human life; and further, that such experimentation needs to be regulated so that it respects the life and well-being of each individual subject, what remains to be determined is what the conditions are under which both of these desiderata are satisfied, especially in the case of PRS's.

The ethical queasiness at using the human body for experimental research in general, is increased when it is done for money. Why? Because the ethical motives we tend to think justify such putting of one's health and well-being at risk seem to be compromised here. If wage labor seems too "economic" a model for participation in paid experimental research, it is because we balk at regarding health or well-being as a commodity. If anything, since working for a wage is undertaken in order to preserve and improve one's life, to provide the means necessary for life and for its amenities, then work which deliberately risks this very goal seems self-contradictory in motive. But this leads me to the second consideration, concerning motives and how these bear on the ethical questions at hand. Before proceeding, let me summarize the analysis thus far:

What is being sold and bought is disposition over the use of one's body for the purpose of putting it at risk with regard to effects on the health, well-being and prospective longevity of the person. The question of whether this capacity to put oneself at risk in this way for money is an alienable possession of the person -- whether the person has a right to do so, or whether another has a right to ask or induce him to do so -- becomes an ethical question in the following contexts:

- (1) Is the person freely and rationally undertaking the risk? (Informed consent, no coercion, etc.)
- (2) Is the risk such that the calculable effects amount to an alienation of the person as a whole? In which case, since the person's life and liberty are unalienable, this amounts to the sale of an unalienable right, and is ethically objectionable. (One may rephrase this in the more pious language of "sanctity of life," or of the person, but the consequence is the same.)
- (3) Is the researcher competently judging (and is the review board competently evaluating) prospective risks and benefits? And is the principle of protection of the individual subject against unnecessary risk being adequately exercised? These are at best heuristic considerations, since the specification of such qualitative terms as "competently" and "adequately" depend on the competence and adequacy of the judges in the matter, and therefore, on the state of the art.
- (4) Since the relation of PRS to researcher is one of contract, are the conditions (1) - (3), as ethical considerations, explicitly formulated in terms of legal requirements on the contract, so that it presupposes and embodies them?

Thus far, the consideration has been sanguine with respect to some crucial ethical questions, which bear directly on the monetary context. The model of wage labor was adduced in order to put the matter into a form analogous to an acceptable contractual situation. But now we need to consider what may be ethically objectionable in a different way. This concerns the matters of motive, consequence and coercion.

Let us return to the question of whether there is a self-contradictory aspect of earning one's living by risking one's life (or, less traumatically, one's well-being). The usual analysis here is to balance risk against benefit. In hazardous occupations, generally, the judgment justifying the risk of life, limb and health is that the benefit to one's own life, from the monetary reward, outweighs the risk. Thus it is not self-contradictory to risk well-being for the sake of well-being, if there is some rational expectation -- i.e., a "good bet" -- that benefit will ensue. The "good bet" necessarily involves imperfect knowledge of consequences, or it would be a "sure thing." Therefore, compensation is presumably commensurable with risk, and no contradiction is involved.

By contrast, it is often argued that what distinguishes risk undertaken for monetary reward from voluntary risk is that the motives are different. The first is, presumably, undertaken for one's own benefit, and the second for the benefit of others, or from principle. Thus, in the second case, an individual calculation of risk/benefit is inapplicable, and the benefit of the individual is subordinated either (a) to the benefit of society or humankind; or to the benefit of some other individual; or (b) to some principle which transcends any considerations of benefit. The contrast is usually made between egoistic and altruistic motives, therefore, on the view that monetary reward connotes egoistic motives of self-benefit, whereas voluntary participation connotes benefit to others or selfless principle as the motive. But this breaks down; for one may work for money in order to support and satisfy the needs of others (one's family, or parents, for example); and one may be self-sacrificing entirely in the service of one's own ego. Since an investigation of motives is hardly feasible, in the case of PRS's, it is not a practical question.

But does it remain an ethical one in principle, that needs taking into account? Is there a general consideration of motives which distinguishes paid from voluntary participation, if it cannot be simply the difference between egoism and altruism? For if monetary reward does not distinguish on these grounds, what else could be involved?

One move may be to contrast even the most altruistic case of PRS working for the benefit of others, from that of the unpaid volunteer, in terms of the degree of altruism. For example, a PRS may be the sole support of a large and destitute family, while a self-sacrificing volunteer may be doing it for the benefit of the whole human family, so to speak. Could we then quantify our motives in this way, then, by calculating how many people are intended to benefit, on one motive as against the other? Or whether the quality of the benefit is greater on one motive than on the other? Is working for the more abstract and universal "good of society" a "higher" motive than working for one's own family? True, there are considerations of universality, nobility, selflessness of motive here. But ethical theory can hardly be said to be clear on this question, and both ethical and decision-theoretical approaches to quantification here are little short of absurd. In any case, imagine a motivational calculus used to measure comparative degrees of altruism, in order to determine whether a PRS gets a high enough score on the altruism scale to warrant ethical clearance for the job! Obviously, what is at issue is some deeper concern that putting one's health at risk requires either a highly noble, self-sacrificing motive, or it cannot be justified; and that doing it for money, (altruistically or not with regard to the uses to which the money may be put) somehow lowers the value of the motive, so that it cannot support the value of what is risked. Thus, the question of motive has bearing on the issue, if at all, only with

respect to the quality or value of the act of putting oneself at risk in an experimental situation. It is the relative merit of motive, in terms of what is required by the act, that gives motive what force it has in this consideration. For example, it would be inappropriate, or comical, to abstain from buying a newspaper on alternate Mondays, with the motive of preserving the northern hemisphere's weather patterns (by saving Canadian forests). Such a motive would require a more significant act. Conversely, it would be inappropriate to commit suicide self-sacrificingly in order to ease the traffic congestion in the Sumner Tunnel. Such an act would require a more significant motive. Thus, it might be argued that the act of putting one's health at risk is of such an order of value, that only those with motives commensurate to the act should appropriately undertake it, or be asked to do so.

Thus, motives, if they enter at all in considering ethical objections to participation in experimentation for monetary reward, enter only in terms of appropriateness to the quality or value of the act. But this would mean determining that only some motives are valuable enough, and others not; and that however altruistic the ultimate motives of the PRS with regard to the uses of the money paid, the very fact of payment degrades the motive to a less than acceptable level. Such considerations seem to me to be egregious, beyond practical determination, and also perhaps, morally arrogant. What is valuable in this consideration is, I think, that it points to the moral weight we put on the quality of the act of putting one's health at risk. And this speaks most directly to what is ethically central.

How does one assess the quality of the act, then, in distinction from the quality of the motives? One standard way is to judge it by its consequences,

and this gets us into risk/benefit analysis once again. For here, the consequences to the subject of the experiment are weighed against the consequences in terms of benefit to society at large. But this remains an empty calculation if the value of the risk is not well conceived. If it is simply a quantified determination of comparative pain and suffering, on the health of one as against the health of untold millions, then the risk/benefit ratios, for any decent research proposal with any small hope of success, come out overwhelmingly on the side of benefits. It is only because we hold the risk of even one individual's health and well-being in particular regard, that it has enough weight to count at all. And again, the question is why? For having determined earlier that such a capacity for risk is alienable, short of risking the person as a whole, and that under these constraints, this capacity may be sold; and having determined that neither egoistic nor altruistic, nor even degrees of altruistic motives mark off PRS's from unpaid volunteers; and further, having determined that even a calculation of consequences, for the sake of risk/benefit analysis, depends on the quality of the act of risks, we are left with the question of why we take such a risk to have the moral weight it does; and whether or not this bears at all on the question of payment for the act of undertaking the risk.

In order to consider this question, let me propose a model which has certain analogies to "doing it for money" in experimental contexts, just as earlier I used the model of wage labor. What is required is a model in which the quality of the act is such that "doing it for money" puts it in ethical question. The model is prostitution. It may be interesting to see how far prostitution is like wage labor, in that it is the sale of a disposition over the use of one's body for a certain purpose, at a certain rate and for a

certain time. Similarly, the question may be asked whether one's capacity to engage in sexual activity is alienable, and may be sold. But that exercise has obvious moves, and needn't be gone through here. Rather, what is at issue is whether the quality of the act of sexual intercourse is such that doing it for money, or paying money for it is ethically objectionable; and if so why? I want to suggest that this model is revealing for a particular reason: that here, just as in participation in experimentation for money, what is being bought and sold is something which is taken to be so intimate to one's person, that there is something disturbing in the notion that it is alienable, as a commodity. In the model of wage labor, we are at the very least culturally or socially inured to the notion of one's labor activity as a saleable commodity. But even here, Karl Marx's critique of alienated labor, in a capitalist economy, argued that such labor, or productive or value-creating activity is the "essence" of being human; and that insofar as wage laborers have no control over the products of their "life-activity," and lose the right of possession over them, in selling their labor-power, they are separated from, or alienated from their very essence. Whatever ethical objection Marx has to capitalism derives from this humanist view of labor. Whether we accept or reject Marx's political economy, or his theory of alienation, the model he proposes has been adapted to modern social life in a variety of contexts, and the term "alienation" has achieved (or been reduced to) notoriety in sociology, psychology, politics, industrial relations, management-theory, and in popular culture. What it suggests is what Marx called "reification": treating human beings as if they were things, and thereby, dehumanizing them.

What is characteristic of the ethical objections to prostitution is that the intimacy, dignity, or love which sexual relations are supposed to express,

in a relation between persons who recognize each other's humanity in this way, has been translated into the terms of an economic exchange, of money for services. Now it may well be that sexual relations, without payment, may also fail to express the qualities of the act which make it distinctively human -- that is, sex may be provided as a service, or as an obligation, or as a recreation without payment, and yet in an impersonal way. But the monetary relation appears to underscore and make fully articulate the quality of the act as a degradation of human relations. But again, why? Because it is believed that payment robs the relation of the voluntary character which it presumably should have, if it is to be fully human. That is, the fully human aspect of the sexual relation is that it is entered into freely by both parties, without coercion or domination; and therefore, that what is given is freely given. Insofar as the seller alienates the disposition over the use of her body, and the buyer possesses this alienated use, prostitution becomes a paradigm of alienation.

Now one may argue that, as in wage labor, the form of contract is preserved, since both parties may, in fact, freely agree to contract for an exchange of services for payment. But it is just this displacement to the arena of exchange, i.e., the transformation of a human relation into a commodity relation, which puts the freedom of the contract in question. Just as Marx argued that the wage laborers are not free to abstain from working, because it is the wages they receive for this work which sustains their lives, and they have nothing else to sell, so too, one may argue that the prostitute is not free to abstain from the sale of her services whereas the "client" or "John" is free so to abstain. And that therefore there is constraint or coercion in the contract, and it is in effect, not a free contract, but rather

a relation of exploitation. One may argue against this, however, that the prostitute is free to seek other employment; or, in present enlightened societies, to be unemployed rather than ply her trade. Only where there is no other recourse, can one make a case for coercion on economic grounds. Thus, on this model, given the rather sanguine and ideal account of what the quality of the sex act should be, and given the interpretation of prostitution as the alienation of a personal relation into the form of a commodity-money exchange, the ethical objection is that prostitution dehumanizes both parties to the exchange, in degrading an essential human relationship.

Now to pursue the analogy to PRS's: first, one would have to characterize the capacity to put one's health at risk as an essential aspect of one's humanity. A simpler approach would be to characterize one's health or well-being as inalienable; but then, any mode of self-sacrifice or risk would be ruled out, if we characterized as inalienable anything at all which a person had no right to surrender. We have more narrowly defined it as that which may not be put at the disposition of another, for money. The sense of this distinction is that we do not ethically rule out any mode of self-sacrifice, but rather regard such self-sacrifice as an ultimate, and even sacred free act. Thus, by a strange dialectic, we ordinarily regard the capacity to put one's health or life at risk, i.e., the capacity for self-sacrifice, as itself an essential human characteristic, and as ethically commendable. Moreover, we characterize an act as self-sacrificing only where it is free. We may regard it as irrational, when it is useless or purposeless, as when the agent out of ignorance of the facts, or the consequences, nobly sacrifices himself or herself in vain. So imperfect knowledge may flaw the act in its intended benefit, but we retain respect for the intention. The quality of the act therefore,

like that of the sex act, is seen to be (a) its intimacy to one's very person, as being an aspect of the essence of the person, and (b) its free or voluntary character. The act done under constraint, therefore, loses this essential character, and its ethical status.

It is clear where such an argument is heading: the researcher and the PRS, in reducing an essential human capacity (to put oneself at risk) to a commodity, are in effect dehumanizing each other! Thus, insofar as the PRS participates out of economic need, his act is not free but coerced; and therefore, there is no viable contract in the exchange, but rather a relation of exploitation.

Now this is a grim consequence. One may say that it deprives the needy PRS of an option to sustain and improve his or her life, and that of dependents. Further, it deprives the researcher of the opportunity to achieve prospective benefits for all humankind. And it characterizes the contract between researcher and PRS as invalid and the relation as exploitative, and mutually dehumanizing.

This is compounded by the plain fact that the range of PRS's are the disadvantaged -- the poor, Blacks, prisoners -- for whom alternative options are comparatively few. In short, even with informed consent etc., as means of protecting the subject from constraint or coercion, there is built-in coercion in the neediness of the PRS, and the availability of payment. But it is a coercion like that of wage labor, and even socialists do not advocate that employment cease, and that workers refuse to sell their labor-power. Rather, they argue that the system which requires wage labor under the coercion of need be transformed into one in which labor is a collective

responsibility of all, as a free act. The more realistic socialist will therefore argue that only with the overcoming of economic scarcity by advanced industry and technology can such a society be realized; and that, as Marx held, capitalism itself is the system which developed these very technological and industrial capacities.

Thus, on the strongest ethical objection to "doing it for money" we face a dilemma: on the one hand experimental research with human subjects is necessary for the preservation and improvement of the well-being of the species; but on the other hand, the only present means of conducting it are in fact coercive and exploitative. This dilemma can be "resolved" in only three ways: (1) giving up paid subjects, and somehow making up the difference with unpaid volunteers (2) failing that, giving up all research but that which can be carried out with unpaid volunteers (3) eliminating the economic need which is the coercive element in paid participation. I put the term "resolved" in quotes, because none of the three alternatives is a solution, in present circumstances. The likelihood of getting enough unpaid volunteers is zero, unless there is a massive effort to educate the public to this need, and to effect an ongoing "crisis" mentality, like that which appears sporadically when blood bank or donor appeals are made urgently. The second, failing the first, and without such a massive reeducation, still fails to meet the desideratum of the necessity of research, though it could lead to a judicious cutting of research projects to the most essential, and to more rigorous requirements for tough evaluation of potential benefits. The third is so long-range a prospect that, though it is an important social goal, it doesn't resolve the problem in this century; and without the massive education and change in the public, won't resolve it in the next, even if need is eliminated.

The conclusion I arrive at is that the strong ethical objection can be met realistically only by the most assiduous responsibility to minimize the coercive and exploitative element in the situation. And at the very least, to recognize it, be sensitive to it, and refuse to hide it, or hide from it.

One model here is suggested by Hans Jonas, in an ideal form, in his paper, "Philosophical Reflections on Experimentation with Human Subjects."⁴ It is that the elites -- e.g., the researchers, biomedical and behavioral personnel and staff, be, so to speak, the first to volunteer; that in general, those whom society counts as "most valuable" and "least expendable" rather than "least valuable" put themselves at risk, in what Jonas calls a "reverse order of availability and expendability" I believe this is ethically correct, but fails to resolve the problem, practically, (as Jonas also recognizes) and so remains in the realm of abstract morality. I have no clear solutions, on ethical grounds, for I believe there remains a dilemma here, and its resolution requires both social change and moral reeducation which go beyond the contexts of the particular issue of experimental research, (though this context helps to throw the problem into relief).

Finally, as to what ethical considerations, if any, enter into making government policy on these matters: it seems clear to me that legislation for the protection of human subjects is not only ethically unproblematic, from the point of view of what the government has a right to regulate; it is also ethically required. Insofar as the government ought to operate for the benefit of its citizens, and not merely mediate between conflicting interests, or serve the powerful against those weaker, government legislation and agency is required for the regulation of experimental research with humans.

It may be argued that the biomedical profession should be self-regulating in this regard, being closest to the situation, and that government interference will get things wrong. But the unrepresented party, in such a case, would be the PRS, who is unorganized, disadvantaged to begin with, and initially at least, unaware of his or her rights. In this regard, it would be part of the task of minimizing coercion if PRS's or both PRS's and unpaid volunteers were organized, educated to their rights and to the needs and problems of research, and represented not simply in the contracting for services, but also in the Review Boards, and in hospital, local, state and federal commissions dealing with these issues. To set up committees, like that for the protection of prisoners, without prisoners as members, is to compound coercion with paternalism. The social benefit to be derived from such representation is that organized, articulate and educated subjects in research come to understand the task of research in a participative way, and begin to form the nucleus of an unalienated population of subjects. Moreover, this very participation, at policy, review and administrative levels, ameliorates to some extent the dehumanizing effects of the commodity relationship, both for PRS's and for researchers.

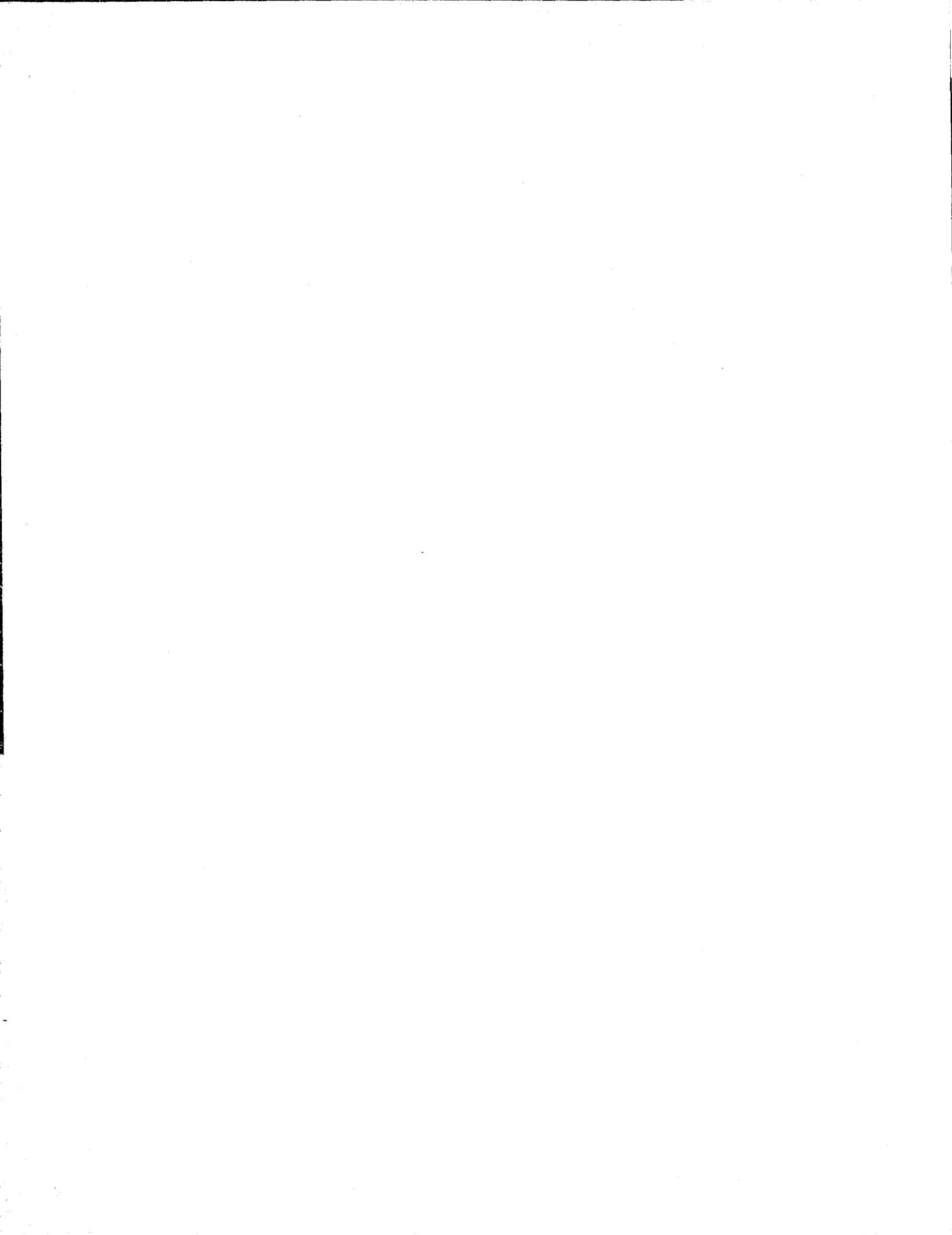
As to prospective restraint of trade, as an ethical question in the political-economic sphere -- i.e., is the government infringing upon the rights of contract among individuals by protective legislation? The ethical aim of disalienating the relation between PRS and researcher would argue against any approach (such as characterization of protective legislation as being in restraint of trade) which would simply reinforce the commodity character of the relationship. In short the relationship between PRS and researcher needs to be socialized, and not further commodified. But mine is not a lawyer's opinion.





TWO IMAGES OF THE PRISON INFLUENCE STRUCTURE AND
THEIR MEANING FOR PRISONER PARTICIPATION IN BIOMEDICAL
AND BEHAVIORAL RESEARCH

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TWO IMAGES OF THE PRISON INFLUENCE. STRUCTURE
AND THEIR MEANING FOR PRISONER PARTICIPATION
IN BIOMEDICAL AND BEHAVIORAL RESEARCH

I. INTRODUCTION

In the law establishing the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Congress asked the Commission to identify the requirements for informed consent to participation in biomedical and behavioral research by prisoners, among other types of persons. Congress spelled out certain elements which make up the requirements of informed consent, one of which is the subject of this paper. Congress charged the Commission to investigate and study, among other things, the competence and the freedom of prisoners "to make a choice for or against involvement in biomedical and behavioral research." The law creating the Commission also defined prisoner to mean individuals "involuntarily confined in correctional institutions or facilities."

It should be noted at the outset that correctional institutions and facilities are extremely diverse in nature, commonly ranging from city or county jails, state and federal prisons, but also including halfway houses and pre-release centers. This diversity is compounded because separate and parallel institutions are maintained for males and females, juveniles and adults. Any attempt to generalize about the nature of informed consent in such institutions runs the risk of oversimplifying a complex issue and ignoring significant differences.

This report will review what is known or believed to be an accurate reflection of the general nature of, and major influences upon, social life and individual behavior in prison. The report will conclude with an assessment of some of the implications of these ideas for understanding the competence and freedom of prisoners to give informed consent.

II. THE SOURCES AND NATURE OF INMATE BEHAVIOR IN PRISON

The separation of prisoners from the outside world raises a basic question that bears on their participation in biomedical and behavioral research. Will prisoners endorse and act upon the conventional values of civil society or will prisoners identify with and orient their behavior toward values in opposition to that of civil society? Explaining why prisoners conform to or deviate from conventional values will require us to examine the influence structure of the prison.

The prison is in many ways similar to most other complex organizations. It has certain goals and objectives such as social defense, deterrence, rehabilitation, and punishment. It has official rules and other social norms by which these objectives are to be achieved. It has an organization, both formal and informal, which spells out the relevant social positions, the channels of communication, the lines of command, and the means of access to various resources. This organization largely determines how the prison's resources, staff, physical plant, equipment, supplies, treatment programs, and inmates, are utilized in the performance of its distinctive functions.

Traditional patterns of authority are maintained in prison by social norms prescribing different roles for the occupants of different positions. Two distinct sets of norms can be identified. One is the set of norms endorsed by the staff and officials of the prison. These norms include the laws of civil society. In addition, there are the prison's official rules that routinize most inmate activities: the time for bed and waking, the food to eat, the work to do, the uniforms to wear, the visitors to see, the kind of haircut to have, etc. There is also a code of ethics, usually informal, requiring that inmates avoid alliances with each other, that they do their "own time," that they

refrain from speaking to officers unless spoken to, that they address officers as mister, and that in many other ways they manifest their subordinate and solitary position. The same laws, rules, and code of ethics also ensures the superior position of staff in their dealings with inmates.

Seemingly running parallel to the official organization of the prison is an un-official society or social system regulating inmate conduct with respect to focal concerns such as length of sentence, relations among prisoners, contacts with staff and other officials, food, and sex, among others. The inmate society has its own norms that are endorsed primarily by the prisoners. The origins of the prisoner's code and its content are a matter of dispute, as we shall see. Inmates have also developed an ethic which enjoins them not to help the staff, not to squeal on their fellow prisoners, to be loyal to all prisoners, and to resist staff interference in prisoner affairs.

Unlike the official rules and regulations of the prison, the inmate code does not demand uniformity of behavior on the part of prisoners. The inmate code encourages symbiotic relationships between staff and prisoners that unites the inmates, increases their power, and aims at subverting the official system.

III. A. THE SOURCES OF PRISON SOCIETY: THE PAINS OF IMPRISONMENT

It is generally agreed even among those who otherwise disagree that in American prisons an inmate society and code of behavior and attitudes exists. One image of the society of prisoners is implied in the notion of the "total institution." Though prisons are only one of many kinds of total institutions in society, in the popular mind they have almost become equivalent. Sykes and Sykes and Messinger have most clearly stated the inspiration and implications of this view of prisons.

Custody, in the view of Sykes and Messinger, produces "the pains of imprisonment." A person's self is mortified (as Goffman terms it), his possessions removed, his usual appearance is stripped away, he undergoes social degradation, and a loss of autonomy.

A loss of autonomy results from the fact that the inmate is subjected to a vast body of rules and demands that are designed to control his behavior in minute detail. "Most prisoners", Sykes continues, "express an intense hostility against their far-reaching dependence on the decisions of their captors and the restricted ability to make choices..." In brief, the rigors imposed on the inmate by the prison officials do not represent relatively minor irritants which he can somehow endure: instead, the conditions of custody involve profound attacks on the prisoner's self image or sense of personal worth by depriving the inmate of liberty, goods and services, heterosexual relationships, security, and autonomy.

B. THE NATURE OF PRISON SOCIETY: THE PRISONER SOLIDARITY IMAGE

In terms of this imagery, prison society develops in response to the problem faced by all convicts of mitigating the pains of imprisonment. Prison society manifests all of the characteristics of a society; social structure, conduct norms, and values. "As a population of prisoners moves in the direction of solidarity, as demanded by the inmate code, the pains of imprisonment become less severe."¹⁰

Prisoners classify each other, and grant deference and respect, in terms of conformity to or deviation from the inmate code. In this sense the inmate code is thought to operate roughly as the legal code may function in free society as the basis for the distinction between them and us. Near the top of the social ladder is the right guy or the real con; the one who most nearly obeys the norms of the prisoners society. The inmate who allies himself with the guards and prison administration may be called a square John; he is presumably on the periphery of the inmate world. Near the bottom of the social ladder is the inmate known as a rat or a squealer who¹¹ violate the norm of loyalty to fellow prisoners by betrayal.

The prime directive of the inmate code is group cohesion. Prisoners support one another against the officials; prisoners reject their rejectors. An important way of manifesting this attitude of rejection is by withholding their cooperation from the staff and administration, and by refusing to become committed to the conduct and values which the staff hold and which the staff prescribe.

Ostensibly the norms of the code are in conflict with those of the official rules of the prison but in fact adherence to the norms serves official purposes, as many writers have observed. The system of accommodation not

only serves the administration's purposes and the aims of a few convict
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leaders, but it is also rewarding to the average convict. Order is
maintained and the convict is protected from the depredations of other
prisoners, his dignity is strengthened and his self-respect restored.

In return for private rewards, inmate leaders exercise a moderating
influence over the inmate masses which in turn enable the custodial staff
to maintain order more effectively. However, the accommodation between
leaders and staff has some negative consequences. The mass of prisoners
depend upon inmate leaders to gain advantages, privileges, and to avoid
violence but this only increases a sense of powerlessness for most inmates.

C. IMPLICATIONS OF THE PRISONER SOLIDARITY IMAGE OF PRISON FOR INMATE PARTICIPATION IN BIOMEDICAL AND BEHAVIORAL RESEARCH

From the perspective of the prisoner solidarity image of prison life, the principle influence over inmate behavior is the prison peer group. Typically, pressure to conform to the inmate code means pressure to conform to criminal values. These values generally stand in opposition to the values of all civil societies and are based upon a rejection of the notion of civil
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society.

Inmate leaders, though they do in fact deviate from the prisoner's code, are granted special privileges by the administration in exchange for
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maintaining order. Leaders would seem then to have little incentive to
14a
participate in biomedical and behavioral research.

Among the prisoner masses there are four general adaptations to prison life that inmates may take with generally different implications for participation in research. It is quite likely that the same inmate will employ different lines of adaptation at different stages in his career in prison and may even
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fluctuate between different adaptations at the same time.

One tack that inmates may take, as implied above, is to conform with varying degrees of intensity to the demands of the inmate code. Though they suffer privations and see all about them deviations from the code, these men would most likely forego participation in biomedical and behavioral research because of their commitment to a code that rejects conventional values and cooperation.

Second, inmates may deviate from the norms of the prisoner's world. Most likely participation in research would constitute a form of deviation. But we have in mind those inmates who deviate from the more general and explicit code of prisoner ethics ("squealer" or "rat" for example). By

virtue of their deviance they are excluded from the system of exchange and commerce that is the prisoner's world. The rather severe deprivation of goods and services that results may be so great that they will volunteer as a subject in biomedical and behavioral research for materialistic reasons. An increase in nature and quality of rewards for participation could increase the likelihood of participation and help wean the inmate from the criminal value structure.

While the adaptations that have been mentioned represent coherent courses of action it is likely that few inmates pursue them with any degree of rigor over the course of their imprisonment. Most prisoners most of the time adapt by "playing it cool", as Goffman refers to it. ¹⁶ This involves an opportunistic combination of conformity and deviance so played as to maximize the inmate's chances of getting out of prison psychically and physically undamaged. Participation in research for these prisoners depends on the costs and benefits not of the research but to them in terms of their life in prison and their chances of getting out. The rate of pay for subjects, the perquisites of subjects, boredom, and a host of other real and imagined considerations weigh in their decision. An increase in the nature and quality of rewards for participation could increase the likelihood of their participation and also help wean them away from the criminal value structure. The inmates also have an incentive to participate in biomedical and behavioral research because participation serves a more subtle psychological purpose. Within the total institution and the deprivations associated with it, the attainment of even minor gratifications granted to participants in research, taken for granted when the inmate was outside the prison but now prohibited by formal institutional rules, takes on an importance which transcends their specific

value to the inmate; the attainment reaffirms the inmate's sense of being an individual, a man capable of autonomous action, and able even to take risks to satisfy his needs. The absence of research for which they could volunteer and be rewarded would only increase their dependence on inmate leaders and increase their sense of powerlessness.

The final adaptation is utilized by those inmates who, from the prisoner solidarity perspective appear never to endorse or act upon the convict code or identify themselves as criminals. ¹⁷ The "square Johns" as they are known in the prison argot take over completely the official staff view of prison life and try to act out the role of the perfect prisoner. This group of prisoners may volunteer to serve as research ¹⁸ subjects for altruistic as well as pragmatic reasons.

D. THE SOURCES OF PRISONER SOCIETY: SUBCULTURAL IDENTITIES

A competing image of prisoner society lacks the compelling imagery of the total institution but nonetheless commands great support. This image sees less solidity in prisoner society and greater diversity of norms and values.²⁰ The sources of this diversity are the subcultural identities of the prisoners. This viewpoint draws its inspiration from the principle that people in a society (including those who spend time in prison) derive many of their understandings, their personal and shared expectations, and their "social construction of reality,"²³ from groups and subcultures other than the one in which they are presently involved. The shared understandings may, at the least, offer potentially latent resistances to new groups and new ways of behaving. Even though they may be currently situated in a prison, inmates' reference groups may be family, friends, or associates who are outside the prison. The inmates may identify with these groups and not with the prison culture.

This image of prison life acknowledges that prisoners comply with the rules of their fellow prisoners (that is, generally consistent with the inmate code and prisoner roles). But this kind of compliance need not have any deep personal significance for the prisoner; characteristics that have this deep personal significance are less sensitive to interpersonal influence²¹ and manifest less variation from one situation to another. For many inmates (and other persons), characteristics that have deep personal significance, such as their self-conception and their value orientation, may be anchored in groups outside the prison and may survive (and help the inmates survive) even the pains of imprisonment. For many prisoners their self-conception and their value orientation may antedate their prison experiences. Characteristics

of deep personal significance are learned and develop in social groups; the family, occupations, schools, gangs, etc. "Inmates may bring a culture with them into prison."

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E. THE NATURE OF PRISONER SOCIETY: THE PRISONER DIVERSITY IMAGE

Prison, rather than homogenizing inmates, allows for a certain amount of differentiation and conflict among the inmates in terms of values and norms. ²³

If the influences that create and support this diversity and conflict are to be understood, Irwin and Cressey suggest that it may be both necessary and helpful to divide inmates, and the shared standards that influence them, into three rough categories: those offenders in prison who are oriented to an outside criminal subculture, those who are oriented to the prison subculture itself, and a third group that is oriented to outside conventional or legitimate subcultures. ²⁴

The career criminals, sophisticated criminals, and professional thieves, owe their loyalty and commitment to criminal subcultures outside of the prison. This group, generally referred to as "thieves", share values which extend rather broadly to offenders elsewhere. Members of the "thief" subculture may assume the "right guy" role in prison. They subscribe to the notion that criminals should not betray each other to the police, should be reliable, wily but trustworthy, cool-headed, etc. In the thief subculture, offenders who are known as "right" or "solid" are those who can be trusted. As a result they enjoy high status.

Thieves must face the recurrent problem of imprisonment. They assume they will be arrested from time to time; this is an occupational hazard. The subculture which they share provides them with behavior patterns and attitudes to be used in order to minimize as much as possible the effects of arrest, trial, and imprisonment. They have information on the "proper" way to undergo the prison experience, how to do their time successfully and with the least possible suffering. ²⁵

It should be borne in mind that the members of this group share a commitment not to prison life but to criminal lifestyles. The status they seek and the deference they pay is to the broader criminal world of which the prison is only a part. Thus, while other convicts may assign thieves a high status because they admire them, thieves are not interested in becoming heavily involved in the criminal machinations and rackets of the prison. Instead, the privileges they are after are those that will make prison life more pleasant; an easy job, extra food, maximum recreation, a little privacy. This is not to say that they will not violate prison rules - they do. They will deal in contraband or food when it will serve their needs. But their objectives are to do their time and to get out, not to acquire prison - derived status by demonstrating their ability to manipulate the prison environment, to run rackets, or to dominate others.

The second group of inmates is referred to as "convicts" and they are oriented primarily to the "convict" subculture. A convict subculture flourishes wherever men are confined. It can be found where men are confined; not only in city jails and federal and state prisons but also in P.O.W. camps, army stockades, concentration camps, and even mental hospitals. Organizations in which men are incarcerated are characterized by deprivations and limitations on freedom that leads to efforts on their part to manipulate the environment, win special privileges, and assert influence over others.

Members of the convict subculture are likely to be inmates who have long records of confinement in institutions; their confinement is likely to have begun at an early age. They have become so conditioned to institutions that it has become a way of life for them. Consequently, they

seek positions of power and influence in the prison making use of knowledge
27
and skills they have developed in other institutions. They participate
in rackets, sell food, clothing and information. Their status derives from
their ability to manipulate the staff and other prisoners. They are known
as "shots", "politicians", "merchants", "hoods", "toughs", or "gorillas".
28

Members of the convict subculture, like thieves, seek priveledges. The difference is, however, that the convict seeks priveledges which he believes will enhance his position in the convict subculture. He also wants to do his time as easily as possible but compared to the thief the priveledges he seeks are not only for his own comfort but also to increase his power, his store of goods, or to increase his freedom within the prison. An easy job would be desirable because it is easy and also because the inmate demonstrates that he can get the job.

Finally, there are prisoners who are oriented to a "legitimate" subculture outside the prison; their reference groups are family and friends outside. They have no loyalty or commitment to the values of thieves or convicts, or if they had, they rejected it. They are often unprepared for prison life and must take it as it comes. They seek status through means provided by the prison administration, through active participation in "constructive" activities such as editing the prison newspaper or by running for election to the inmate council.

This group of inmates generally conform to what they think administrators expect of good prisoners. They isolate themselves or are rejected by the convict and thief subcultures. They are oriented primarily to achieving goals in prison through means which are legitimate both within and outside the prison.

F. IMPLICATIONS OF THE PRISONER DIVERSITY IMAGE OF PRISON FOR INMATE PARTICIPATION IN BIOMEDICAL AND BEHAVIORAL RESEARCH

The prisoner diversity image of the prison implies that there is no single dominant influence over virtually all inmates, as suggested by the other image. Adaptation to prison life is mediated by subcultural values and reference groups. One of the reference groups discussed is basically oriented to life within the prison. Those who maintain their basic orientation to life outside may be further divided: those who generally wish to maintain their life styles and their identities, and those who desire to make significant changes in their life styles and their identities. These groups exercise great influence on prisoners behavior and bring pressure to bear to force conformity to their norms and values. Three groupings of inmates were discussed; two of which (the convict subculture and the thieves subculture) would seem to share values that appear at first blush to be indifferent to participation in biomedical and behavioral research. Only the values of the legitimate subculture would seem to support participation as a subject in research.

But as we have seen, it is necessary to distinguish individual adaptations to prison from group identities, especially in trying to assess the implications of the prisoner diversity image for participation in biomedical and behavioral research.

For the inmate masses, there are three basic adaptations to life in prison; "doing time", "jailing", and "gleaning". Not all convicts can be classified in these terms. Some fail to cope and commit suicide or become psychotic. Some vacillate from one to the other, and others appear to be following two or three of them simultaneously.

"Time doers" try to maximize their comfort and luxuries and minimize their

discomfort and conflict and get out as soon as possible. Doing time is characteristic of the thief in prison but it appears to be the major adaptation of inmates generally. The emphasis on getting out as soon as possible has lead "time doers" in recent years to "program", that is they follow (at least nominally) a treatment plan that has been outline by the treatment staff, recommended by the classification board, or devised by the inmate himself. It is generally believed that to be released on parole as early as possible an inmate must "get a program." Similarly it is apparently believed by some inmates that participation as a volunteer in biomedical and behavioral research is considered favorably by parole boards in their deliberations. Whether these beliefs are "true" or not is somewhat beside the point. In many cases what people believe to be true is the basis of their behavior and the foregoing is no exception. Some inmates who are adapting to prison by doing time will participate in biomedical and behavioral research for this (possibly erroneous) reason. They may also participate in order to enjoy luxuries and perquisites that are difficult to obtain otherwise. While participation will not necessarily influence their criminalistic philosophy and behavior, it may make life in prison a little more bearable.

Another adaptation that may be utilized by inmates to cope with life in prison is "jailing". Inmates who do not retain or who never had any commitment to outside social worlds tend to make a world out of prison.³⁰ This is the characteristic style of the state raised youth. For jailers, luxuries are not, as for most other prisoners, ends in themselves. Luxuries have an instrumental value as well. The rewards of consumption exist along with the additional reward of increased prestige in the prison society

because of the display of affluence. This suggests that for those inmates who jail, how you get luxuries is about as important as the luxuries themselves. If, as seems likely, this is the case, then participation of jailers in biomedical and behavioral research is improbable for two reasons. One, participation implies cooperation with the staff and is a violation of the convict code. Second, participation in research does not require the use of manipulative skills so highly esteemed by jailers as a means of acquiring scarce goods and services.

Gleaning is the tact taken by inmates who choose to radically change their life styles and their identities and follow a sometimes carefully devised plan to better themselves using whatever resources exist in the prison to do this. Gleaners read, pursue formal education, may learn a trade through vocational education programs or job training, take university correspondence courses or regular college courses when available. They try to improve themselves in other ways. They may develop their social skills and physical appearance.

Gleaners tend to cut themselves off from their old friends or other persons with criminal identities. However, their new identity must be acceptable to their older view of reality; the future they are preparing for cannot be the humdrum life that they rejected when they became part
32
of the criminal world. Insofar as participation in biomedical and behavioral research has some direct benefit to the gleaner, either while in prison or in terms of their future, inmates who take this tack could be expected to volunteer.

IV. THE PRISON INFLUENCE STRUCTURE AND THE COMPETENCE AND FREEDOM OF PRISONERS TO GIVE INFORMED CONSENT TO PARTICIPATION IN BIOMEDICAL AND BEHAVIORAL RESEARCH

We have briefly outlined two views of influences on prisoners and prison life, noting some differences and similarities between them. We also briefly examined the possible implications for prisoner participation in biomedical and behavioral research of these two views. In this concluding section we shall examine the major issue. Here we shall look briefly at what the two images of prison may suggest about the competence and freedom of prisoners to give informed consent.

A. THE NATURE OF INFORMED CONSENT

One of the leading cases on informed consent and institutionalized persons is John Doe v. Department of Mental Health for the State of Michigan.³³ In this case, the Circuit Court for the County of Wayne, Michigan examined the elements of informed consent from the perspective of a patient involuntarily committed to a mental hospital and held that he is incapable of giving such consent. In assessing the impact of the prison influence structure on prisoners ability to give informed consent, it may be useful to review the court's arguments in the Doe case.

In the Doe case the court looked at competency, knowledge and voluntariness, basic elements of informed consent, through the eyes of the involuntarily detained mental patient. Competency, the court said, requires the ability of the subject to understand rationally the nature of the experimental procedure, its risks, and other relevant information. In the court's opinion, mental patients lack the requisite competence to consent, although its arguments seem tautological and ill-informed.

The court argued that the very nature of their incarceration diminishes

the patient's capacity to consent, the first element of informed consent. He is vulnerable as a result of his mental condition, the deprivation stemming from involuntary confinement, and the effects of "institutionalization". Even though the patient may be intellectually competent to make a decision, the routine of institutional life where most decisions are made for him by the staff and administration may apparently reduce the capacity of the patient to make a decision. Furthermore, the court observes, institutionalization tends to strip the individual of the support which permits him to maintain his sense of self-worth and the value of his own physical and mental integrity.

The second element of an informed consent is knowledge of the risk involved and the procedures to be undertaken. The court apparently feels this may be a serious problem with regard to consent particularly when experimental procedures are involved and the nature of the risks are unknown even to the experimenter.

The third element is voluntariness. The court returns to its earlier argument that involuntarily confined patients live in an inherently coercive atmosphere.³⁴ By this the court seems to mean that (1) the patient's freedom from the institution may depend upon his cooperation with the authorities; (2) the patient's freedom within the institution may depend upon his cooperation with the authorities; and (3) the patient's position in the institution is inherently inferior to that of the doctors and the administrators. For these reasons a patient could not voluntarily give informed consent, the court concludes.

B. INFORMED CONSENT IN PRISON

Examination of the elements of informed consent in the light of knowledge of the prison influence structure leads to a somewhat different conclusion than

the court in the Doe case reached with regard to involuntarily committed
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mental patients.

As regards the competence of prisoners to give informed consent, the Doe court seems to see this as (1) a question of the prisoner's loss of autonomy to make day-to-day decisions and (2) the stripping away of the prisoner's identity. The thrust of both the prisoner solidarity image and the prisoner diversity image of the prison is that the inmates are, despite the rigors of imprisonment, able to maintain or develop an identity, though there is a difference of opinion as to the source or origin of that identity. The prisoner solidarity view of the prison is more likely to see the inmate's pre-prison identity as left at the prison gates; similarly, this viewpoint sees inmates as more generally lacking in autonomy than does the prisoner diversity image. Both images are in agreement that both staff and prisoners share power and influence within the prison, though they are by no means on an equal footing. The meaning of autonomy as used here in terms of the accommodation between staff and inmates is an empirical issue that cannot be resolved at a theoretical level with any degree of certitude. However, given the level of agreement between the prisoner diversity and the prisoner solidarity images on this matter, the burden of proof is on those who would deny that prisoners have sufficient autonomy to give informed consent.

We would suggest, furthermore, that to see autonomy in prison in categorical terms (either inmates have autonomy or they do not have autonomy) is too simplistic. We believe that concept of "elastic autonomy" fits the
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prison better than the older notion of autonomy. Elastic autonomy means
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that autonomy is neither fixed nor inherent in any given position. Rather,

it depends upon the situation and the inmate's behavior and can contract and expand. At the least the notion of elastic autonomy in prison reminds us that some prisoners have sufficient autonomy (while by definition some prisoners may not ³⁹) to meet the criteria of capacity to make a decision regarding their participation in biomedical and behavioral research.

The second element of an informed consent is knowledge of the risk involved and the procedures to be undertaken. Meyer claims this knowledge is absent and reviews a study of the knowledge of volunteering and non-⁴⁰volunteering prisoners to support his conclusion. Like most of his other non-economic conclusions, this is hastily arrived at and without careful analysis. He argues that the study's finding, that volunteers' comprehension of the risks of a malaria project in which they will participate is little different from that of nonvolunteers, is the result of doctors who cannot communicate with laymen plus the below average educational level of the inmates. Even granted that these problems exist and may interfere with regard to the details of experiments, they can be ⁴¹corrected, and are not a serious barrier to prisoners giving informed consent.

The third element in informed consent is voluntariness. There is no doubt a prison is an inherently coercive atmosphere in the three senses that the term was used in the Doe decision and discussed above. But the real question is whether the inherently coercive atmosphere of the prison is so repressive as to negate the possibility of prisoner's voluntarily giving their consent. Both the prisoner solidarity image and the prisoner diversity image of the prison are in agreement that the notion that the staff and officials have complete authority and power over all decisions in a myth.

The two images of the prison are also in agreement that the prisoners have a great deal of power and influence in how the prison is run. Here again, the relative influence of inmates and staff over decisions by inmates to volunteer or not to volunteer is an empirical question that cannot be otherwise answered with any degree of theoretical certainty. And if necessary, it seems likely that mechanisms could be developed in the prison for insulating experiments and the process of volunteering from pressures by both staff and other prisoners. But again, the burden of proof is on those who would deny that prisoners can voluntarily give informed consent.

In summary, the state of our knowledge of prison and prison life is fragmentary and sometimes contradictory. But in terms of the two major viewpoints we have reviewed there seems to be a rather strong implication that prisoners have the freedom and competence to give informed consent.

FOOTNOTES

1. Clarence Schrag. Crime and Justice: American Style. (Washington, D.C.: United States Government Printing Office, 1971) p.204.
2. John Irwin. The Felon. (New Jersey: Prentice-Hall, 1970); Gresham M. Sykes and Sheldon L. Messinger. "Inmate Social System" in L. Radzinowicz and M.E. Wolfgang (eds.) The Criminal in Confinement. (New York: Basic Books, 1971), pp.77-85.
3. Study of prisons in Norway and Sweden failed to produce evidence of a strong and cohesive prison inmate society. See Stanton Wheeler, "Socialization in Correctional Institutions" in Radzinowicz and Wolfgang, The Criminal in Confinement, pp.97-116.
4. The most explicit formulation of the concept of the total institution and most responsible for its use in everyday language is Erving Goffman, Asylums (New York: Anchor Books, 1961). What is often overlooked or ignored in more recent applications of the concept is that Goffman denoted many specific institutions as total institutions; homes for the blind, aged, orphaned, and indigent; TB sanitarium, mental hospitals, and leprosaria; jails and penitentiaries; army barracks, ships, boarding schools, work camps, abbeys, monasteries, convents, and other cloisters. Ibid. pp.4,5. Although the purposes of segregation may vary, Goffman argues that the strategies of control are remarkably similar. See also Samuel E. Wallace (ed.) Total Institutions (Chicago: Aldine Publ. Co. 1971).
5. Gresham M. Sykes. The Society of Captives (New York: Atheneum, 1965).
6. Sykes and Messinger, op. cit.
7. It is interesting to note that Sykes conducted his research at the New Jersey State Maximum Security Prison between 1954 and 1957. Goffman did field work at St. Elizabeths Hospital, Washington D.C. at about the same time, in 1955 -1956. One is tempted to say that the notion of the total institution is a child of the 50's. Its relevance to the changed social conditions of the 1960's and 1970's is problematic.
8. Sykes, op. cit., p.73.
9. Ibid.
10. Sykes and Messinger, op. cit., p.82.
11. Sykes and Messinger, op. cit., p.79.
12. Irwin, op.cit., pp.62-63.
13. Robert Merton, Social Theory and Social Structure. (New York: Columbia University Press, 1949) pp.357-368.
14. Irwin, ibid.

- 14.a For a somewhat contradictory view see John D. Arnold, et al. A Study of One Prison Population and Its Response to Medical Research, in J. Katz (ed.) Experimentation With Human Beings (New York: Russell Sage Foundation 1972), p.1024.
15. See Goffman, op. cit., pp.61-66. Other commentators have made similar observations. See for example Sykes and Messinger, op. cit., p.85.
16. Goffman, ibid.
17. The prisoner solidarity approach does not allow for the possibility that some prisoners may remain loyal to the norms and values of the free society that exists outside the prison despite the pains of imprisonment. Thus Goffman, ibid., refers to this adaptation as "conversion".
18. Arnold, et al., op. cit., report that a large number of prisoner volunteers are "loners". They describe "loners" as rejects from established cliques, but their loners may actually be rejectors rather than rejected inmates.
20. The prisoner solidarity perspective saw the pains of imprisonment as the cause and the prisoner society and code of behavior as the effect. The other image adjoins a neat casual analysis. Instead, it suggests that men entering prison are not necessarily "stripped" of their prior identities. "They bring a set of values with them when they come to prison, and they do not leave these values at the gate." See John Irwin and Donald R. Cressey, "Thieves, Convicts and the Inmate Culture" in H.S. Becker (ed.) The Other Side (New York: The Free Press, 1964) pp.240-241.
21. Donald L. Garrity, "The Prison as a Rehabilitating Agency" in D.R. Cressey (ed.) The Prison (New York: Holt, Rinehart and Winston 1961) pp.358-380.
22. Irwin and Cressey, op. cit., p.225. The prisoner solidarity viewpoint claims that this culture is stripped away by the processes of mortification and degradation.
23. The image of prisoner solidarity fitted nicely with the conception of the prison as a monolithic bureaucratic organization. What we are calling the prisoner diversity image of prison life almost suggests that the bureaucratic nature of prison is on the wane, a result which the introduction of prisoner unions could hasten. Future research on prisons should explore this issue. See generally Warren G. Bennis (ed.) American Bureaucracy (Chicago: Aldine Publ. Co., 1970)
24. Irwin and Cressey, op. cit.
25. Irwin and Cressey, op. cit., pp.230-231.
26. Irwin and Cressey op. cit., pp.232-233, point out that persons with long histories of institutionalization may have very little contact with the thief subculture. This subculture does not flourish in institutions for juveniles, and their graduates have not necessarily had extensive criminal experience

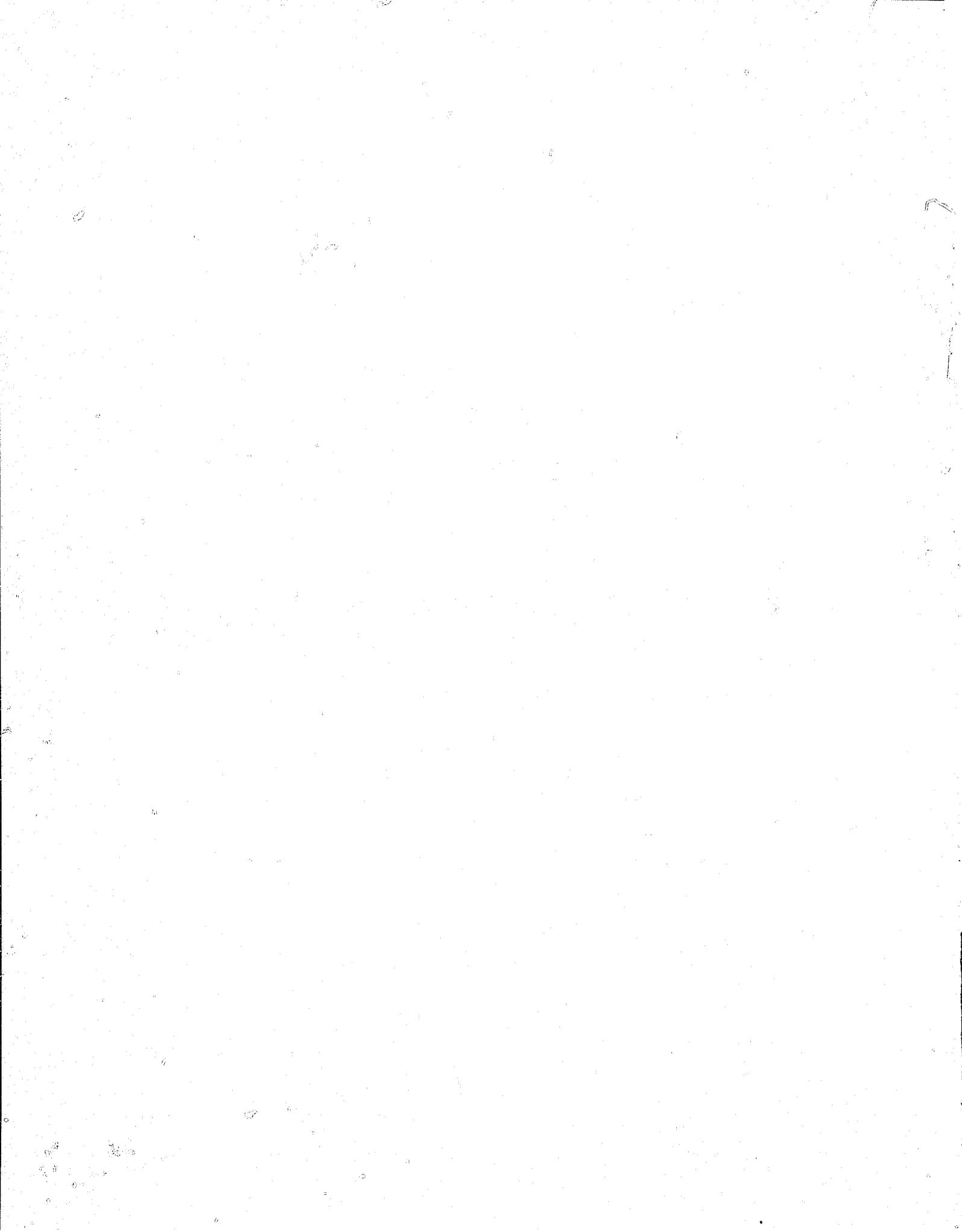
on the outside. Some form of the convict subculture does exist in juvenile institutions though not to the extent that it exists in adult prisons. See also Barry Schwartz, "Peer Versus Authority Effects in a Correctional Community", Criminology, Vol.11, No.2 (1973) pp.233-257.

27. It should be noted that the values of what Irwin and Cressey call the convict subculture is very similar to the values of lower class males outside of the prison. See Walter B. Miller, "Lower Class Culture as a Generating Milieu of Gang Delinquency", Journal of Social Issues, Vol.14 (1958) pp.5-19. This suggests that even the convict subculture has referents outside of the prison and does not arise solely because of the pains of imprisonment.
28. Irwin and Cressey, op. cit. p.234.
29. John Irwin, The Felon (New Jersey: Prentice-Hall 1970) pp.68-79.
30. On the basis of interviews with 116 ex-prisoners, Irwin estimates that about 15 percent could be classified as "jailers". Ibid. p.74 n. 22.
31. Irwin, ibid., p.75.
32. Irwin, ibid., p.79
33. 42 U.S.L.W. 101, July 31, 1973.
34. In the course of discussing the third element of informed consent the court mentions "inherently coercive atmosphere" three times (see mimeo copy of the opinion of the court, pp.27-29). This approach to establishing truth apparently works on a variant of the famous Bellman's rule of three principle expounded by Lewis Carroll in The Hunting of the Snark: "What I tell you three times is true." See Martin Gardner, (ed.) The Annotated Snark (New York: Simon and Schuster, 1962), p.38
35. We make no claim that the analysis and the conclusions reached here are of wider applicability. It should be noted, however, that many arguments concerning experiments in prison adopt a Goffmanesque perspective either explicitly or implicitly. See for example the negative conclusions reached regarding informed consent by prisoners by Peter B. Meyer, Medical Experimentation on Prisoners: Some Economic Considerations, (Washington, D.C.: American Bar Association, 1975).
36. Elastic autonomy is more congenial to the prisoner diversity image.
37. The concept of elastic autonomy was first used by Rue Bucher, Joan Stelling, and Paul Dommerruth, "Autonomy and Monitoring on Hospital Wards" unpublished paper, no date.
38. Michael Mills and Norval Morris make reference to the extremes of prisons and prison life in terms of a continuum between a Siberian labor camp on the one hand and on the other a small, open prison, decently run and containing short-term prisoners. See "Prisoners as Laboratory Animals" Society, Vol.11, No.5 (1974) pp.60-66.

39. The concept of elastic autonomy should not be thought to exclude the approximately 10 percent of the prison population that may be mentally retarded (Bertram S. Brown and Thomas F. Courtless, The Mentally Retarded Offender (Rockville, Md: National Institutes of Mental Health, 1971)). Dealing with the mentally retarded as though they were all the same is as unproductive as dealing with prisoners as though they were all the same.
40. Meyer, op. cit., pp.17-18.
41. See Mills and Morris, op.cit., p.66 recommending a prisoner advisory group. There are other equally and perhaps even more satisfying explanations of the volunteer - non-volunteer study results. One is to be found in the generally high esteem in which we hold experts. Another is the view of the medical experiment as a "substitute parent". See Arnold, at al., op. cit., p.1023.
42. See footnote no. 41.

AN ACCEPTABLE CONTEXT FOR BIOMEDICAL RESEARCH

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AN ACCEPTABLE CONTEXT
FOR BIOMEDICAL RESEARCH

by John Irwin

Most of the arguments against biomedical research on prisoners which have been presented to or discussed by the commission may usefully be sorted into two main categories – which are actually a soft and a hard version of the same argument. The hard argument, briefly stated, is as follows: “The prison milieu is so brutal, degrading, and coercive; and drug research itself is rife with insidious dangers and implications that the very idea of biomedical research in prison is repulsive and intolerable.” This version is not difficult to counter. In the first place the conditions of imprisonment are variable and, therefore, changeable. Moreover, the level of brutality, degradation, and coercion to a great extent have been related to the particular prison’s or prison system’s autonomy and isolation. Not permitting research in prisons, categorically, contributes to this situation of autonomy and isolation, and the continuation of the most undesirable aspects of imprisonment. All penetration into the prison enterprise generally mitigates these undesirable conditions.

In addition, biomedical research is itself variable. It has ranged from tests of highly toxic and dangerous drugs to the most benign cosmetics. As in the case of undesirable conditions of imprisonment, permitting drug companies to operate with autonomy and in isolation has encouraged irresponsible research on drugs. Accreditation and review of research procedures and protocols have, I suppose, generally reduced the potential dangers to a tolerable level. When this is so, and only when, we are willing to permit research on some human subjects. The question becomes then, why not prisoners? Because, the argument must be, that there are special conditions which obtain in the prison context that will not permit the degree of voluntary action upon which we insist in order to

permit drug research. And this is the soft version of the argument against biomedical research in prison. Expanding it slightly; "the prison context has a variety of obvious and very subtle coercions which are deeply inbedded in the prison processes. Since there are some dangers in biomedical research, though they may be minimized greatly by accreditation and review processes, we must insist on experimentation only on persons who are free or nearly free from coercion, and this is not true of prisoners."

The response to this argument begins by proceeding in the same direction as that to the first. The prison condition is variable and changeable. To this must be added that all human subjects are never totally free of coercions. There are always obvious and subtle pressures operating in all social contexts. In addition, denying the opportunity to prisoners to volunteer for biomedical research when this opportunity is afforded to other persons is in fact directly reducing the amount of voluntarism which prisoners may exercise.

Furthermore, repeating another aspect of the response to the hard argument, taking away drug programs eliminates from the prison context one of the few outside, somewhat autonomous, components which can and should have an amelorative impact on the prison process. It must be admitted that it does not necessarily have this impact. We could imagine, and probably find many examples of, instances in which drug companies and prison administrators cooperate fully in pursuing their own separate and unacceptable courses of action, each agreeing covertly or overtly not to interfere with the others operations. In fact, this seems to be partially true of Jackson prison. The drug programs were to a great extent islands within the prison context. Each separate enterprise — the prison and the drug research — had carved out separate spheres in which they

operated relatively autonomously. For instance the drug companies left to the prison administrators the final say on eligibility and the prison administrators took no interest in approving the drug protocols.

Even in this situation, which is definitely improvable, there was some degree of beneficial impact on the prison operation and the life of the prisoners. At least there were outside observers who had different investments, perspectives, and purposes, and who, therefore, exercised (informally and weakly perhaps) some degree of restraint on possible excessive abuses towards prisoners, and some influence in humane directions. Moreover there are structural arrangements in which the beneficial impact of outside interests on the prison operation is maximized. These will be discussed below.

Consequently biomedical research on prisoners should not be denied categorically, but permitted under specific conditions. In this way, it is my opinion, the abuses can be reduced to an acceptable level and other benefits can be gained. What is required is to adopt, not the contract model as opposed to the fiduciary model, which was suggested by one of the commission members, but a rights model instead of one of paternalism. Denying prisoners the right to volunteer when they have requested that they be given this right, because the government or some representative body of the government believes that they are not capable of making the choice is more a paternalistic decision than a fiduciary one. A contract model suggests that the contractors be allowed to strike their own bargain. This may be acceptable in a free market place where agents of relatively equal power operate. However, in the case of prisoners bargaining with prison authorities or drug companies, because of the extreme disparity of power, some protections for the weaker parties must be built into the arrangement and this

requires a human or civil rights approach in which minimal rights are established and guaranteed through the exercise of government power.

This, in my understanding, has been the historical approach to defining and then implementing rights and freedom. These concepts are relative and elusive, and more often have been approached indirectly by locating those conditions – such as the tyrannical power of the church or state, or the exercise by private and public institutions of systematic discrimination against races of people – which reduce or restrict them than by specifying directly what constitutes a state of freedom.

In the prison setting there are several obvious and less obvious restraints to voluntary action which impinge upon biomedical research and which are not present, at least to the degree to which they are in prison, in the outside social, political context. I would argue further that these special prison coercions or restraints on freedom which obtrude into the biomedical research issue are not essential in the operation of a system of incarceration or essential to the accomplishment of the legitimate goals of incarceration. Therefore removal of these restraints is possible, consistent with the operation of an effective system of incarceration, and generally ameliorative in regards to the undesirable conditions of imprisonment. Moreover, I believe, the removal would make drug research consistent with the values and concerns of the commission.

To fully implement the civil or human rights model it will be necessary to not only formulate guidelines and institute an accreditation process, but also to establish an on going review mechanism. The initial guidelines are needed of course, but a permanent system of discovery, policy adjustment, and grievance

review is necessary to ensure implementation of the guidelines and to make adjustments when presently unrecognized and unacceptable coercive forces emerge or are discovered.

In establishing this procedure one essential feature should be included. This is some method of systematic input from all segments involved, particularly the prisoners. This is absolutely necessary to avoid the pitfalls of paternalism, elitism, and authoritarianism which inevitably lie in the path of all hierarchical social organizations and which must be carefully and continually avoided lest any particular organization tumble in as most have before it.

Having offered a general approach to the issue, specific coercive relationships and processes which obtain in the prison milieu must be discussed. The most obvious and conceptually the least problematic is the monetary incentive of drug research. Two separate issues are involved here. The first is that other opportunities to earn wages in the prison either are non-existent or too limited and indigent prisoners, who are the vast majority, are unduly coerced into volunteering for biomedical research. This problem has an easy theoretical solution, but a more difficult practical one. Alternative pay sources for all prisoners, or the vast majority at least, is the answer. However, in a period of tight government budgets, fiscal conservatism, and general ill will towards prison populations, this would be difficult to actually accomplish. For instance the small sum of thirty dollars a month for all the prisoners in Jackson would cost in excess of a million dollars annually. The solution to this practical problem lies on the other side of the monetary issue. The drug companies do not pay prisoners nearly as much as they pay subjects in the free society. They argue that their primary reason for not paying the same amount is not to save themselves money, which is a relatively small

sum compared to the total cost of drug research, but to reduce the extreme coercive potential of relatively large monetary incentives to prisoners. These arguments have merit, but they should make us nervous because drug companies, irrespective of their true reasons, are saving money by using prisoner populations. This offers us a solution to the other problem, that is, the absence of funds to supply wages to large numbers of prisoners. The drug companies should be required to expend the same fee on prisoners that they do on free subjects. The majority of this fee would go into a general fund from which wages for the general prison population could be paid.

The other coercive force which was identified by the commission — that of the relatively higher level of comfort and privilege which prisoners experience while at the drug centers — should be ignored. In my opinion it is balanced by the perceived dangers of the drug and the actual discomfort from the drugs which the prisoner subjects often experience. Moreover, it is a minor incentive, one which would be unnecessary and very difficult to eliminate.

There is a cluster of incentives and restraints, which influence the drug research enterprise and which the commission has not discussed, that surround the issue of arbitrary, discriminatory, and partial decision making which is virtually endemic in prisons. Prison officials have been granted wide discretionary powers in order to “rehabilitate” prisoners, maintain control and incapacitate “dangerous” individuals. Too often they use this discretionary power to make arbitrary decisions in order to punish persons for acts which have not been proven against them, to reward persons who fall into their favor, and to isolate persons who they find troublesome or repulsive. This in fact is a mode of operation that all decision makers tend to adopt if they are not prevented from doing so by checks from

below or outside their organization. The prison has developed this arbitrary decision making mode to the extreme because they have been granted considerable autonomy and wider discretionary powers as a result of their special task — handling convicted felons — a task which is seen as particularly difficult and potentially explosive. Society in effect has thrust this task upon the prison administrators and asked only that they keep it out of their sight.

In spite of the intense arguments to the contrary, it is my opinion that discretionary, and thereby, arbitrary decision making is not necessary to the prison operation and, in fact, it contributes to most of the escalating problems in prison. This is not a universally accepted viewpoint, however. Many persons, correctional reformers among them, contend that wide margins of discretion are necessary to operate a system of rehabilitation which is built upon the concept of individualized treatment. In recent years the failures and the excessive punishment which have resulted from the operation of rehabilitation systems have been thoroughly described. There is a swing away from rehabilitation as a goal which can be accomplished or is legitimate for the criminal justice system. For instance, there have been a growing number of statements by eminent experts on the criminal justice system arguing against rehabilitation. See American Friends Service Committee, Struggle for Justice; Norval Morris, The Future of Imprisonment; Andrew Von Hirsche, Doing Justice. In addition, many persons continue to argue that the system must have discretionary powers to incapacitate "dangerous" individuals. Again it has been the discovery of more rational observers of the system that attempts to do this, because of no effective means of predicting who will be dangerous, are unjust and counterproductive. If we take away rehabilitative and incapacitating functions from the prison it is left with two legitimate goals — punishment and general deterrence. Both of these are maximized by operating with

the least arbitrary decision making procedures.

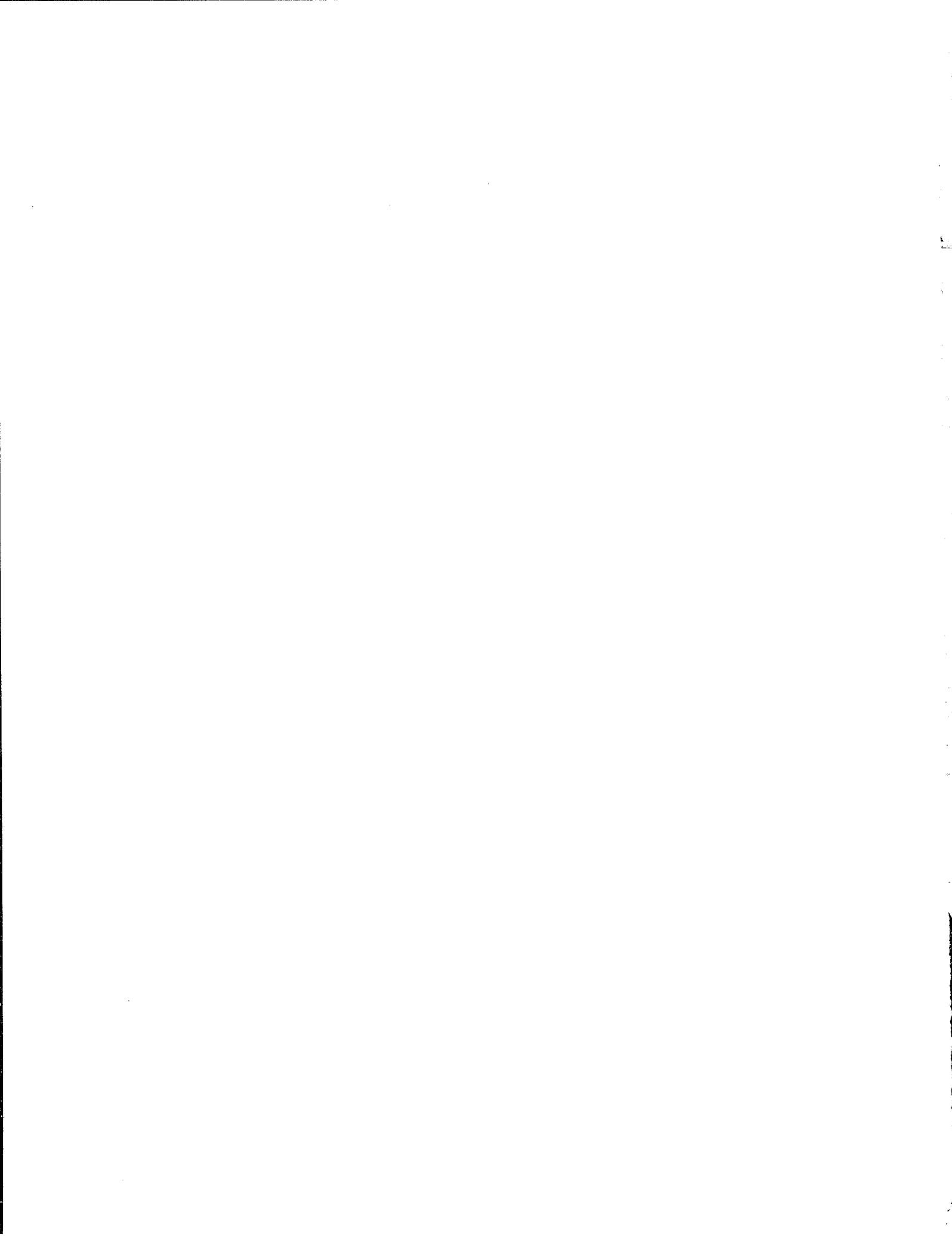
There is one last function of discretionary decision making power which, though the prison officials feel make it essential, is illegitimate and also counter-productive. This is the use of discretionary power to maximize internal compliance and control. In the past, prison officials selected out convict "leaders" and granted them special privileges in return for help in maintaining an informal system of control. In the current more highly heterogeneous and conflictive prison setting this style of operation is no longer effective, but prison officials continue to exercise arbitrary power to punish and isolate persons they define as trouble makers. This is also ineffective. In the contemporary prison the prisoners have become much more sensitive to arbitrariness and often respond to its exercise in a very disruptive, sometimes violent, manner. Consequently, we must conclude that there are no legitimate or productive reasons for exercising wide margins of discretionary power in the operation of the prison.

There are several points at which discretionary power directly touches upon biomedical research. The most obvious is in the establishment of the criteria of eligibility for the research program which at present is probably done more for the purpose of increasing compliance and control than any other reason. The procedure of determining the eligibility of potential volunteers, if done discretionarily and sometimes arbitrarily, is susceptible to abuse and produces resentment. Rejection from the drug programs is another area of potential abuse and resentment, and should be protected from arbitrariness. There is a strong possibility that some prisons allow information from drug research participation to seep into the parole decision making procedures, which themselves are very arbitrary decisions. This should be eliminated or minimized by a review

mechanism.

These are a few of the many known and unknown potential misuses of discretionary power which encroach on the limited freedoms of the prisoner and can, and often do, obviate the biomedical research programs. To uncover and reduce the impact of arbitrary decision making a review and grievance mechanism is absolutely necessary. The planning of an effective procedure will require more thought and discussion than has been allowed here. However, allow me to spell out two basic principals which should guide this planning. The first is independence from the prison system and the second is representation of all the relevant group and social categories – such as, prisoners, families, civil rights organizations, the legislature, but particularly, the prisoners.

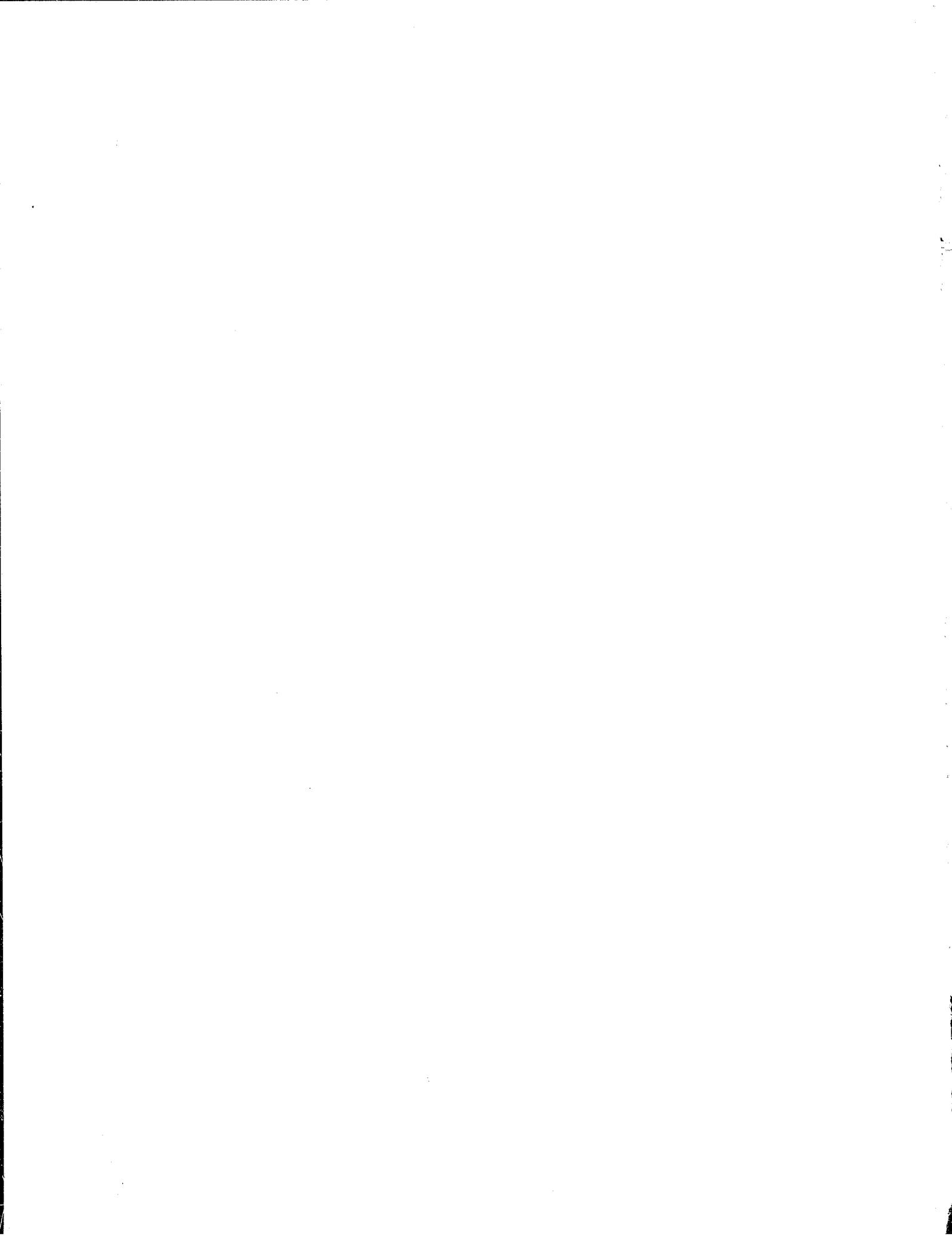
In closing, I should comment that in addition to the procedures for review and grievance in regards to these areas of decision making, an adequate system of accreditation and review of pharmacological and health concerns is a basic necessity and perhaps these two functions could be performed by one mechanism. However, the problems and needs in this area are outside my areas of knowledge and I refrain from any extended recommendations on them.



6

PSYCHOLOGICAL, BEHAVIORAL AND/OR SOCIAL RESEARCH
INVOLVING PRISONERS AS VOLUNTEER SUBJECTS

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INTRODUCTION

Just as historically the governmental power to tax has been the power to destroy so too in recent years the governmental power to regulate has become the power to destroy. Of the four types of research outlined in the Commission's staff paper on "Prisoners as Research Subjects (Biomedical therapeutic, Biomedical non-therapeutic, Non-therapeutic behavioral and Therapeutic behavioral) only therapeutic psychosocial research intrinsically addresses itself to the issue of delivering on the "promise of rehabilitation".

Therefore I will take an unequivocal stand that if Congress wishes to officially abolish treatment, rehabilitation and education and training beyond the routine academic-vocational fare as appropriate goals in the Criminal Justice System then such abolition ought to be the legislative mandate. However, if the intent of Congress is to provide treatment services in a safe effective and humane manner to wards of the state including prisoners a commitment to research is essential and the regulatory process must be so designed as to facilitate all the aims of regulation including evaluation of increasingly scientifically based effective methods.

Further the issue of a prisoner's "Right to Treatment" was not at all approached thus ignoring the potential infringement of this right for all time and for all future prisoners by either abolishing research for effective methods or by stifling correctional research through over-regulation.

The question is then in four parts: (1) Shall there be regulation of correctional research, (2) If there is to be regulation what are the purposes of such regulations, (3) How shall the purposes of regulation be implemented and (4) How shall such regulation be monitored as to its effectiveness relative to the purposes. I propose to address each question serially as follows.

I. SHALL THERE BE REGULATION? There are basically three types of answers to the question of whether or not to regulate. The first possible answer is that no additional federal regulation is needed above and beyond the existing laws, professional ethics and the scrutiny of interested parties. This is the actual mechanism now in place and it has proven rather effective over time. By effective is meant that research efforts were not stifled and that such abuses as did arise were corrected or abolished through varying combinations of adverse publicity, administrative and judicial action.

However, historically a typical political response to regulation by adverse publicity is to desire to placate interested parties through institutionalization of concern through a regulatory mechanism. Although this process has most often proven costly, ineffective for positive ends and thus contraproductive the temptation is obviously overwhelming. I shall therefore a priori presume that the congressional mandate to the Commission shall be interpreted and implemented as a call to further regulation of research.

II. Therefore I will now address the second question, that is the issue of GOALS AND PURPOSES OF POSSIBLE REGULATION of social, psychological and behavioral correctional research.

GOAL #1: To regulate correctional research in such a manner as to facilitate the development of effective correctional methods for two purposes:

- (a) to replace currently available methods which are well known to be ineffective at best and more often desocializing, destructive of productive skills, enhancing of commitment to negative criminal identity and therefore a detriment to the incarcerated individual and the nation

- (b) to allow the criminal justice system at some future time to be able to offer to volunteer "wards of the state" effective tested and researched programs that could believably be used by interested individual prisoners to prevent future incarcerations and thus self limit his punishment and integrate himself in the social mainstream. As more effective methods of such self enhancement and self regulation become available through research to the ordinary citizen and conversely not available to prisoners if proper research is not done then a condition of ineffective correctional methods now condoned by historical precedent will step into "cruel and unusual punishment" by the standards of the future.

GOAL #2: All correctional research into methods which do not infringe on ordinary, constitutional and/or such additional "basic rights of prisoners" as may be defined by the commission should be allowed to employ prisoners who volunteer via informed consent. The regulatory mechanism should be designed to audit the quality of informed consent and protection of basic rights. The actual review of research design and purposes should be left to the innovator, his administrative sponsors and the after review to the scientific, professional and interested public upon

publishing so as to not stifle or stereotype research into lines of action which are currently known and which are also known to be generally ineffective.

GOAL #3: In cases possibly involving irreversible outcomes such as biological changes or change in the structure or nature of the sentence a regional set of review boards should be created by Congress to review all such proposals prior to implementation using the following tests:

- (1) Is there any reason to believe there might be an advancement of correctional practice.
- (2) Has the potential irreversible effect such a minimal magnitude as to be overshadowed by the possible benefit.
- (3) What adequate provision is there for care, compensation and reversal of "bad" effect if such occurs.

If the above three criteria hold in a context of informed consent then the only additional necessary action is enforced periodic monitoring to determine continued compliance.

GOAL #4: That all research reviewed by federal regulation shall be published so as to prevent the loss of information that currently occurs when correctional agencies hide their bad or ineffective results from others likewise good or unexpected results must be

published even if and especially if they contravene current practice.

III. HOW SHALL THE PURPOSES OF REGULATION BE IMPLEMENTED?

- (1) I recommend regional boards whose territories of responsibility are contiguous with the Federal Circuit Courts. This will provide protection from co-optation by state government or by the federal bureaucracy.
- (2) Each board shall be semiautonomous and its actions reviewable by a specified Federal Circuit Court Judge in its circuit.
- (3) The members of each regional board should be selected by a joint congressional oversight committee and approved by Congress as otherwise the executive branch would be merely talking to itself.
- (4) The charge of each regional board would be as listed in the goals to insure continuation of promising correctional research while ensuring proper regard and safeguards for prisoner rights.
- (5) The regional boards would be empowered to approve or disapprove research in progress or proposed. Appeals by any concerned parties would be directed to the specified Federal Circuit Court Judge, whose decision, except under extraordinary circumstances, would be final.

- (6) If on regular monitoring, the regional board found serious enough error in procedure which appeared to be intentional and non-rectifiable it would have the power, subject to appeal, to close any correctional research program in its circuit after due processing of the facts and coming to a determination.
- (7) A minimal central office could serve to provide coordination for national (interdistrict research) and monitoring of the semiautonomous boards.
- (8) The regional boards would preferably be small (3 or 5 persons), full time, salaried and from at least three of the following types of people; correctional research, the general law, civil rights and advocacy law, science, medicine and/or psychiatry and/or psychology, and/or the general public.

IV. Some budget should be provided to do studies of the correctional research process, the nature of the results and the impact of research findings so as to provide information not only to researchers but also to Congress to update the law in this area. Without such a built-in evaluation mechanism the regulatory process in the above form or any other form will proceed to stagnate and expensively impede progress in correctional research and the continued protection of prisoners rights.

SUMMARY

In summary, I am proposing the simultaneous fostering of both effective correctional research and the protection of the rights of prisoner volunteers through a set of protective guidelines and potentially productive goals with executive branch, state and local implementation monitored and controlled by semiautonomous regional boards selected by Congress and having its appellate level in the 10 circuit courts while maintaining effectiveness through ongoing centrally controlled and self-monitoring and evaluation.

POST SCRIPT

The above document nowhere supposes that effective correctional methods yet exist nor that any believable correctional research has ever been done. My effort was to keep the argument pure and clear without descending into the murkiness of claim and counterclaim re the validity of recidivism statistics, correctional research and the currently fashionable negative evaluation of the possibility of effective correctional practice.

I am reasonably convinced from my own experience in founding, supervising and monitoring Asklepieion programs over the last seven years that this combination of a Synanon type therapeutic community in conjunction with Transactional Analysis and other "therapies" plus effective social, vocational and academic training and with adequate community based followup post incarceration allows prisoner volunteers who complete the 2-3 year program to reliably reenter and remain in the social mainstream and live productive lives. Further my continuing research into the principles of effective correctional practice begun while Program Development Coordinator and Warden-Designate of the former Federal Center for Correctional Research at Butner, North Carolina indicates that other mixes of methodology also have a similar potential.

All these methods however were first developed outside of corrections and were brought into corrections experimentally. Thus any ban or regulatory procedure that functions overzealously producing a functional ban on research into effective corrections will inevitably ensure

that no new innovation produced by corrections will be used or if used, tested, so as to properly evolve or, as is more likely, new methods that become available in the greater society to alleviate human psychosocial suffering and disadvantage will not be quickly or perhaps ever be available to prisoners. Such an outcome would pervert the intent of Congress to protect all of a prisoners rights including the right to learn how to become a productive citizen and would also pervert societies need and desire for such reintegration of our incarcerated members.





THE LAW OF INFORMED CONSENT IN HUMAN EXPERIMENTATION:
PRISONERS

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Experimentation," June 1, 1976.



INTRODUCTION

Before an investigator can use any person as a subject in biomedical or behavioral research, he must obtain that person's informed consent. This consent must be voluntary, competent and understanding.¹ Unlike a minor or a severely mentally ill person, prisoners are not incompetent to give informed consent. It is not usually alleged that prisoners are less able to understand the risks, discomforts and benefits that may be the result of experimentation than free-living individuals. The problem in obtaining informed consent from prisoners is that the very fact of their incarceration may prevent them from giving their consent voluntarily.

The issue of experimentation on prisoners is not a new one. It is reported that Persian kings allowed their physicians to use prisoners as experimental subjects. In the sixteenth century the Duke of Tuscany permitted Fallopius to use prisoners for his experiments. Queen Caroline, the wife of King George IV, let her physician use six condemned criminals for experimental smallpox vaccinations before submitting her own children to the procedure.²

For many reasons prisons are almost ideal places to conduct research. Life is routine and subject to few variations. The population is relatively stable, which makes long-range studies feasible. The imposition of experimental procedures that might inconvenience free-living subjects is not a burden on prisoners. It is also less expensive³ to use prison subjects than it would be to use free-living subjects.

BIOMEDICAL RESEARCH

Regardless of these considerations, there has been a great deal of controversy concerning whether or not prisoners are capable of giving an informed consent to such research. Because of the very nature of incarceration it can be argued that prisoners do not have a real choice concerning their participation in these activities. This concern is articulated in the Nuremberg Code where it is stated:

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.⁴ (emphasis supplied)

The issue in regard to prisoners is whether they are so situated as to prevent them from exercising free choice.

Some argue that not only are prisoners without free choice, but that they are used as research subjects because they are not able to choose otherwise.⁵ Indeed, one defense tactic at the Nuremberg Trial was to try to demonstrate that prisoners are exploited by researchers in the United States. Dr. Andrew Ivy was called by the prosecution as an expert witness in high altitude experiments and medical ethics. During the cross-examination Dr. Ivy was questioned concerning malaria experiments that were done in the United States penitentiaries. The prisoners who participated were paid \$50 at the commencement of the experiment, and \$50 when it was terminated. Some of Dr. Ivy's testimony

follows:

Q. Witness, you said yesterday that the prisoner who ordinarily had to sign a waiver according to which, if I understand you correctly, that they gave up any claim if it proved a fatality, did I understand you correctly?

A. Yes. They signed an agreement, if I recall it correctly they would make plans for themselves in case of accident.

Q. Not only if they were injured, but if the patient should be a fatality?

A. I believe the expression, "heirs and assigns" was included, yes.

Q. Then the people gave up all claims for their heirs too. Now, witness, in your experiments did you have such waivers signed by the subjects?

A. No. Our subjects, conscientious objectors, were given insurance against possible damage or injury.

Q. Insurance. Why did your subjects get insurance, and why did the prisoners have to give up all claims? Why this distinction?

A. I do not know.

Q. Witness, on the basis of your great experience, don't you have any idea why there was this distinction? You are an expert in all these fields.

A. Well, I presume it was out of sympathy for the C.O.'s. The soldiers in the Army were insured by the government, and, I thought - I should believe that might have been thought to be a good idea to insure the C.O.'s for the same reasons that they were taking experiments that had a small amount of hazard in them.

Q. Was there sympathy not felt in the case of prisoners who had volunteered for experiments on behalf of the general public?

A. I had nothing to do with that or determining the conditions. Thus I cannot answer "yes" or "no."⁶

* * *

[Dr. Ivy was asked if it was ethical to carry out experi-

ments on prisoners who were asked to waive all their rights.]

A. Yes, I believe it can be reconciled with the basic medical ethics.⁷

* * *

[Dr. Ivy went on to state that he thought prisoners participated in experiments for idealistic reasons. He said that prisoners had stated that they participated in the malaria tests because they were patriotic, wanted to help our soldiers, or had a friend or relative who might contract malaria.]

Q. If all the persons apply for idealistic reasons, why are they offered pecuniary recompense?

A. I suppose it is to serve as a small reward for the unpleasantness of the experience.

Q. Don't you believe that money was the motive for many of them - a hundred dollars?

A. That is rather small. From the point of view of prisoners in the penitentiary in the United States. A hundred dollars isn't much money.

Q. For a prisoner that would be quite a lot of money it would seem to me, for someone at liberty it is not so much.

A. Our prisoners in the penitentiary in the United States, when they work in factories in the prisons receive pecuniary compensation for that work.⁸

* * *

Q. If one declares one's self to be a volunteer, must one not weigh the advantages against the disadvantages?

A. I believe so.

Q. The disadvantages being the risk of serious disease, the advantage is fifty or a hundred dollars.

A. I should say the advantage is being able to serve for the good of humanity.

Q. For what reason was the money not paid immediately - but in two payments? . . .

A. I presume that that is just the common way of doing business in the United States when an agreement is involved. I presume the lawyers had something to do with that.

Q. Was the reason not this: that the prisoner would lose his enthusiasm for the experiment and would cease to cooperate? Could that have been the reason for being a little circumspect in the payment?

9

A. I doubt it.

[In addition to defending the malaria experiments, Dr. Ivy defended the work of Colonel R.P. Strong who injected attenuated plague organisms into 900 condemned prisoners in Manila in the early 1900's. After demonstrating disbelief in the fact that there were 900 condemned convicts in a city the size of Manila the defense asked Dr. Ivy about the safety of the procedure. Dr. Ivy responded that Dr. Strong did work on guinea pigs first and knew the procedure was safe.]

Q. Regarding Strong's experiments . . . you said the experimental subjects had a temperature of one degree Fahrenheit [above normal], and that the harmlessness of the experiment was absolutely no surprise to the author because he could foretell the successful results. Did I understand you correctly?

A. On the basis of animal experiments.

Q. For what reasons were criminals who had been condemned to death used for these experiments, in view of those facts?

10

A. I do not know.

Thus the defense tried to demonstrate that in the United States prisoners are coerced into being experimental subjects by the offer of rewards including payment of money, that they are not as well protected as are other subjects, and that they are subjected to dangerous experiments for which other groups would not volunteer.

MOTIVATION

In determining the voluntary or involuntary nature of a prisoner's consent, his motivation becomes an important factor. If he is motivated to participate in an experiment for improper reasons, or by forces that are coercive or that unduly influence him, his consent may be involuntary and therefore invalid.

The issue of what motivates prisoners to participate in research has been discussed in the medical literature. Two individuals who have worked with prisoners since 1949 have stated that they believe participation in research relieves some of the monotony and oppressiveness of the prison routine, and that for some, money may act as a motive, although prisoners can earn almost as much in other prison activities as they can as experimental subjects. Some prisoners are less reluctant to be visited by their children in the hospital environment, and some are motivated by altruism. There is also the hope held by some prisoners of more favorable treatment in the future by prison authorities.¹¹

Dr. Frank Ayd lists eleven motivating reasons, the first being financial reward. He agrees with Freund's statement that the "amount paid should not be so large as to constitute undue influence - that is, so large as to obscure an appreciation of the risk and weaken the will to self-preservation. We ought not be put in the business of buying lives."¹² The other motives Ayd lists are hope for reduction of sentence, direct or indirect seeking of medical or psychiatric help, escape from a lonely and tedious existence, curiosity, and a few other factors.¹³

Although much of this work is speculative in nature, some more objective studies have been done. Arnold, et al., found that whether or not a prisoner volunteers as a research subjects depends to a great extent on the type of penal institution in which the prisoner is incarcerated, and the prisoner's value scale. ¹⁴ Dr. Arnold did his research in a county prison in which two types of studies were being conducted - one dealing with the treatment of malaria and the other with the effects of drugs on certain body functions. In this prison there was very little constructive activity provided for the prisoners and therefore little competition for their time and interest.

The prisoners who volunteered for such studies were moved to a special part of the prison where they were treated more like members of a free society. Clean linens were provided, there were beds instead of bunks, the quality of the food was better, and food was available twenty-four hours a day. When asked, most of the prisoners described ¹⁵ the general living conditions in the prison as "impossible situations." More than fifty percent indicated that their decision to volunteer was based in part on their desire for better living conditions. Most of the volunteers were "loners" who were not members of any of the cliques that were found in the prison. The third factor was the general level of fear within the prison, which exists in many state and county prisons. Many prisoners stated that it was safer in the research project than in the prison itself. One prisoner stated that you could go to sleep without being afraid that someone would "bust you ¹⁶ in the head," or "set fire" to your bunk while you were asleep.

In giving an informed consent, one must evaluate the risks involved in the research project. Arnold found that risk taking is an integral part of the life of many of the prisoners. Many of these men are dedicated professional criminals whose "professional lives are often devoted to activities that expose them to personal risk." The very fact that risk is involved may give an activity status ¹⁷ in certain inmate groups. The fact of incarceration affected the prisoners' willingness to take risks. In one group of thirteen volunteers, twelve indicated that the risk of adverse physical effects had little influence on their decision to volunteer as long as they were in jail. In some cases they were attracted by the risk. However, only eight would volunteer for a similar experiment if they were free-living.

In another group of fourteen inmates, three expressed no concern about long-range effects because they rarely planned ahead for anything. One prisoner stated he would volunteer for anything regardless of risk. "As a professional thief, he regarded life as just one long chance [and] viewed his long-range survival with much doubt." ¹⁸

Prisoners also felt that they needed money to ease their way back into society when they were released. Without money they knew they would have to return to crime, at least immediately following their release. One way to obtain some money while in prison is to become an experimental subject. However, most of the money earned is spent while in prison. ¹⁹

Finally, a number of prisoners stated that by becoming research subjects they could make a positive contribution to society, about

half of those interviewed felt that it would improve their chances of getting a job once released, and a very few felt it would increase their chances of getting paroled.²⁰

Martin, et al., conducted several studies to determine why individuals volunteer as research subjects.²¹ One study involved two groups of prisoners, volunteers and non-volunteers, for the Malaria Project at Jackson County Jail, in Missouri. Inmates with sentences of less than one year were asked to participate. The project and risks involved were carefully detailed and each inmate was told he would be paid but that there would be no reduction in sentence. Inmates who volunteered received additional information, whereas non-volunteers did not. Thirty-six inmates who volunteered and twenty-four who did not comprised the sample. It was found that those who volunteered understood the nature of the disease and its threat to human life no better than non-volunteers although the volunteers were given much more information. Sixty percent of the volunteers described the project in terms of high-risk although it had been explained that it was a low-risk experiment. About half of the volunteers gave altruism and half gave money as the reason for volunteering. Almost all the non-volunteers stated respect for the volunteers. The authors express the belief that this respect may be the most important consideration in deciding to volunteer.

The second study involved four groups of people - low income individuals, policemen and firemen, professionals (scientists, lawyers and educators) and prisoners - who were asked whether or not they would volunteer for four hypothetical experiments. The experiments involved

investigating malaria, new-drug toxicity, the common cold, and the effects of air pollution. These experiments presented different degrees of risk, different time demands, varying requirements for interrupting family life and employment, and different degrees of social importance. Little information was given, but all questions were answered.

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The following table shows the results.

Volunteer Group

| | Malaria | | Test Drugs | | Cold | | Air Pollution | |
|---------------|---------|----|---------------|----|------|----|---------------|----|
| | Yes | No | Yes | No | Yes | No | Yes | No |
| Prisoners | 40 | 20 | 44 | 16 | 49 | 11 | 50 | 10 |
| Low Income | 7 | 19 | 9 | 17 | 10 | 16 | 17 | 9 |
| Fire & Police | 3 | 37 | 5 | 35 | 11 | 29 | 28 | 12 |
| Professional | 0 | 28 | 1 | 27 | 2 | 26 | 26 | 2 |

Clearly prisoners and low-income individuals were more likely to volunteer for risky experiments. However, all groups were more willing to volunteer for the less risky experiments than for those that had higher risks. Thus, the element of risk certainly entered into the decision-making process for all the people involved.

This study also found that there was a greater willingness to volunteer when the volunteer was not obligated to others. Half of the persons living alone would have volunteered for the malaria experiment whereas only a fifth of those who had family responsibilities would have volunteered for this experiment.

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From these studies one sees that prisoners are motivated by a variety of factors to volunteer for research. The need for money certainly enters into it. This is demonstrated not only by these

studies but by the statements of prisoners. One prisoner has stated that the only way he could raise bail money was to participate in experiments in a county jail.²⁴ He also testified he needed money for books and writing materials.²⁵ Another prisoner commented, "Yeah, I was on research, but I couldn't keep my chow down. Like I lost about thirty-five pounds my first year in the joint, so I started getting scared. I hated to give it up because it was a good pay test."²⁶

One prisoner who made \$30 a month participating in a study of the topical application of dimethylsulfoxide (DMSO) said that he knew a couple of inmates who were burned so badly by it that they were hospitalized. But, he said, "Thirty is a full canteen draw [all one can buy in the prison store] and I wish the thing would go on for years - I'd be lost without it."²⁷

There are more subtle reasons stated such as altruism, the need for respect, lack of concern regarding risks or a desire to encounter such risks, relief from boredom, and curiosity. The true impact of these subtle motivations is for social scientists, not lawyers, to decide. Assuming, however, that these motivations do exist, do they work to invalidate the ability of a prisoner to give his informed consent? Or, to put it another way, do these motivations unduly influence the prisoner, coerce him to participate, or cause such duress, as these terms are defined by law, as to deprive him of his consensual capacity?

DURESS AND COERCION, AND UNDUE INFLUENCE

A. Duress

In order to review the law that relates to duress (or coercion) and undue influence, one must look to areas of the law that have little to do with experimentation - the law of contracts, wills and criminal procedure. It is very difficult to simply state the law of duress or undue influence. One authority on contract law has stated that the cases on this subject are far from uniform and are inconsistent due to the very different fact patterns involved.²⁸

Duress is generally evidenced by the following:

- 1) Personal violence or threats thereof;
- 2) Imprisonment or threats of imprisonment;
- 3) Threats of physical injury or of wrongful imprisonment or prosecution of a husband, wife or child, or some other close relative;
- 4) Threats of wrongfully destroying, injuring, seizing or withholding land or other things; or
- 5) Any other wrongful acts that compel a person to manifest apparent assent to a transactions without his volition, or cause such fear as to preclude him from exercising free will and judgment in entering into a transaction.²⁹

To establish coercion the facts must indicate that he was actually induced by the duress to give his consent and would not have done so otherwise. This must be to such an extent that "the action is not based on a voluntary personal judgment previously made."³⁰ The

pressure that is brought to bear on the person must be wrongful. It can be wrongful even if it is lawful and non-tortious. Contracts that are made under duress or coercion are voidable, but they are not void and can be ratified by later acts.

Thus, to establish duress or coercion one must demonstrate a threat, or threatening situation, of such intensity that the person threatened loses the ability to choose or to act freely. A review of one case may further explain how courts view this problem. In Fox v. Piercey,³¹ the plaintiff, a fireman, became drunk and disorderly at a party and was arrested for drunkenness. The chief of the department asked for his resignation, but Fox refused. Fox claimed the chief said, "If you do not resign, I will blast you and smear you in every newspaper in Salt Lake City. I will make it so miserable you can't get a job in the city." According to Fox he resigned as a result of this threat. He went to the civil service commission and then to court in an attempt to rescind his resignation. Fox claimed it was void because it was made under duress.

The trial court found that the chief did not make the alleged threat. It did find, however, that the chief said that unless he resigned he would be discharged, and that the discharge would attract publicity that would adversely affect future employment opportunities. It decided that Fox resigned when "frightened and alarmed and under the influence of duress"³² and the resignation was therefore void.

The appeals court reversed the decision of the trial court. It said, "Duress is unlawful constraint whereby one is forced to do

some act against one's will." The threats must be such as to overcome the will of an ordinarily reasonable man. It stated that the modern rule is "that any wrongful act or threat which actually puts the victim in such fear as to compel him to act against his will constitutes duress." Since the chief could discharge Fox for his offense, his statement was not wrongful. In addition, he did not state or imply he would publicize the discharge, but merely advised Fox what the consequences of discharge would be.

Even though this situation "created great fear for the economic welfare of himself and his family," duress was not established. Thus duress is not inherent in a particular situation. One cannot merely look objectively at the threatening situation but must look to "the state of mind induced [by threats] in the victim," in that particular situation in order to establish duress.

Ascertaining the state of mind of an individual is a difficult task. One must look to the external factors that make up the particular situation and determine if the situation is so threatening as to prevent a person from acting freely. Surely if one acts at the point of a gun we can safely assume that he is acting under duress. Threats to ruin one's business have been found to cause duress. However, prison conditions pose much subtler problems in determining the existence of duress. After a short discussion of undue influence we will analyze a specific prison situation in an attempt to determine whether coercive conditions exist.

B. Undue Influence

Undue influence is similar to duress but is different in one important factor. For undue influence to exist, there must be evidence of a confidential relationship of some sort. If a party in whom another reposes confidence misuses that confidence to gain his own advantage while the other has been made to feel that the party in question will not act against his welfare, the transaction is the result of undue influence. The victim must act in a way contrary to his own
38
wishes.

Under the law of wills, "anyone in a position to influence the
39
testator" is in a confidential relationship with him. In certain circumstances confidential relationships have occurred between patient and nurse, father and son, and neighbors who did housework for an infirm individual. There is nothing wrong with influencing a person. One may comfort an elderly or dying person in the hope that he will
40
leave you a large bequest, or reward you in some way. The influence must be "undue," that is, it must lead to the destruction of a person's
41
ability to weigh various influences.

In most cases dealing with undue influence, the testator's state of mind is usually weakened by illness or some other incapacity, the suspected beneficiary actively participated in the execution of the will, and the will is "unnatural," that is to say that the natural objects of the testator's bounty have been ignored.

Thus, where an eighty-three-year-old woman suffering from Parkinson's

disease, hypertension, nephritis and arteriosclerosis made a gift of \$6,000 worth of stock to a doctor who treated her daily for a period of years, the gift was overturned as being the result of undue influence. 42
The court found that a confidential relationship of the "highest sort" existed and that the transaction was therefore subject to "close scrutiny." 43 If it was shown that she had received independent 44 advice in making the gift, the outcome may have been different.

It is interesting to note that Rhode Island has a statute denying convicts the right to make wills while in prison, without judicial permission. The apparent reason for this is to prevent undue influence upon a prisoner to name a prison authority as a beneficiary or to aid 45 the convict in making a will.

DURESS AND UNDUE INFLUENCE IN THE PRISON SETTING

To demonstrate that coercion exists in prisons in regard to experimentation, the poor state of prison conditions is often mentioned. If the conditions are sufficiently poor, and the enticements to participate are sufficiently great, there is little question that coercion can exist.

Because a finding of duress or undue influence must be based on the facts of a specific situation, it is necessary to present the circumstances of the following case in a lengthy and detailed manner. This case was settled prior to trial and therefore there is no opinion by the court.

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This case involved non-therapeutic experimentation at the Maryland House of Corrections. It consisted of exposing prisoners to a number of diseases, including typhoid, dysentery, shigella, malaria, Rocky Mountain spotted fever, cholera and influenza, and then treating them with drugs to determine the drugs' efficacy.

According to the complaint, the prison housed 1640 inmates, 700 beyond its capacity. There was unremitting noise, violence and homosexual attacks. Two men occupied a cell measuring 5 x 8 x 7 feet equipped with two bunks and an open toilet. Prisoners were not provided with sufficient necessities to maintain health and personal hygiene. It was necessary to purchase food from the commissary to supplement the prison diet. Clothing, toothpaste, soap, razor blades, deodorant, paper, envelopes, stamps, cigarettes, etc., had to be bought

at the prison commissary at a cost equal to or greater than the cost of these items at a private supermarket. It was estimated that necessary supplies cost a minimum of \$11.00 every two weeks. Money could be obtained from outside sources, the prison welfare fund, prison wages, or by participating in experiments. 500 of the 1640 prisoners did not have jobs. Except for brief recreation periods, these prisoners were not allowed to leave their cells. The average pay for prison jobs was \$.65 per day. The prisoners' welfare fund was available only to indigent prisoners who had less than \$2.00 in their commissary account and had no prison job. The fund did not provide enough money to maintain even minimum personal hygiene.

The Infectious Disease Area (IDA) where the studies were conducted contained thirty-three beds divided into three wards. It was spacious, well-lighted, air-conditioned, quiet, equipped with a color television, radios, and a kitchen for snacks and sandwiches. Frequent private showers were permitted. The IDA paid \$10.00 per prisoner per day. The prisoner received \$2.00 plus \$1.00 for each stool or blood sample taken. The remaining \$8.00 went to a special fund for use by the hospital. At the time of the suit the fund contained approximately \$28,000. Among other things, the complaint stated that because of the disparity in conditions between the IDA and the general prison facilities, the defendants were coerced into participating in the research studies.

The allegations of duress can be examined on an issue by issue basis. Averring that money motivates and influences prisoners to

participate is not a radical stand to take. When C. Joseph Stetler, President of the Pharmaceutical Manufacturers Association, testified on this issue before a Congressional subcommittee, he readily acknowledged that financial reward is "the most important factor behind prisoner participation" in experimentation. ⁴⁷ It is beyond question that money influences free-living individuals as well as prison inmates. It can be safely assumed that most of the work force would not report to work but for the promise of a paycheck. But in the case under discussion the promise of financial reward probably results in coercion or undue influence. Pay for participation in the prison research is more than three times as great as that paid for other employment found within the prison. But more important than this, participation in experimentation is the only way prisoners can earn enough money to maintain a minimum standard of living. If the charges are accurate, one must participate in the experiments to acquire the minimally required diet, and to be able to obtain those items needed to maintain personal hygiene. As a result, one's physical well-being is threatened by refusing to participate in the experiments and trying to live on the prison wages. For those who do not have a job and must rely on the prison welfare fund, the coercive factors are even more egregious.

The disparity in living conditions provides a further coercive force. If an investigator said to a prisoner, "Unless you participate in our experiment, you will be sent to live in crowded, unsanitary and dangerous living conditions," a "wrongful" threat of the type discussed above would be established. For all intents and purposes, this is what is alleged in the case under discussion. Indeed, the



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disparity in living conditions is so great that one who lives in the IDA is virtually "released" from the prison, the most coercive promise that can be made.

One professor of ethics and law has analyzed this problem as follows:

[T]here are certain basic freedoms and rights which we possess that entitle us (morally) to certain things (or states of affairs). We would all, no doubt, draw up different lists of these rights and freedoms: but included in them would be safety of person, freedom of conscience and religion, a right to a certain level of education, and, for some of us, a right to some level of health care. When the "reward" is such as only to give us the necessary conditions of these rights and freedoms - when all that the reward does is to bring us up to a level of living to which we are entitled, and of which we have been deprived by man - then the "reward," I think, constitutes duress. A reward which accrues to one who has achieved this level, or who can easily achieve it (other than by taking the reward-option), and which hence serves only to grant us "luxury" items, does not constitute duress, and hence does not render choice unfree, no matter how great this reward may be.

The final evidence of duress or undue influence in this case is the "unnatural" result, a standard similar to "unnatural" wills discussed above. For \$2.00 per day, the prisoners were willing to risk contracting a number of serious diseases which could have serious and debilitating effects. But this fact, without more, would not establish duress.

If the prisoners in this case lived in a prison that provided them with the minimal requisites for a decent standard of living so that the prisoner would not have to participate in experiments to acquire this standard of living, the offer of \$2.00 per day and better living conditions would not be coercive. It might be fairer to say that this prison environment, not the offer by the IDA, is what is coercive.

The IDA merely provided the prisoners with what they should have been given in the first place. But the prisoners should not have had to risk their lives or health to get those things which they deserve.

The Maryland House of Corrections is not particularly unique in its conditions. In Statesville Prison in Illinois, where a project to test anti-malarial drugs was carried out, the element of fear of attack was so pervasive that in 1974 nearly forty men were placed in solitary confinement at their request for their own safety.⁴⁹

In Texas State Penitentiary at Huntsville where studies of respiratory diseases and cholera vaccines were conducted, inmates were paid \$5.00 per day for participation in research, and nothing for prison work.⁵⁰

Promise of release or reduction of the sentence as a reward for participation in a study must always be considered inherently coercive. As discussed above, threat of imprisonment produces duress under the law. By offering to release a prisoner or to reduce his sentence for his participation in an experiment, one is also saying that failure to participate will keep him imprisoned. It is safe to assume that more than anything else, a prisoner desires his freedom. He should not be goaded into bartering his body to obtain this strongly desired goal.

This point of view has not always been adopted, however. When Goldberger, in 1915, conducted pellagra experiments on convict volunteers, formal agreements were drawn up prior to the experiment with the prisoners' lawyers for their subsequent pardon and release.⁵¹

In 1948, Governor Dwight Green of Illinois formed a committee to

examine the practice of paroling prisoners for participation in the malaria studies that were the focus of the cross-examination of Dr.

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Ivy discussed above. The Green Committee readily acknowledged that the possibility of reduction in sentence may influence the prisoner's decision to volunteer. The report states that the parole system exists to reward "good conduct and industry" and "exceptional bravery or fidelity in a good cause."⁵³ As participation in an experiment is a form of good conduct, parole for such participation is permissible. The committee report does recognize that, "A reduction of sentence in prison, if⁵⁴ excessive or drastic, can amount to undue influence."

An indication that any reduction in sentence unduly influences prisoners to participate in experimentation is a widely accepted concept today can be seen from surveys conducted by Jessica Mitford, Urban Information Interpreters and the Health Policy Program of the School of Medicine, University of California, San Francisco, in 1973, 1974 and 1975. All the states that responded stated that no special parole considerations are given to inmates who participate in medical⁵⁵ experimentation. However, policy and practice are not always the same. Connecticut was one of the states that replied that parole considerations are not influenced by such prisoner participation in⁵⁶ experiments. In 1975 a suit was filed in the United States District⁵⁷ Court in Connecticut alleging that such was the practice. Although this case involves behavior modification, it is included in this section because it is an excellent example of coercive forces and undue influence.

The three plaintiffs were incarcerated in the Connecticut Correctional Institute in Somers, Connecticut and, allegedly, were coerced to join the experimental behavior modification program for pedophiles. Two of the plaintiffs had been denied parole and had been informed that this was due to their lack of participation in the program. The third plaintiff who had not participated was about to become eligible for parole and was told by prisoners and members of the staff that his failure to join the program would result in the denial of parole.

The behavior modification techniques included the use of faradic aversive conditioning and covert sensitization. In the faradic electric conditioning portion of the program, electrodes were placed on the upper thighs of the prisoner. He was then shown slides of adults and slides of children. When a slide of a child was shown, the prisoner received a painful electric shock unless he asked for a change of slides within three seconds. In a second situation, the prisoner could not avoid the shock regardless of what he did. In the third situation, the prisoner received a shock whenever he told the researchers that he fantasized a sexual situation after being shown a slide of a child. This behavior modification program consisted of twenty twenty-minute sessions.

The covert sensitization portion of the program consisted of interviewing the prisoner regarding his previous involvement with children, his pedophilic fantasies, and his phobic, anxiety-provoking and disgust-invoking fantasies. These were then combined in a taped narrative and played to a hypnotized prisoner. In the narrative, the

prisoner's sexual fantasies were paired with suggestions of aversive events, such as becoming violently ill, being attacked by rats, dogs or hornets, being unable to breathe, and being castrated with a hot iron. The covert sensitization sessions lasted sixty-seventy minutes and were conducted twenty times.

The plaintiffs had the program explained to them by the investigator and were told they could refuse to participate. They were also told the parole board favored participation. At various times during their incarceration, several correctional officers stated to the plaintiffs that participation in the program was essential for a favorable parole decision.

Clearly this situation constitutes duress and undue influence. It can be safely said that correctional officers and the parole board are in a "confidential relationship" with the prisoners as that term was explained above, i.e., they are in a position to influence the prisoners. This suit never came to trial as it was settled shortly after it was filed. The behavior modification program was closed. The prisoners were given new parole hearings in front of a board which was not familiar with the program, and no mention of the program was permitted. All three plaintiffs were granted parole.

WAIVER OF RIGHTS

Before leaving this topic there is a final analogy that should be drawn. After arrest but prior to conviction, there is much opportunity for coercion to be brought to bear on the suspect to either confess to the crime, or to plea bargain and plead guilty in hope of obtaining a shorter prison term. As the suspect is in custody or about to be imprisoned, the analogy to the prison situation is obvious.

The first case to be discussed is Miranda v. Arizona,⁵⁹ the famous coerced confession case. The court recognized certain facts concerning in-custody interrogation. First, that modern interrogation techniques are "psychologically rather than physically oriented."⁶⁰ Second, that "the very fact of custodial interrogation exacts a heavy toll on individual liberty and trades on the weakness of individuals,"⁶¹ and third, that "the process of in-custody interrogation of persons suspected or accused of a crime contains inherently compelling pressures which work to undermine the individual's will to resist and compel him to speak where he would not otherwise do so freely."⁶² After acknowledging all the pressures and stresses that are brought to bear on an arrested person, the court did not prohibit the use of custodial confessions. It allowed the use of these confessions if certain warnings were given.⁶³ The warnings that are required prior to in-custody interrogation serve the same purpose that informed consent serves in the experimental situation. The police are about to put their prisoner "at risk" by asking him certain questions and must

therefore inform him of these risks as well as his right not to participate in the interrogation. Perhaps the most important warning is that the prisoner has the right to counsel. This right assures the prisoner that someone acting in his interest will be present if he so desires. This rule is applicable to the prison experimentation situation - that even if certain coercive factors are present, safeguards can be constructed to reduce the effect of the coercion which would enable the prisoner to give informed consent.

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The second case, Brady v. United States, involved the voluntary nature of guilty pleas. Brady was charged with kidnapping and not liberating his victim unharmed. Under the statute then in effect a person could be sentenced to death only upon the recommendation of the jury. The judge was unwilling to try the case without a jury and Brady claimed he pleaded guilty so that a jury would not be able to make such a recommendation. In addition, his co-defendant had pleaded guilty and was prepared to testify against him. Brady was asked twice if his plea was entered voluntarily and without coercion of any kind. He answered "yes" both times and was sentenced to thirty years imprisonment.

The court stated that "waiver of constitutional rights not only must be voluntary but must be knowing, intelligent acts done with sufficient awareness of the relevant circumstances and likely consequences." Brady claimed that the Fifth Amendment was violated if he was encouraged or influenced to plead guilty by an opportunity or promise of leniency, and that it is "coerced and invalid if influenced

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by the fear of a possibly higher penalty." The Court stated that "we decline to hold, however, that a guilty plea is compelled and invalid under the Fifth Amendment whenever motivated by the defendant's desire to accept the certainty or probability of a lesser penalty rather than face a wider range of possibilities extending from acquittal to conviction and a higher penalty authorized by law for the crime

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charged." It found that the situation in this case was no different than (1) a defendant who pleaded guilty because his lawyer advised that the judge would probably be more lenient than the jury, (2) a defendant who was advised by counsel that the judge is more lenient on those who plead guilty than those who go to trial, (3) the defendant who was permitted to plead guilty to a lesser included offense, (4) a defendant who pleaded guilty with the understanding all other charges

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would be dropped. The Court also pointed out that the defendant had competent counsel at all times.

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These two cases are included here to demonstrate that an individual may be placed in situations which appear to be inherently coercive, but may waive very important rights if adequate safeguards are provided. However, it must be pointed out that the plea bargaining cases are not strictly applicable to the issue of experimentation on prisoners. The Court realized that if plea bargaining were outlawed due to its coercive nature, the criminal justice system would collapse. If, however, experimentation on prisoners were prohibited because of its coercive nature, the consequences would be relatively minor.

BEHAVIOR MODIFICATION IN PRISONS

A. Prisoner Autonomy in Consenting to Medical Treatment

Prior to undergoing any invasive medical procedure, an individual⁷⁰ must give his consent or the touching will constitute a battery.

This rule is best expounded in the often-quoted opinion of Justice⁷¹ Cardozo in Schlœendorff v. Society of N.Y. Hospital. In this opinion he stated:

Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages.⁷²

Although this statement has been cited with approval for over⁷³ sixty years, it is not clear that it applies to prisoners. A number of cases would seem to hold otherwise.

⁷⁴In Haynes v. Harris, a prisoner maintained that he should be allowed to determine whether or not he should obtain medical treatment. He claimed that in the absence of consent, the treatment constituted corporal punishment. The court stated, "This contention is obviously without merit. One of the paramount purposes for which a defendant is committed to the Medical Center is that he have the benefit of receiving from trained and qualified personnel proper examination,⁷⁵ diagnosis and all necessary available treatment."

⁷⁶In Peek v. Ciccone, a prisoner who was sent to the United States Medical Center for Federal Prisoners was forcibly injected with

thorazine when he refused to take the medication in oral form. His claim of cruel and unusual punishment was dismissed.

In a similar case, a prisoner who refused medication was placed in solitary confinement.⁷⁷ He claimed the medication caused chest pains and other mental defects and asked for a writ of habeas corpus (release from prison) because such treatment constituted cruel and unusual punishment. The court, citing the language in Haynes v. Harris quoted above, dismissed the case.

In Smith v. Baker,⁷⁸ a prisoner brought suit under the Federal Civil Rights Act claiming an injection of Prolixin given to him against his will and religious beliefs violated his civil rights. The court said, "It is well established that medical care which is administered over the objections of a prisoner does not constitute the denial of any federal rights."⁷⁹

A prisoner in another case claimed that the treatment he received was inadequate. The court found that:

The prisoner cannot be the ultimate judge of what medical treatment is necessary or proper for his case. See Ayers v. Ciccone, 300 F. Supp. 568 (W.D. Mo. 1968) Aff'd per curiam 413 F.2d 1049 (8 Cir. 1969). In the absence of factual allegations of obvious neglect or intentional mistreatment, the courts should place their confidence in the reports of reputable prison physicians that reasonable medical care is being rendered.⁸⁰

Perhaps the strongest statement on this topic was made by a court in dicta.⁸¹ In Ramsey v. Ciccone, the court said:

Even though treatment is unusually painful, or causes unusual mental suffering, it may be administered to a prisoner without his consent if it is recognized as appropriate by recognized medical authority or authorities.⁸²

In contrast, the court also stated, "[T]reatment causing unusual pain, [or] mental suffering which was not considered appropriate by any recognized branch of the healing arts" would constitute cruel and unusual punishment.⁸³

This rule somewhat lessens the requirement set down two years earlier when the court found that an allegation of cruel and unusual punishment would be substantiated by showing that the nature of the treatment or medication or its administration is not sanctioned by any "substantial medical authority."⁸⁴ (emphasis supplied)

From this exposition of cases one could assume that prisoners have very little to say about the medical care they receive. The apparent unanimity of these cases is readily explainable. Although they constitute the majority of cases in this area, all of these cases are from two courts - the Federal District Court of the Western District of Missouri and the Eighth Circuit Court of Appeals. The reason for this is that the United States Medical Center for Federal Prisoners is located in Missouri. As a result, there is little chance for a diversity of opinions to occur. Second, the vast majority of these cases (perhaps all) were brought by inmates without the help of counsel and were ineptly presented. Amazingly, none of these cases cites Schloendorff or the line of cases that followed it. In addition, the inmates may have asked for the wrong kind of relief, e.g., habeas corpus.

Two cases we have been able to find in other jurisdictions decide otherwise. In Irwin v. Arrendale,⁸⁵ a prisoner sought to recover

damages for battery from a prison physician for injuries received when he was x-rayed without his consent. The court found that the relationship between a physician and a patient is a consensual one, and that physicians who treat without consent commit a battery. A state may order compulsory medical examination only to protect the public health.

The Ninth Circuit Court of Appeals also decided a case contrary to the Eighth Circuit. A prisoner alleged that a hemorrhoidectomy was performed on him without his consent and that he was denied necessary analgesics after the operation. He claimed that he vigorously and repeatedly opposed any operation and filed suit under the Federal Civil Rights Act. Summary judgment was granted the defendant by the trial court and was reversed by the appeals court which stated:

Allegations that prison medical personnel performed a major surgical procedure upon the body of an inmate, without his consent and over his known objections, that were not required to preserve his life or further a compelling interest of imprisonment or prison security, may foreshadow proof of conduct violative of rights under the 14th Amendment sufficient to justify judgment under the Civil Rights Act.

. . . .

A constitutionally protected right to be secure in the privacy of one's own body against invasion by the state except where necessary to support a compelling state interest has been recognized. Roe v. Wade, 410 U.S. 113, 153-156 (1973).

The same court in a non-medical case has found that a prisoner has a right to be free from unprovoked assaults by agents of the state while in state custody.

There can be no question that these latter cases which state a

prisoner must consent to his own medical care provide us with the better rule. The fact of imprisonment should not deprive a person of his capacity to decide whether or not to consent to his own health care. The right to privacy of one's body should be practically inviolable, and a competent adult, whether in prison or free-living, should be the final arbiter of what is done to his body. Fortunately, the cases that have dealt with physically invasive behavior modification techniques have adopted this rule.

B. Behavior Modification Cases

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In Mackey v. Procnier, a prisoner at Folsom State Prison in California was transferred, with his consent, to the California Medical Facility at Vacaville for the purpose of undergoing shock treatment. In his complaint he alleged that a drug, succinylcholine, which causes breathing to stop, resulting in enormous fright, was administered to him without his consent. As a result he suffers from frequent nightmares in which he relives the experience and wakes up unable to breathe. The sensation of fright probably cannot be overstated. The drug is given as part of an aversive therapy program in hope of developing an association between violent behavior and the consequences of the drug, which causes cessation of breathing for two minutes. Dr.

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Arthur Nugent, the chief psychiatrist at Vacaville and a supporter of the drug, has stated it "induces sensations of suffocation and drowning." He is quoted as saying, "Even the toughest inmates have come to fear

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and hate the drug. I don't blame them, I wouldn't have one treatment
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myself for the world."

The court found that if the use of the drug was as alleged, it
could "raise serious constitutional questions respecting cruel and
unusual punishment or impermissible tinkering with the mental process,"
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and sent the case back to the lower court to be tried.

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Knecht v. Gillman presents a similar fact pattern. The prisoners
in this case alleged they were subjected to injections of the drug
apomorphine while imprisoned in the Iowa State Medical Facility
(I.S.M.F.). They had not consented to the use of the drug and claimed
such use without consent constituted cruel and unusual punishment. The
trial court refused to issue injunctive relief and the appeals court
reversed.

The court found that apomorphine was administered as part of a
program of aversive stimuli in the treatment of inmates with behavior
problems. The drug was administered by a nurse after an inmate violated
the behavior protocol established for him. The drug was administered
for such behavior as not getting up, giving cigarettes against orders,
talking, swearing, or lying. Inmates or staff would observe these
behaviors and report any infractions to the nurse, who would give the
injection without a nurse or doctor actually observing this behavior,
and without specific authorization of the doctor.

The drug is administered by taking the prisoner to a room, which
contains only a water closet, where he is given an injection. He is
exercised and starts to vomit within fifteen minutes. The vomiting lasts
from fifteen minutes to an hour. It was not clear if the initial consent

of the inmate was obtained but in at least a few instances no consent was obtained. Once a consent is given, withdrawal is not permitted.

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Under an Iowa statute, a prisoner can be transferred to the I.S.M.F. for diagnosis, evaluation and treatment. Since the drug is clearly not used for diagnosis or evaluation it must be used for treatment.

The court found that "it is not possible to say that the use of apomorphine is a recognized and acceptable medical practice in an institution such as I.S.M.F." 98 However, it refuses to prohibit use of the drug on prisoners who knowingly and intelligently consent to its use. 99

The court also found that although the use of the drug is called treatment, without consent being obtained it is actually punishment. "To hold otherwise would be to ignore what each of us has learned from sad experience - that vomiting (especially in the presence of others) is a painful and debilitating experience." 100 It then went on to set forth the safeguards that must be observed prior to using the drug. First, written consent must be obtained which describes the treatment in detail. Second, consent may be revoked at any time. Third, each apomorphine injection must be individually authorized by a doctor and shall be authorized only upon personal observation by a member of the professional staff.

This case is important in two respects. It clearly establishes the proposition that aversive therapy can constitute punishment even though it is called treatment. In addition, it clearly states that prisoners are capable of consenting to be subjects in experimental

programs. The applicability of this finding is somewhat limited by the fact that if this experiment is successful the prisoner will directly benefit, whereas the biomedical experimentation that was discussed earlier would not benefit the prisoner or would only indirectly benefit him.

The holding in Knecht is in accord with Wolff v. McDonnell,¹⁰¹ a United States Supreme Court case which was decided after Knecht. Wolff stands for the proposition that certain procedural safeguards must be observed in prison disciplinary proceedings.¹⁰² The Wolff standards are specifically adopted in another case challenging behavior modification, Clonce v. Richardson.¹⁰³ Clonce deals with the S.T.A.R.T. (Special Treatment and Rehabilitative Training) program, a "demonstration project" located at the Medical Center for Federal Prisoners designed to treat "highly aggressive and assaultive inmates who are found in any correctional institution - federal, state or local."¹⁰⁴ The program uses deprivation of privileges and various status levels in an attempt to change inmate behavior. Prisoners at the lowest level have the fewest privileges and as they earn their way into higher levels, their privileges increase.

The program is involuntary. Prisoners who are selected for the program are not notified of this selection, and no hearing is held prior to placement in the program. Inmates in the program are totally segregated from other inmates. No prisoner in the program is permitted to leave the unit for the purpose of attending religious services. While at the lowest status level (orientation level) the inmate is not allowed to possess, send or use political or educational material.

A prisoner is only entitled to a subscription to his hometown newspaper and a Bible of a recognized religion. As the prisoner progresses to higher levels the material he is allowed to read increases. A prisoner's actions are under constant surveillance - the ratio of correctional officers to prisoners is one to two. Commissary privileges are denied at the orientation level and are increased as the inmate progresses to higher status levels. Inmates at the orientation level are allowed to shower and change their clothes a maximum of twice weekly. The number of showers and clothing changes increases with the prisoner's status. Inmates at the orientation level are permitted two one-hour recreation periods each week.

The prisoners allege that their transfer to S.T.A.R.T. without notice and hearings denies them due process and equal protection of law. The respondents deny this since all inmates in the S.T.A.R.T. program were in segregation prior to their transfer.

The court holds that a prisoner who is transferred into the S.T.A.R.T. program, or a behavior modification program like S.T.A.R.T., "which involves a major change in the conditions of confinement is entitled, at a minimum, to the type of hearing required by the Supreme Court's opinion in Wolff v. McDonnell." ¹⁰⁵ The fact that the S.T.A.R.T. program is labeled "treatment" for the prisoner's benefit and not a form of punishment is irrelevant since it involves a major change in ¹⁰⁶ the conditions of the prisoner's confinement.

The inmates also asked the court to find that a prisoner selected for the S.T.A.R.T. program had the right to withdraw at any time.

Unfortunately, the court refused to consider this point as the S.T.A.R.T. program had been terminated at the time of the action and the court found the issue to be moot. Elsewhere in the decision there is a puzzling statement that may indicate how the court would decide this issue. The court states:

Forced participation in S.T.A.R.T. was obviously designed to accomplish a modification of the participant's behavior and his general motivation. He was forced to submit to procedures designed to change his mental attitudes, reactions and processes. A prisoner may not have a constitutional right to prevent such experimentation but procedures specifically designed and implemented to change a man's mind and therefore his behavior in a manner substantially different from the conditions to which a prisoner is subjected in segregation reflect a major change in the conditions of confinement.¹⁰⁷ (emphasis supplied)

It is not clear whether the court means that the prisoner may not prevent such experimentation generally, or may not prevent such experimentation on him personally. If the latter is the case, then it would appear that the prisoner could not refuse to participate. Since this finding was not required for the court to reach its decision, and no rationale was given for it, its importance should not be overstated.

This case does differ from Knecht and Mackey in that it does not require the use of drugs or other painful stimuli. The effects on the prisoner are considerably less outrageous than in the Knecht and Mackey cases. However, the cases are similar in that it is not the experimental nature of the behavior modification programs that causes the courts to regulate their use. Clonce merely states that a negative change in the prisoner's conditions of imprisonment must be accompanied by due process safeguards. It is not clear that informed consent would be required.

It is highly likely that the Mackey and Procunier cases would not have been decided differently if the use of the drugs involved was not experimental. That is to say, if there were substantial evidence that such programs do change a prisoner's behavior it would not mean that we could inject them with drugs that cause cessation in breathing or violent vomiting without their consent. The mere efficacy of a program should not lead to its use without the person's consent.

The final form of behavior modification to be discussed is the most invasive - psychosurgery. Although there are no cases involving psychosurgery conducted on prisoners, there is at least one case in which a court permitted a person about to be tried to undergo a lobotomy in an attempt to cure him of his criminal tendencies.

The major case in this area, Kaimowitz v. Department of Mental Health, involves an inmate in a state mental hospital. Louis Smith, the inmate involved, was to undergo experimental psychosurgery in a study which was to compare the efficacy of this procedure with the efficacy of certain drugs in reducing violent behavior. Smith signed a consent form and a review committee approved the procedure. Gabe Kaimowitz, an attorney, learned of the program and along with Smith filed suit to prohibit it. The court found that there is no "scientific basis" for establishing that removal or destruction of an area of the brain would have any direct therapeutic effect in controlling aggressivity. The procedure was also found to be irreversible, and to pose "substantial risk to the research subject."

The court went on to hold that Smith, who had been involuntarily

confined in the institution for seventeen years, was not capable of giving his informed consent because "the very nature of his incarceration
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diminishes the capacity to consent to psychosurgery."

Institutionalization tends to strip the individual of the support which permits him to maintain his sense of self-worth and the value of his own physical and mental integrity. . . . The privileges of an involuntarily detained patient and the rights he exercises in the institution are within the control of institutional authorities. . . . [S]uch minor things as the right to have a lamp in his room, or the right to have ground privileges to go for a picnic with his family assumed major proportions. For 17 years he lived completely under the control of the hospital. nearly every important aspect of his life was decided without an opportunity on his part to participate in the decision-making process.

The involuntarily detained mental patient is in an inherently coercive atmosphere even though no direct pressure may be placed upon him. He finds himself stripped of customary amenities and defenses. Free movement is restricted. He becomes part of communal living subject to the control of institutional
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authorities.

Aside from institutionalization the court found that coercion exists "when his very release from the institution may depend upon his cooperating with the institutional authorities and giving consent to experimental
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surgery." This point is buttressed by the fact that Smith rescinded
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his consent to the surgery after his release from the hospital.

Whether or not the court's statements regarding the ramifications of institutionalization are accurate is open to question. However, at least one commentator has stated the same type of situation occurs
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in prisons. He states that considerable pressure to acquiesce to the wishes of their keepers occurs in prisoners. "The infantilizing, depersonalization, helplessness, and anonymity that occur within a

prison environment force the prisoner into a state of total dependency. This is conducive to a state not unlike that found between
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parent and child."

The court itself undercuts its argument on the effect of institutionalization by relying on the experimental nature of the procedure for disallowing Smith's consent. It stated that when the psychosurgical procedure under discussion "becomes an accepted neurosurgical procedure and is no longer experimental . . . [an] involuntarily detained mental
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patient could consent to such an operation." This conclusion is somewhat illogical in that, "The non-experimental status of this procedure may increase the prospective patient's knowledge concerning the risks and benefits involved, but it in no way counteracts the effects of institutionalization on his ability to consent in a truly informed
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fashion." Thus the court's apparently strong feelings on this issue are considerably tempered. Assuming there is a psychological concept known as institutionalization, this would suggest that prisoners who have been confined for lengthy periods of time should not be asked to volunteer for either behavioral or biomedical research. It does not mean that all research must be stopped.

From an examination of the foregoing cases, one can discern the attitude courts are taking toward informed consent and behavioral research. The S.T.A.R.T. program being the least invasive of all the proposed programs of behavior modification was the least regulated by the court. The issue of consent was skirted, but the court ruled that certain due process protections were required. The use of drugs

that cause severe vomiting or fright is more invasive and the courts set forth a requirement that informed consent must be obtained. Psychosurgery, which is the most dangerous and invasive technique, and which is the only one that is irreversible, was prohibited by the court by finding that a confined person could not consent to it. The courts seem to realize that behavior modification cannot be treated as a unitary concept. Varying behavior modification techniques have varying risks and should be regulated accordingly. But perhaps even more important than the variety of risks is that these techniques shock the conscience of the courts and offend their concepts of humane treatment to differing degrees.

However, the Mackey and Knecht cases do serve to establish one important point. Prisoners, protected by the proper safeguards, are legally capable of giving their informed consent to behavioral research even though it involves the use of procedures that cause a great deal of pain and suffering.

LEGISLATIVE AND REGULATORY RESPONSES

The previous discussion has analyzed the role of the common law (judge-made law that comes about through the resolution of specific cases) in the regulation of experimentation on prisoners. The common law can be codified or changed by statutes passed by state or federal legislatures, or regulations promulgated by administrative agencies when the agencies are given such authority by legislative mandate. Twenty-one states have legislation or regulations which permit biomedical research and twenty-three states permit behavioral research. Eight states have chosen to ban biomedical research, one by legislation, six by regulation, and one by moratorium. Five states ban behavioral research, one by legislation, three by regulation, and one by moratorium.

The legislative and regulatory responses cover the entire spectrum, from merely permitting experimentation as in Iowa,¹²² Georgia,¹²³ and Montana,¹²⁴ to those which bar the practice altogether as in Illinois,¹²⁵ Missouri,¹²⁶ New York¹²⁷ (which has banned participation in pharmaceutical experimentation), Oregon¹²⁸ (which has banned all medical, psychiatric or psychological experimentation on prisoners), Pennsylvania,¹²⁹ and Vermont.¹³⁰ Several states that discourage or ban medical research permit research that will aid the corrections process, such as Kentucky,¹³¹ New Jersey,¹³² New York,¹³³ and South Carolina.¹³⁴

In virtually all of the states that do permit any sort of experimentation, the requirement that informed consent must be obtained is explicitly set forth. In these states an implicit finding must have

been made that prisoners are capable of giving informed consent even though they are incarcerated. This is specifically found to be the case by the North Carolina Attorney General. ¹³⁵ Arizona law simply states that the consent of the superintendent and prison physician must be obtained, that the prison physician or the investigator must disclose the dangers of participation, and that the prisoner must consent in writing. ¹³⁶ On the other hand, other states have very detailed requirements regarding informed consent. California has a statute that bans the use of "organic therapy" (shock therapy; the use of drugs, electric shocks or infliction of physical pain used in a program of aversive, classical or operant conditioning; and psychosurgery, which is also regulated by a separate statute) ¹³⁷ without the consent of the inmate. ¹³⁸ In order to obtain informed consent the physician must explain: (1) The nature and seriousness of the illness; (2) The nature of the proposed therapy and its duration; (3) The likelihood of improvement or deterioration without the administration of the proposed organic therapy; (4) The likelihood and degree of improvement, remission or cure resulting from the therapy, and the extent of changes in and intrusion upon the person's personality and patterns of thought; (5) The likelihood, nature and duration of side effects; (6) The uncertainty of benefits or hazards because of the lack of sufficient data; (7) Reasonable alternatives to the treatment; and (8) Whether or not the treatment is considered experimental.

¹³⁹ Massachusetts proposed policy requires the prisoner to sign a consent form which explains: (1) The nature, duration and purpose

of the investigation; (2) The method by which the investigation is conducted; (3) All inconveniences, hazards, discomforts and risks reasonably to be expected; (4) The effects on the subject's health; (5) A description of the benefits; (6) A disclosure of alternative procedures; (7) An offer to answer any questions; and (8) An instruction that the subject is free to withdraw at any time without affecting the conditions of his confinement. The subject must be given a copy of the form twenty-four hours prior to the time it is to be signed.

The issue of reward for participation in research is dealt with in a variety of ways. In North Carolina an attorney general's opinion states that the Department of Corrections should make no promise of pecuniary award, sentence commutation or any other kind of reward, or else coercion is intimated to the inmate. ¹⁴⁰ In Virginia incentives ¹⁴¹ are discouraged but if approved, the state has set up a rate schedule. For oral medication an inmate receives 25 cents per dose with a maximum of \$1.00 per day, \$1.00 per injection with a \$2.00 per day maximum, ¹⁴² \$1.50 for a stomach intubation, and 10 cents per urine collection.

Connecticut also sets forth a fee schedule in its regulations. For studies in excess of seven days the prisoner must be paid a minimum of \$25.00 and a maximum of \$75.00. The specific fee is set by the Research Advisory Committee which reviews all protocols. For an initial blood drawing the prisoner is paid \$10.00, for a spinal puncture he is paid \$15.00, for urine and fecal samples - \$1.00 each, for a unit ¹⁴³ (500 cc) of blood for research purposes - \$20.00, etc. Fifty percent of the total amount of all money paid to inmates in any one

research project must be paid to the prison welfare fund. A direct charge of twelve percent of the total payment to prisoners is paid to the state, as well as an indirect charge of six percent. Michigan has a general statement on compensation which states that compensation may be proportionate to the discomfort or inconvenience involved, but not to the risk involved. The inducement cannot be so great that it would coerce an inmate to accept a risk beyond that which he would otherwise willingly incur. No promise concerning a recommendation to the Parole Board or prison administration may be made.

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Tennessee law requires payment to prisoners to be commensurate with payment for the same services to non-inmates, "taking into consideration the special conditions of inmates."

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A number of states require the prisoners to sign a waiver, releasing the state from any liability for adverse results. It can be said without question that requiring the inmate to waive his rights against the state is poor policy since it reduces the state's incentive to protect the inmate.

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State regulation in this area runs from excellent to non-existent. There is certainly no uniformity, which indicates the present state of the art in this area. However, a large number of states do permit prisoners to give informed consent to experimentation.

The federal government through the Department of the Army and the Department of Health, Education and Welfare has promulgated regulations concerning the use of prisoners as research subjects. The Army absolutely prohibits the use of prisoners of war under any circumstances.

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Use of prisoners who are not prisoners of war is prohibited:

Unless it has first been determined that there will be no undue inducements to such participation, taking into account such factors as whether the earnings, living conditions, medical care, quality of food, and other amenities offered to participants in the study are significantly greater than those available to non-participating prisoners.¹⁴⁸

A prisoner being held in pre-trial confinement may not be used as a subject unless the purpose of the experiment is to diagnose, treat or prevent a condition from which he is suffering, or it is to study the effect of confinement upon the prisoner, and involves no risk to him.¹⁴⁹ Finally, a senior medical officer from the U.S. Army Medical Research and Development Command Headquarters and a member of the legal staff must conduct a site visit at the prison in which the research is to be conducted.¹⁵⁰

Detailed consent standards are set forth (apparently derived from proposed H.E.W. regulations) including a fair explanation of the procedures to be followed, a description of risks and discomforts, a description of benefits, disclosure of alternative procedures to be followed, an offer to answer inquiries, and an instruction that the prisoner is free to withdraw from participation at any time without prejudice to him.¹⁵¹ The use of any exculpatory language is prohibited¹⁵² and consent must be in writing except in exceptional circumstances.

The Department of Health, Education, and Welfare has proposed two sets of regulations which include guidelines for obtaining informed consent from prisoners. In the first set of proposed regulations, which were formally referred to as "a draft working document," the Organi-

zational Review Committee was required to certify, "(1) that there will be no undue inducements to participation by prisoners as subjects in the activity, taking into account, among other factors, the sources of earnings generally available to the prisoners as compared with those offered to participants in the activity . . . and (4) that no prisoner will be offered any reduction in sentence or parole for participation in such activity which is not comparable to that offered for other activities at the facility not of a research, development demonstration or similar nature."¹⁵³

The Organizational Review Committee also sets rates of remuneration in accordance with the duration, discomfort and/or risk of the activity, but not in excess of that generally available

¹⁵⁴ to the inmates. No person confined pending arraignment, trial or sentencing may participate in research.¹⁵⁵

If a prisoner must withdraw for medical reasons, prior to the completion of the study, the Protection Committee will determine how much he is to be paid for such participation.¹⁵⁶

Prisons in which participation of inmates in experimentation is to occur must be accredited by H.E.W.¹⁵⁷

When the second draft of the regulations was published several changes were made. In determining the absence of undue inducements the Organizational Review Committee, in addition to taking into account the earnings of the prisoners, must also take into account whether such factors as the living conditions, medical care, quality of food and amenities would be better than those generally available to the

¹⁵⁸ prisoner. Although this broadens the Organizational Review Committee's authority to determine the presence of unfair inducements, it was done

at the price of removing the Department's authority to accredit institutions. ¹⁵⁹ The proposal to accredit institutions was criticized by

a number of people "principally because of the jurisdictional problems inherent in any attempt to impose a Federal regulatory requirement on an autonomous state facility." ¹⁶⁰ In light of the remaining regulations that control the conduct of experimentation at these autonomous state facilities, this objection seems rather anomalous. As discussed earlier in this paper, existing conditions in a prison may act to coerce a prisoner to volunteer as a research subject. To assure that such conditions do not exist, inspection of these institutions should be required. An inherent conflict of interest exists when those responsible for prison conditions must decide whether or not those conditions are so poor as to coerce inmates into volunteering as subjects in experimental programs. By setting up accreditation standards for prison research, H.E.W. would not take control of the prisons. It would merely refuse to fund research that was proposed to be conducted in those prisons which do not meet certain standards.

The second draft does not include a section prohibiting a reduction in sentence or granting of parole as a result of participation in research. Because of the inherently coercive nature of such a reduction in sentence or offer of parole, this practice should not be allowed.

In the second draft, rates of remuneration are not based on discomfort or risk, but only on the duration of the activity. However, remuneration still must not exceed that paid for other employment, and if the prisoner must withdraw for medical reasons, he must not lose any anticipated remuneration. ¹⁶¹

The elements of informed consent in the regulations that H.E.W. has actually adopted are identical to the Army regulations set out
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above.

As in the case of a number of states, the federal regulatory scheme accepts the notion that prisoners can consent to be subjects of experimentation as long as adequate safeguards are provided.

SUMMARY AND CONCLUSION

In this paper we have tried to set forth the barriers that might exist which would render a prisoner incapable of voluntarily consenting to biomedical and behavioral research. We have discussed the conditions that exist in prisons that might coerce or unduly influence the prisoner to participate in experiments against his will. We have also discussed the role of monetary incentives and the problem of promising prisoners early release in exchange for their participation in research. The following summarizes the discussion:

1) If a prisoner volunteers to be a research subject because conditions in the prison are abysmal, and the only way he can obtain minimally decent living conditions is to participate in research, then his participation cannot be deemed to be voluntary. For this reason we would urge the Department of Health, Education, and Welfare to reconsider its intention to accredit prisons to ensure that these conditions do not exist. Only an independent agency with no stake in either the prison conditions or the proposed research can perform this task in an objective manner.

2) As far as rewards for participation are concerned, we have established that these too can be coercive. If a prisoner must earn money to maintain his health and personal hygiene, or to obtain a minimally decent standard of living, and this money can only be earned by participating in research, then the payment of such money would constitute duress. However, where remuneration serves merely as a reward for participation in research, it would not be coercive if the reward

were not so great as to cause a person to incur great personal risks that he would not otherwise take.

3) A prisoner should never be offered parole or a reduction in sentence for his participation in research as this would be inherently coercive. If a judge, when sentencing a person convicted of a crime, said, "I will sentence you to three years in prison if you do not wish to volunteer as a research subject, but only to two years in prison if you do volunteer," we could all agree that the prisoner in "volunteering" would be acting under duress. An offer of parole or sentence reduction would, in effect, produce a similar situation. We should not adopt the practice of incarcerating individuals for purposes of punishment or rehabilitation and then ask them to trade the use of their bodies in return for their freedom.

4) Not only should an offer of parole or sentence reduction be prohibited, but any action that may lead the prisoner to believe that such was the case must be guarded against. For this reason guards, wardens, and all other correctional personnel should not be permitted to ask prisoners if they wish to participate in research. As such individuals are in a "confidential relationship" with the prisoners, i.e., in a position of control over them, such a request stands too great a chance of unduly influencing the prisoner's decisions.

5) The importance of the availability of an independent counselor to whom the prisoner can turn for advice cannot be overstated. As we saw in the undue influence case, the coerced confession case, and the coerced guilty plea case, the courts have given great weight to the

protective role of independent counselors. This role can be played by the protection or consent committees required in the proposed federal regulations, or by a physician, lawyer or other independent person of the prisoner's choice.

6) The bodily and mental integrity of the prisoner should never be violated without his consent, as was held in the Mackey and Knecht cases. The prisoner must receive a fair explanation of the procedures to be followed, a description of risks and discomforts, a description of benefits, disclosure of alternative procedures that might be available, an offer to answer inquiries, and an instruction that he may withdraw from participation at any time without prejudice to him. The consent form should be given to him at least twenty-four hours prior to its signing, and the prisoner should receive a copy of it after it is signed. The prisoner should not be asked to waive his rights against anyone or any entity which might be liable for injuries that he may sustain. Prisons in states that have such a requirement should not be accredited for the purpose of conducting research.

This paper does not discuss the numerous policy considerations that surround the prison research controversy. We do not discuss the ethical issues of using persons whom society has incarcerated as research subjects, or problems of the subsidization of drug companies who pay prisoners less than they would have to pay free-living individuals to participate in similar projects, or the problem of placing the burden of medical research on a very small segment of the population

for the benefit of us all. Our task was not to decide whether or not prisoners should ever be subjects of biomedical and behavioral research.

If, however, it is decided that prisoners are a proper population on which to perform biomedical and behavioral research, it is our conclusion that the law will not bar such participation, provided that the safeguards discussed in this paper are adopted.

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ALTERNATIVES TO THE USE OF PRISONERS IN RESEARCH
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The use of inmates in American prisons for medical research developed primarily during World War II under what was then thought to be the exigencies of wartime. From a scientific point of view, this was an important landmark in that much of the work done in prisons was designed to forestall complications and inadequacies of new drugs, vaccines and procedures for the ultimate consumer, namely, the American soldier, sailor and airman. The idea was relatively new of testing for and resolving complications of medical therapy by relatively controlled and limited trials in volunteers without putting at risk large populations. The morality of the use of prison volunteers bothered some people at the time and a number of committees and commissions addressed themselves to this problem. Most prominent of these was the Ivy Commission in Illinois.

As the quest for greater consumer safety, as well as more predictable efficacy of new medicines intensified, so did the use of one special population, namely, prison inmates, to predetermine these risks. At the time of the high watermark of prison research

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several years ago, we could identify over fifty institutions in which some form of medical research was being carried out. It is likely that the majority of these was in connection with the development of new or the re-examination of old pharmaceutical products.

This historical perspective explains a number of dilemmas currently facing the clinical investigator of new medicines:

1. The prison system developed relatively smoothly and easily at a time when attention was just turning to the need for quantitative clinical research.
2. Since the style of prison research had been well established when the need for quantitative research escalated, very little effort went into developing alternative ways of carrying out this research. In other words, the prison system was a ready-made solution to the new medicines problem.
3. Because the prison system was so successful, it is probable that even if a substantial effort were made to find alternatives, they would have presented too many additional difficulties and too much additional cost to have competed successfully with the prison system.
4. Until the ethical questions and public disquiet over the use of prison inmates in medical research intensified, there was little reason to abandon a successful

and proven system. In fact, in the minds of many people, it seemed unlikely that an alternative system of cloistered normal volunteers could be developed outside the prison system.

5. Many people had participated directly in the use of prison volunteers. For some of these there was no substantial concern over the ethical problem and it was often felt that, given enough time, the public disquiet would cease.

Needless to say, the disquiet over medical research in prisons has not ceased and the more recent experience is that more and more penal institutions, for one local reason or another, have discontinued, or have been required to discontinue, their activities in medical research.

There were a number of ethical questions raised by the use of prison volunteers. There are other questions raised by the use of normal volunteers. I would identify the problems of normal volunteers first as follows:

- A. Why use normal subjects and not patients for testing new medicines?
- B. Why should normal subjects be cloistered or incarcerated for new medicine testing?

Phase I drug testing is a uniquely American procedure. Phase I drug testing is an exercise to establish human tolerance and safety

and is usually carried out in normal individuals. In some other developed countries, it is illegal to use placebo controls and normal subjects. In Western Europe many new drugs reach the marketplace years before they are approved by the American FDA and there are those who argue that the practice of using normal, cloistered subjects in new medicine testing is unethical and scientifically unnecessary. A part of this argument refers to the more rapid introduction of new medicines abroad than in the United States.

In answer to Question A (above), a normal subject is primarily a subject with less at risk than any subject with a disease process. The general style of research involving the first use of a potential new medicine in man is to give small single doses of the compound to a small number of subjects and then to increase the size of this single dose in gradual increments in subsequent trials. The major concern during this period of the introduction of a new compound to man is the safety of the individual subjects. In spite of elaborate testing in animals, about one-third of over three hundred new compounds studied by us has demonstrated properties not easily predicted from animal studies. These properties can range from the relatively trivial to some which are potentially life-threatening.

The only safeguards against the latter that we have been able to devise are:

- a. the initial dose is always very small
- b. the subject should be without any detectable disability that could be complicated by an unexpected reaction to the test medicine.

- c. the dose increments are relatively small
- d. the subject should be monitored meticulously for every kind of adverse drug reaction during the trial and should be followed a reasonable time thereafter for evidence of delayed effects.

In general, few, if any, patients can enter this phase of a new medicine trial with the same security as a normal subject.

This is countered by an ethical argument which goes as follows: No subject should be asked to do something from which he does not benefit. Answer: Very few patients can conceivably benefit from these early dose-ranging studies, and to pretend that they might be benefited is grossly misleading. Furthermore, most other medications a patient might be taking must be withdrawn during a safety and tolerance trial of a new medicine. This in itself would be to the substantial harm of the many patient subjects over and above the unavoidable risks of the new medicine itself.

The business of early drug testing keeps circling around the normal volunteer for other compelling reasons:

- 1. There are fewer abnormalities of chemical or physiologic measurements to distract us from the critical business of early identification of adverse drug effects. As we become more and more meticulous in this business, these abnormalities become more critical. There is an evolution here such that only a very small percentage of volunteer subjects are even suitable for early safety studies. The use of patients becomes prohibitively difficult for early drug studies.

2. Normal volunteers actually have more time available than most patient subjects.

The following response is given to Question B (page 3) on control of research, or why should new medicines be studied in cloistered populations?

One of the reasons the record of Phase I drug trials is so good (as compared to a number of other types of clinical research), is that they have usually been carried out among cloistered populations. This has to do with three problems. First, the volunteer receives only those medications intended for study and he receives them in a controlled and regulated fashion. Second, he can be intensively monitored to detect potentially harmful effects at the earliest possible moment, and third, the properties of the drug can be identified early and with greater confidence. Other subjects then are not unwittingly placed at risk later on in the study of a new drug.

One of the early attractions of the prison volunteer system was the apparent control of the investigator over diet, other drugs, compliance with the study, the ability to observe closely, and the elimination of parallel hazards, such as driving, etc. When the non-prison but cloistered normal volunteer is compared to the prison volunteer, we can see many problems with the prison setting. For one thing, prisons are run for their own purposes. They are not designed or operated around the needs of medical research. There are many conflicts between the needs of the prison and of the investigator.

Needless to say, diet is less controlled than we would often like it to be. In some prisons, drugs of abuse circulate widely and complicate observations on new medicines. I do not wish to labor this point, but there is substantial scientific gain in moving from the prison setting to an arrangement dedicated solely and uncompromisingly to medical research. If this is true of the setting, it also applies to the volunteer. In other words, it is better to have a volunteer who is dedicated to the research than one dedicated to improving his lot in prison.

Problems of Research on Normal Subjects

There is no question that the social problems of managing normal young men or women on an extended cloistered study are substantial. In prison, this is the task of the warden. In a non-prison setting, this is the responsibility of the investigator.

If this new approach to human experimentation is viable, there will be an entirely new discipline evolving--one in which the experimenter is first an ethicist; second, a behavioral manager; and last and probably least, a biological scientist. The solution to the behavioral problems of a long-term or relatively long-term cloistered existence of a group of volunteer subjects has been the single largest barrier to establishing alternate populations to prisons. Nevertheless, with effort, this problem has also been solved.

As an example, the Truman Laboratory, together with the Quincy Research Center, has experience with approximately 800 normal men and

women subjects cloistered for periods of up to eight weeks. From this experience, several conclusions are possible:

1. We have been able to complete the proposed study with 98.5 percent of all volunteers and nearly complete compliance with the protocol. This is a higher rate of completion of work than we have ever been able to do with over 8000 volunteers in prison over 29 years of experience. The reasons for the default are almost equally divided between three groups:
 - a. In one group, withdrawal from the study occurred because the volunteer, for personal reasons, wished to terminate. This reflects the relative frequency (0.5%) that volunteers have withdrawn in accordance with the conditions of the informed consent. This is a lower rate of withdrawal than we have seen with prison volunteers for this reason.
 - b. About 0.5 percent were terminated by us for various reasons related to their compliance with the protocol or for behavioral problems. Again, this is a smaller percentage than we have seen in the prison setting.
 - c. About 0.5 percent were terminated because of emergent medical problems, either from the drug or for other medical reasons.

2. The management of human behavior in a cloistered setting imposes a greater sensitivity from the investigators about volunteer selection, indoctrination, and on-going relationships than has ever been the case in the prison setting. This apparently will have to be mastered by each group by trial and error. Despite the difficulties, this is an achievable objective.
3. The physical facilities become of great importance to the cloistered volunteer. He must have complete freedom to leave when and if he chooses, but the facility must be attractive and interesting enough for him to voluntarily submit to control of diet, activity, use of other drugs, and even on occasion water consumption, for extended periods of time.
4. Informed consent becomes vastly more complicated because none of this works if the volunteer is not adequately prepared for such total control of his life style before he embarks on such a study.

Problems of Cost

If the first problem in using non-prison volunteers is behavioral, the second largest problem has been cost. It is manifestly impossible to generalize about all prison experience. Nevertheless, it is probable that any non-prison cloistered study will be more expensive than the counterpart prison study. Although

one expects the cost increment to arise from hoteling and food costs, the biggest increment in costs actually comes from the greater supervision and closer medical control of the volunteers in the non-prison setting than is often the case with the prison study. This introduces a very difficult point: that is, many things have been done in the past in a less defensible manner in the prison setting than would be permissible outside the prison.

Problems of Liability and Financial Protection of the Volunteer

While the argument about informed consent and peer review in prisons and elsewhere has raged, we have virtually neglected the parallel and equally important problem of compensation. The volunteer for a medical experiment deserves certain stipulated protections whether he is in prison or not:

1. He deserves the very best in medical protection and supervision.
2. If an accident were to occur, he deserves just and equitable financial protection whether or not the accident occurred as part of the "unknown" risk of the study or from an error or omission on the part of the medical attendants or the protocol designers.

In other words, the volunteer should carry only an irreducible minimum of physical risk. Society should carry the rest.

How Does Compensation Affect Informed Consent?

Until recently there has been an implied ability of an investigator to compensate volunteer subjects for injury through the medical malpractice insurance program. With the current crisis in malpractice coverage, it is apparent that many clinical researchers are not covered by standard malpractice policies. Consequently, the ability to compensate for injury is seriously impaired unless special insurance or self insurance capacity is available.

This applies directly to the full disclosure provision of the informed consent. If no compensation is possible, it would appear to be a necessary part of informed consent. If compensation is available, the informed consent should so state, as well as a general indication of the procedure for obtaining it. This would seem to follow naturally from the practice of identifying the responsible institution and individuals in the informed consent.

The fact that this has not hitherto been appreciated probably has to do with the widespread assumption that medical malpractice covers these problems. Even so, medical malpractice compensation requires litigation or the threat of litigation, whereas the responsible provision of compensation probably ought to be available by a simpler exercise, such as arbitration or admission of injury by the investigator. There is some case law precedent for these requirements in a recent Massachusetts court case.

We have a model statement about indemnification for the informed consent form as follows:

OUR MUTUAL UNDERSTANDING AND AGREEMENT

1. We have taken every precaution to assure the safety and well-being of all who have agreed to take part in this study. Please tell us about any problems or conditions which will make it easier to participate and, for your benefit, follow the instructions given, report any difficulties, discomforts or unusual changes. We appreciate your cooperation and confidence.
2. Once in a great while, there will be an unexpected reaction, even an injury. Report this immediately. We will provide medical attention at once, explain what could have happened. We will recommend continuing or stopping your participation, depending on the situation. Your decision will be final.
3. If there is an injury due to your participation which causes damage, we will provide medical and health care, any needed rehabilitation or other service to help you recover promptly. Also, we will provide compensation in accordance with the schedule of payments or under the worker compensation law plus _____% additional. You will be entitled to these benefits as long as there is damage because of your participation, provided you follow medical advice. This program is for your protection and for your family.

4. The benefits are available on the basis of a claim to the _____
(name of investigator or sponsor)
without necessity for any legal action. They are payable unless you have deliberately or wilfully caused the injury, or clearly acted against medical advice or other official instructions.
5. You may, however, reserve the right to sue for damage. If you do, you will not be entitled to the benefits but will have to prove that the injury was the result of negligence or some other fault or failure recognized by law and any decision may also be subject to appeal to a higher court and other possible delays. Also, if you sue for damages, you cannot later change to the injury benefit program.
6. Any unsettled differences between us shall be resolved by arbitration, if you select it. Decisions of the arbitration panel shall be final, binding and enforceable under the law. If you do not choose to arbitrate, you may sue under the rules of the court.
7. Our recommendation for our mutual understanding and best interest is to settle our problems as quickly as possible and to agree on health care, compensation and arbitration, if needed.

How do the prison system and the non-prison system compare with respect to informed consent? Unfortunately, a complete analysis of this question is very complicated. Nevertheless, certain aspects of the systems can be compared:

1. A simple indemnification system can be worked out for non-prison volunteers. It is not clear how the same system can be applied to prisoners. Furthermore, there is some question as to whether prisoners would seek indemnification as readily as non-prisoners. There is evidence of uncompensated injury to prisoners and this suggests, though it does not prove, that prisoners do not now have adequate indemnification potential.
2. As investigators, we all shun the potential of liability for harm. It is time we face up to this problem and consider the welfare of our subjects ahead of our own risk potential. Fortunately, the incidence of harm in Phase I drug studies is extremely low, but it is not zero. In comparison to occupational hazards, it is undoubtedly lower than window washing and mining, but it should be covered by compensation, as are other occupational hazards.
3. It is possible that the risks unique to the prison setting will turn out to be far too heavy for the continued use of prison volunteers, without any other new action.

Professionalism

The prison setting has inhibited the proper maturation of professional skills in new drug testing. The reasons for this are largely geographic. The prison setting has not been attractive. Furthermore, the prison setting has not encouraged the development of new technologies. Most prison programs, even of long duration and distinction, have about them an air of impermanence for staffing and equipment, as well as for the programs themselves. Phase I pharmacological studies probably deserve lifetime career commitments. The concentration of effort in Phase I drug studies in the prisons has been a major barrier to this. As a consequence, we have not moved forward in step with other aspects of medical research.

Informed Consent

There continues to be more public concern about the validity of informed consent in prisons than about any other aspect. Our published studies indicate that it is relatively difficult to get high quality informed consent in the prison setting. In order to get high quality informed consent, special instructional procedures need to be developed, used and tested. There have been few prison situations where this has been done. The prison is only one of several settings where informed consent poses unique problems. Other areas are: HMOs, indigent medical patients, students and employees. Each of these may pose special problems.

As one analyzes informed consent both in and out of prison, it appears that the actual differences between the prisoner and the non-prisoner depend on the urgency with which the volunteer feels he needs to make his decision. The sense of urgency is often visible, especially in prisons where the volunteer purposefully short cuts the process of due deliberation. In a sense, he makes his decision before he hears the instructional material.

Long-term Follow-up and Extended Care

In addition to medical protection during the course of the study, the volunteer subject deserves follow-up and extended care. The prison setting presents a number of problems with long-term follow-up. For one thing, a volunteer is extremely unlikely to return to a prison for follow-up. Very few programs have provided non-prison locations for follow-up. It also goes without saying that no one can predict whether a former prison inmate can report anywhere for medical care after his discharge, even if he knows where or to whom to report.

All too few inmates are given a written record of their informed consent with identification of the physicians or sponsoring institutions. They frequently are unable to identify the individuals or institution to whom they could or should turn for help after the experiment is over. The only institution they can turn to is the prison and there are problems with this approach.

Alternate Solutions

Where do we go from here? Although there was initial doubt about the existence of alternate groups, this has been proved wrong. Alternate groups exist. These potential volunteers are ready and eager to participate.

The job for the investigator, however, is more difficult. The job specifications for a Phase I investigator working with non-prison, cloistered volunteers would be more than that of a clinical pharmacologist. He will have greater need for understanding human behavior, and he will need to fit the biological problems into a new ethical and social framework.

In return for this, here is an opportunity for Phase I investigators to develop a new professionalism to the enormous benefit of all concerned.

In summary, the prison system played a crucial role at one time in medical research. These programs were continued long after we should have turned to appropriate substitutes. We have payed a large price for this in terms of public disquiet, and the time is fast approaching when we will have to turn to alternate population groups for any one of a number of reasons. One of the most likely barriers to continued prison research is the development of new risks for the investigator from action by the courts.

The Future

The non-prison volunteer system gives us a chance to look at Phase I pharmacologic research and perhaps other medical research in an entirely new context. This is possible because of three new conditions:

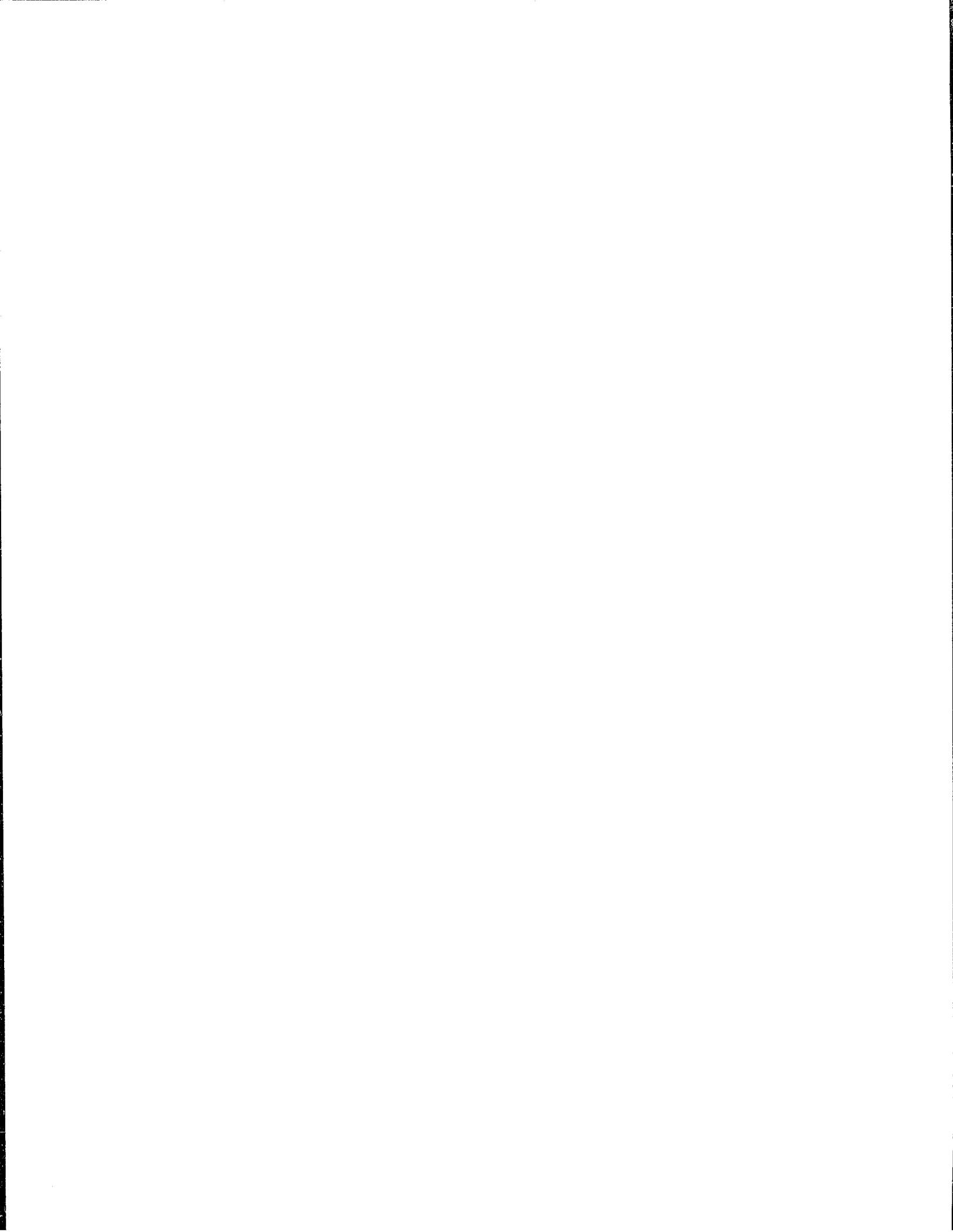
1. The volunteer can be paid a stipend comparable to wages paid for other services.
2. Indemnification in the fashion of workmen's compensation can bring this into harmony with other employment opportunities.
3. The volunteer can choose medical research against other forms of limited employment without any special coercive force.

By our current estimates, the safety of Phase I drug testing, with the full range of medical monitoring and cloistering of volunteers, is slightly greater than is the risk of our office secretaries. It is about one-seventh that of window washers and one-ninth that of miners.

Since the volunteer program is now folded into a standard insurance program which can continue to be compared with occupational risks, we should in the near future abolish the mystery about the level and extent of medical risks of Phase I drug testing.

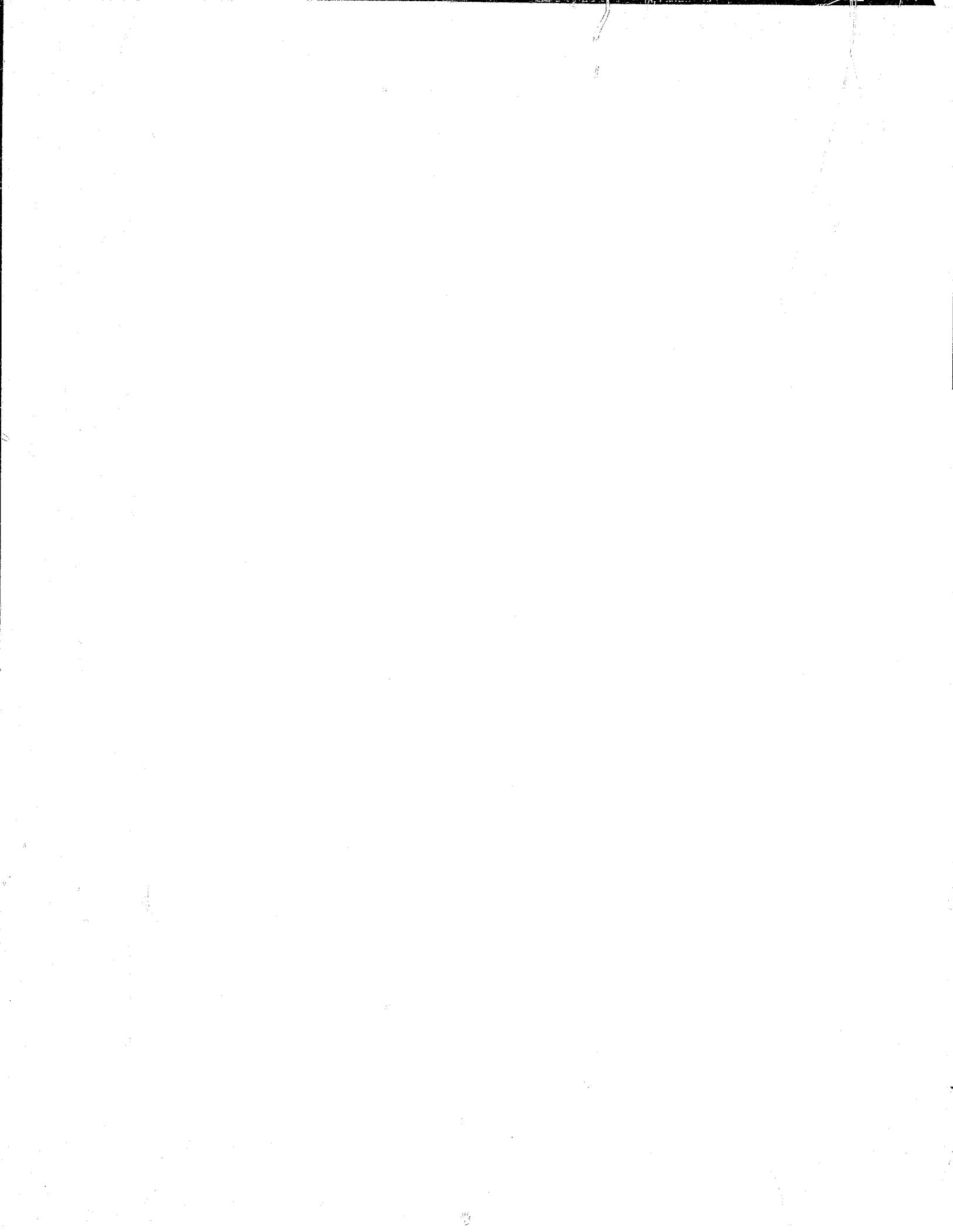
NOTE: The opinions expressed here represent the distillation of 29 years of experience with Phase I and Phase II drug testing in normal volunteers. About 8000 prison volunteers in three different prisons and over 800 non-prison volunteers have participated in the first human trial of over 300 new compounds.





AN INTERNATIONAL SURVEY OF CLINICAL
RESEARCH IN VOLUNTEERS

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INTRODUCTION

The current interest in the use of volunteer subjects, especially prisoners, in medical research projects in the United States, prompted a review of the policies and practices of other countries in regard to research in "normal" subjects. The staff of the Commission for the Protection of Human Subjects asked us to prepare such a report for them.

In order to assemble the necessary information in a short time a questionnaire survey form was devised which directed the inquiry to the major areas of interest.

When a therapeutic agent is studied in volunteers, several types of information may be obtained according to the design of the study. These include:

- (1) Absorption, distribution, excretion and metabolism (bioavailability or pharmacokinetic studies).
- (2) Dose-ranging studies to find the minimal dose which displays pharmacological activity, and
- (3) Safety studies, to evaluate the potential of a compound to cause undesirable side effects, organ-system pathology as exhibited by physical signs and symptoms or biochemical (clinical laboratory) abnormalities.

Studies of type (1) and (2) (clinical pharmacology studies) are carried out in healthy volunteers, patients with diseases other than those for which the study drug is intended, or patients with sufficiently mild illness such that the administration of sub-optimal doses (in dose-ranging studies) will not prove

hazardous. Studies of this type are usually of short duration (less than one week).

Safety studies are often of longer duration (over one month). They may be carried out in patients who are being treated with the drug under study. When it is desired to exclude the possibility of the influence of the underlying disease on drug effects and to completely control the use of other medications, healthy institutionalized subjects, such as prisoners, may be the prime participants in such studies.

METHODS

In order to distinguish among the types of studies which might be carried out, a specific questionnaire was devised. The survey form is reproduced in Attachment 1. Physicians active in clinical research in seventeen countries were polled in this survey to ascertain both the protection afforded human subjects by the laws of those countries and the requirements for clinical pharmacology data to support new product registration. The countries reported here provide a picture of clinical research practice around the world, as of the date of this report. Represented are seven European nations (Belgium, France, Germany, Holland, Italy, Spain and Sweden), five English speaking countries (Australia, Canada, New Zealand, South Africa and the U.K.), four Latin American nations (Brazil, Colombia, Mexico and Peru) and Japan.

RESULTS (See Table I)

A. Clinical Pharmacology Studies

In all the countries surveyed, clinical pharmacology studies are conducted in normal subjects. Almost uniformly these same countries do not permit such studies to be conducted in prisoners. In theory, prisoner studies could be done in the U.K., but in actual practice outside of the United States no research is conducted in prisoners. As can be seen from the tabulation, all countries permit studies in normal adult volunteers. Several also permit studies in normal children. In such cases parental consent is required.

In general, clinical pharmacology studies are conducted in patients with the disease the drug is intended to treat. The use of patients with other diseases is not uniformly approved, but may be permitted if data relevant to the primary indication may be obtained. The requirement for specific governmental approval (IND or clinical trials certificate) to conduct clinical pharmacology studies in normal subjects or patients, also varies between countries (see table). It is interesting to note that in all the countries surveyed, human pharmacokinetic and pharmacodynamic data are "helpful" to support new drug registration. In about half the countries, such data are mandatory. Only France and Japan require that such data be generated in the indigenous population; other countries accept foreign data.

B. Safety Studies

With the exception of Italy, no country requires long-term (1-3 months), controlled studies in volunteers before initiating studies in patients. For registration purposes, however, Belgium, Canada and the U.K. in some cases, require such data. Since prisoners are not used for such studies, it is assumed that such data often is generated elsewhere.

C. The Evaluation of Drugs in Children

In order to support claims for the pediatric usage of new drugs, all countries surveyed, with the exception of Colombia and possibly Sweden in some cases, require that data generated in children be supplied. The requirement for pediatric pharmacokinetic data is not uniform, but most countries ask for it as part of the registration dossier. Pediatric clinical pharmacology data usually is obtained from children with the disease for which the drug under study provides therapy.

CONCLUSIONS

In none of the countries surveyed was it found that prisoners are used as volunteer subjects for medical research projects, and we know of no country other than the United States where this is done. In addition to the ethical questions regarding the ability of prisoners to give free consent, comments included the recollection of German prisoner research during World War II and the inappropriateness of the facilities available in the

prisons of many countries. To our knowledge there is no prison anywhere in the world outside of the United States which contains a medical facility designed for the purpose of carrying out research.

In most countries volunteers are drawn from students, civil servants (military, police and firemen), and medical and paramedical personnel. Healthy volunteers provide information on the pharmacodynamics and metabolism of new drug entities, particularly when it is necessary to exclude the possible influence of diseased organ systems or other drugs on the drug under study.

In most countries longer term studies to determine the safety of a new drug entity are done in the patient population which the drug is intended to treat. This provides a measure of how the drug may be expected to behave in clinical practice under the more usual conditions of use and when combined with the usual concomitant therapies. The subjects of such studies receive the presumed benefits of the new therapy to balance the possible unknown risks of any new agent.

The limitations of doing such studies in patients rather than healthy volunteers is that a placebo control group cannot usually be included (although a comparative active control with standard therapy is permitted) and the need for additional therapy in a patient group may confound the interpretation of side effects.

Should a regulatory authority's recommendations or guidelines suggest that chronic safety studies be done in comparison with placebo and in the absence of concomitant therapy, the result is for all practical purposes, a mandate that such studies be done in institutionalized volunteers. A patient population cannot be treated with a placebo for extended periods and a non-institutionalized population cannot guarantee absolute control of concomitant therapy. Such studies are not done outside the United States. It appears that foreign countries which request the submission of such data depend primarily on U.S. prison studies to provide it.

ACKNOWLEDGEMENTS

We express our appreciation to the Medical Directors of Merck Sharp & Dohme Research Laboratories and Merck Sharp & Dohme International who carefully and promptly supplied the information on which this report is based.

Attachment 1

QUESTIONNAIRE - PROTECTION OF HUMAN SUBJECTS & PATIENTS
QUESTIONS/COUNTRIES

1. Can you conduct clinical pharmacology studies in normal subjects?
2. If "Yes" to 1, in
 - a. Prisoners?
 - b. Adult volunteers?
 - c. Children?
3. Can you conduct clinical pharmacology studies in patients?
4. If "Yes" to 3, in
 - a. Those with disease drug is intended to treat?
 - b. Those with other diseases?
5. Do you need permission from a government agency to conduct studies in
 - a. Normal subjects?
 - b. Patients?
6. Are human pharmacodynamic (effects on body) studies
 - a. Helpful to obtain registration?
 - b. Mandatory to obtain registration?
 - c. Required to be conducted locally?
7. Are human pharmacokinetic (distribution and metabolism) studies
 - a. Helpful to obtain registration?
 - b. Mandatory to obtain registration?
 - c. Required to be conducted locally?
8. Are long-term controlled safety studies (1-3 mos.) in normals required
 - a. Before studies in patients can begin?
 - b. For registration?
9. Do pediatric claims have to be supported by pediatric data?
10. Are pediatric pharmacokinetic data required for a pediatric claim?

TABLE I
QUESTIONNAIRE - PROTECTION OF HUMAN SUBJECTS & PATIENTS
QUESTIONS/COUNTRIES

| | Belgium | France | Germany | Holland | Italy | Spain | Sweden | Japan | Australia | Canada | N. Zealand | S. Africa | U.K. | Brazil | Colombia | Mexico | Peru |
|---|---------|--------------------|---------|---------|-------|-------|--------|-------|--------------------|--------|------------|-----------|-------------------|--------|----------|--------|------|
| 1. Can you conduct clinical pharmacology studies in normal subjects? | Yes | Yes ⁽¹⁾ | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| 2. If "Yes" to 1, in | | | | | | | | | | | | | | | | | |
| a. Prisoners? | No | No | No | No | No | No | No | No | No | No | No | No | Yes? | No | No | No | No |
| b. Adult volunteers? | Yes | Yes ⁽¹⁾ | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| c. Children? | No | No | Yes | Yes | Yes? | No | ? | No | No | Yes | No | No | Yes? | No | Yes | Yes | Yes |
| 3. Can you conduct clinical pharmacology studies in patients? | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes? | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| 4. If "Yes" to 3, in | | | | | | | | | | | | | | | | | |
| a. Those with disease drug is intended to treat? | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| b. Those with other diseases? | No | Yes? | No | Yes | No | No | Yes | Yes | Yes ⁽³⁾ | Yes | No | No | Yes | No | Yes | No | No |
| 5. Do you need permission to conduct studies in | | | | | | | | | | | | | | | | | |
| a. Normal subjects? | Yes | No ⁽¹⁾ | No | No | Yes | Yes | Yes | No | Yes | Yes | Yes | Yes | No | No | No | No | No |
| b. Patients? | Yes | Yes | No | No | Yes | Yes | Yes | No | Yes | Yes | Yes | Yes | Yes | No | No | No | No |
| 6. Are human pharmacodynamic studies | | | | | | | | | | | | | | | | | |
| a. Helpful to obtain registration? | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| b. Mandatory to obtain registration? | No | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes? | No | Yes | No | Yes | No | No | No | No |
| c. Required to be conducted locally? | No | Yes | No | No | No | No | No | Yes | No | No | No | No | No | No | No | No | No |
| 7. Are human pharmacokinetic studies | | | | | | | | | | | | | | | | | |
| a. Helpful to obtain registration? | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| b. Mandatory to obtain registration? | Yes | No | Yes | No | Yes | Yes | Yes | Yes | Yes? | No | Yes | No | Yes | No | No | No | No |
| c. Required to be conducted locally? | No | Yes | No | No | No | No | No | Yes | No | No | No | No | No | No | No | No | No |
| 8. Are long-term controlled safety studies (1-3 mos.) in normals required | | | | | | | | | | | | | | | | | |
| a. Before studies in patients can begin? | No | No | No | No | Yes | No | No | No | No ⁽²⁾ | No | No | No | No ⁽²⁾ | No | No | No | No |
| b. For registration? | Yes | No | No | No | Yes | No | No | No | No | Yes | No | No | (3) | No | No | No | No |
| 9. Do pediatric claims have to be supported by pediatric data? | Yes | Yes | Yes | Yes | Yes | Yes | Yes? | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No | Yes | Yes |
| 10. Are pediatric pharmacokinetic data required for a pediatric claim? | No | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No | Yes | No | No | No | No | No | No |

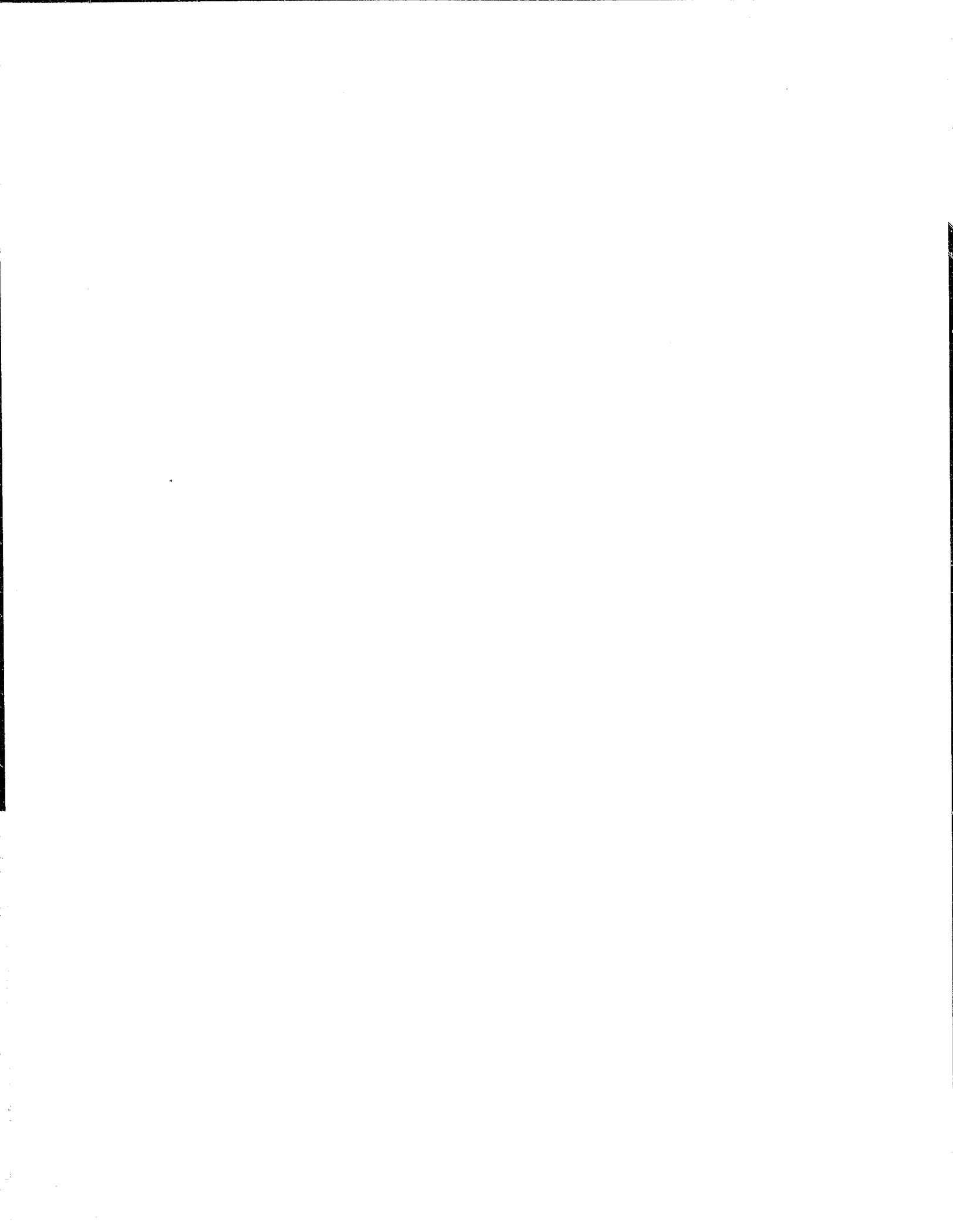
(1)

There is no law covering the administration of drugs to normal subjects. An investigator can undertake studies at his own risk but he opens himself to criticism if any untoward results occur.

(2)

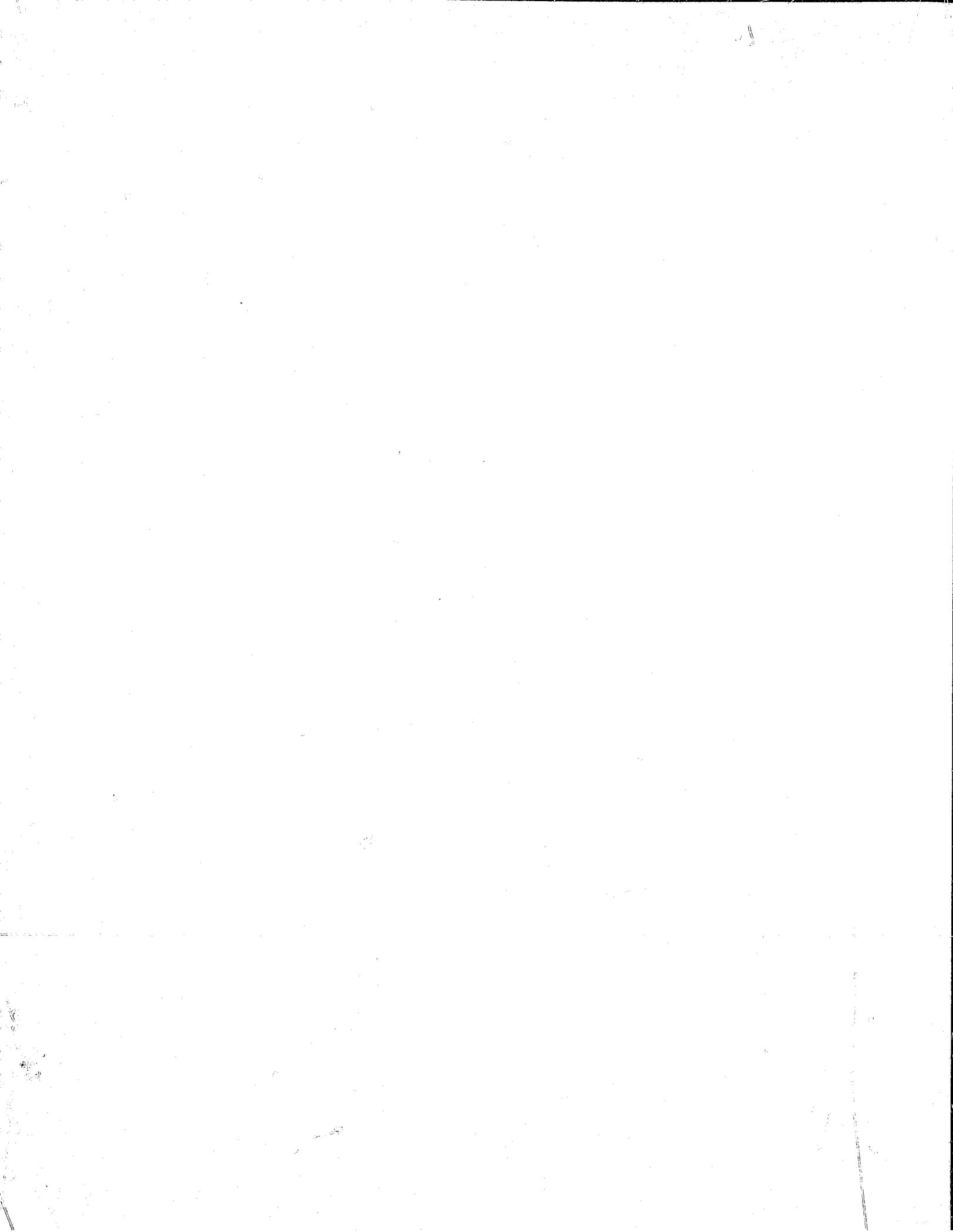
(3)

Would be helpful Depends on specific compound



RESEARCH IN PRISONS: A PRELIMINARY REPORT

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RESEARCH IN PRISONS

This report concerns the participation of prisoners in biomedical research in five state prisons. The report is divided into three sections. The first, which is based on conversations with selected members of review boards, describes the structure of these boards and their procedures for reviewing research protocols at each of the prisons. The second section, based on 41 interviews with principal investigators, concerns the types of projects that have been undertaken at these prisons and the issues of informed consent and of risk and benefit as viewed by researchers. The third section examines research in prisons from the point of view of prisoners. This section is based on 181 interviews with subjects in four prisons and with 45 prisoners in two of those prisons who do not participate in research projects.

Summary of Findings

The structure of the review process differs among the five prisons. In some places it includes institutional review boards with general assurances (IRB's); in others it includes review committees appointed by the state department of corrections, by prison authorities, or by university officials. The review process at some prisons includes committees created by drug companies. Biomedical and legal consultants and prisoner representatives may also play a role. In each case the review process includes a number of stages involving a combination of some of the above groups.

The research described by the principal investigators in the five prisons is predominantly pharmaceutical research, mostly Phase 1 testing. In most of these studies, drugs are administered orally and blood and urine samples are analyzed. Very few of the experiments, according to investigators, are intended to benefit subjects, although researchers feel that a medical and/or psychological

benefit may occur in some cases. The research also entails some medical and psychological risk according to investigators, although they estimate the probability of serious risk to be very low or nonexistent. All investigators report the existence of procedures for treating subjects who might suffer harmful effects due to the research. Our analysis of consent forms provided by investigators indicates that almost all describe the purpose of the experiment, and all describe the procedures. About 85 percent mention and list risks. An analysis of the reading ease of consent forms indicates that a large proportion are at a difficult reading level. The difficulty does not appear to be solely attributable to the use of medical and technical terminology; some of the difficulty may be related to the complexity of sentence structure and the nature of many of the non-technical terms that are employed. Reading difficulty according to our analysis appears to be greater for consent forms associated with projects that investigators estimate to entail relatively high risk. The explanation provided in the consent form, however, is supplemented in all cases by oral explanation.

The prisoners interviewed, who have participated in research at some time since July 1, 1974, are generally supportive of biomedical research in prisons. The near consensus of favorable attitude among subjects occurred in all four institutions where prisoners were interviewed. Practically all of these subjects said that the information they received in advance of the experiment was understandable and correct, that the researchers were willing to answer any questions the subject might have, and that their participation was voluntary. About 33 percent of the subjects indicated that they expected the research would involve some risk, but a few subjects nonetheless felt that they had specific difficulties as a result of the experiments that they did not fully expect. Subjects offered a number of reasons for participating in research, the most prevalent being

financial. About 90 percent of them said that they would be willing to participate in future experiments.

Prisoners who have never participated in research projects, or whose participation is not recent, are less favorable on the average toward research in prisons than are the current subjects themselves, and differences of opinion about research are more apparent within the group of nonsubjects than within the group of subjects. Some of these nonsubjects are strongly opposed to research in prisons. Prisoners offer a number of explanations for not participating including assertions that they have not been asked, that they fear the possibility of serious harmful effects, that they mistrust research or researchers, or that they are opposed to the idea of research in general. Some say that they would participate if they were asked and/or if the personal benefit to themselves were more substantial. Nonsubjects whom we interviewed have a slightly lower level of formal education than do the subjects and the former appear less likely to have a prison job. Furthermore, for those inmates who hold jobs, the number of hours worked per week is slightly lower for nonsubjects than for subjects.

Relatively few prisoners offered suggestions about how studies on human beings might be improved. Increased payment, better facilities (for example, rooms to be used exclusively for research purposes), more complete explanation of possible harmful effects (for example, pamphlets or written materials explaining projects) and better treatment (for example, taking more time with subjects and exercising more care) were among the suggestions of prisoners. Some nonsubject prisoners suggest abolishing the research program.

Principal investigators, like the subjects themselves, offered few suggestions. Some proposed that rules and review procedures be simplified (there is too much to do) and that they be made less rigid. Others suggested that larger review committees be established, that committee members should

have experience in dealing with prisoner volunteers, and that the committee procedure be made less susceptible to the biases of individual members.

Methodological Note

Interview procedure. The data of this report have been collected primarily through the use of interviews. Questions were initially provided by Dr. Bradford Gray of the Commission. The staff of the Survey Research Center (SRC) converted the initial questions into a format appropriate for interviewing, pretested the interviews and worked with the Commission staff to make needed modifications in questions. In addition, SRC added several questions which were asked of a small subgroup of subjects in order to understand the possible implications of scaling procedures and questionnaire wording. Several forms of a brief interview schedule were also developed by SRC to be used with prisoners who were not subjects in research.

Sample. The five prisons to which we refer in this report do not comprise a sample in the technical sense, since they were not selected on the basis of probability methods. They do, however, comprise over half of the state prisons where biomedical research is being conducted and they include prisons that differ widely in size and geographic location. Probability sampling methods were used in the selection of research projects, subjects, and nonsubject prisoners within each of four prisons. We therefore judge the data of this report to provide good illustrations of the character of the review process and of the perceptions and attitudes of subjects concerning research now taking place in some state prisons.

Confidentiality. We have assured persons in each of the research sites that our reports, whether written or oral, will not include the names of institutions or persons associated with these institutions. It is our purpose to understand the procedures employed in protecting human subjects, and the attitudes

and perceptions of persons who play a role in the research process. It is not our purpose to expose, positively or negatively, particular individuals or institutions. Persons who have contributed to this research--prisoners, prison officials, researchers, officials of drug companies, and members of review boards--have demonstrated trust through their participation in this study. We have made every effort to honor that trust by treating their data with appropriate confidentiality.

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The Structure and Procedures of Review Committees

The information in this section was collected through conversations during the period February 12-24, 1976, with nine persons associated with review procedures at five geographically dispersed prisons. Respondents in the case of each prison included the chairman of an IRB or of a committee responsible for reviewing and passing on research protocols. In two of the five cases, the chairman asked other persons to be present during the interview to add to the information he was able to provide. Two additional persons were contacted by telephone to provide supplementary information. All of the information presented in this section is based on the responses of the above persons and on documents which they provided.

The Structure of Review Committees

In four of the prisons, review procedures predate federal requirements, having been created as early as 1960. In one case, the committee was established in response to DHEW requirements. In the view of respondents, few changes of significance have been necessary over the years. One such change is that review boards and committees now make decisions on the basis of unanimous vote rather than on the basis of majority vote. Four require unanimous votes, and the fifth is moving in that direction.

Another change has been the addition of nonmedical persons, particularly lawyers, community representatives, and, at two institutions, prisoner representatives. Problems of prisoner participation, in the view of some respondents, center on how to select a representative democratically in an undemocratic setting, how to insure that the representative be free from coercion whether from board members or from prisoners, and how to maintain the representative's interest in the review process. The alternatives which were

described suggest that the representative be,

1. the president of a democratically elected prisoners' organization;
2. a state ombudsman for prisoners; or
3. an ex-prisoner recently released from the prison where biomedical research is being done.

Despite the above changes, however, the structure of the review boards has remained fairly constant. There is little turnover among the members of these boards and committees, with replacement generally occurring only when a member moves or dies or, infrequently, when someone "just doesn't work out." Members are appointed by deans of medical schools, by state prison officials, or, in the case of drug company review committees, by research facility directors. Correction authorities are not always represented on institutional review boards, but in all cases they are involved at some stage of the review process.

Decisions about research protocols in each case involve at least two stages. For example, a proposal may go through an IRB as well as through a special board established for the prison. A drug company may have its own review board that plays a role in the decision process. Return of protocols to investigators for purposes of modification might be done at any time, usually by one of the committees involved. The group that communicates the final decision to an investigator varies from case to case. For example, it may be an institutional review board, a drug company review committee or a review committee appointed by the department of corrections.

The source of proposed protocols also varies among the five prisons. Proposals may come from investigators on a university faculty, from companies, or from other research institutions. In all five cases an institutional review board with a general assurance and/or a review committee

outside of a company that proposed the research is set up to review these proposals from the point of view of subject treatment.

Practically all of the research conducted in these five prisons is biomedical research. All of the research, whether biomedical or behavioral, is supposed to go through the review process. The cooperation between prison authorities and review boards, according to respondents, makes it unlikely that research could bypass this process. The number of protocols reviewed within a given 12 month span in the five cases ranges from less than 20 per year to 50 or 60 per year.

The respondents associated with four of the prisons studied feel that the review procedures work very well. Some respondents cite the cooperation which exists between prison authorities, investigators, and members of review committees as an explanation for the effectiveness of the procedures. (In three of the five cases investigators are on one of the review committees. When their own protocols are up for review they abstain from voting.) In explaining why the process works well in their view, respondents also cite the integrity which guides the actions of investigators, the fact that no single committee has absolute say about what will ultimately be decided, and the fact that review of protocols using prisoners as subjects does not differ in significant ways from review of other protocols.

Though very few protocols are rejected at any stage of the review process, few are approved as submitted. Changes most commonly are made regarding informed consent -- e.g., simplification of language of consent forms, more detailed description of risks, or inclusion of a statement that no immediate medical benefits to the subject should be expected. Other recommended changes mentioned by respondents include modifications in such research design features as initial dosage levels, staging of increases of dosage levels, etc. The review process was said sometimes to aid the in-

investigator in more clearly articulating his initial conceptions. While most of the review boards or committees are concerned primarily with the requirements of informed consent from the subject, the review process touches on a number of other areas which are thought to strengthen the protocols.

Several reasons were offered to explain why few protocols are rejected. Boards and committees do not see their function primarily as judgmental but as facilitative. They make recommendations to improve the conduct of research. Another reason is that just as the composition of the boards has been stable over the years, so has its relationships with investigators. Most of the investigators submitting protocols for review are associated with organizations with which the review committees have had long-standing relations. Thus respondents say that the investigators have come to know what is expected of them, realize that access to subjects is controlled by the committees, and are willing to make the recommended modifications. Investigators who are new to the review process were said to take a longer time to go through it and to have more changes to incorporate.

In every case described, the protocols are individually received by committee members and consultants before being discussed. The investigator may appear at the board or committee meeting but only to answer questions posed by the members. The review process, according to respondents, does not end with the final decision on the proposed research. While elaborate arrangements do not exist for the purpose of continuing review of the actual conduct of research, periodic reports are required of the investigator. The frequency and form of reports depend upon the nature of the research and are determined when the protocol is approved. Additionally, there is usually a requirement that any unanticipated results be reported immediately upon their occurrence to the board or committee. For example, the investigator will in-

form the chairperson of a board, who will then decide whether formal action by the Board is necessary.

Respondents emphasized that the time and effort required for regular on-site monitoring of the actual conduct of research is neither possible nor appropriate. In all five cases, most of the board members were reported to have made at least one visit to the prison research facility or other location where prisoners are used as subjects. But respondents say that the limited time which these board or committee members, who hold positions in other (sometimes several) organizations, can devote to the review process makes it difficult to regularize the monitoring process. In addition, respondents expressed the feeling that some things cannot be legislated, and that among these things is the integrity which an investigator must bring to his work. Although various regulatory agencies seem unable to trust the investigator, prisoners and prison authorities must and do trust the investigator. Respondents say that it is not always possible to explain to laypersons the details of a given protocol.

In two of the five cases the process of obtaining informed consent is witnessed by a guard or layperson. In all cases the procedures for obtaining informed consent are reviewed along with the review of the proposal.

Recruitment of Prisoners as Subjects of Research

The method of informing prisoners of the need for volunteers for research varies from place to place. They may include an announcement and description of the research program during the orientation process when prisoners enter the prison, the posting of a notice on bulletin boards, and informal verbal canvassing by prison authorities of prisoners who might gain some medical benefit from the treatment of a specific ailment. However, most of the research described by these respondents offers no immediate medical bene-

fit. The risk involved in the type of research conducted in prisons is estimated by the respondents to be very slight.

Prisoners are screened in all five prisons on the basis of one or more of the following criteria:

1. health, especially the absence of certain traits such as high blood pressure, liver abnormalities, renal ailments, hepatitis;
2. type of crime committed, screening out those who have been convicted of certain violent crimes;
3. reliability, eliminating those whose past participation in research was characterized by lack of cooperation; and
4. release date and establishment of date for parole board hearing.

The bases for screening potential volunteers are established by prison authorities and representatives of the other organizations participating in the review process. In three of the five cases, formal agreements exist between the prison and drug company or review committee. These agreements include rules governing the selection of volunteers, the rates of compensation for volunteers, the conduct of volunteers who must leave the prison ground for purposes of research, the confidentiality of information obtained by investigators from prisoners, and types of research permitted.

Some attempt is made to establish rates of compensation which are comparable to those rates set for work in the prison system. However, it is generally still more profitable financially for a prisoner to participate in a research project than to perform most kinds of work in the prison. Furthermore, a substantial difference exists in the rates at which civilian subjects are paid and in the rates set for participating prisoners.

Summary Comments of Review Committee Respondents.

The respondents made the following summary remarks concerning prison-based research and the current federal guidelines used to regulate this research.

1. Human research is necessary. There is no substitute for it. Animal research is necessary but not sufficient to determine what is going to happen to people when new drugs or procedures are being developed.

2. Prisoners prefer that there be more studies in which they might participate.
3. The prison setting is such a structured one that participation in research is highly attractive to prisoners because it offers some choice, allows them to say yes or no, to participate or not. Given the nature of prison life, participation in research is probably the area in which it is most nearly possible for the prisoner to give informed consent.
4. A witness should be present while informed consent is being obtained. This witness should be a layperson who can gauge more adequately than can medical persons the volunteer's understanding of the research procedures and the content of the consent form.
5. The procedures used to review prison-based research do not differ from those used to review research using civilian subjects. If anything, the review of prison-based research is more carefully executed than are other reviews.
6. Though investigators were initially resentful of the paperwork required for the review of protocols, most of them now accept it as routine and necessary for research involving human subjects. Only in one case were the investigators described as irritated by the length of the review process and by the necessity for the modification of protocols. Even in this case, however, it appears that some researchers appreciate the effort made by the review board to facilitate the conduct of research.
7. Most of the respondents feel that the current federal regulations are adequately stated and adequately applied. However, one respondent stated that the guidelines would be more than adequate if they were actually followed by the State Department of Corrections and by the state legislature.
8. There is a danger that regulatory requirements may begin to take up so much of the time and effort of investigators that progress in research may be seriously hampered.

Principal Investigators and Their Subjects

Complete information about the total number of studies done in prisons is available to us for only four of the five prisons from which data were obtained. (We could not gain access to the entire list of projects in the fifth prison because of the time needed to obtain approval from state and prison officials.) A total of 81 projects proposed by 31 investigators passed through review committees during the sample period of July 1, 1974 to June 30, 1975 in the four prisons. Projects were sampled at different rates at the four prisons. One hundred percent were taken in two of the prisons where the number of projects was relatively small, while in the other two prisons projects were sampled at lower rates, so that we might obtain a total of 40 projects distributed as equally as possible among the prisons. We were able to learn through an institutional review board located at a university of two projects conducted at the fifth prison. The result was a selection of 42 projects directed by 24 investigators at the five prisons. We completed interviews for 41 of these 42 projects.

Types of Projects

All of the projects are pharmaceutical. Among those for which detailed information could be obtained, 21% involved the evaluation of a drug for a purpose that had already been approved by the FDA and 6% involved evaluation for a purpose other than that for which it had been approved. Eighty two percent of the studies were done under an Investigational New Drug Application from the FDA. The major characteristics of the studies as reported by investigators are summarized in Table 1.

Table 1

Which of the following are directly involved in the study, whether as an experimental intervention, as a procedure being evaluated, or as a means of collecting data for the study?
(Check the major elements)

| | <u>%*</u> | <u>No.</u> |
|---|-----------|------------|
| Administration of drug, chemical agent, or blood product (other than isotope or anesthetic) | 100 | 41 |
| Obtaining of bodily fluids for analysis or experimental use | 76 | 31 |
| Use of data from existing records | 12 | 5 |
| Obtaining of medical history directly from patients | 10 | 4 |
| Administration of an isotope | 7 | 3 |
| Dietary manipulation | 7 | 3 |
| Interviews (other than medical histories or obtaining consent for participation) | 2 | 1 |
| Questionnaire - self-administered by subjects | 2 | 1 |
| Measurement of electrical activity of body (e.g., EEG, EKG, Galvanic Skin Response) | 2 | 1 |
| Other non-invasive measurement of bodily activity (e.g., temperature, blood pressure) | 7 | 3 |

*Since investigators could check more than one feature, the percentages do not add to 100%.

Table 2 summarizes the kinds and routes of substances that were administered.

Table 2

| <u>Question</u> | <u>% of Investigators</u> | <u>No. of Investigators</u> |
|---|-------------------------------|---------------------------------|
| Is the substance being administered: | | |
| A drug or chemical agent | 87 | 33 |
| Blood or blood products | 3 | 1 |
| Other | <u>10</u> | <u>4</u> |
| | 100 | 38 |
| Is this a Phase I, II, III, or IV test? | | |
| Phase I | 80 | 28 |
| Phase II | 6 | 2 |
| Phase III | 3 | 1 |
| Phase IV | 8 | 3 |
| Don't know | <u>3</u> | <u>1</u> |
| | 100 | 35 |
| By what route is the drug administered? | | |
| Orally | 68 | 26 |
| Intramuscular or subcutaneous injection | 16 | 6 |
| Intravenous injection | 8 | 3 |
| Topical | <u>8</u> | <u>3</u> |
| | 100 | 38 |

Types of Subjects

All but one of the studies employed healthy subjects and over 80% of the subjects are between 19 and 40 years of age according to investigators. Investigators also reported the racial composition of their subjects, which is shown in Table 3. A second column in the table shows

the race of subjects obtained through interviews with subjects themselves.

Table 3

Race of Subjects: Percent

| | <u>% Estimated by Investigators</u> | <u>% Obtained through Interviews with Subjects</u> | <u>No. of Subjects</u> |
|-------|---|--|----------------------------|
| White | 54 | 59 | 105 |
| Black | 28 | 30 | 54 |
| Other | <u>18</u> 100% | <u>11</u> 100% | <u>19</u> 178 |

The similarity in the two distributions implies some validity in the estimates made by investigators and in our measure of these estimates through the survey method. Some discrepancy might be expected between the two sources of information presented in Table 3 since subjects came from only four of the five prisons where investigators are located.

Investigators report that payment is provided subjects in all of their projects, and 99% of the subjects themselves report that they were paid. Investigators and subjects also provide very similar reports concerning the amount of pay that subjects receive for participating in research. These data, presented in Table 4, are interesting not only because of the substantive information that they provide but also because they imply some validity to the survey measures. The differences that exist between the distribution of reports by investigators and by subjects may be explained partly by the fact that some investigators have more subjects than others and that investigators provide information about five prisons while the subjects come from only four. Nonetheless, the correspondence between the two distributions is fairly close, suggesting that prisoners

and investigators see the facts about pay in much the same way, and that they are reporting them with reasonable accuracy to us. The correspondence is all the more impressive considering the retrospective nature of the data and the fact that some subjects who have participated in two projects that took place in close sequence may have combined the two in their thinking. For example, one investigator carried out two experiments with the same set of subjects. In one experiment an antibiotic was administered in liquid form, while in the other experiment precisely the same antibiotic was administered in capsule form. While the investigator referred to these as two experiments, (and consent forms were signed for each) some of the subjects, who participated in "both," discussed them as if they were one experiment.

Table 4

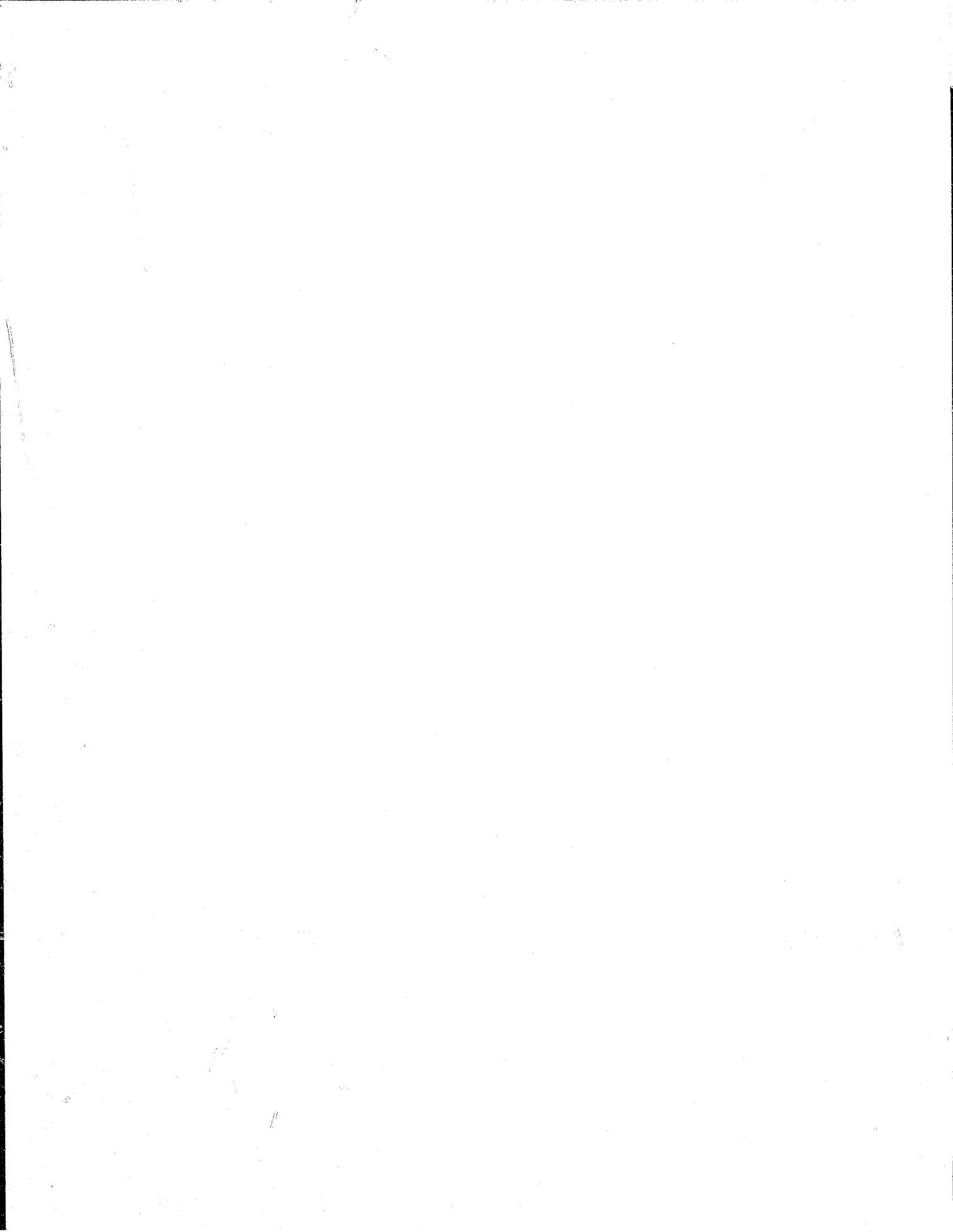
Total Amount of Pay Received by Subjects per Project
as Reported by Investigators and Subjects

| | <u>Project Investigators*</u> | | <u>Subjects#</u> | |
|-----------------|-------------------------------|-------------|------------------|------------|
| | <u>%</u> | <u>No.</u> | <u>%</u> | <u>No.</u> |
| \$10 or less | 4 | 1 | 7 | 10 |
| \$11-\$20 | 12 | 3 | 14 | 20 |
| \$21-\$50 | 28 | 7 | 30 | 45 |
| \$51-\$100 | 48 | 12 | 37 | 55 |
| \$101-\$150 | 8 | 2 | 7 | 11 |
| More than \$150 | -- | -- | 5 | 7 |
| | <u>100%</u> | <u>25**</u> | <u>100%</u> | <u>148</u> |

* Question: "Of those who are paid, what (is/was) the average payment?"

Question: "How much (were you paid) all together?"

** Some investigators, not included in this table, answered the question in terms of dollars per day.



CONTINUED

3 OF 8

Principal investigators and subjects also come very close to agreeing that money is the main reason why subjects participate in research. The reasons that investigators attribute to subjects are presented in Table 5 and the reasons offered by the subjects themselves are presented in Table 26. In both cases money is mentioned more frequently than any other reason. Thus investigators on the average appear reasonably realistic in their perception of this reason for subjects' participation.

Table 5

What do you feel are the main reasons why people agree to participate in this study?

| | <u>%</u> <u>Investigators*</u> | <u>No. of</u> <u>Investigators</u> |
|---|-----------------------------------|---------------------------------------|
| Money, financial reimbursement | 83 | 34 |
| Other personal advantage; e.g., better food, environment, etc. | 44 | 17 |
| Subjects like the experience; it's interesting | 32 | 13 |
| To help others, to help society | 20 | 8 |
| To help in general | 3 | 2 |

*This column adds to more than 100% since respondents may offer more than one reason.

Risks and Benefits of Research

Five of the studies in the sample were intended to benefit subjects medically, and one was intended to benefit subjects psychologically, according to investigators. While medical and psychological benefits

were not intended in a large number of studies, investigators reported nonetheless that there was some probability of these benefits occurring. In 19% of studies, the probability of medical benefit was estimated to be medium or high, and in 17% of the studies the probability of psychological benefit was estimated to be medium or high.

Estimates of risk are summarized in Table 6. None of the investigators reported the existence of high risk in their research, and when asked if any subjects had actually experienced harmful effects due to the study, one investigator reported that one of his subjects had suffered temporarily disabling effects.

All investigators reported that there were provisions for treating subjects should they suffer harmful effects due to the research. In addition, 35% of the investigators reported that financial compensation to subjects for harmful effects is provided in their studies. An equal number report that no such provision exists, while 30% of the investigators did not know whether or not such a provision exists.

Informed Consent

Consent forms were used with all the subjects in all the studies. In addition, investigators reported that they provided an oral explanation of the study to all subjects. Investigators report spending an average of 33 minutes with subjects on each project explaining the study and obtaining consent. Most investigators report that they are personally involved in obtaining consent. (Table 7)

Table 6*

Percent of Studies Where Probability of Risk Was:

| Question | None | | Very Low | | Low | | Medium | | High | | Total |
|---|------|----|----------|----|-----|----|--------|---|------|---|-------|
| | No. | % | No. | % | No. | % | No. | % | No. | % | % |
| What was the probability of <u>temporary or minor psychological stress</u> or discomfort due to the research? | 3 | 8 | 32 | 82 | 3 | 8 | 1 | 2 | 0 | 0 | 100 |
| What was the probability of <u>serious psychological complications</u> due to the research? | 22 | 71 | 9 | 29 | 0 | 0 | 0 | 0 | 0 | 0 | 100 |
| What was the probability of <u>minor medical complications</u> due to the research? | 6 | 15 | 30 | 73 | 4 | 10 | 1 | 2 | 0 | 0 | 100 |
| What was the probability of <u>serious medical complications</u> or injuries due to the research? | 20 | 50 | 20 | 50 | 0 | 0 | 0 | 0 | 0 | 0 | 100 |
| What was the probability of <u>fatal complications</u> due to the research? | 24 | 60 | 16 | 40 | 0 | 0 | 0 | 0 | 0 | 0 | 100 |
| In this study what was the probability of a breach of confidentiality of a sort which might <u>cause embarrassment</u> or damage the reputations of subjects? | 35 | 87 | 5 | 13 | 0 | 0 | 0 | 0 | 0 | 0 | 100 |
| In this study what is the probability of a breach of confidentiality of a sort which might <u>entail legal risks</u> for subjects? | 36 | 90 | 4 | 10 | 0 | 0 | 0 | 0 | 0 | 0 | 100 |

10-20

*Figures are reported for the experimental group of subjects only.

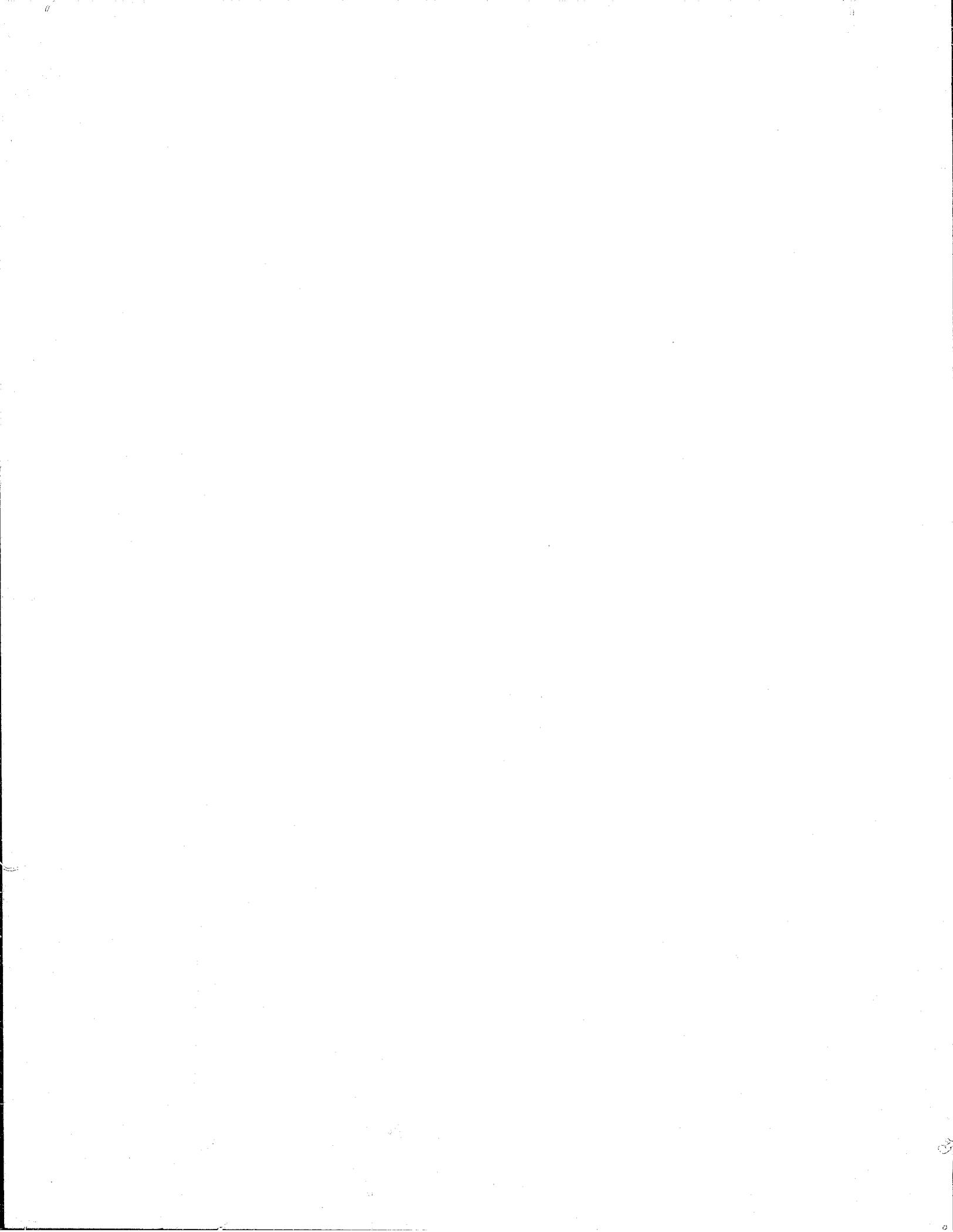


Table 7

Do you yourself usually obtain consent, is it usually done by someone else, or do you share this responsibility with someone else?

| | <u>% of Investigators</u> | <u>No. of Investigators</u> |
|--|-------------------------------|---------------------------------|
| Investigator usually obtains consent | 49 | 20 |
| Investigator shares consent responsibility | 44 | 18 |
| Others usually obtain consent | <u>7</u> 100% | <u>3</u> 41 |

Table 8 summarizes aspects of the study that investigators report having emphasized when they explained it to subjects, and Table 9 indicates whether they presented it to subjects as a request or recommendation.

Table 8

Are any of the following emphasized when you describe this study to a prospective subject or proxy...

| | <u>% of Investigators*</u> | <u>No. of Investigators</u> |
|--|--------------------------------|---------------------------------|
| Direct benefit to the subject | 29 | 12 |
| Benefit to other individuals in the future | 78 | 32 |
| Benefit to scientific knowledge | 73 | 30 |
| Something else (discomforts, side effects, money, procedures and time) | 10 | 4 |

*Since more than one response could be checked, the percentages do not add to 100%.

Twenty six percent of the investigators reported that at least one prospective subject declined to participate after being given information about the research. Among these 26% of the projects, an average of 8% of the potential subjects declined to participate, according to investigators. Furthermore, 40% of the investigators reported that at least one subject withdrew after having begun the experiment. In these studies, they reported that an average of 14% of the subjects had dropped out.

The Consent Forms Used by the Investigators

Subject consent to participation in medical experiments must be voluntarily given. An informed decision must be made based upon sufficient understanding of the nature of the investigation as well as the implications of subject involvement. The basic and supporting elements of information necessary for consent are considered below through analysis of 41 consent forms, all of which have been approved by a review committee.

The nature of the investigation. An expression of the purpose of the investigation and the purpose behind particular procedures can be considered an element basic to informed consent. As shown in Table 10, a statement of investigator purpose appeared in 39 of 41 (95%) of the consent forms received from the various researchers. These 39 forms differed however, in the degree to which the purpose was explained. Some forms mentioned the purpose--that is, a brief statement of purpose was included in the form, possibly one or two sentences in length. Other forms provided detailed descriptions of the purpose which elaborated on the objectives of the study. (This distinction between "mentioned" and

"detailed description" will be used throughout this section.) From a total of 41 forms, 27 (66%) mention a purpose, while 12 (29%) describe the objectives of the project in detail. Two consent forms were identified with no mention of purpose.

Table 9

When you are obtaining consent, is participation in this study presented to subjects as your request, as your recommendation, or both?

| | <u>% of Investigators</u> | <u>No. of Investigators</u> |
|----------------|-------------------------------|---------------------------------|
| Request | 54 | 22 |
| Recommendation | 0 | 0 |
| Both | 2 | 1 |
| Neither | <u>44</u> 100% | <u>18</u> 41 |

Table 10

Consent Form Elements Related to Investigator's Purpose and Degree of Explanation

| <u>Element</u> | ----- Degree of Explanation ----- | | | | | | <u>Total</u> | |
|----------------------|-----------------------------------|----------|-----------------------------|----------|----------------------|----------|--------------|----------|
| | <u>Mentioned</u> | | <u>Detailed description</u> | | <u>Not mentioned</u> | | | |
| | <u>No.</u> | <u>%</u> | <u>No.</u> | <u>%</u> | <u>No.</u> | <u>%</u> | <u>No.</u> | <u>%</u> |
| Statement of purpose | 27 | 66 | 12 | 29 | 2 | 5 | 41 | 100 |
| Prior research | 17 | 41 | 2 | 5 | 22 | 54 | 41 | 100 |

For nearly all cases where a detailed description of purpose had been presented, a mention of prior research (relevant to the proposed investigation) served as supporting rationale. Thus, 19 (46%) of all consent forms either referred to, or described in detail, prior research.

Research Procedure and Design. In adhering to written consent standards, all authors included a statement of procedures to be followed. As evident in Table 11, differences are found in the degree to which procedures, either experimental or routine, are explained. Although 32%

Table 11

Consent Form Elements Related to Research Procedures and Design and the Degree of Explanation

| Element | -----Degree of Explanation----- | | | | | | Total | |
|---|---------------------------------|----|----------------------|----|---------------|-----|-------|-----|
| | mentioned | | detailed description | | not mentioned | | | |
| | No. | % | No. | % | No. | % | No. | % |
| Statement of procedures to be followed | 13 | 32 | 28 | 68 | -- | -- | 41 | 100 |
| Expected duration of the research | 27 | 66 | -- | -- | 14 | 34 | 41 | 100 |
| Two (or more) procedures or treatments are under comparison | 26 | 63 | -- | -- | 15 | 37* | 41 | 100 |
| Double blind procedure | 6 | 15 | -- | -- | 35 | 85* | 41 | 100 |
| Placebo use | 8 | 19 | -- | -- | 33 | 81* | 41 | 100 |
| Method of assigning treatment to subjects | 3 | 7 | -- | -- | 38 | 93* | 41 | 100 |
| Protection of confidentiality | 15 | 37 | -- | -- | 26 | 63 | 41 | 100 |
| Review committee approval | -- | -- | -- | -- | 41 | 100 | 41 | 100 |
| Identification of research sponsor | 10 | 24 | -- | -- | 31 | 76 | 41 | 100 |

* It would have been useful to relate some elements to particular projects, since whether an element is needed in a consent form depends on whether it is involved in the project. Time did not allow for such an analysis.

very briefly mention this element, the majority have provided a more detailed explanation of their proposed plans. Particular supporting elements relevant to the research procedures and design are also listed in Table 11. Variance exists in each of these specific areas with one exception--none of the consent forms mention that the research proposal has been approved by an Institutional Review Board or review committee.

The expected duration of the subject's participation is not mentioned in 34% of the consent forms. In addition, many consent forms referred to the design of the study and noted, for example, that two or more procedures or treatments were under comparison, that a double blind procedure was to be employed, and/or that a placebo might be used. Sixty three percent of all consent forms include reference to such procedures.

Benefits. Information on benefits expected from research participation is outlined in Table 12. Given the fact that 85% of the research under analysis involves bioavailability experimentation, the results regarding research benefits are expected. Only 10% mention an expected benefit to subjects, with the majority disclosing expectation of benefit to either general or scientific knowledge and/or other individuals.

Table 12

Consent Form Elements Related to Research Benefits and the Degree of Explanation

| <u>Element</u> | ----- Degree of Explanation----- | | | | | | <u>Total</u> | |
|---|----------------------------------|----------|-----------------------------|----------|----------------------|----------|--------------|----------|
| | <u>mentioned</u> | | <u>detailed description</u> | | <u>not mentioned</u> | | | |
| | <u>No.</u> | <u>%</u> | <u>No.</u> | <u>%</u> | <u>No.</u> | <u>%</u> | <u>No.</u> | <u>%</u> |
| Benefits to subject | 4 | 10 | -- | -- | 37 | 90 | 41 | 100 |
| Benefits--general or scientific knowledge | 22 | 54 | -- | -- | 19 | 46 | 41 | 100 |
| Benefit people | 22 | 54 | -- | -- | 19 | 46 | 41 | 100 |

Risks. The inconveniences, hazards or inherent risks for investigational procedures, treatments and/or drugs are generally disclosed within specified sections of consent forms. Table 13 lists the number of risks that have been mentioned per form. The overwhelming percentage of forms mention at least two or more risks as either physical, psychological, or discomfort, and 39% have disclosed seven or more such risks. Some forms include long lists of risks, consisting of 20 or so different symptoms or side effects. Six consent forms do not mention risk.

Table 13

Risk Frequency (Physical, Psychological, or Discomfort)
as Mentioned throughout Consent Form

| <u>Number of Risks Mentioned</u> | <u>Consent Form</u> | |
|----------------------------------|---------------------|-----------|
| | <u>No.</u> | <u>%</u> |
| 0 | 6 | 15 |
| 1 | 2 | 5 |
| 2 | 4 | 9 |
| 3 | 6 | 15 |
| 4 | 3 | 7 |
| 5 | 2 | 5 |
| 6 | 2 | 5 |
| 7+ | <u>16</u> | <u>39</u> |
| | 41 | 100% |

Table 14 includes a list of topics which are related to risk (e.g., types of risks, precautions taken to reduce risk) and provides data on the number of consent forms which mention each of these things. Most forms mention risks, but do not provide a detailed description of the expected discomforts. In a subsequent analysis we found that 17% of the

consent forms mentioning a physical risk did not mention expected discomforts.

Precautions taken to reduce risk include safety measures employed to avoid unnecessary side effects, collateral hazards, and so on, or any type of initial screening (physical examination, etc.) for the exclusion of high risk individuals. Seventy three percent of the forms either mention or describe in detail the type of precaution to be taken. The mention of follow-up procedures to detect harmful effects as a result of experimentation is rarely found in prisoner consent forms even though

Table 14

Consent Form Elements Related to Risks Inherent to
Investigational Drugs, Treatments, and/or Procedures
with the Degree of Explanation

| Topic | ----- Degree of Explanation----- | | | | | | Total | |
|---|----------------------------------|----|----------------------|----|----------------|-----|-------|-----|
| | mentioned | | detailed description | | not mentioned* | | | |
| | No. | % | No. | % | No. | % | No. | % |
| Physical risks | 26 | 63 | 4 | 10 | 11 | 27 | 41 | 100 |
| Psychological risks | 5 | 12 | -- | -- | 36 | 88 | 41 | 100 |
| Discomforts expected | 24 | 59 | 3 | 7 | 14 | 34 | 41 | 100 |
| Precautions taken to reduce risk | 25 | 61 | 5 | 12 | 11 | 27 | 41 | 100 |
| Follow-up procedures to detect or minimize harm | 6 | 15 | -- | -- | 35 | 85 | 41 | 100 |
| Compensation for harmful, adverse effects | -- | -- | -- | -- | 41 | 100 | 41 | 100 |
| Investigator release from responsibility for harmful, adverse effects | -- | -- | -- | -- | 41 | 100 | 41 | 100 |

* It would have been useful to relate some elements to particular projects, since whether an element is needed in a consent form depends on whether it is involved in the project. Time did not allow for such an analysis.

investigators may employ such procedures. Moreover, there is no written disclosure of compensation for harmful effects, although the investigator does not release himself (on the form) from responsibility for harmful occurrence. Finally, while risk is mentioned in the consent form, the degree of risk is rarely evaluated.

Participation in the study. Table 15 presents the proportion of forms that define several conditions of the subject's participation in the research.

Table 15

Consent Form Elements Related to Subject Participation with the Degree of Explanation

| <u>Element</u> | <u>Mentioned</u> | | <u>Not mentioned</u> | | <u>Total</u> | |
|---|------------------|----------|----------------------|----------|--------------|----------|
| | <u>No.</u> | <u>%</u> | <u>No.</u> | <u>%</u> | <u>No.</u> | <u>%</u> |
| Subject can withdraw if he wishes | 39 | 95 | 2 | 5 | 41 | 100 |
| Compensation for participation | 10 | 24 | 31 | 76 | 41 | 100 |
| Effects of refusal: No detrimental consequences | 19 | 46 | 22 | 54 | 41 | 100 |
| Statement that participation is voluntary | 32 | 78 | 9 | 22 | 41 | 100 |
| Participation is recommended by physician, investigator | -- | -- | 41 | 100 | 41 | 100 |

Consent form readability. The Flesch Readability Yardstick* is a statistical formula developed for the objective measurement of readability and comprehension difficulty. The "reading ease score" for a selected reading passage is based on word length, i.e., the average number of syllables per 100 words, and sentence length, i.e., the average number of words per sentence. The Flesch formula was selected for the analysis of prisoner consent forms over other readability formulas primarily because of its general applicability to technical material.

For this area of analysis, consent forms were classified as either "short" or "long" forms. If the particular form in question contained less than 300 words, an overall readability level was determined by analyzing the entire passage. For those forms where the text exceeded 300 words, readability scores were obtained separately for three aspects of the form: purpose, procedure, and risk/discomfort.

The reading ease scores for purpose, procedures, and risk are shown in Table 16 for long form versions of consent. (An interpretation of the numerical scores as to grade level approximations, writing style, etc. appears in the bottom half of the Table.) According to the Flesch formula, 81% of the long forms require subject reading ability at the college level for comprehension of the investigator's purpose.** Material

* Flesch, Rudolf, "A New Readability Yardstick," Journal of Applied Psychology, vol. 32, no. 3, June 1948, pp. 221-233.

** Flesch, Rudolf, How to Test Readability, New York: Harper and Brothers, 1951.

Table 16

Reading Ease Scores by Elements of Purpose, Procedures, and Risks for "Long Form" Versions of Consent

| Element | 0-30 | | 30-50 | | 50-60 | | 60-70 | | 70-80 | | 80-90 | | 90-100 | | Total | |
|-------------------|----------------|----|-----------|----|------------------|----|----------|----|-------------|----|-------|----|-----------|----|-------|-----|
| | Very difficult | | Difficult | | Fairly difficult | | Standard | | Fairly Easy | | Easy | | Very easy | | Total | |
| | No. | % | No. | % | No. | % | No. | % | No. | % | No. | % | No. | % | No. | % |
| Purpose | 9 | 27 | 18 | 55 | 2 | 6 | 3 | 9 | 1 | 3 | -- | -- | -- | -- | 33 | 100 |
| Procedures | 5 | 15 | 14 | 41 | 11 | 32 | 4 | 12 | -- | -- | -- | -- | -- | -- | 34 | 100 |
| Risks/discomforts | 7 | 20 | 16 | 47 | 5 | 15 | 6 | 18 | -- | -- | -- | -- | -- | -- | 34 | 100 |

Interpretation of the Reading Ease Score:

| Reading Ease | Grade | Description of Style | Typical Magazine | Syll. per 100 words | Average Sentence Length |
|--------------|---------------------|----------------------|-----------------------------------|---------------------|-------------------------|
| 90-100 | 5 | very easy | comics | 123 | 8 |
| 80-90 | 6 | easy | pulp fiction | 131 | 11 |
| 70-80 | 7 | fairly easy | slick fiction | 139 | 14 |
| 60-70 | 8-9 | standard | digests, TIME mass non-fiction | 147 | 17 |
| 50-60 | 10-12 | fairly difficult | HARPER'S, ATLANTIC | 155 | 21 |
| 30-50 | college | difficult | academic, scholarly | 167 | 25 |
| 0-30 | college graduate | very difficult | scientific, professional | 192 | 29 |



associated with risks/discomforts and procedures is a bit less difficult than that for purpose. As to the short forms, six out of seven score "difficult" and the other scores "fairly difficult". (Data not shown.)

The following statements illustrate a "very difficult" and a "fairly difficult" text:

Example 1: In our studies on the effect of ethandrolone* on the body and to the appearance and disappearance of ethandrolone after oral doses, there is the opportunity to study nor-ethandrolone indirectly. A direct study of this major metabolite (40-60% conversion in the body) thus may be accomplished by oral administration.

Reading ease score = 13.9; very difficult

Example 2: Radioactive substance stays on a part of the drug, and a chemist can look for this trace of radioactivity in the urine, stools, and blood. In this way we can find out whether a drug is absorbed (taken up by the body), how it is digested or metabolized (handled by the body), and how it is excreted.

Reading ease score = 54.7; fairly difficult

The frequent appearance of medical/technical terminology may explain, in part, the difficult levels of readability. A positive, but weak, correlation was found between the frequency of medical terminology and reading difficulty. However, Table 17 shows that 35 percent of the reading material has between 0 and 5 percent medical terms; 56 percent has between 5 and 10 percent medical jargon. Furthermore, technical terminology is less frequent than medical terminology.

* Not the actual name of the chemical on the consent form.

Table 17

Medical and Technical Term Appearance throughout Explanation of the Investigator's Purpose and Procedure for "Long Form" Version of Consent

| Type of Term* | Term Frequency | | | | | | | | | |
|---------------|----------------|---|-------------------------------------|----|-------|----|------------------|---|-------|-----|
| | None | | Greater than 0% but less than 5% | | 5-10% | | Greater than 10% | | Total | |
| | No. | % | No. | % | No. | % | No. | % | No. | % |
| Medical | - | - | 12 | 35 | 19 | 56 | 3 | 9 | 34 | 100 |
| Technical | - | - | 29 | 85 | 5 | 15 | - | - | 34 | 100 |

* Medical term defined as word appearing in medical dictionary and not appearing in Dale list of 3,000 familiar words. A technical term is one not identified in either the medical dictionary or Dale's list, but of a technical nature, e.g., double-blind procedure, milligram percent, etc..

Table 18

Overall Medical and Technical Term Appearance for "Short Form" Versions of Consent

| Type of Term | Term Frequency | | | | | | | | | |
|--------------|----------------|---|--------------------------------------|-----|--------|----|------------------|---|-------|-----|
| | None | | Greater than 0% but less than 15% | | 15-30% | | Greater than 30% | | Total | |
| | No. | % | No. | % | No. | % | No. | % | No. | % |
| Medical | - | - | 6 | 86 | 1 | 14 | - | - | 7 | 100 |
| Technical | - | - | 7 | 100 | - | - | - | - | 7 | 100 |

A suggestive correlation ($r = -.63$) has been found between principal investigator's estimate of risk in his project and the readability of the description of risks in the consent form. Researchers appear to make their statements more involved and complicated and therefore more difficult to understand as they perceive the risks to be more severe, perhaps because more symptoms are listed when risk is relatively high.

(In any event, all consent forms contain at least one medical and one technical term.) The extent to which these terms are defined is shown in Table 19. Appropriate lay explanations of medical terms are found never or very rarely in 81% of all consent forms, with marginal attempts in explaining terminology for 19%. A few consent forms (4) were identified as having all technical terminology defined, but again the majority (73%) do not explain technical jargon.

Review Committee Decisions

Twenty-two percent of the investigators reported that they had had informal discussions with review committee members about the study prior to the submission of their proposal. Among these, 33% of the informal discussions resulted in modifications in the consent form or proposal. In 12% of the cases of formal review the committee requested more information. Of these cases, 25% were requests for more information on procedures, 25% on risks, 25% on benefits, and 25% on other miscellaneous issues.

In 22% of the reviews, the committee required modifications in how consent would be obtained from prospective subjects. For example, one investigator was asked to add some of the possible effects of the experiments. Another was asked to "make things more understandable." One investigator reported that the review committee required that he tell subjects "exactly how much blood would be taken in terms that the subject could easily understand. So we devised the use of 'one shot glass' as a measurement for subjects."

Seven percent of the reviews required modifications in reducing risk,

Table 19

Lay Explanation of Medical and Technical Terms for both "Long" and "Short" Form Versions of Consent

| <u>Type of Term</u> | <u>Very Rare (0-10%)</u> | | <u>Rare (10-35%)</u> | | <u>Ocassional (35-60%)</u> | | <u>Frequent (60-85%)</u> | | <u>Very Frequent (85-100%)</u> | | <u>Total</u> | |
|---------------------|--------------------------|----|----------------------|----|----------------------------|---|--------------------------|---|--------------------------------|----|--------------|-----|
| | No. | % | No. | % | No. | % | No. | % | No. | % | No. | % |
| Medical | 33 | 81 | 7 | 17 | 1 | 2 | - | - | - | - | 41 | 100 |
| Technical | 27 | 73 | 5 | 13 | - | - | 1 | 3 | 4 | 11 | 37 | 100 |



discomfort or inconvenience to subjects. For example, the committee "requested monitoring of lab tests be repeated at the end of the trial for the safety of the volunteers." Four percent required modifications in the scientific design of the study. For example, "There was a request to do the initial study with a very small group to check out the analytical methodology." In another case, a suggestion was made to employ a technology not available in the prison facility and this required moving the experiment to a hospital location. Seven percent of the reviews required modifications in the proposed selection of research subjects. For example, the committee required the exclusion of prisoners who had a specified illness, and the committee increased the age range of potential subjects.

Most of the investigators thought that the judgments and recommendations of the review committee were sound, although some indicated that the changes required were very minor, like changing the numbering system of the pages in the protocol.

Sixty-three percent of the investigators had had further contacts with the review committee regarding their studies subsequent to the initial review. About equal numbers of these contacts were initiated by the research staff and by the review committee. In many of these cases reports of the research are provided to the committee. Some of these involved routine progress reports and follow up. One investigator wanted to place an addendum into his protocol. Another was called by the committee because a consultant to the committee requested, after the project had been approved, that the investigator make a change in the consent form concerning the amount of blood to be drawn.

Suggestions Offered by Investigators

Investigators' comments by and large indicate that the review procedure works fairly well. A large number of the investigators had no suggestions for improvement, or indicated that if all review committees worked like theirs, that everything would work well, and both subjects and investigators would be better protected.

Some investigators, however, did offer suggestions. One suggestion that came from several respondents proposed allowing more flexibility in the regulations. For example, one investigator said that "it is difficult to write a set of regulations in Washington and have them apply without allowing any flexibility in those regulations....To live absolutely by not only FDA but NIH regulations on federal grants, we probably couldn't do it....We do not have the manpower to follow NIH exactly," even though he felt that "we've got as good a review procedure as anybody else." Similarly, another investigator felt that the review committee needs to be "given more latitude than the federal regulations permit."

Other investigators felt that the review procedure would be better off if it took less time, and that it should be made less of a burden. One, however, proposed "a closer monitoring of individual investigators - more 'on site' visits by review committees and at the federal level."

One investigator felt that as it stood, the review procedure was susceptible to too much individual bias. "For example, a member of the committee may believe that the use of a placebo control in an analgesic study is unethical. It becomes then impossible to carry out a meaningful

study with an analgesic drug in that institution." Another proposed that review committees be larger, since it is easier, in his view, to integrate new members in larger committees than in smaller ones. One investigator pointed to the special character of research with prisoners: "It's worthwhile to have people with some experience in dealing with prison volunteers and have an understanding of the prisoners' understanding of your project. Some sophisticated researchers don't realize this if they don't have the experience."

The number of specific suggestions offered by investigators is not great, perhaps because, as a number of respondents indicated, "I feel they do a good job. I can't see the need for any changes." Or as another put it, "[There is no need for] modification that I can think of. I'd like for it to be less of a burden, but we accept it as a way of life."

Prisoners As Subjects

Prisoners were interviewed in four of the five institutions which comprised our sample. The objective was to interview fifty different individuals at each prison who had participated in projects reviewed between July 1, 1974 and June 30, 1975.* Sampling procedures were used to select, on the average, nine projects at each institution, and the appropriate research investigators and/or prison officials were asked to send letters to subjects who were to be selected on a random basis. Those inmates who wanted to be interviewed could then sign and return the letter to the warden's office or to our interviewer. Letters were sent to substantially more than fifty inmates at each prison to compensate for (1) those persons who could not be contacted or interviewed (e.g., people who were transferred, released, or under disciplinary detention); (2) those prisoners who might prefer not to be interviewed; and (3) the prisoners who had served as subjects in more than one of the sampled projects. We estimate that at least seventy-five percent of the subjects who were selected by our sampling procedure, and who were in the prison at the time our survey was conducted, agreed to be interviewed. One hundred and eighty-one "subjects" were interviewed; this translates into a slightly smaller number of prisoners because some inmates were asked about their involvement in more than one project and they count therefore as more than one subject in our sample.

The prisoners were not paid to participate in our study. Those who agreed to be interviewed were highly cooperative, and detailed comments

*The sampling time frame was extended for one institution because of the small volume of research conducted there.

were offered by many prisoners. A few of the inmates had participated in a large number of projects and it was not always clear whether they were responding exclusively in terms of the project(s) about which they were being interviewed.

The Ways in Which the Prisoners Learned of the Projects

Most of the prisoners learned about the projects through communications initiated by the researchers or their representatives. As indicated in Table 20, more than half of the subjects saw a notice on a bulletin board or were "called in" by the researchers. The prisoners who were called in include those who had previously indicated that they wanted to participate in research projects and/or those who had already served as subjects in other studies.

Table 20

How Did You First Learn About the Study?

| <u>Response</u> | <u>% of Subjects</u> | <u>No. of Subjects</u> |
|--|----------------------|------------------------|
| Saw a notice on a bulletin board | 34 | 59 |
| Were called in by the researchers | 22 | 38 |
| Heard about the project (or research program) from other subjects | 13 | 23 |
| Received a letter or pamphlet | 9 | 15 |
| Worked at the clinic | 7 | 12 |
| Found out about the research program at a prison orientation | 4 | 7 |
| Asked about the project or program | 3 | 6 |
| Heard about the program from a friend | 2 | 4 |
| Found out about the program while they were patients at the clinic | 1 | 2 |
| Other; don't know | 5 | 9 |
| | <hr/> 100 | <hr/> 175* |

*Six respondents did not answer this question

Approximately one-fourth of the respondents heard about the projects through informal channels -- friends or other subjects told them about it, or they sought out information on their own. The ways in which the subjects learned about the projects seemed to vary from prison to prison. Many prisoners in one institution mentioned "notices on bulletin board;" in another prison, subjects were often called in by the researchers; letters and orientation sessions were used frequently in one prison; and, in another institution, many people learned about the research by holding jobs in the clinics and through informal channels.

The Quality and Quantity of the Information Provided to the Prisoners

Practically every subject reported that the information he was given, at the time he agreed to participate, was clear and understandable (see Table 21). One prisoner did not answer this question, but his responses to all the other questions were favorable.

Table 21

When You Agreed to Participate, Did You Feel That the Information that Was Given to You Was Clear and Understandable?

| <u>Response</u> | <u>% of Subjects</u> | <u>No. of Subjects</u> |
|-----------------|----------------------|------------------------|
| Yes | 99 | 179 |
| No | 1 | 1 |
| | <hr/> 100 | <hr/> 180* |

* One respondent did not answer the question

Another prisoner, who was interviewed about his participation in three different projects, said that the information he was given on one study was

neither "clear nor concise." He saw the investigator as willing to answer only certain types of questions and eventually consulted another doctor to get more information. Additionally, he felt that since the inmates were taking risks for medical science, they should be given information on the results of the experiments. This prisoner was well-educated, had some medical knowledge, and -- according to our interviewer -- seemed to be very intelligent.

Most subjects, however, said that the information they were given was clear. One prisoner commented that they "broke it down so you could understand it;" another said that things became clear, but only after the researcher answered a series of questions; and one respondent noted that "they even give you a copy" of the consent form. Other prisoners qualified their positive responses by noting that they understood the possible side effects, but did not understand the medical terms. A small subgroup of prisoners were asked an additional question on the clarity of the information they were provided. The question was the same as the one in Table 21, but provided four rather than two response alternatives: "completely clear and understandable," "mostly clear and understandable," "mostly unclear," or "completely unclear." Seventy-seven percent of the prisoners answering this question said "completely clear" and 23 percent responded "mostly clear." It might be assumed, therefore, that some of the subjects who gave "yes" responses to the question in Table 22 may have perceived the information as being somewhat less than "completely clear."

Almost 97 percent of the subjects said that the information they were provided was correct and accurate (see Table 22). A small minority of those who responded favorably to this item qualified their answers. For example, some people added "as far as I know" or "they must have told it pretty

straight" -- implying, perhaps, that they had no way of conclusively knowing whether the information was correct. One prisoner who said "yes" noted that he was having some problems which he was not told about -- but he was not certain that these problems were a result of his participation in the research project.

Table 22

Now that You Have Participated In the Research, Do You Feel that the Information You Were Given Was Correct and Accurate?

| <u>Response</u> | <u>% of Subjects</u> | <u>No. of Subjects</u> |
|-----------------|----------------------|------------------------|
| Yes | 97 | 175 |
| No | 1 | 2 |
| Don't know | 1 | 2 |
| No Response | 1 | 2 |
| | 100 | 181 |

Six prisoners, from three different institutions, did not answer this question affirmatively. Two prisoners preferred not to answer the question at all. One said that because the information was unclear, he couldn't offer a judgment on its accuracy. Another provided no response but gave generally favorable answers to other questions. Two prisoners said that they didn't know if the information was correct. One simply said, "How could I know?;" the other had gotten a rash after participating in a project and wondered if they had "told me everything." Two negative responses were recorded. One subject said that the researchers "changed their minds" and took more blood samples than they said they would. The other subject said "not really" but did not offer an explanation. [Note: our interviewer was not sure that this respondent was clearly distinguishing

among the studies he had been involved in.] Finally, a very small subset of prisoners were asked another, similar question about the accuracy of the information they had been provided. Their responses support the the generalization that the information provided to prisoners is considered to be accurate from the point of view of almost all subjects.

All subjects were asked, "When you agreed to participate, did you feel that the researchers were willing to answer any questions you might have?" With one exception, the people who responded to this question said "yes" (see Table 23). Many of the prisoners added comments like "we were told to ask questions", "any and all", "definitely", and "of course". The one prisoner who responded negatively said, "not really -- got the run-around when I asked."

Table 23

Did You Feel Researchers Were Willing to Answer
Any Questions You Might Have?

| <u>Response</u> | <u>% of Subjects</u> | <u>No. of Subjects</u> |
|-----------------|----------------------|------------------------|
| Yes | 99 | 178 |
| No | 1 | 1 |
| | <u>100</u> | <u>179*</u> |

*Two respondents did not answer this question

This prisoner had an eighth-grade education and our interviewer noted he may have been confused as to which research project he was being interviewed about. Nevertheless, a poorly-educated subject might have trouble asking questions about a complex research project and some extra effort may have to be made, on the part of the investigators, to properly interpret and answer those questions.

From their perspective, subjects were given an adequate amount of information about the research projects. Over 80 percent of the subjects reported they were given as much information about the research as they wanted (see Table 24). Twenty subjects (11 percent) said they were provided more information than they wanted and nine (5 percent) were given less than they wanted. In contrast to the better-educated inmates, poorly-educated respondents more frequently said that they received too much information. A few persons in the better-educated group said that they received less information than they wanted; no one in the poorly-educated group said he received too little information. It is possible that those prisoners with a limited education (3-9 years) have a difficult time processing large amounts of information and/or don't see the information as being relevant to their decision to participate.

Table 24

Adequacy of Information: Quantity

| <u>Response</u> | <u>% of Subjects</u> | <u>No. of Subjects</u> |
|-------------------------------|----------------------|------------------------|
| More information than wanted | 11 | 20 |
| As much information as wanted | 84 | 150 |
| Less information than wanted | 5 | 9 |
| | <hr/> 100 | <hr/> 179* |

| <u>Responses by Education Level</u> | <u>% of Subjects</u> | | |
|-------------------------------------|----------------------|-----------|-----------|
| | Low | Medium | High** |
| More information than wanted | 18 | 8 | 7 |
| As much information as wanted | 82 | 89 | 83 |
| Less information than wanted | 0 | 3 | 10 |
| | <hr/> 100 | <hr/> 100 | <hr/> 100 |

* Two respondents did not answer this question.
 ** Education Levels: Low=3-9 years; Medium=10-12 years; High=13 or more years

The Decision to Participate

The prisoners who participated in our sample of projects apparently had few problems in deciding whether or not to assume the role of research subject. Table 25 indicates that almost 90 percent of the respondents said that it was "not at all difficult" to decide to participate in the research project they were being asked about. Only twenty subjects reported some difficulty in making the decision to get involved in the project. Preliminary analyses suggest no systematic differences between the prisoners who had difficulty and those who had no difficulty in making this decision. Highly-educated subjects reported virtually the same average level of difficulty as their poorly-educated counterparts.

Table 25

How Difficult Was It for You to Decide to Participate?

| <u>Response</u> | <u>% of Subjects</u> | <u>No. of Subjects</u> |
|----------------------|----------------------|------------------------|
| Not at all difficult | 89% | 161 |
| Not very difficult | 5 | 10 |
| Somewhat difficult | 5 | 9 |
| Very difficult | 1 | 1 |
| | <hr/> | <hr/> |
| | 100 | 181 |

Prisoners who had previously participated in relatively few projects did not find the decision any more difficult than those who had been involved in numerous projects. Inmates who were coming up for parole in the near future did not differ significantly from those who would not be eligible for quite a while. Subjects who received a high amount of pay for participating in the project tended to report more difficulty than those participating in lower-paying studies. Though this relationship was not statistically significant, a trend in this direction would be

expected if the higher-paying projects involved greater risk and/or time. (Preliminary analyses suggest that, at least in three prisons, pay might be more strongly related to the amount of time required for participation than to the amount of risk involved.)

The respondents seemed to have three main reasons for deciding to participate in the research projects. Financial reimbursement was the most frequently mentioned reason and appeared to be the most important reason for many prisoners (see Table 26). Second, many people said they participated because they wanted to "help" -- they expressed a desire to help society, medical research, or people with specific medical problems.

Table 26

What Are the Main Reasons You Participated In the Research?

| <u>Reason</u> | <u>% of Subjects</u> | <u>No. of Subjects*</u> |
|---|----------------------|-------------------------|
| Money, financial reimbursement | 70 | 126 |
| To help others, help society | 27 | 49 |
| Personal advantage (other than money) gained by participating | 19 | 34 |
| Curiosity; research is interesting | 7 | 13 |
| To help science, research, knowledge | 4 | 8 |
| To help others with specific medical or health problems | 3 | 5 |
| To get medical attention | 3 | 5 |
| To help (not specified who or what) | 1 | 2 |
| Because everyone else participates | 1 | 1 |
| To help specific others (e.g., my children) | 1 | 1 |
| (Other reasons) | 7 | 12 |
| (No reason mentioned) | 1 | 2 |

*Some subjects (80) mentioned more than one reason and therefore the percentages total more than 100%.

Third, a significant number of prisoners participated because the research afforded them some personal advantage besides money. Physical examinations, relaxation, or an improved environment were cited by many people as an important, though often secondary, reason for getting involved in the projects.

The importance of money as an inducement for participation is very clear. Many of the prisoners who cited financial reimbursement as a factor simply smiled or laughed and said "the money." A small number implied that they were "supplementing" their income and were using the cash they received to improve their living situation at the prison. Others, however, said that they needed money, and for some, participating in the research projects seemed to be a way of getting it. Three forces might account for this need: (1) certain prisoners have a special need for money (e.g., a family in need of financial assistance); (2) some subjects don't have prison jobs or make less money than some other prisoners (6% of subjects reported not having a job); and (3) other prisoners received no financial support from outside. Comments included: "I don't have anybody to send me money" and "I had no income coming from the 'streets'" and "I wasn't working at the time." A couple of respondents said that if they had had money, they would have never gone "over there" (to the research laboratory or clinic). On the other hand, some subjects emphasized that they did not participate in the research for the money.

A good number of subjects said that they participated because they wanted "to help." Though the prisoners who wanted to help often had other reasons for participating some inmates said that their desire to help was their only or most important reason. People confined to an institution may have few

opportunities to make contributions "to society," and some prisoners may view participating in medical research projects as one of the only ways they can make a positive impact. One out of every four subjects mentioned helping "others" or "society." A few said they wanted to help advance medicine (many of these persons expressed some interest in medicine) or to help in finding a cure for a particular medical problem (these individuals often mentioned that the research was related to some medical problem faced by themselves, their children, etc.).

Almost one out of five subjects mentioned some type of personal advantage (other than money) when answering the question on reasons for participating. A few prisoners cited the "physical exams" as the most important reason for signing up for a study. The health-care services, at more than one prison, were seen as inadequate -- and the physicians conducting the research programs were well-respected and known for the thoroughness of their examinations. For example, one inmate (an older man) felt he was in need of a good physical and saw the research program as the "only way" to get one. Various other benefits were mentioned by the subjects, including "getting away," "the change of scenery," and the "better environment of the clinics." The subjects also made frequent mention of the food, the better sleeping arrangements, and the chance to watch television and to participate in other activities. These side benefits seemed to be at least a secondary inducement for most people; a few subjects, however, cited these benefits as the most important reason for participating and the importance of these inducements appears to be recognized by the research investigators.

The great majority of prisoners did not see their research activities as having any bearing on their parole situation (see Table 27). Only four (of the 181) respondents said "yes, participation would help." The same number said "probably, might, or could," and three said "might or might not." The individuals providing these responses and the "don't know" were inmates at two of the four prisons where subject data were collected. In one of these prisons, 24 percent of the respondents didn't know if their participation would help their parole cases and ten percent responded "yes," "could," "might or might not."

Table 27

Do You Feel Your Participation in Research Will Help
Your Case When it Comes up Before the Parole Board?

| <u>Response</u> | <u>% of Subjects</u> | <u>No. of Subjects</u> |
|-----------------------------|----------------------|------------------------|
| Yes | 2 | 4 |
| Probably will, might, could | 2 | 4 |
| Might or might not | 2 | 3 |
| Probably won't | 5 | 8 |
| No | 78 | 136 |
| Don't know | <u>11</u> | <u>20</u> |
| | 100 | 175 |

* Six respondents did not answer this question.

In the other prison, 80 percent reported negatively, but eight percent didn't know and almost ten percent of the inmates saw some chance of their participation helping them.

Finally, very few subjects mentioned any reasons for not wanting to participate in the research (see Table 28). The few reasons mentioned focused on the possibility of harmful effects, unpleasant procedures such as blood tests, the time away from jobs or classes, or a mistrust of research or the researchers.

Table 28

Did You Have Any Reason for Not Participating?

| <u>Response</u> | <u>% of Subjects</u> | <u>No. of Subjects</u> |
|--|----------------------|------------------------|
| No reason mentioned for not participating | 94 | 171 |
| Fear of harmful effects | 1 | 2 |
| Mistrust researchers or research | 1 | 2 |
| Procedures unpleasant, uncomfortable, or painful | 1 | 2 |
| Having to take time away from prison job or school | 1 | 2 |
| Time involoved | 1 | 1 |
| (Other) | <u>1</u> | <u>1</u> |
| | 100 | 181 |

All subjects were asked, "Before your participation actually began, did you think there might be some possibility of harmful effects to you as a result of your participation?" Sixty respondents (34 percent) said yes and 118 (66 percent) said no, they did not think there might be some possibility of harmful effects. There was a positive, but very weak, relationship between the subjects' tendency to report risk and the risk of the project as reported by the investigators.*

*The correlation between the risk of minor medical complications, as reported by investigators, and the risk of harmful effects, as reported by subjects is .09, (n = 155). When risk of serious medical complication is the criterion the correlation is .14 (n = 153).

The weakness of this relationship may be due partly to the fact that most investigators and subjects did not see their projects as being risky--most reported no risk or very little risk of medical complications. The finding may also be artifactual--it is possible that the prisoners couldn't remember how much risk they expected or were confusing the various studies in which they had participated. On the other hand, this weak relationship could be due to a weakness in the consent process or an inability on the part of some subjects to clearly understand the risks which have been described to them.

Subjects were broken into two groups based on their level of education: the first group included those persons who had completed eight or less years of formal education, and the second group included those with nine or more years of school. For the more educated prisoners, a small relationship was obtained between subjects' expectations of harmful effects and the risk of minor/serious medical complications as reported by investigators ($r = .20$, $n = 122$). For prisoners with eight or less years of education, there is virtually no relationship between these two variables ($r = .04$, $n = 28$). Either the less educated prisoners never clearly understood the risks or could not remember the risks which they may have, at one time, expected.

The respondents who said that there was no possibility of harmful effects were asked why they felt that way (see Table 29). The reasons most frequently given were related to the researchers rather than to the specific research project. Twenty prisoners suggested that they trusted the doctors, that the doctors knew what they were doing, and/or that the doctors wouldn't conduct a study that was likely to have harmful effects. Other prisoners

seemed to have made their own judgements about the potential harmful effects of the research--they were familiar with the drugs or with the research procedures and felt they were safe. Many prisoners based their opinions on what they had been "told" or on the way the study had been "explained to them." Although the prisoners frequently mentioned the explanations they had been given, they seemed to be referring to oral, rather than written, explanations. Consent forms were rarely mentioned in this context.

Table 29

Why Did You Feel There Was Not a Possibility of Harmful Effects?

| <u>Response</u> | <u>% of Subjects</u> * | <u>No. of Subjects</u> |
|---|------------------------|------------------------|
| Trust the doctors or researchers, they know what they're doing, they wouldn't do the study if it were harmful | 17 | 20 |
| Prisoners knew the drugs and procedures to be used; felt the drugs were safe | 14 | 17 |
| Told there was no harm/or the effects explained were obviously not harmful | 13 | 15 |
| The way the study was explained and/or prisoners' understanding of the research | 9 | 11 |
| Medications had been tested before given to humans; previous tests with drug | 8 | 10 |
| Researcher or assistant said there was no harm | 7 | 9 |
| Prisoner's own previous experience in research projects | 4 | 5 |
| Other prisoner's experiences in previous research projects | 3 | 3 |
| Specific side effects not harmful or serious | 3 | 3 |
| Prisoner's good health | 3 | 3 |
| Knew researchers or worked in clinic | 2 | 2 |
| Consent form said there was no harm | 1 | 1 |
| Researchers were taking precautions | 1 | 1 |
| No reason mentioned or "don't know" | 15 | 18 |
| | 100 | 118 |

* Percentages calculated on the basis of the number of respondents who reported no possibility of harmful effects.

The people who saw some possibility of harmful effects also tended to base

their feelings on what they had been told or on the way the research had been explained. Only two people mentioned the consent forms when explaining to our interviewers why they thought there might be some harmful effects (see Table 30).

The great majority of subjects agreed that their participation in the research project about which they were being interviewed was voluntary (see Table 31). Six persons, however, said that they did not feel free to refuse. The six individuals who answered this question negatively were from one institution and, as such, comprised a significant minority of the respondents from that prison. Five of these prisoners said that if they refused to participate in the study, they would not (or probably would not) be asked to participate in future studies. Similarly, the sixth respondent felt that some inmates need the research because it affords them a little better life, and thus, they take whatever comes up to ensure they won't be dropped from the list. These respondents, nonetheless, generally reported that they received as much information about the research as they wanted, felt that the information was clear and accurate, and saw the investigators as willing to answer their questions. Additionally, five of the six did not anticipate (before their participation began) some possibility of harmful effects as a result of participating in the studies. This suggests that the involuntary situation they perceived was not tied to any particular study, but instead was a function of their reaction to a practice of not recalling prisoners who recently refused to participate in a project.

Subjects' Opinions about Research in Prisons

Table 32 indicates that over eighty percent of the respondents would be very willing, and more than ten percent would be somewhat willing, to participate in a project similar to the one about which they were being interviewed. This suggests that most of the subjects seemed to approve of the

Table 30

Why Did You Feel There Was a Possibility of Harmful Effects?

| <u>Response</u> | <u>% of Subjects</u> * | <u>No. of Subjects</u> |
|--|------------------------|------------------------|
| Prisoner was told about possible harmful effects (respondent did not specify who told him) | 28 | 17 |
| Doctor, researcher, or assistant said there might be harmful effects | 15 | 9 |
| Prisoner feared side effects of the particular drug/medication | 12 | 7 |
| Harm was inferred because the drug was being studied | 8 | 5 |
| Consent form said there might be harmful effects | 3 | 2 |
| Prisoner feared disease or "catching something" | 2 | 1 |
| Prisoner mistrusted researchers | 2 | 1 |
| No reason mentioned or "don't know" | <u>30</u> | <u>18</u> |
| | 100 | 60 |

* Percentages calculated on the basis of the number of respondents who reported some possibility of harmful effects.

Table 31

When You Agreed to Participate, Did You Feel That It Was a Purely Voluntary Matter; That is Did You Feel Free to Refuse?

| <u>Response</u> | <u>% of Subjects</u> | <u>No. of Subjects</u> * |
|-----------------|----------------------|--------------------------|
| Yes | 97 | 174 |
| No | <u>3</u> | <u>6</u> |
| | 100 | 180 |

* One respondent did not answer this question.

research conducted at their prison. Those subjects who did not say "very willing" were asked why they might be unwilling to participate again. The main reasons cited included the fear of harmful effects and the unpleasantness of the procedures (see Table 33).

Some of their unwillingness was associated with, and probably a result of, bad reactions to the drug being evaluated in the project the subjects were being interviewed about. A small subset of prisoners in one institution were asked extra questions regarding their experiences as research subjects. The first question was: "Did you have any difficulties as a result of the research that you did not expect to have? Did you have no unexpected difficulties at all, very few difficulties, some difficulties, or very many difficulties?" More than half of these prisoners (8 out of 13) said "none at all"; two reported "very few difficulties"; one said "some difficulties"; and two replied "very many."

Except for those who reported no problems, the prisoners were asked to describe the unexpected difficulties they had experienced. The difficulties included such things as nausea, an allergic reaction to a drug, and violent behavior and its subsequent repercussions. Copies of the consent forms used in the various studies in which the prisoners had participated were examined. Each consent form mentioned, in some way, the appropriate "unexpected difficulties" experienced by the subjects. In two cases, the problems cited by the subjects were clearly mentioned in the consent forms. In two other instances, the reactions were noted as possible effects, but this was done within the context of a long list of risks. It may be that the lengthy list overwhelmed the subjects with information and the various effects listed were not comprehended or remembered. On the other hand, the difficulty experienced by another subject may have been unexpected because the consent

form seemed to be designed to avoid a lengthy list of effects. Prominently noted in this consent form was "various allergic reactions" along with an explanation that the reactions could be serious and a couple of examples. The examples did not include the specific reaction reported by the prisoner and, as such, might have seemed unexpected from his perspective.

Table 32

How willing would you be to participate in a similar research project?

| <u>Response</u> | <u>% of Subjects</u> | <u>No. of Subjects*</u> |
|--------------------|----------------------|-------------------------|
| Very willing | 87 | 155 |
| Somewhat willing | 11 | 20 |
| Not very willing | 1 | 2 |
| Not at all willing | <u>1</u> | <u>2</u> |
| | 100 | 179 |

* Two respondents did not answer the question

Table 33

Why might you be unwilling to participate again?

| <u>Response</u> | <u>% of Subjects</u> | <u>No. of Subjects*</u> |
|--|----------------------|-------------------------|
| Fear of harmful effects | 16.7 | 4 |
| Procedures unpleasant, uncomfortable, or painful | 16.7 | 4 |
| Depends on exactly what the research would be | 12.5 | 3 |
| General fear of unknown | 8.3 | 2 |
| Inconvenience | 8.3 | 2 |
| Would not go if I didn't need the money | 8.3 | 2 |
| Lack of personal benefit | 8.3 | 2 |
| Mistrust researchers or research | 4.2 | 1 |
| Poor health | 4.2 | 1 |
| Boring | 4.2 | 1 |
| No response | <u>8.3</u> | <u>2</u> |
| | 100 | 24 |

* Percentages calculated on the basis of the number of respondents (24) who were asked this question

Forty-four of the 181 subjects offered suggestions for improving the way in which research on human beings is conducted. Many of these people suggested that the research facilities could be improved and that the procedures could be carried out better. Miscellaneous suggestions included such things as: make it easier to get away from prison jobs to participate in research projects; "full-pay" for participating--presumably pay equal to what non-prisoners would get; offer "good-time" instead of pay because inmates who are broke are going to jump at the offer of pay; conduct more research on people "outside" the prison in the "free world"; and listen to what the prisoners have to say about their reactions to drugs rather than just taking blood samples. The majority of the respondents had no suggestions for improvement and some of these people commented favorably on the researchers and the research program. Favorable statements included comments such as: "doing a pretty good job"; "they do a good job right now--very fair"; "[we] don't feel like guinea pigs"; "they make improvements as they go along"; and the research is "approved by so many different groups" that a bad study couldn't be conducted. (See Table 34 for suggestions.)

Non-subjects' Opinions about Research in Prisons

In two of the institutions, interviews were conducted with inmates who had never served as research subjects or who had not participated in projects over the past few years. Thirty such individuals were randomly selected for interviews at one prison and twenty-seven were actually interviewed. (One individual preferred not to be interviewed and two were unable to answer call.) At the second prison, the smaller of the two, seventeen individuals were randomly selected and all agreed to be interviewed.

Table 34

Suggestions for how researchers could improve
the way they do studies on human beings

| <u>First suggestion mentioned</u> | <u>No. of Subjects</u> |
|---|------------------------|
| Carry out research procedures better; be more efficient | 7 |
| Improve the facilities used during the research | 6 |
| Improve the food | 5 |
| More pay | 4 |
| Take more time to do the research; don't rush | 3 |
| More information (on things other than harm, procedures, or outcomes) | 3 |
| Improve instructions to subjects on procedures | 1 |
| Test medications thoroughly before they are given to subjects | 1 |
| More humane treatment/procedures | 1 |
| Conduct more research | 1 |
| (Other) | 1 |
| <u>Second suggestion mentioned</u> | |
| More pay | 4 |
| Improve the facilities used during the research | 3 |
| More humane treatment/procedures | 2 |
| Better explanation of possible harmful effects | 2 |
| More information (on things other than harm, procedures, or outcomes) | 1 |
| Improve instructions to subjects on procedures | 1 |
| (Other) | 1 |

The "non-subject" prisoners differ in a number of respects from the prisoners who served as research subjects. The subjects are more likely to hold prison jobs than are the inmates who chose not to participate in research projects. For those inmates who hold jobs, the number of hours worked per week is slightly greater for the subjects than for the non-subjects. Additionally, subjects in both prisons have a somewhat higher level of formal education than their non-subject counterparts. (These comparisons are based on data provided by our sample of respondents and not on prison records.)

Prisoners in one of the prisons were asked if they might agree, at some point in time, to participate in a medical research project. Forty-seven percent answered affirmatively and were asked why they might decide to participate. Reasons offered by these individuals include financial reimbursement and/or the nature of the investigation (e.g., the research would have to focus on a specific disease or condition of interest.) Some of these inmates saw their participation as being contingent upon a sizeable payment and the expectation that the results would benefit others either within the prison walls and/or outside "on the streets."

The majority of those inmates who said that they would not participate in the research program based their decision on doubts about the efficacy of medical research and on a mistrust of the medical researchers and procedures. Others feared harmful effects that might ensue as well as being treated as "guinea pigs." Additionally, a few respondents cited the "bad experiences" that they or other inmates had while serving as research subjects. About twenty percent of the "non-subject" respondents in this institution said that they had participated in a project at an earlier time. These inmates said they had participated either for the

money or for the better health care available at the clinics.

Non-participants at both institutions were asked why, in their opinions, prisoners agreed to participate in research. The great majority of these individuals felt that money was the reason why the inmates agreed to serve as subjects. Satisfaction of curiosity (i.e., to find out more about research) and personal advantages other than money also were mentioned by some respondents. Although certain non-subjects would themselves consider participating in a project to help others, they did not see the "desire to help others" as a factor which might explain the participation of present subjects. Subjects were seen by certain non-participants as the "neediest" of all inmates, who must be in it [research] for the money. Subjects were viewed by some as being either (1) "economically stripped" with no income "from the streets"; (2) "loafers" or inmates with low or no important job situation within the walls; or (3) "drug lovers" taking the opportunity to "get a free high."

Respondents at both institutions were asked their opinions about the research program. It is clear that non-subjects on the average have less favorable opinions than subjects. On the positive side, six non-participants commented on the money involved and, for example, saw these funds as being helpful to inmates. Others expressed the belief that the prison research program was advancing medical knowledge. Four inmates commented on the voluntary nature of the program. It is noted, however, that some non-participants took the stance of "different strokes for different folks" and approved of the "voluntary" system with reservations.

The most frequently mentioned negative comments referred to the adverse effects of the research. Ten non-participants mentioned their contacts with subjects who appeared "dopey" or "stupefied" or had experienced

substantial weight losses. Some respondents felt that the researchers were either careless or neglectful based on these respondents' observations of temporary or permanent physiologic impairments. One respondent was particularly concerned about the absence of adequate follow-ups on subjects, on the one hand, and the research implications of using the same subjects repeatedly, on the other. [Note: our interviewer commented on the intelligence and probable scientific knowledge of this respondent.] Five non-participants felt that the research program exploited the prisoner, but only five said there was a need for more detailed explanation regarding the nature of the projects. One inmate felt that people should be able to choose among projects and should not be dropped as potential subjects if they choose not to participate in a particular project.

ADDENDUM

Appendix A

What is the highest grade or year of college you completed?

| <u>Level of education</u> | <u>% of Subjects</u> | <u>No. of Subjects</u> * |
|--|----------------------|--------------------------|
| Third grade | 1% | 1 |
| Fourth grade | 1 | 1 |
| Fifth grade | 0 | 0 |
| Sixth grade | 3 | 5 |
| Seventh grade | 3 | 6 |
| Eighth grade | 9 | 16 |
| Ninth grade | 9 | 17 |
| Tenth grade | 8 | 15 |
| Eleventh grade | 10 | 19 |
| Twelfth grade | 28 | 50 |
| One year of postsecondary education | 12 | 21 |
| Two years of postsecondary education | 12 | 21 |
| Three years of postsecondary education | 3 | 5 |
| Four years of postsecondary education | <u>1</u> | <u>1</u> |
| | 100% | 178 |

* Three respondents did not answer this question.

Appendix B

Are you involved in any of the following activities or programs?

| <u>Program or activity</u> | <u>% of Subjects*</u> <u>involved in the program</u> | <u>No. of Subjects</u> <u>involved in the progr.</u> |
|----------------------------|---|---|
| Education program | 51% | 92 |
| Self-help activities | 43 | 76 |
| Training program | 16 | 29 |
| Clubs or groups | 33 | 59 |

*Some subjects were involved in more than one program or activity and therefore the percentages total more than 100%.

Appendix C

How many hours a week do you work on your regular prison job?

| <u>Response</u> | <u>% of Subjects</u> | <u>No. of Subjects</u> * |
|-------------------------|----------------------|--------------------------|
| 1-10 hours/week | 6% | 10 |
| 11-20 hours/week | 3 | 4 |
| 21-30 hours/week | 8 | 12 |
| 31-40 hours/week | 44 | 70 |
| 41-50 hours/week | 16 | 25 |
| 51-60 hours/week | 11 | 17 |
| More than 60 hours/week | 11 | 18 |
| Don't know | <u>1</u> | <u>2</u> |
| | 100% | 158 |

* Twenty-three respondents did not answer this question. Eleven of them (6% of all respondents) did not hold a job at the prison.

Appendix D

Have you been a subject in any other research projects?

| <u>Response</u> | <u>% of Subjects</u> | <u>No. of Subjects</u> |
|-----------------|----------------------|------------------------|
| Yes | 75% | 135 |
| No | $\frac{25}{100\%}$ | $\frac{46}{181}$ |

| <u>Number of other projects participated in</u> | <u>% of Subjects</u> | <u>No. of Subjects</u> |
|---|----------------------|------------------------|
| 1 | 18% | 24 |
| 2 | 5 | 7 |
| 3 | 18 | 24 |
| 4 | 7 | 9 |
| 5 | 9 | 12 |
| 6 | 10 | 14 |
| 7 | 1 | 1 |
| 8 | 1 | 2 |
| 9 | 1 | 2 |
| 10-15 | 17 | 23 |
| 16-20 | 6 | 8 |
| 21-30 | 4 | 5 |
| 31+ | $\frac{3}{100\%}$ | $\frac{4}{135}$ |

Appendix E

Approximately how many years have you served in prisons?

| <u>Response</u> (number of years) | <u>% of Subjects</u> | <u>No. of Subjects</u> * |
|-----------------------------------|----------------------|--------------------------|
| 1 | 9% | 16 |
| 2 | 2 | 4 |
| 3 | 13 | 23 |
| 4 | 4 | 8 |
| 5 | 15 | 27 |
| 6 | 7 | 13 |
| 7 | 7 | 13 |
| 8 | 6 | 10 |
| 9 | 8 | 15 |
| 10 | 6 | 10 |
| 11 | 6 | 10 |
| 12 | 1 | 2 |
| 13 | 4 | 7 |
| 14 | 1 | 1 |
| 15 | 1 | 2 |
| 16-20 | 7 | 13 |
| 21-30 | 2 | 4 |
| 31-40 | <u>1</u> | <u>2</u> |
| | 100% | 180 |

* One respondent did not answer this question.

Appendix F

How many felonies have you been convicted of?

| <u>Response (number of felony convictions)</u> | <u>% of Subjects</u> | <u>No. of Subjects</u> * |
|--|----------------------|--------------------------|
| 1 | 26% | 47 |
| 2 | 29 | 53 |
| 3 | 18 | 32 |
| 4 | 8 | 15 |
| 5 | 7 | 13 |
| 6 | 3 | 5 |
| 7 | 2 | 4 |
| 8 | 2 | 3 |
| 9 | 1 | 1 |
| 10 | 1 | 2 |
| 11-15 | 1 | 2 |
| 16+ | <u>2</u> | <u>3</u> |
| | 100% | 180 |

*One respondent did not answer this question.

Appendix G

What were you convicted of on this sentence?

| <u>Response</u> | <u>% of Subjects</u> | <u>No. of Subjects</u> * |
|---|----------------------|--------------------------|
| Robbery | 33 | 60 |
| Homocide | 18 | 33 |
| Larceny, burglary, theft | 14 | 26 |
| Assault-battery | 9 | 17 |
| Rape | 8 | 15 |
| Drugs | 7 | 12 |
| Breaking and entering | 3 | 5 |
| Carrying concealed weapon; possession of weapon | 2 | 4 |
| Kidnapping | 2 | 4 |
| Fraud, forgery | 2 | 3 |
| Unlawful driving away | 2 | 3 |
| Escape, bond jumping, parole violation | 2 | 3 |
| Fraudulent check | 1 | 2 |
| Indecency | 1 | 2 |
| Arson | 1 | 1 |
| Bribery, extortion | 1 | 1 |
| Destruction of property | 1 | 1 |
| Prostitution/procurng | 1 | 1 |
| Receiving stolen property | 1 | 1 |
| Other (sex abuse, lewd and lascivious acts) | 2 | 4 |

* Some subjects were convicted for more than one offense and therefore the percentages total more than 100%.

Appendix H

How many months or years have you been in this prison on your present sentence?

| <u>Response</u> | <u>% of Subjects</u> | <u>No. of Subjects</u> * |
|--------------------|----------------------|--------------------------|
| Less than 6 months | 6% | 11 |
| 6 months - 1 year | 11 | 19 |
| 1+ - 2 years | 19 | 34 |
| 2+ - 5 years | 41 | 74 |
| 5+ - 10 years | 19 | 35 |
| More than 10 years | <u>4</u> | <u>7</u> |
| | 100% | 180 |

* One respondent did not answer this question.

Appendix I

How much longer does your sentence have to run?

| <u>Response</u> (number of years) | <u>% of Subjects</u> | <u>No. of Subjects</u> * |
|-----------------------------------|----------------------|--------------------------|
| 1 | 18% | 32 |
| 2 | 7 | 13 |
| 3 | 9 | 15 |
| 4 | 3 | 6 |
| 5 | 7 | 13 |
| 6-10 | 14 | 26 |
| 11-15 | 5 | 8 |
| 16-20 | 9 | 15 |
| 21-30 | 5 | 8 |
| 31-40 | 2 | 3 |
| 41 to life | 19 | 34 |
| Other responses | 1 | 1 |
| Don't know | <u>1</u> | <u>2</u> |
| | 100% | 176 |

* Five respondents did not answer this question.

Appendix J

When will you be eligible for parole?

| <u>Response</u> | <u>% of Subjects</u> | <u>No. of Subjects</u> * |
|---|----------------------|--------------------------|
| Within 6 months or less, already eligible | 37% | 65 |
| 6 months - 1 year | 27 | 47 |
| 1 - 2 years | 10 | 17 |
| 2 - 3 years | 6 | 10 |
| 3 - 5 years | 7 | 12 |
| More than 5 years | 11 | 19 |
| Never | 1 | 1 |
| Don't know | $\frac{1}{100\%}$ | $\frac{1}{172}$ |

* Nine respondents did not answer this question.

ADDENDUM II
to
RESEARCH IN PRISONS

Survey Research Center
Institute for Social Research
The University of Michigan
April 4, 1976

The purpose of this Addendum is to provide the Commission with some additional information on biomedical research involving prisoners. The data to be presented below center around three main issues: (1) similarities and differences between prisoner subjects and non-subjects; (2) characteristics of consent forms in relation to characteristics of research projects; and (3) the amount of compensation received by prisoners in relation to the risk involved and the amount of time spent on the project.

Tables 1, 2, and 3 provide comparative data on subjects and non-subjects along three variables: Employment Status, Race, and Education. The data presented in these three tables are based on interviews conducted in two prisons. Table 1 illustrates that the subjects in our sample were more likely to hold prison jobs than were the randomly selected non-subjects. Table 2 shows that black inmates constituted 41 percent of the non-subject sample but only 18 percent of the subject sample. In one of the two prisons, a disproportionately large number of white respondents (as opposed to the black and other minority respondents) were subjects rather than non-subjects. In the other prison, the distribution of subjects was similar to that of non-subjects. Table 3 compares subjects and non-subjects in terms of their education. The two groups seem to differ along this variable; for example, 57 percent of the subjects had at least a high school education but only 26 percent of the non-subjects had completed twelve or more years of school.

The next set of tables focuses on characteristics of the research projects in relation to the content of the consent forms used in those projects. Table 4 indicates that nine investigators reported that placebos were used in their projects and in six of these cases placebos were mentioned or alluded to in the consent forms. Three consent forms did not mention placebos, and placebos

apparently were not mentioned in the oral explanations given to the subjects participating in these projects. [All investigators were asked to tell our interviewers about all the topics covered orally when obtaining consent from subjects. None of the investigators who were interviewed reported that placebos were mentioned in their oral explanations. It is possible that some investigators might have explained the use of placebos to subjects, but failed to report this to our interviewers.]

Single- or double-blind procedures were used in 17 projects, and four of the consent forms used for these projects mentioned the blind procedure (see Table 5). In the 13 projects where these procedures were used but not noted in the consent forms, they were not mentioned orally either. Table 6 illustrates that multiple treatments or procedures were used in 35 projects. These projects include those that employed single- or double-blind procedures, random assignment of treatments, cross-over designs, placebos, control group(s), and/or multiple treatment or experimental groups. Twenty-four of the relevant consent forms mentioned the use of multiple treatments or procedures and the other 11 did not. For these 11 projects, the oral explanation apparently did not include a reference to the multiple treatments. The methods used for assigning subjects to treatments were mentioned in three consent forms (see Table 7). Subject assignment methods were not mentioned in the consent forms (nor orally) in the 32 other projects which used multiple treatments or procedures.

Table 8 shows that confidentiality often is not mentioned in consent forms where there is "no risk of a breach of confidentiality." According to the investigators, there was some (low) risk of a breach of confidentiality in only five projects and the consent form associated with each of these five projects did mention confidentiality. Table 9 is based on investigators' estimates of

the risk of medical complications to subjects as a result of participating in the projects. For those projects with a very low risk of minor medical complications, physical risks were mentioned in approximately half of the consent forms. Physical risks were mentioned in 90 percent of the consent forms for projects with a very low risk of serious medical complications or a medium risk of minor complications. (As reported in Table 6, page 20, of the Research in Prisons report, no projects were described as having a low, medium or high probability of serious medical complications.)

As noted in Table 10, 13 investigators reported that provisions had been made for financially compensating subjects for harmful effects. An equivalent number said that no provisions had been made, and 11 said that they didn't know whether such provisions existed. None of the consent forms mentioned any provisions for financially compensating subjects for harmful effects.

Table 11 focuses on the extent to which "procedures to be followed" were explained to subjects. [Note: it was assumed that an explanation of procedures would be appropriate for each project in the sample. Consequently, this table was formatted differently than the preceding tables.] Procedures were explained orally to the subjects who participated in practically every project. Additionally, procedures to be followed were described in detail in 28 consent forms.

The final table in this Addendum focuses on the pay received by subjects in relation to some characteristics of the research projects. Subjects who participated in projects with "no risk" of medical complications received less pay than those who participated in projects with "a very low" risk of complications. However, the average pay received by subjects was lower when the medical complications were seen as "serious" than when the complications were reported as "minor." (The correlation between pay and a variable which combines

the probability and seriousness of medical complications was .07, n = 127).

The relationship between pay and the risk of psychological complications also was weak. (Pay was negatively correlated with a variable which combines the probability and seriousness of psychological stress-- $r = -.31$, n = 94).

The amount of time spent on the project was the only variable which was associated with pay. Subjects who reported relatively high levels of pay also reported relatively lengthy involvement with the project. (The correlation between pay and time spent on the project, as reported by subjects, was .43, n = 106. A similar correlation was obtained when time involved was based on investigators' estimates.) A "by-prison" analysis indicates that pay tended to be associated with time spent on the project in three of the four prisons where subjects were interviewed.

Table 1

Subjects vs. Non-Subjects: Employment Status^{*}

| <u>Employment Status</u> | <u>Subjects</u> (n = 93) | <u>Non-Subjects</u> (n = 44) | <u>Total</u> (n = 137) |
|--------------------------|-----------------------------|---------------------------------|---------------------------|
| Employed | 89% | 64% | 81% |
| Unemployed | <u>11</u> | <u>36</u> | <u>19</u> |
| Total | 100% | 100% | 100% |

* These data represent the responses of subjects and non-subjects, in two prisons, to the question: "Do you have a regular prison job?" In both of these prisons, subjects were more likely to hold jobs than were the non-subjects.

Table 2

Subjects vs. Non-Subjects: Race^{*}

| <u>Race</u> | <u>Subjects</u> (n = 93) | <u>Non-Subjects</u> (n = 44) | <u>Total</u> (n = 137) |
|----------------|-----------------------------|---------------------------------|---------------------------|
| Black | 18% | 41% | 25% |
| Other minority | 7 | 7 | 7 |
| White | <u>75</u> | <u>52</u> | <u>68</u> |
| Total | 100% | 100% | 100% |

* These data represent the subjects and non-subjects who were interviewed in two prisons. In one of these prisons, the distribution of subjects and non-subjects by race was roughly equivalent. In the other prison, a disproportionately large number of the white respondents (as opposed to the black and other minority respondents) were subjects rather than non-subjects.

Table 3

Subjects vs. Non-Subjects: Education*

| <u>Highest Grade</u> | <u>Subjects</u> (n = 93) | <u>Non-Subjects</u> (n = 43) | <u>Total</u> (n = 136) |
|----------------------------------|-----------------------------|---------------------------------|---------------------------|
| seventh or less | 4% | 10% | 6% |
| eighth | 11 | 2 | 8 |
| ninth | 5 | 14 | 8 |
| tenth | 9 | 28 | 15 |
| eleventh | 13 | 21 | 15 |
| twelfth | 30 | 5 | 22 |
| one year post-secondary | 15 | 12 | 14 |
| two or more years post-secondary | <u>12</u> | <u>9</u> | <u>12</u> |
| Total | 99% | 101% | 100% |

* These data represent the education levels of subjects and non-subjects who were interviewed in two prisons. One non-subject did not provide information on his education.

[Note: the data presented in Tables 4-12 were collected from five prisons.]

Table 4

The Use of Placeboes in Research Projects
in relation to
the Mention of Placeboes on Consent Forms

| | <u>A Placebo Was Used</u> (No. of Projects) | <u>A Placebo Was Not Used</u> (No. of Projects) | <u>Total</u> (No. of Projects) |
|---|--|--|-----------------------------------|
| Use of a placebo was <u>mentioned</u> on the consent form | 6 | 2 | 8 |
| Use of a placebo was <u>not mentioned</u> on the consent form | <u>3</u> * | <u>30</u> | <u>33</u> |
| Total | 9 | 32 | 41 |

* Additionally, these investigators did not mention the use of a placebo in their oral explanations to subjects when obtaining consent.

Table 5

The Use of Single- or Double-Blind Procedures in Research Projects
in relation to
the Mention of Single- or Double-Blind Procedures on Consent Forms

| | <u>A Blind Procedure</u> <u>Was Used*</u> (No. of Projects) | <u>A Blind Procedure</u> <u>Was Not Used</u> (No. of Projects) | <u>Total</u> (No. of Projects) |
|---|---|--|-----------------------------------|
| Use of a blind procedure was <u>mentioned</u> on the consent form | 4 | 2 | 6 |
| Use of a blind procedure was <u>not mentioned</u> on the consent form | <u>13</u> ** | <u>22</u> | <u>35</u> |
| Total | 17 | 24 | 41 |

*A project was classified as using a blind procedure if the investigator reported that either a single-blind or double-blind procedure was employed.

** Additionally, these investigators did not mention the use of a blind procedure in their oral explanations to subjects when obtaining consent.

Table 6

The Use of Multiple Treatments or Procedures in Research Projects
in relation to
the Mention of Multiple Treatments on Consent Forms

| | <u>Multiple Treatments Were Used*</u> (No. of Projects) | <u>Multiple Treatments Were Not Used</u> (No. of Projects) | <u>Total</u> (No. of Projects) |
|---|--|---|-----------------------------------|
| Use of multiple treatments was <u>mentioned</u> on the consent form | 24 | 2 | 26 |
| Use of multiple treatments was <u>not mentioned</u> on the consent form | <u>11</u> ** | <u>4</u> | <u>15</u> |
| Total | 35 | 6 | 41 |

* A project was classified as using multiple treatments or procedures if the investigator reported that any of the following were used: single- or double-blind procedures, random assignment of treatments, cross-over designs, placebos, control group(s), and/or multiple treatment or experimental groups.

** Additionally, these investigators did not mention the use of multiple treatments or procedures in their oral explanations to subjects when obtaining consent.

Table 7

The Use of Multiple Treatments or Procedures in Research Projects
in relation to
the Mention on Consent Forms of the Methods Used to Assign Subjects to Treatments

| | Multiple Treatments Were Used* <hr/> (No. of Projects) | Multiple Treatments Were Not Used <hr/> (No. of Projects) | <u>Total</u> (No. of Projects) |
|--|--|---|-----------------------------------|
| Assignment methods were <u>mentioned</u> on the consent form | 3 | 0 | 3 |
| Assignment methods were <u>not mentioned</u> on the consent form | <u>32</u> ** | <u>6</u> | <u>38</u> |
| Total | 35 | 6 | 41 |

* Methods for assigning subjects to treatments seem applicable only to those projects which used multiple treatments or methods. A project was classified as using multiple treatments or procedures if the investigator reported that any of the following were used: single- or double-blind procedures, random assignment of treatments, cross-over designs, placebos, control group(s), and/or multiple treatment or experimental groups.

** Additionally, these investigators did not mention the method for assigning subjects to treatments in their oral explanations to subjects when obtaining consent.

Table 8

Risk of a Breach of Confidentiality
in relation to
the Mention of Confidentiality on Consent Forms

| | <u>No Risk of a Breach of Confidentiality</u> (No. of Projects) | <u>Some (Low) Risk of a Breach of Confidentiality</u> (No. of Projects) | <u>Total</u> (No. of Projects) |
|--|--|--|-----------------------------------|
| <u>Confidentiality was not mentioned on the consent form</u> | 26 | 0 | 26 |
| <u>Protection of confidentiality was mentioned on the consent form</u> | 7 | 4 | 11 |
| <u>Limits on confidentiality were mentioned on the consent form</u> | <u>2</u> | <u>1</u> | <u>3</u> |
| Total | 35 | 5 | 40* |

* One investigator did not provide data on the risk of a breach of confidentiality, but the relevant consent form mentioned confidentiality. None of the investigators mentioned confidentiality in their oral explanations to subjects when obtaining consent.

Table 9

Risk of Medical Complications
in relation to
the Mention of Physical Risks on Consent Forms

| | <u>No Risk of Medical Complications</u> (No. of Projects) | <u>Very Low Risk of Minor Medical Complications</u> (No. of Projects) | <u>Very Low Risk of Serious Medical Complications*</u> (No. of Projects) | <u>Total</u> (No. of Projects) |
|--|--|--|---|-----------------------------------|
| Physical risks were <u>not mentioned</u> on the consent form | 2 | 7 | 2 | 11 |
| Physical risks were <u>mentioned</u> on the consent form | 3 | 6 | 16 | 25 |
| Physical risks were <u>described in detail</u> on the consent form | <u>1</u> | <u>0</u> | <u>3</u> | <u>4</u> |
| Total | 6 | 13 | 21 | 40** |

* Also included in this "serious medical complications" category are projects where the investigators estimated that the risk of minor medical complications was greater than "very low" (i.e., low or medium).

** One investigator provided incomplete information on medical complications, but the relevant consent form mentioned physical risks.

Table 10

Provisions for Financially Compensating Subjects for Harmful Effects
in relation to
the Mention of These Provisions on Consent Forms

| | <u>Provisions for Financial Compensation</u> (No. of Projects) | <u>No Provisions for Financial Compensation</u> (No. of Projects) | <u>Uncertainty Regarding Provisions</u> [*] (No. of Projects) | <u>Total</u> (No. of Projects) |
|--|---|--|---|-----------------------------------|
| Provisions were <u>mentioned</u> on the consent form | 0 | 0 | 0 | 0 |
| Provisions were <u>not mentioned</u> on the consent form | <u>13</u> | <u>13</u> | <u>11</u> | <u>37</u> |
| Total | 13 | 13 | 11 | 37 ^{**} |

* Eleven investigators responded "don't know" to the question "Is there any provision for giving financial compensation to subjects should they suffer any harmful effects due to this research?"

** Data provided by four investigators were insufficient for inclusion in this table.

Table 11

Oral Explanations of "Procedures to be Followed"
in relation to
the Mention of These Procedures on Consent Forms

| | <u>Procedures Were Not Explained Orally</u> (No. of Projects) | <u>Procedures Were Explained Orally</u> (No. of Projects) | <u>Total</u> (No. of Projects) |
|--|--|--|-----------------------------------|
| Procedures were <u>not mentioned</u> on the consent form | 0 | 0 | 0 |
| Procedures were <u>mentioned</u> on the consent form | 2 | 11 | 13 |
| Procedures were <u>described in detail</u> on the consent form | <u>0</u> | <u>28</u> | <u>28</u> |
| Total | 2 | 39 | 41 |

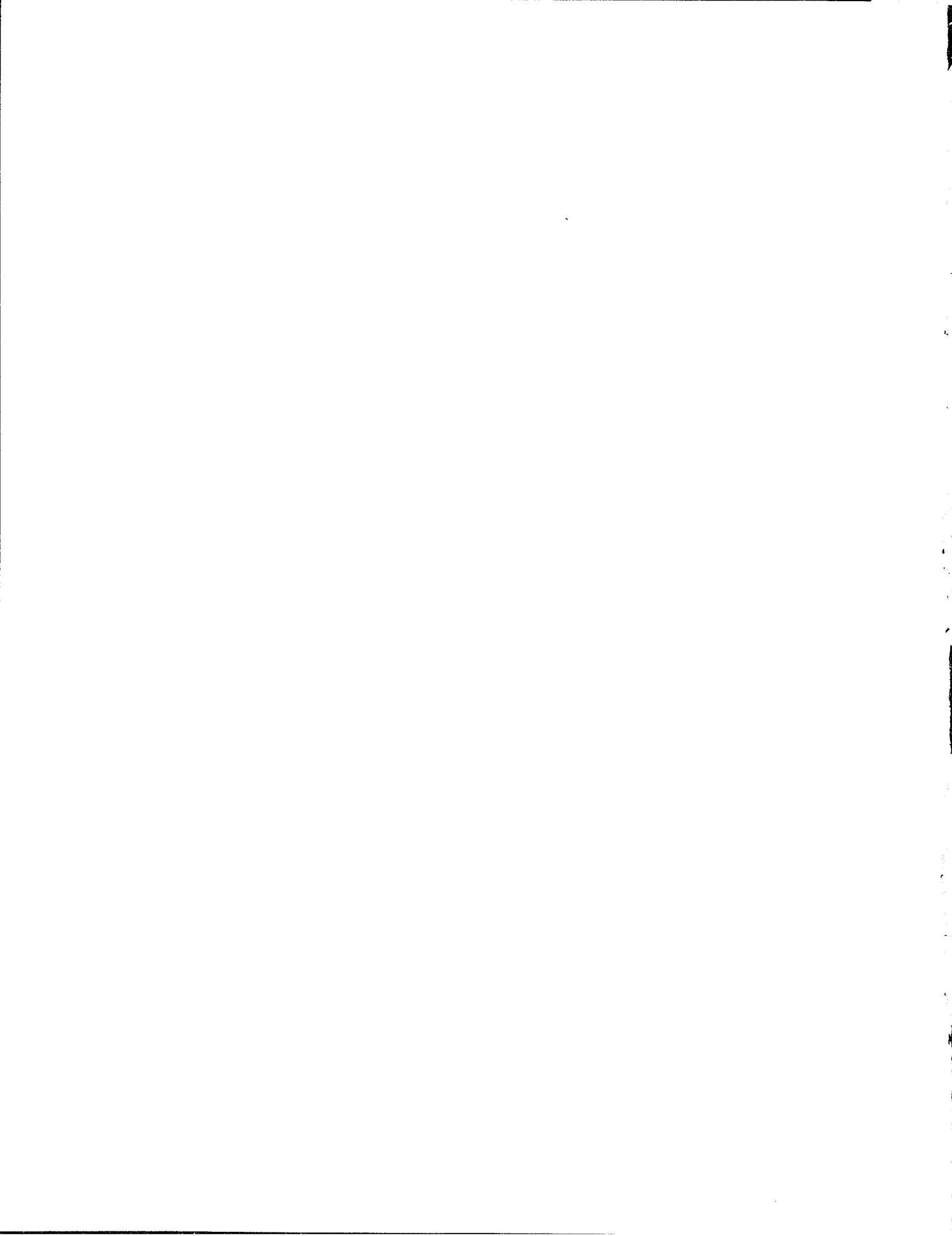
[Note: the data presented in Table 12 were collected from four prisons.]

Table 12

Amount of Pay Received by Prisoners for Serving as Subjects
in relation to
Selected Characteristics of the Research Projects

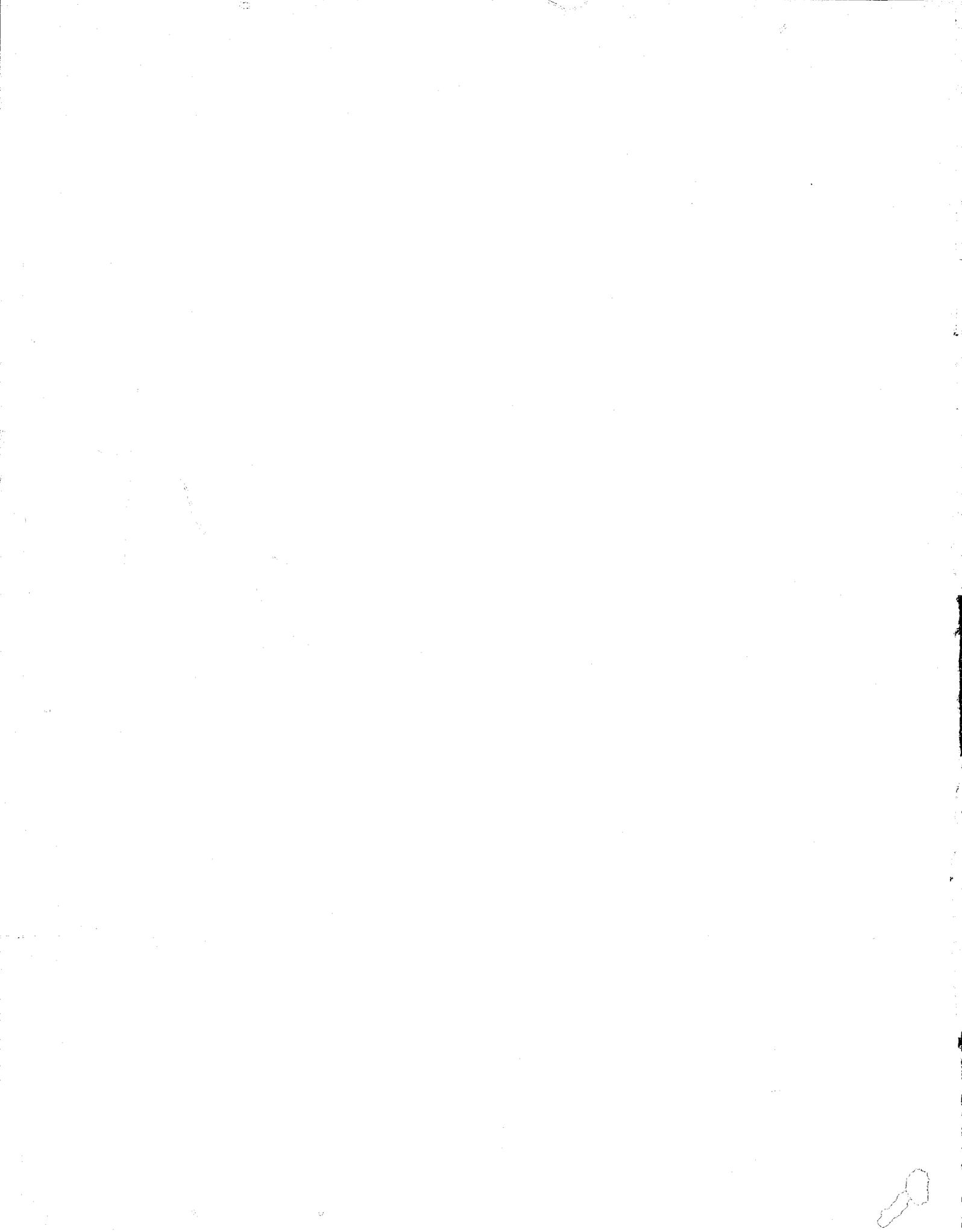
| | <u>Average Amount of Pay</u> |
|--|------------------------------|
| <u>Risk of Medical Complications</u> | |
| -no risk | \$47 |
| -very low risk of minor complications | 71 |
| -very low risk of serious complications (or low-medium risk of minor complications) | 59 |
| <u>Risk of Psychological Complications</u> | |
| -no risk | 71 |
| -very low risk of minor psychological stress | 72 |
| -very low risk of serious psychological stress (or low-medium risk of minor stress) | 38 |
| <u>Time Involved</u> * | |
| (1) very small amount of time | 25 |
| (2) | 26 |
| (3) | 37 |
| (4) | 60 |
| (5) | 77 |
| (6) | 78 |
| (7) very great amount of time | 160 |

*These time estimates are based on prisoners' responses to two questions regarding the amount of time they spent on the research project: (1) average time per day and (2) number of days.



SURVEY: USE OF PRISONERS IN DRUG TESTING, 1975

Pharmaceutical Manufacturers Association



Survey - Use of Prisoners in Drug Testing, 1975

Fifty-one companies responded to this Survey by March 10, 1976. These companies account for about three-quarters of annual Pharmaceutical Research and Development expenditures of the PMA membership. Sixteen indicate use of prisoners in research; thirty-five do not use prisoners. The findings are summarized below. Responses refer to R&D activities conducted by firms, either by their own employees or under contract, in calendar year 1975.

1. Did your company conduct any research involving prisoners (i. e., residents of prisons, jails or other correctional facilities) as subjects in 1975? YES: 16 NO: 35

THE ANSWERS TO QUESTION 2-8 WHICH FOLLOW RELATE ONLY TO THE 16 COMPANIES WHICH CONDUCTED RESEARCH USING PRISONER VOLUNTEERS.

2. Was the research conducted by your own employees or under a contract? If both, please indicate percentage for each.

Company Employees: 4 Contractor: 10 Using both: 2

3. Did the research with prisoners involve:

| | | |
|----------------------|---------|-------|
| Phase I drug testing | YES: 14 | NO: 2 |
| Other drug testing | YES: 7 | NO: 9 |

4. Approximately how much of your Phase I drug testing was conducted on prisoners?

Response to Question 4, is shown below, together with percentage breakdown for testing indicated in Question 3.

| <u>Question 3, Testing with Prisoners</u> | | <u>Question 4</u> |
|--|-------------------------------------|---|
| <u>Phase I testing as a percentage of all testing with prisoners</u> | <u>Other testing with prisoners</u> | <u>Use of Prisoners in Phase I testing as a percentage of overall company Phase I tests</u> |
| 100% | - | 100% |
| 100 | - | 55 |
| 100 | - | 55 |
| 100 | - | 50 |
| 100 | - | 25 |
| 100 | - | 13 |
| 100 | - | 12 |
| 100 | - | 2 |
| 100 | - | 50 |
| 90 | 10% | 75 |
| 85 (+ 10% Devices) | 5 | 75 |
| 70 | 30 | 10 |
| 50 | 50 | 3 |
| 25 | 75 | 85 |
| - | 100 | - |
| - | 100 | - |

5. Of this Phase I testing on prisoners.

TOTALS

a. How many different substances were tested? 71

Median 3
Mode 2
Range 1-20
Inter-Qu. Range 2-7

b. How many protocols were involved? 100

Median 5
Mode 3.5
Range 1-28
Inter-Qu. Range 2-5

c. How many prisoners were involved? 3593

Median 150
Mode 150
Range 21-1381
Inter-Qu. Range 89-299

NOTE: Testing includes the following:

Influenza Vaccine
PPD Tine (Skin Test)
Draize Sensitization Test
Topical Sensitization and primary irritation evaluation

6. Please list the prisons from which the research subjects were obtained, and indicate if the prison is a state, county or municipal facility. Indicate also percentage of research conducted in each installation.

| <u>Location</u> (alphabetical, by state) | <u>Prison</u> | <u>State, County, City Facility</u> | <u>Number of companies testing in prison indicated</u> | <u>Percentage of company-testing with-prisoners conducted in prison indicated</u> |
|---|--|---|--|---|
| Florence, AZ | Arizona State | State | 1 | 100 |
| Vacaville, CA | California Medical Facility | State | 4 | 100 each |
| Vacaville, CA | Correctional Medical Facility | State | 1 | 50 |
| Vacaville, CA | Solano Institute for Medical and Psychiatric Research | State | 2 | 45, 15 |
| Indianapolis, IN | Marion County Jail | County | 1 | 10 |
| Pendelton, IN | Indiana Reformatory | State | 1 | 90 |
| West Boylston, MA | Worcester County Rehabilitation and Detention Center | County | 2 | 100, 50 |
| Jessup, MD | House of Correction | State | 1 | 100 |
| Plymouth, MI | Detroit House of Correction | City | 1 | 6 |
| Ionia, MI | Ionia Reformatory | State | 1 | 4 |
| Jackson, MI | State Prison of Southern Michigan | State | 2 | 90, 85 |
| Kansas City, MO | Leeds Farm Municipal Correction Institute | City | 1 | 50 |
| Deer Lodge, MT | Deer Lodge Institute | State | 1 | 50 |
| Deer Lodge, MT | Montana State | State | 1 | 100 |
| Coldwell, NJ | Essex County Corrections Center | County | 1 | 100 |
| Dayton, OH | Dayton Workhouse | State | 1 | 55 |
| Lebanon, OH | Lebanon Correction Institute | State | 1 | 50 |

7. Were detainees (persons in prison prior to conviction and held in lieu of bail) utilized in the research?

YES: 0 NO: 14

DON'T KNOW: 2

8. Were the prisoner-subjects located in maximum or minimum security prisons? Please indicate also percentage for each category.

| | <u>Companies</u> | <u>Percentage</u> |
|---------------------------|------------------|---|
| Maximum only: | 2 | 100% |
| Minimum only: | 10 | 100 |
| Both maximum and minimum: | 3 | 70 (max) and 30 (min) 45 (max) and 55 (min) 81 (max) and 19 (min) |
| Don't know: | 1 | - |

9. On what groups of subjects did your company conduct Phase I drug studies in 1975? Please indicate if possible the percentage of the total number of subjects coming from each group.

Prisoners • College Students • Medical Students •
 Company Employees • Residents of foreign countries •
 Institutionalized Individuals • Others •

| Prisoners | College Students | Medical Students | Company Employees | Residents of foreign countries | Institutionalized Individuals | Other |
|-----------|------------------|------------------|-------------------|--------------------------------|-------------------------------|-------|
|-----------|------------------|------------------|-------------------|--------------------------------|-------------------------------|-------|

[lines add to 100%]

| | | | | | | |
|--|------|-----|-----|-----|-----|-----|
| • 100% | - | - | - | - | - | - |
| • - | 100% | - | - | - | - | - |
| • - | 80 | - | - | - | - | 20 |
| • - | 80 | - | - | - | - | 20 |
| • 75 | - | 3% | 12% | 10% | - | - |
| • 60 | - | - | - | - | - | 40 |
| • 55 | 1 | - | 14 | - | - | 30 |
| • - | 53 | 29 | - | - | - | 18 |
| • - | 50 | - | 10 | - | - | 40 |
| • 50 | 45 | - | 5 | - | - | - |
| • - | 50 | 50 | - | - | - | - |
| • - | 44 | 15 | - | - | - | 41 |
| • - | 40 | 5 | - | - | - | 55 |
| • - | 39 | 3 | - | - | - | 58 |
| • - | 35 | 5 | 30 | 30 | - | - |
| • 25 | 19 | - | - | - | 42% | 14 |
| • - | 23 | - | 6 | - | - | 71 |
| • 12 | 17 | 4 | - | 21 | - | 46 |
| • 17 | 15 | - | - | 9 | 10 | 49 |
| • - | 10 | - | 10 | - | 10 | 70 |
| • - | 10 | - | - | 10 | 50 | 30 |
| • 13 | - | - | - | - | 65 | 22 |
| • 10 | 50 | - | - | 10 | 10 | 20 |
| • 9 | 6 | 6 | 8 | 31 | - | 37 |
| • - | - | 100 | - | - | - | - |
| • - | - | 5 | - | - | 20 | 75 |
| • - | - | - | 100 | - | - | - |
| • - | - | 15 | - | 43 | - | 42 |
| • - | - | - | - | - | - | 100 |
| • - | - | - | - | - | - | 100 |
| • - | - | - | - | - | - | 100 |
| • Prisoners, College Students and Company employees: | - | - | - | - | 85% | 15 |
| • 50 | - | - | 23 | - | - | 27 |

9. Question 9 continued:

Companies not listed, either did not conduct Phase I studies or did not respond to this question.

Use of residents of foreign countries is made by foreign owned companies, and by U. S. companies in research abroad.

"Others" include the following: Hospital patients • Members of fraternal organizations • Armed Forces personnel • Outpatients • Allied medical personnel • Physicians • Nurses • Population at large • Students.

10. Does your company have an insurance policy or any other mechanism for compensating subjects who might be injured in research?

YES: 33 NO: 12

NO RESPONSE: 6

If Yes, is this compensation in the form of medical care, financial award, or both?

Medical Care only: 11 Financial Award only: 7

Both: 14 No response or explained in comments: 19

Comments concerning compensation:

"Although we have no specific insurance policy for monetary compensation, it is our company policy to bear all costs for medical care in case of injury or significant side effect requiring such care."

"Upon request, the investigator is provided a statement: '...' agrees that it will provide payment for medical costs incurred by any patient as a direct result of the drug or application thereof related to the patient's participation in this trial to the extent that the patient's medical expenses are not otherwise covered by existing health care programs or insurance policies."

10. Comments continued

"Company policy covers subjects for Medical Expenses and Loss of Income. In addition active follow-up procedures are placed in operation to insure that subjects injured in research obtain best available medical care."

"The Company's product liability insurance policy covers claims against the Company alleging injury arising out of drug testing in those cases where, despite informed consent, the Company may be deemed to be legally at fault. The Company's insurance policy also covers claims against the investigator so long as he has followed the Company's protocols and has not been otherwise negligent."

"As a matter of policy, the company is responsible for care and followup as well as evaluation of adverse events associated with studies. Each case is handled on an individual basis."

"A claim would be made under the comprehensive general liability policy held by the company."

"Approach on a case-by-case basis."

"Any medical complication related to the administration of a drug would be evaluated by our medical staff as well as that of the prison, and possibly by a consultant, and any expenses resulting from such a complication, if confirmed to be drug-related, would be borne by the investigator."

"We do not have specific insurance for medical care to cover clinical test subjects. - We do have general insurance to cover liability for any such purpose. "

"Insurance, which would protect us in case of liability action brought by injured subject."

"Financial award would occur only in the event of litigation, and would be underwritten by the insurance company. - Continuing medical care for those injured in research is a Company policy which is implemented at the discretion of the Medical Department!"

"Subjects are covered under the Comprehensive General Liability Coverage of '...' secondary to the liability insurance of the investigator. "

"We have not as yet had any need to use this mechanism. "

"We are covered by an insurance policy which would encompass those areas decreed by the underwriters. "

10. Comments continued

"Would be handled as a product liability claim."

"Details not available -- will furnish at later date."

"We have self-insurance policy in case anyone presents a claim."

"Company self insurance."

"We have a specific endorsement to our product liability insurance policy which provides a maximum \$500,000 coverage per occurrence."

"If a subject is 'injured' during Phase I study we provide medical care until that subject has fully recovered. We do not have an insurance policy for such expenses."

"The Company carries liability insurance to cover any cases where the Company is held legally liable for injuries resulting from its research."

"We have had no instances where a demand for medical care or compensation has been made. We do not have health insurance per se, but if an allegation of negligence is made we are insured."

"Liability indemnification contract."

"Company will be responsible for medical expenses incurred by participants in its clinical trials under the following conditions:

1. There was no material deviation from the protocol.
2. Company is given prompt written notice of the claim.
3. The investigator and persons involved in the study cooperate fully in the investigation of the claim.
4. No negligent act was committed by the investigator or his agent if a non-company employee was the investigator.

Company will pay such expenses whether or not it has insurance coverage."



SUMMARY REPORT AND RECOMMENDATIONS ON PRISONS:
The National Minority Conference
on Human Experimentation

Two Workshops of the National Minority Conference
on Human Experimentation, held January 6-8, 1976,
were devoted to the topic of
research involving prisoners.



NATIONAL URBAN COALITION

PRESIDENT - M. Carl Holman

NATIONAL MINORITY CONFERENCE ON HUMAN EXPERIMENTATION

CONFERENCE CHAIRMAN - David A. Browne
CONFERENCE DIRECTOR - Geraldine Brooks
ASSISTANT DIRECTOR - Evelyn Armstrong
SECRETARIAL STAFF - Joann Hysan/Patricia Lightfoot

THIS REPORT WAS PREPARED BY THE NMCHE STAFF

INTRODUCTION

Summary of Plenary Sessions

The attached summary represents a comprehensive, but far from complete, survey of the papers, plenary sessions and workshop tapes relative to prison research. Due to time constraints on staff in an auditing of the tapes and review of the papers, we would like to apprise the Commission that we regard this as still not as comprehensive a report as desirable. Without a personal audit of the actual tapes, it is difficult, if not impossible, to get a true picture of the sessions involved. We would recommend, therefore, that we have these tapes professionally transcribed for your further review.

PARTICIPANTS - Plenary Session - Prisons

Moderator - Professor Heywood Burns
J.D., NYU Law School, New York, New York

Presentors of Papers:

Joyce Cooke, Ph.D., Department of Philosophy
Howard University, Washington, D. C.

Larry I. Palmer, J.D., Cornell University Law School

L. Alex Swan, Ph.D., J.D., Fisk University
Nashville, Tennessee

Respondents:

Lewis Douglas, Executive Deputy Commissioner Corrections
State of New York

Richard "Mafundi" Lake, Director IFA Defense Committee
Former inmate Alabama Prison System

Frank Pogue, Ph.D., Professor and Department Chairman
State University of New York at Albany



CONTINUED

4 OF 8

SUMMARY OF THE PLENARY SESSIONS AND WORKSHOP SESSIONS

Use of Prisoners in Human Experimentation

A careful and thoughtful perusal of the papers presented before the plenary session on research in prisons allows the reader the opportunity to appreciate the excellence of these in-depth, scholarly pieces of work. A review of the workshop recommendations made to the Commission on this subject provide a terse, concise set of guidelines designed for action rather than philosophical discussion. However, listening to the tapes made during the plenary session -- the presentation of the papers and the responses to their delivery -- and to the following workshop sessions provide the auditor with the real essence of the problem of human experimentation in prisons. No other medium has captured the interplay of diverse ideas, the diversity of the Conferees, the final symbiosis achieved.

Debate ranged from the complete abolition of the prison system to a more realistic -- and hopeful -- change through government intervention and the eventual establishment of a national model for research design. Between these extremes, even without lengthy discourse on the more horrendous examples of abuse in prison-based experimentation, there appeared a serious concern for the moral and civil rights of this captive/coerced subject group and the minority population which they represent; an immediate need for a research moratorium to investigate and evaluate both behavioral and biomedical research in the prison setting; and the establishment of permanent safeguards for prisoner-experiment subjects.

There are basic ethical considerations about the prison system in society and the relationship between the needs of the state and the prison system. Experiment subjects are viewed as not only subjects of research but subjects of the state; that the imposition of the will of the state is an imposition on the will of the subjects. The relationship of the issue of race, religion and nationality and scientific experiments on human beings looms large because of the Nazi concentration camp experiments on captives during World War II. Since there is a disproportionate Third World representation in prisons today, it is agreed that the issue of prisoners and race are merged. It is unethical to ask minority prisoners to bear the greater portion of risk when benefitting society at large. Any required risks should be evenly distributed in the prison society itself as well as among all ethnic groups in society.

There appears to be an obvious correlation between human research in prison and the kind of health care services available to those people who usually become prisoners: the poor and the minorities. The lack of adequate health care delivery to this widespread population, therefore, must bring up the question of the fine line between research and treatment. As this inadequacy is shared by the poor, both in and out of prison, it is felt that the two concerns cannot be separated; that prisoners and the poor share the same inducements, the same lack of knowledge, the same lack of legal redress as research subjects. That, in fact, the poor are the same victims as the prisoners in human experimentation.

The principle of informed consent, first formulated in the Nuremberg Code spells out requirements governing medical experimentation on human beings. This principle is of paramount importance to the legality of using prisoners as subjects. A basic tenet of the Code states: "The voluntary consent of the human subject is absolutely essential." The prison environment, regarded as intrinsically coercive, casts serious suspicion upon the very concept of authentic consent, insofar as the latter implies autonomy. Few decisions of any nature can be made in the prison setting which are free, which are unpressured, which are informed. Whereas there can be no consent without sufficient information, there can be consent without willingness. Hence the Nuremberg Code stresses the voluntary nature of consent. Voluntary consent means free and full affirmative judgement. By definition, no informed consent is possible within the context of confinement in prison with its coercive environment as the backdrop of such choices. Without the ethical requirements of informed consent, it is impossible to justify the legal requirements now accepted.

Yet some prisoners insist that they have a legal right to participate in research experiments. Proponents of the establishment of a research model feel that by including prisoners in the complete research process, this facet -- as part of the entire research project -- can be legitimized. The prisoner as volunteer should be viewed as a participant in the experimentation process from the evaluation of the project's purpose, and its risks and benefits, subject selection, project progress review to final evaluation.

Obviously, prisoner participation in the research process is just a portion of future guidelines and safeguards delineated. A general consensus of opinion was voiced for a complete moratorium, rather than a total ban, on research experimentation until a national investigation is completed to determine the nature and current status of all experimental research design. The process of human experimentation and the allocation of public, professional and subject decision-making authority within that process must be understood to avoid the abuses of the past. The policies that determine how and why human experimentation is started is important to the manner in which value conflicts are resolved, whether the process can achieve the desired degree of social control.

A careful examination must be made of the purposes of any research that proposes to involve prisoners as subjects. Other questions to be answered: Are prisoners the appropriate subjects for this particular form of experimentation? What are the societal needs? What are the possible types of risk of harm that may flow and what steps have been taken to minimize those risks of harm? Who sets the priorities of these experiments? Who selects the subjects? Who monitors the project's progress? Who makes the necessary ethical and legal evaluation of the project's outcome?

The major method of reviewing the decisions throughout the process of human experimentation in prisons and the consequences of such experiments is through public scrutiny. Toward the end goal of a national model, it is recommended that a research unit which will affect all funding agencies and all prison administrators and all researchers, composed of inmates themselves and designated persons, should crystalize and set up guidelines for all prison research activities. Every prison experiment must involve a stage where either state or professional participants evaluate the research design and the scientific merits of the project. Before the question of consent is even presented to any prisoners, a host of other issues should be resolved in the formulation of research policy and in the administration of research. All prisons should establish an ongoing, in-house ethics committee to regularly discuss the absence of health care services and misuses on prisoners in biomedical, psychological, criminal and social research. The findings of these committees would act as active control in the process. Further, the process model forces the investigators, sponsoring agencies and prison administrators to articulate their own values about the purpose of incarceration, use of experimentation as a part of this purpose and the use of the incarcerated as subjects. Some serious questions of personal and professional morality must be faced before -- as well as during -- the project's undertaking.

In articulating the position of the Conference on human experimentation on prisoners, it was stated that it was not necessarily what position to take about experimentation in general or about no experimentation in society, but a question of strategy. It should be considered a political reality that human experimentation will continue and a political reality that it will be continued in the prison system. The political reality, therefore, is to focus on how best to protect, to safeguard the subjects of these experiments. It is the obligation of the Conference, the Commission and Congress to safeguard prisoners' -- subjects' -- rights. And, just as doctors cannot regulate doctors and lawyers cannot regulate lawyers; a permanent commission should be established not with the purpose of learning for society, but a body directed toward protecting the subjects of society's learning process.

STATEMENT ON CONFERENCE RECOMMENDATIONS

A cursory examination of the recommendations to the Commission from Workshops #7 and 8 on the use of prisoners in human experimentation would initially appear to be contradictory. For example, an item recommending a complete ban on all research may be in juxtaposition with a recommendation to establish a permanent Commission to evaluate and monitor prison research.

We would point out that this apparent contradiction reflects only the fact that from the outset recommendations were formed from a consensus of opinion rather than unanimous vote. The first line of #7's Preamble best illustrates this. . . "for a variety of reasons and from divergent perspective. . ."

Despite these sets of seemingly polarized viewpoints and recommendations, we would draw your attention to the fact that the composite recommendations show a similarity in pattern to the various alternatives suggested in the plenary session: a question of the validity of the prison system itself; a question of the use of the minority population within prisons as subjects; a question of the fine line between research and treatment; a question of the validity of informed consent in the prison setting. Additionally, there is a moratorium suggested allowing investigation and evaluation as well as for the establishment of a permanent oversight body to conduct and monitor any future human experimentation on prisoners.

Workshop 7

Resolution and Recommendations
of the
Workshop on Prisons

National Minority Conference
on
Human Experimentation
January 8, 1976

PREAMBLE

For a variety of reasons and from divergent perspectives, all of us believe that the prison system is in need of fundamental modifications. Some of us believe that prisons should be abolished. Others seriously question whether all of those presently incarcerated should be there. Therefore, our recommendations on biomedical and behavioral research reflect our honest skepticism about making recommendations for institutions whose social utility is in doubt.

I. RECOMMENDATIONS ON BIOMEDICAL RESEARCH ON PRISONERS

We recommend an immediate moratorium on all nontherapeutic biomedical research on prisoners until such time that comprehensive evaluation is made of the current status of human experimentation and health care delivery in prisons. By "nontherapeutic" research, we mean to include all biomedical research on healthy prisoners, i.e., prisoners who have not been accorded status as "patients."

During the moratorium, we recommend that there be a thorough and systematic attempt to develop methods to adequately control research in prisons. This attempt should include consideration of the following:

1. The purpose of the research.
2. Criteria for selection of subjects.
3. Assessment of risks of harm before actual implementation of any proposed research.
4. The responsibility of state and Federal regulatory bodies for administration of any prison research.
5. The responsibility of professional organizations for prison research.
6. The role of prisoners in the supervision of prison research.
7. The need for mechanism for monitoring and evaluating the prison research.
8. The supervision of current research in prisons.

9. The need for special legislation to control certain types of treatment.
10. Methods of reviewing the consequences of human experimentation.
11. Legislation to fix financial responsibility, including responsibility for any physical or other harm to prisoners who are subjects of experiments, on someone or institution other than the prisoner.
12. Providing means for prisoner access to court, legislatures, and national commissions.

II. RECOMMENDATIONS ON BEHAVIORAL RESEARCH ON PRISONERS

We understand neither the risk of harm nor the potential benefit of the wide variety of ongoing behavioral research programs in our prison system. First, we recommend that the focus of behavioral research be redirected. Any further deliberation on behavioral research in prisons should address the question of what is there about our social institutions that generates the need for so many behavioral research programs aimed at modifications of individual behavior. Second, we recommend that there be a shift of emphasis in all future inquiries away from behavioral research focusing on the individual prisoners to research endeavors aimed at understanding the nature of these institutions, and their effect on individual prisoners.

III. RECOMMENDATIONS ON INFORMED CONSENT

We are unwilling at this time to delineate the requirements of "informed consent" for research involving prisoners because of our doubts about the prison environment and whether true "informed consent" is possible in our nation's prisons.

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Workshop 8

Resolution and Recommendations
of the
Workshop on Prisons

National Minority Conference
on
Human Experimentation
January 8, 1976

POLICY:

Long Range Goal

The group realizes a distinct need for change and advocates abolition of the prison system as it presently exists in the United States.

We also recognize the necessity of federal, state, and local government making new commitment to eliminating dehumanizing conditions in prisons and creating viable community based alternatives in incarceration.

Therefore, the following Recommendations are of an interim nature in order to enhance and facilitate attainment of the foregoing long-range goal.

RECOMMENDATIONS:

1. That the Congress consider and legislate the establishment of a permanent Commission to develop guidelines, and to regulate and monitor human experimentation. The composition of this Commission should adequately reflect the diversity of the citizenry regarding race, sex, age, status, etc. This Commission should have the powers necessary to enforce regulations regarding human experimentation and set penalties for violations of such guidelines as they may establish.
2. That composition of the present Commission be altered to include black and other minority males, and representation of those persons who become subjects of human experimentation.

We express our dissatisfaction at composition of the present Commission.

3. That all bio-medical research and human experimentation in prisons and jails be banned.
4. That Human Review Committee with prisoner representation be established.
5. That psychosurgery on all prisoners be banned.
6. That the U.S. Department of Health, Education, and Welfare or the proposed new Commission be mandated to provide technical and legal resources to persons particularly, prisoners who are potential subjects of human experimentation.

PARTICIPANTS - Workshop #8 - Prisons

Iry Joyner, Commission for Racial Justice, New York, New York
Frank McClellan, Duquesne University Law School, Pittsburgh, Pa.
Mafundi - ex-inmate, Alabama Prison System
Dorothy Taylor, New Orleans, Louisiana
Lennox S. Hinds, NCBL, New York, New York
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STATE OF NEW YORK
DEPARTMENT OF CORRECTIONAL SERVICES
ALBANY, N. Y. 12226

BENJAMIN WARD
COMMISSIONER

January 19, 1976

Mr. M. Carl Holman
President
The National Minority Conference
on Human Experimentation
1201 Connecticut Avenue, N.W.
Washington, D.C. 20036

Dear Mr. Holman:

This is to let you know that I found the recent conference on Human Experimentation one of the best organized that I have recently attended. More important, however, I found it to be a conference which raised issues of unequalled importance to the minority community.

My only disappointment ... and one which I hope can be remedied ... is that three days or a single conference was not sufficient time to explore this issue.

The conference was the first effort that I know of to organize the thinking of the minority community about this issue. Indeed, I must confess that I was unaware of the existence of the National Commission until first receiving your invitation to participate.

As with the development of all public policy positions, it takes two steps. First the opportunity to focus on the issues ... followed by the second step of discussing the issues with associates so that the ideas become more crystallized.

The conference was an excellent first step in the process. It is important I believe to complete the process and take the second step by convening another conference, now that we have all had the time to think about these issues.

Thus, I do hope that the Coalition will arrange a second conference and needless to say I will be happy to participate in such a conference.

Sincerely,

Lewis L. Douglass

Executive Deputy Commissioner

LLD:11

cc: Ms. Geraldine Brooks

12-13

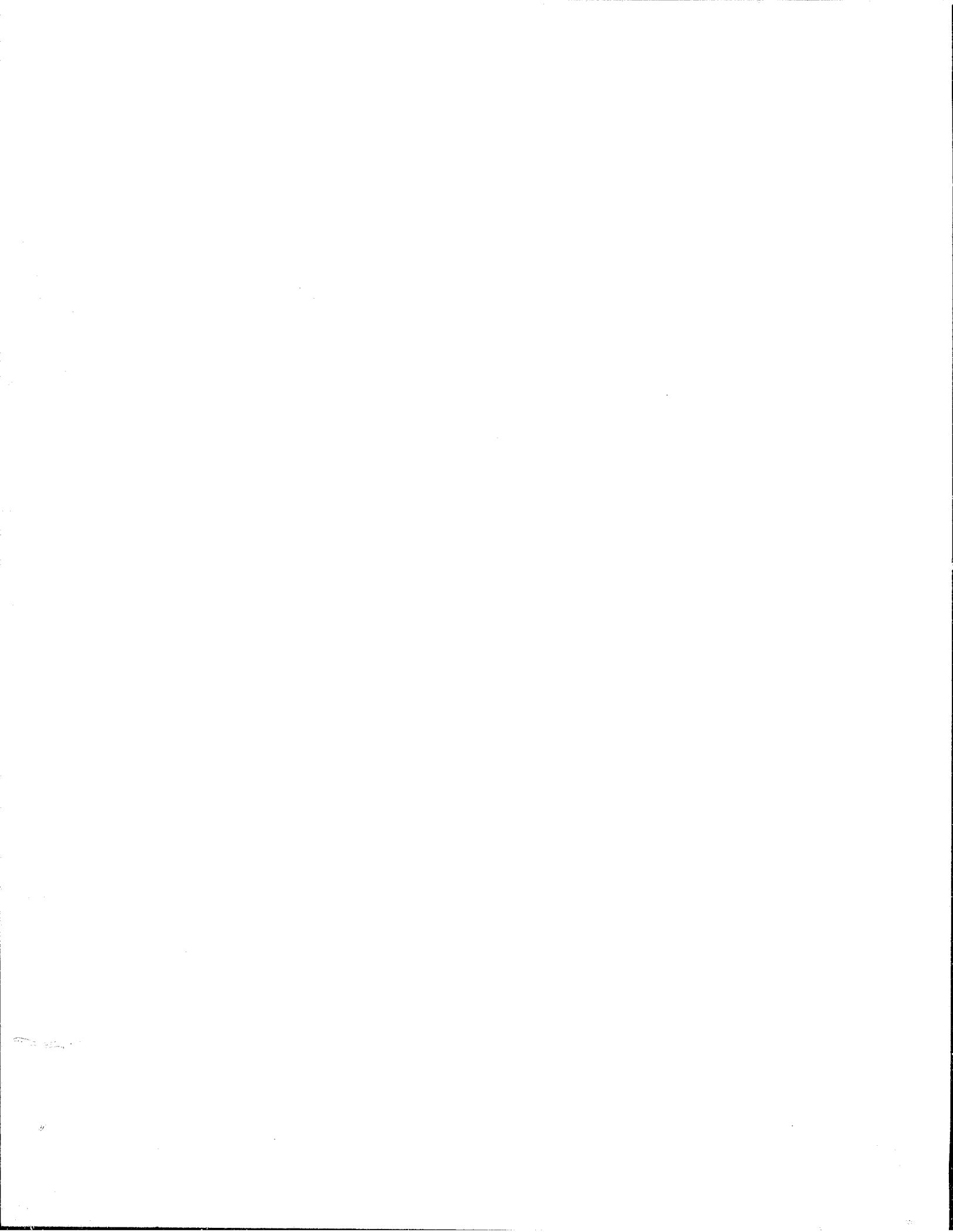
Part II

PAPERS PREPARED FOR THE NATIONAL MINORITY
CONFERENCE ON HUMAN EXPERIMENTATION

13

THE PROBLEMS OF INFORMED CONSENT,
FOCUSSING ON PRISONS

Joyce Mitchell Cook, Ph.D.
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INTRODUCTION

"Informed consent" has been identified by a majority of writers as the central, though not exclusive, ethical issue raised by the research activity called human experimentation.¹ This activity is, in my judgment, more accurately to be thought of as (human) experimentation on human beings. The reason I propose that we think of this type of research activity as experimentation on human beings is two-fold: 1) Since we can conceive of no experimentation being carried out by giraffes, gorillas, gnus, and the like, we may safely assume that all experimentation is human experimentation, in view of which assumption 2) we are the more likely to keep steadily in mind the crucial fact that such research activity is carried out by human beings on human beings, who though commonly referred to as human subjects are, in point of fact, human objects for the purposes of the experiments.

When we perceive the research activity in this way we are the more readily perceptive of the main ethical issue here, which has two aspects not always clearly brought out in the growing literature on the subject. On the one hand there is the question of the ethicality of the experimenter insofar as he is acting on another human being; on the other hand, there is the question of the ethicality of the human being who agrees to serve as object-

being-acted-upon by the experimenter.

Adequately to address the issue of informed consent we must consider both aspects, not merely in isolation from each other but in the context in which they are raised. To appreciate the point I am making is to see that we cannot justify a given experiment carried out on human beings simply by pointing out that the experiment by its nature and design violates no commonly accepted ethical principles. For one implication of the two-sided ethical question we may raise about any such experiment is that Experimenter Jones may perform exactly the same experiment on Mr. Smith and on Mr. Brown and his action may be ethical in the case of Mr. Smith but unethical in the case of Mr. Brown. A further implication is that it may be ethical for Mr. Smith to submit to Experimenter Jones' action but unethical for Mr. Brown to submit to the same action on the part of Experimenter Jones. In short, strictly speaking experiments are neither ethical nor unethical.² Experimenters may be ethical or unethical; and those who submit to such experiments may be ethical or unethical by their submission.

It will be the burden of this paper to argue these points and to spell out the ethical requirements, addressing the problem of informed consent as directed by the conference organizers by focussing upon the problem of experimentation on prisoner/inmates. At the conclusion of our analysis we shall be in a position to

recommend a proposal for the consideration of this body.

Our set task is not to address the ethicality of experimentation on human beings in general. Rather we are to consider the problem of informed consent. It seems advisable straightway to point out the relationship between the two problems.

In addition to informed consent the following issues have been identified as requirements for human experimentation: equality, the competence of the experimenters, prior animal experiments, prohibited subjects, and proper records.³ It is not clear to me whether these are altogether distinct from the issue of informed consent. How, for example, can the subject be informed of risks if there have been no previous animal experiments? How can the subject be informed if the researchers are incompetent? Depending upon our characterization of informed consent, some classes of persons may be excluded from participation as subjects. Pappworth in defending equality as part of the code for governing experimentation argues that "no experiment should be contemplated, proposed or undertaken to which, if he were in circumstances identical to those of the intended subjects, the experimenter would even hesitate to submit himself, or members of his own family, or anybody for whom he had any respect or affection. This principle of equality should be the corner-stone of the whole edifice of any

code. It is essentially a restatement of the Golden Rule...."⁴

Hans Jonas makes a similar point when he argues that "it would be the ideal, but is not a real solution, to keep the issue of human experimentation within the research community itself."⁵ By this Jonas means that the call for volunteers as experimental subjects should first be put to those persons who may best, by virtue of their knowledge and dedication to the cause, identify with the aims of such research.

Both Pappworth, a physician, and Jonas, a philosopher, seem indirectly to suggest that whereas informed consent may be the central ethical issue raised by experimentation, other ethical upheld in experimental medicine. The quality of consent obtained, in their opinion, leaves much to be desired.

We begin by asking what, in the language of Pub. Law 93-348; is the "...nature and definition of informed consent in various research settings," and, secondly, how shall we "...identify the requirements for informed consent to participation in biomedical and behavioral research by children, prisoners, and the institutionalized mentally infirm."⁶ The enabling act calls further for an investigation of what in effect is being done in regard to these matters. It is well at the outset to appreciate the fact that the

question of what is being done is an empirical question not an ethical question. This point seems to have escaped the notice of Dr. Lasagna, for example, when he observes that "the problem [of informed consent] boils down to a sober weighing of costs and gains, not a preoccupation with moral cliches and stereotyped mottoes. Much has been written...on the need for 'informed consent', but little research has been conducted on what this term actually means. What do we consider a 'fair shake' as far as the subject is concerned? How much tailoring of our presentation is required by differences in age, personality, or I.Q. among patients? What minimal information do we want conveyed before we ask whether a subject is willing to participate in an experiment ...?"⁷

I submit that Dr. Lasagna mistakenly thinks that empirical research is required to answer each of his questions, whereas, I should contend that the meaning of the term "informed consent" invites analysis rather than empirical research. More importantly the question of fairness is also a philosophical (value) not an empirical question.

In what follows I shall examine the definition of informed consent (Section I); Section II addresses the special group category, focussing on prisoner/inmates; Section III considers difficulties peculiar to behavioral research as opposed to biomedical research, again chiefly with reference to prisoners. Finally in Section IV, I offer conclusions and recommendations.

I. INFORMED CONSENT. Nature and Definition

There is considerable confusion in the literature over whether informed consent is a concept or a principle. This is no mere semantic confusion, but a confusion that tends to disguise the ethical issue in human experimentation. Thus some authors speak of the concept of informed consent and having indicated what they take it to mean, proceed to refer to it as a process that admits of steps researchers might follow to ensure that they obtain it. A signature on a consent form may "prove" that informed consent has been obtained. But a signature on a consent form does not prove that the ethical requirements for informed consent have been met.

Certainly there is a concept of informed consent, just as there is a concept of a promise and a concept of truth-telling. But truth-telling is also the name of a principle and is defended by some persons as a moral principle governing statements people make. The distinction between truth-telling as a concept and as a principle may most readily be grasped in terms of the kinds of questions appropriate to each. One sort of evidence is called for if we are attempting to ascertain whether someone is telling the truth and another type of evidence or justification is called for if we are attempting to defend the principle of truth-telling.

Similarly, in regard to the problem of informed consent, there are two separate questions calling for two kinds of evidence. If we want to know whether informed consent has been obtained in regard to a given experimental subject, we look for certain determinations of fact, such that the subject was given such and such information, that he said he understood, and that he seemed quite eager to sign the consent form, and so on. The emphasis on the part of the researcher must be to inform; the emphasis on the part of the prospective experimental subject must be to consent--willingly not reluctantly. But if informed consent indicates an ethical principle, as many writers have contended, something more than a recital of facts is called for if we are to attempt to establish the principle. What reasons may be addressed in favor of the principle of informed consent? What is the precise formulation of the principle?

According to Richardson, the principle of informed consent was first formulated at Nuremberg

...after the Second World War as a specification of the wrong done by German doctors who used concentration camp prisoners for medical experimentation. These doctors reasoned in a humanitarian way. They knew that the prisoners were marked for an early death and that they themselves were utterly helpless to prevent this or ameliorate their condition. In principle, the prisoners were as good as dead and, separated from all friends and family, now experienced only the torment of anticipating their doom. Since the prisoners were going to die anyway, the doctors reasoned, why not take advantage

of the situations to benefit all mankind? Why not use them for medical experimentation?⁸

Lest we wrongly assume that German doctors invented what Pappworth, among others, has condemned as a violation of medical morality, let us recall that a number of these doctors during their trials cited as precedents for their own experiments published research describing similar experiments carried out elsewhere in the world, including three American experiments. Nor should we assume that experimentation with prisoners began with those cited by German doctors at Nuremberg in 1947, for indeed, such cases have been recorded for centuries.⁹

I would have us consider this history at this point merely to reinforce my contention earlier on that it is not experiments per se that are ethical or unethical but rather experimenters and experimentees. If Pappworth is right, the vast majority of published accounts of experiments on patients examined in his book fail to mention whether informed consent was sought and obtained, sought and not obtained, or not sought at all.¹⁰ This omission seems to suggest (though it does not prove) that the researcher/writers regarded the consent issue as irrelevant to the conduct of their research activity.

Secondly this historical note should make us wary of leaving such questions of ethics to the researchers themselves, whether

they have the endorsement of peer groups or not. Nor can we agree that the late Justice Felix Frankfurter's claim with respect to lawyers should apply to medical researchers. According to Frankfurter, "there were no courses on ethics [in law school], but the place was permeated by ethical presuppositions and assumptions and standards. On the whole, to this day, I am rather leery [sic] of explicitly ethical instructions. It is something you ought to breathe in."¹¹ Frankfurter seems not to have appreciated the difference between courses in ethics and ethical instruction. Courses in ethics do not provide ethical instructions (families, churches, friends do that) but rather they provide training in identifying ethical issues, in formulating ethical principles, in exposing presuppositions, assumptions, in assessing alleged justification for ethical principles, and so on. Justice Frankfurter in the quotation under review here has made the common mistake of confusing morals with moral philosophy, of confusing morality with ethics. As for the notion of breathing in ethical (moral) instruction I am tempted to observe that pollution is an acute problem in our society in recent times.

If I seem to dwell too long on preliminaries I do so for what appears to me to be a very good reason. Facts are relevant to ethical decisions but the latter are not reducible to the former without remainder. The principle of informed consent may be

construed as a proposal for regulating the conduct of interested parties in the context of experimenting on human beings. It is not to be thought of as being handed down from on high, nor is it to be construed as an eternal verity. But notwithstanding these caveats, we may ask whether the proposal represents our best insight into moral situations and this question in turn inevitably leads to a discussion of values including the value of persons.

The wholesale condemnation of the practices of some German doctors to which we have already alluded is predicated upon the compromise of the intrinsic value of persons. The principle of informed consent is a proposal to ensure that the intrinsic value of persons acting and being acted upon in biomedical experimentation shall not be compromised. Thus the Nuremberg Code, grandparent of modern codes, spells out in ten clauses requirements governing medical experimentation on human beings. We shall cite here only parts of the first clause:

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. The latter element

requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.¹²

It is instructive to note that this code spells out not only the consent component but the informational component as well and that it does this in a way that implies that there can be no consent without sufficient information. Whereas there can be no consent without sufficient information, there can be consent without willingness. Hence the Nuremberg Code stresses the voluntary nature of the consent. The second sentence in the passage cited elaborates the first: voluntary consent means free and full affirmative judgment.

In subsequent formulations and discussion of the principle subtle shifts have taken place and it is our purpose to see what they are and also to ask why. I have been unable to trace back to the first occurrence of the shift from labeling the issue

"voluntary consent" to "informed consent," The 1946 statement of the American Medical Association on requirements for human experimentation includes the older expression: "1. The voluntary consent of the person on whom the experiment is to be performed must be obtained."¹³ Similarly the committee appointed in 1948 by then Governor Green of Illinois emphasized the same point,

That the subjects must be volunteers informed of the possible hazards. Volunteering exists when a person is able to say "yes" or "no" without fear of being punished or of being deprived of privileges due to him in the ordinary course of events.¹⁴

Webster's Dictionary tells us that consent indicates "a complying, granting, or yielding, willing or reluctant, to request or demand. Thus to speak of voluntary consent is to remove the ambiguity concerning whether the consent is willing or reluctant. Nor, since consent may be willing or reluctant, is the expression redundant as is "informed consent" as we shall show anon.

But consent also implies cognitive awareness of what is being consented to. One cannot say "I consented to x, but I had no idea what x was." Consent is not a blank check upon which the consent giver writes his name, leaving the amount to be filled out by the experimenter/endorsee, notwithstanding the fact that all experiments carry some risks, however small.¹⁵ If consent then implies being informed of that to which one consents, why the expression

informed consent, which clearly is redundant? To speak of informed consent is erroneously to suggest that consent may be blind or uninformed.¹⁶ Worse yet, and this is why I belabor the point, it turns our attention away from the crucial ethical emphasis which lies with the voluntary nature of consent, not with the informational aspect. Notice that when we speak of informed consent, it always makes sense to ask whether it has been freely given; but if we speak of voluntary consent we can neither ask whether it has been freely given nor whether it is informed. To ask the former is to betray a lack of understanding of what "voluntary" means; to ask the latter is to fail to observe the cognitive component of consent. If "voluntary consent" is a superior label to "informed consent" why have we adopted the latter label?

I submit that the shift here noted benefits someone, namely the researcher upon whom the responsibility for obtaining consent is said to rest. Although it is no easy task to inform the prospective experimental subject, who in many cases is poorly educated -- one writer has claimed that it is necessary to have a Ph. D. in biology in order to understand some of the experiments being done¹⁷ -- it is still less easy to blink the numerous evidences of reluctant consent. This is particularly true of some of the special groups we shall examine in the next section of this paper.

It is not only the language of the Nuremberg Code that has been abandoned in contemporary discussions of ethical requirements governing human experimentation, it is also the stricture against using certain classes of persons as experimental subjects. I believe that the two points are connected. Thus, whereas the Nuremberg Code would proscribe the use of prisoners, children, the mentally infirm, and seriously ill persons presumed incapable of free choice, contemporary guidelines invoking the legal concept of consent by proxy or third-party consent tend to bend the concept of voluntary consent to comprise as many classes of persons as possible. The neo-Procrusteans among us find the principle of informed consent to be almost as flexible as the types of research they can conceive.

In the remainder of this section we shall focus on the ethical principle of informed consent with a view toward defending its relevance to the ongoing debate as to what ought to constitute the ethical requirements for experimentation on human beings.

The concept of a person it seems to me is a moral concept. As such, it holds the key to most of the ethical issues that are examined in the relatively new field called variously medical ethics or bioethics. Is it morally right to pull the plug from a heart-lung machine in the case of a patient who is irreversibly comatose? Is it morally right to have an abortion? Is it morally right for parents to refuse permission

to operate on a seriously defective child who will die without the operation but who will live on with the defect after the operation? To answer these questions we must have a clear moral concept of a person.

The ethical requirement of informed consent--voluntary consent I shall prefer to call it--is no less dependent for its full explication upon the moral concept of a person. Needless to say, I cannot here undertake to attempt to establish a moral theory of persons. Suffice it to note that a person is the locus of values and as such is above all values. Persons have dignity, a famous philosopher has argued, and are therefore priceless. Persons are coequal centers of freedom.

Jonas shows the interconnection between the problem of human experimentation and persons in the following passage:

What is wrong with making a person an experimental subject is not so much that we make him thereby a means..., as that we make him a thing-- a passive thing merely to be acted on, and passive not even for real action, but token action whose token object he is. His being is reduced to that of a mere token or "sample."¹⁸

The principle of informed consent is a proposal to legitimize on ethical grounds the experimenter's intrusion upon the inviolability of the personhood of the experimental subject. Since, in the experiment, violence¹⁹ is going to be done to someone's personhood, the violence must be redeemed by the full and free consent of the person in question. The immorality of violating personhood cannot be redeemed by the results obtained, and by results we mean to include material benefits, extraneous to the

purpose of the experiment, that may accrue or falsely may be believed to accrue from participation in the experiment, whether on the part of the experimenter or experimentee. Thus the motives of the participants are crucial to a determination as to whether ethical requirements are being met. Not only must the motive of the experimental subject be to promote medical progress and/or the public good, but also the motive of the researcher must have this end in view.

The ethical requirement of informed consent is justified by reference to the inviolability of persons and thus implies a test for the selection of subjects as well as of experimenters. To permit any other motive an outlet in the experimental context may well be to encourage disrespect for persons, whether on the part of the subject or the experimenter. In this light one may readily accede to Jonas' claim that the research community itself constitutes the ideal pool to which to direct appeals for volunteers. Prima facie, the research community, better than other communities, can identify with the goal of medical progress.²⁰

If the number of research community volunteers is too small for research needs, the appeal will be directed beyond.²¹ Nothing we have said thus far precludes on ethical grounds the use of persons drawn from the public at large, provided there is informed (voluntary) consent and the motive that redeems loss of personhood. But it does seem, from what we have said, that there will be a class of prohibited subjects. In the next section of this paper we shall indicate the boundaries of this class.

II. INFORMED CONSENT: Should some classes of persons be excluded from participation as subjects in biomedical experimentation?

In the preceding section we have outlined what appear to be reasonable ethical requirements governing the use of human beings in biomedical research. We must now consider whether the ethical requirements as outlined can be met in cases in which the experimental subjects belong to certain groups, groups identifiable by special settings (i.e., prisons or mental institutions) or by special circumstances (i.e., by the circumstance of being a legal minor, or of being aged, or of being terminally ill, or of being psychiatrically ill).

There is an expression in the literature that bridges both the special setting and the special circumstanced group, namely, "captive groups." Although the term does not include all the groups I have mentioned it does include two of the three groups emphasized by Pub. Law 93-348: prisoners and the institutionalized mentally ill persons. Since the third group of interest to us will not be intended when subsequently we shall use the expression, "captive groups," I propose that we begin this section considering them first.²²

A. Infants and Minor Children Generally

As we have seen, the principle of informed consent has been tailored with a view toward keeping the class of "prohibited subjects" as small as possible. Thus, in the case of infants

and children, the burden of informed consent must necessarily fall upon the researcher and a third party, whether parent (s) or legal guardian. The use of members of this group as subjects in biomedical research is problematic, nonetheless. On the one hand, there is the sick child whose parents or legal guardian may be presumed to be anxious upon learning that known, tested procedures or treatments are ineffective. It is conceivable that an anxiety factor may impair free judgment, a prerequisite to consent to an experimental therapy. However, I see no objection on principle to the use of sick children in biomedical experiments, provided 1) there is the relevant third-party informed consent and 2) the experimental procedure or treatment is directly related to the particular illness of the child to be experimented upon.²³

As to a second category comprising children who are well, the situation strikes me as quite different. In the case of healthy children who have nothing themselves to gain from the experiment, it appears to me that for their parents or guardian to consent to their use in experiments is to offer them upon the sacrificial altar of medical progress, about which we have spoken earlier on. Even if the parents/guardians themselves have volunteered as subjects in biomedical research--and I would propose that they do so as an acid test of their commitment to medical progress (or to the public good if they prefer to

see it in this light)--it is by no means evident to me that a parent has a right to consent to the use of his minor offspring in such contexts as we are here discussing. Nor is the right to give consent established in the case of older children who themselves indicate a willingness to participate in such experiments.

If the state can legitimately interpose itself as the ward of a minor in order to secure medical relief for children whose parents, on religious or other grounds, refuse consent, ought not the state afford equal protection to physically well minors whose parents may have forgotten that experiments, by their very nature, are risky, no matter how small the foreseeable risks? Public policy, it seems to me, ought to extend to these cases at least to the extent of ensuring a) the competence of the parents, b) the competence of the researchers c) the quality of the research design, d) the favorable cost-benefit ratio; and, in the case of children judged old enough to understand what to expect from their participation, e) the willing consent of the prospective child so indicated. By monitoring these parameters of the research project, the public shall have safeguarded its interest in the right to life and limb of its healthy children, if not to the full extent it has been known to take in some sick children, at least to a greater extent than obtains at present.

With this proposal of safeguards relative to healthy children,

we come short of facing the ethical verdict on biomedical experimentation on healthy children. To sharpen the ethical issue I now cite a case reported by Dr. Lasagna, which seems to fall inbetween the two categories of sick and healthy children:

One experiment with retarded children that superficially seems disturbing turns out to be unobjectionable, in my opinion, on full examination. Newly admitted children to the Willowbrook State School in New York State have actually been infected with hepatitis virus by dosing the children with serum from Willowbrook patients with hepatitis. This seems at first glance abhorrent, but in fact everyone admitted to the school appears to develop hepatitis anyway during the first six to twelve months. In the inoculated children, the dose can be adjusted, and immunity can be acquired by experiencing a disease that is no more severe than the usual (rather mild) illness clinically acquired. Furthermore, the experimental group can be housed separately and exposed to the hepatitis virus without simultaneous infection from other organisms endemic in the institution. In this case, the protocol was reviewed and approved by several agencies, informed consent is always obtained from the parents, and the use of children who are wards of the state is scrupulously avoided.²⁴

I, for one, cannot agree with the author that the initial abhorrence disappears upon further examination of the case as reported here. Three observations seem pertinent: First of all, is this a case of biomedical research, notwithstanding the reference to "experimental groups"? If it is experimental, what is its purpose, for there appears to be no new knowledge forthcoming in regard to the aetiology and management of hepatitis.

But if it is an experiment, the argument "I shall deliberately dose you with hepatitis, because you are going to get it anyway," seems to me to have slid down the slippery slope of the German doctors at Nuremberg who attempted to defend their experiments on the grounds that their subject/victims were going to die anyway. Shall we allow this sort of rationale to range over the terminally ill, who are going to die anyway, so why not experiment on them? Shall it extend to the public at large--we are all going to die anyway?

I would make a second observation to the effect that cases such as Willowbrook (and I might add the Tuskegee Syphilis Study and the experiments of Dr. Stough) merely add to the wariness engendered at Auschwitz of entrusting ethical requirements to the professionals, which relates to my third observation. Let me indicate it briefly in this fashion: if children institutionalized at Willowbrook generally contract hepatitis, why not direct efforts toward improving the physical conditions under which the children live, instead of regarding the disease as inevitable? Or is it much cheaper to dose the children with serum than to attack the conditions that spawn its high incidence? And to tie in with my previous point, why are institutionalized children who are wards of the state, "scrupulously avoided" in such experiments? Why cannot the other children receive equal protection

from risks of experiments? It seems to me that a case could be made out of making all mentally retarded children who are institutionalized (publicly not privately) wards of the state thus to protect them from being used in biomedical research unrelated to actual illnesses they might have.²⁵

As a final point on the subject of the participation of children in biomedical research experimentation I think it is instructive for us to update the biblical story of Abraham and Isaac. In the modern version we have only to substitute medical progress "or the public good" for God to see contemporary Abrahams offering their children as sacrifices, though without in return having any promise that they will get them back "as good as new" nor any justifiable appeal to the idol of medical progress (or the public good). According to one influential analysis of the Abraham story,²⁶ Abraham was remiss, from an ethical point of view, for he would violate the moral law that a father should love his son. Moreover, Abraham was remiss, ethically speaking, in keeping from Sarah his wife and Isaac his son, the purpose of his journey to Mt. Moriah. In short, the divine command to sacrifice Isaac entailed a "teleological suspension of the ethical."

What Abraham resolved to do, from an ethical point of view, deserves the name "murder", the religious (and higher) expression for this is that Abraham would "sacrifice" Isaac. Granting that

most experiments involving healthy children pose minimal risks, I should contend that the analogy still holds, since one must trust, i.e., have faith in the researchers on this point. Thus our updated version of the Abraham story raises the question how far in the name of medical progress (or the public good) we want to suspend the ethical requirement that persons and would-be persons be respected as co-equal centers of freedom. I reiterate my contention that we ought not experiment on healthy children at all.

B. Captive Groups: Prisoners and the Institutionalized Mentally Ill

The use of criminals in medical investigations appears to be as old as the history of "medical art" itself. In former times criminals were known to have been donated outright to medically curious practitioners.²⁷ What arguments, if any, were construed to justify this trafficking in human flesh I cannot say. I can only conjecture that the status of being a criminal afforded no residue of rights for the criminal insofar as his life and limb are concerned. A criminal donated for medical research was not a person, whether the term "person" be taken in a moral or legal sense.

In our enlightened age, we hear much about the "right of prisoners" to volunteer as subjects in biomedical research experimentation. Nonetheless, a recent study concludes that "There is enough evidence to support the termination of human

experimentation in the prison, even if the evidence doesn't demand it."²⁸ Others favor the continuation of inmate participation, a position advocated by Drs. Hodges and Bean, who have written as follows:

We feel that the use of prison volunteers for medical research is justified and highly desirable for the investigator, for the subjects, and for society. It not only permits the conduct of human investigation under ideal circumstances, but it enables the participants to feel that they are serving a useful function as indeed they are.²⁹

In the paragraphs that follow we shall rehearse and criticize the arguments both favoring and disfavoring the use of prisoners in biomedical research. Among issues to be considered are 1) what motives prompt the prisoner's interest in being subjects and what motives prompt the researcher's interest in using prisoners as subjects; 2) what benefits, if any, redound to the prisoners themselves; 3) what interpretation is to be put upon the notion of volunteering within the confines of a prison, and 4) the ultimate question: is the use of prisoners in biomedical experimentation consistent with the ethical requirements outlined in Section I. (The empirical question, Does the current practice in regard to participation of prisoners as subjects in biomedical research meet the ethical requirements will not be stressed here. One must note, however, that even those who favor

prisoner participation readily acknowledge abuses in the present systems and qualify their advocacy by the proviso of further safeguards to prisoner safety and prisoner rights to follow-up treatment.)

1. Motives: Why do healthy prisoners volunteer as subjects in biomedical research--if, indeed, they do volunteer? Why do researchers invite inmate participation?

Such information as we have concerning the motives of prison volunteers is based on scattered direct testimony of prisoner participants. Acknowledging the absence of systematic studies of prisoner's motives, we need not take this testimony at face value. Nor should we be overly concerned as to which, among multiple motives, may be assessed as the dominant motive. For our purpose it suffices to consider whether any of the motives reported in the literature strikes us as sufficiently worthy so as to count in the debate over continuing biomedical research in prisons.

The recorded list of prisoner motives includes the following:

- 1) the motive to escape the boredom of ordinary prison routine;
- 2) the motive to escape possible violence (including sexual violence) at the hands of other inmates;
- 3) the motive to increase self-esteem by contributing to a worthy cause;
- 4) the motive to impress other inmates in regard to daredeviltry;
- 5) the motive to improve chances of getting a job, once released from prison;

6) for those prisoners who regard themselves as "loners," the motive of acquiring a "substitute parent" in the person of the research physician; and 7) almost uniformly reported, hence, the universal, if not dominant, motive of earning money.

Other variations on these motives have also been recorded.³⁰ For example, when the research is being carried out in prison wards in free-world hospitals, there is the motive to escape into the free world.³¹ In the words of one writer, there sometimes is the motive to gain "feminine proximity."³² One may enlarge the list simply by referring, on the one hand, to the conditions of prison life, and on the other hand, to the value persons, including prisoners, place upon freedom.

Discrepancies in direct testimony provide the wedge for rejecting some testimony at face value. For example, the same prisoners who exaggerate to other non-participating prisoners the risks incurred by them in the experiment, tend to minimize such risks when discussing these matters with their families.³³ There is also the possibility that prisoners report what they think investigators want to hear. Moreover, many prisoners believe, despite disclaimers to the contrary, that their participation in experiments will influence parole boards in their favor.³⁴

Two of the reported motives deserve special attention, since they bear directly upon the determination we shall make of whether

to continue human experimentation in prisons. In regard to the motive of contributing to society (or to medical progress), we note that it has been convincingly argued elsewhere that no society that places a premium on the individual as over against the state can with logic consistency demand pure sacrifice, that is to say, sacrifice without personal gain, from any of its members. Speaking specifically of human experimentation, Hans Jonas observes that

What is asked goes decidedly beyond, even runs counter to, what it is otherwise deemed fair to let the individual sign over of his person to the benefit of the "common good." Indeed, our sensitivity to the kind of intrusion and use involved is such that only an end of transcendent value or overriding urgency can make it arguable and possible acceptable in our eyes.³⁵

Jonas considers a declaration of war, but not the cause of medical progress, to posit an "overriding urgency."

Although I can readily agree with much of Jonas' careful analysis of the ethical issues raised by human experimentation, I cannot concur with his opinion that prisoners might be allowed to volunteer for medical experimentation. Whereas Jonas is prepared to prohibit the use of "captive" groups in medical experimentation, he remarks in a footnote that "captive"

refers to captives of circumstances, not of justice. Prison inmates are, with respect to our problem, in a special class. If we hold to some idea of guilt, and to the supposition that our judicial system is not entirely at fault, they may be held to stand in a special debt to society, and their offer to serve--from whatever motive--may be accepted with a minimum of qualms as a means of reparation.³⁶

It is this line of thinking that pervades the arguments of a number of writers who favor use of prisoners as experimental subjects, albeit the rationale is only obliquely indicated. Let us give it a full-dress review.

According to Jonas in the passage just cited, the moral acceptability of participation of prisoners presupposes two things: 1) the idea of guilt and 2) the supposition that our judicial system is "not entirely at fault."

Apropos the first point, I would ask whose sense of guilt is intended here, the prisoners' or ours--the judging public? If Jonas is saying that prisoner must have a sense of guilt in order for his participation in biomedical research to be morally acceptable, then he indirectly is proposing a criterion of selection for inmate participation. Ought we then to require that a prisoner demonstrate a sense of guilt to be eligible to participate in biomedical research? On the other hand, perhaps Jonas is saying that we, the public, must have an idea of guilt by reference to which we comprehend the prisoner's motive to expiate his guilt. Either interpretation points to a sense of guilt on the part of the prisoner, and the attendant notion of settling accounts.³⁷

We come now to consider a critical difficulty in this view: incarceration, apparently, is not a sufficient penalty for the crime.

Having stripped the prisoner of all rights we value, we find it morally acceptable to invite him to exercise the one right most of us disvalue, namely, the right to surrender his toehold on personhood by becoming a subject in biomedical experiments! I submit that this is curious rehabilitation to say the very least. Let us reiterate Jonas' remark, cited in part above, which, it seems to me, decisively puts the moral issue raised by human experimentation:

What is wrong with making a person an experimental subject is not so much that we make him thereby a means (which happens in social contexts of all kinds), as that we make him a thing--a passive thing merely to be acted on, and passive not even for real action, but for token action whose token object he is. His being is reduced to that of a mere token or "sample.... compensations of personhood are denied to the subject of experimentation, who is acted upon for an extraneous end without being engaged in a real relation where he would be the counterpoint to the other or to circumstance. Mere "consent" (mostly amounting to no more than permission) does not right this reification. Only genuine authenticity of volunteering can possibly redeem the condition of "thinghood" to which the subject submits.³⁸ (Emphasis added)

Unwittingly Professor Jonas has hemmed himself into an indefensible position. Either he must say that a prisoner is not a person to begin with (in which case he is incapable of genuine authenticity of volunteering) or he must say that merely by

being passive, by neither acting nor by being engaged in a real relation, a person may after all do something, i.e., make amends for his wrongdoing. I need not elaborate the logical howler this latter alternative poses. It seems to me that it is the former alternative, the tendency for the most part, to view the prisoner as a non-person that accounts for the lack of moral qualms over his use as an experimental subject. But since the advocacy of his right to volunteer presupposes the prisoner to be a bit of a person, those who argue for this right also espouse the irony of the view that a valid expression of personhood is the resolution to become a thing. We shall have more to say about the prisoner's right later on.

We began this discussion by noting that prisoners have sometimes reported that they are prompted to volunteer for experiments in order to contribute to medical progress or to the public good. By way of evaluating this motive, I have attempted to show that by the very same stroke by which the prisoner freely consents to be an experimental subject, he forfeits his toehold on personhood qua experimental subject. His contribution to society therefore is the final capitulation to the image entertained by others of him in the first instance, in that he becomes the non-person others regard him to be. My assessment of his motive, therefore, is that it fails to be worthy to count in the deliberation of whether or

not to continue human experimentation in prisons. It goes without saying that I am not denying that prisoners may be motivated to contribute to medical progress or to the public good. What I am saying is that we ought not to permit a self-stultifying outlet for this motive. One cannot, it seems to me, recover the dignity of persons by becoming a thing.³⁹

At this point I shall address the widely reported motive of earning money. Let us not quibble about the small pittance involved. As researchers are quick to point out, it is the prison officials, generally speaking, not they who determine the quid pro quo, and the latter also are quick to point out (if, indeed, they speak at all) that they deliberately keep the sums small so as to discourage the money motive. To this I should remark that if prostitution is not legal in the free world, why should it be legal within the confines of a prison? For where the money motive predominates in the decision to volunteer as an experimental subject, make no mistake, we are dealing with prostitution--the selling of one's body for financial gain. The price is thus a secondary issue. As I see it, the money motive is to be discredited along the same lines as the altruistic motive, i.e., that it leads to a self-stultifying expression.

The inviolability of persons is not the only ground from which to reach the same conclusion. On utilitarian grounds as

well one may discredit the money motive. A utilitarian view regards the best motives as those that regularly lead to right acts and the worst motives are those that least frequently lead to right acts. Considered in this light, the money motive of prisoners appears to lead to a network of wrong acts and should not be encouraged.

The same authors who concluded their study by observing that there is enough evidence to terminate human experimentation in prisons even though the evidence is not conclusive have reached their conclusion independently of the considerations we have just entertained. In point of fact they leave the door open to further experimentation in prisons by observing that

most inmates appear to favor experimentation; and since it is their bodies which serve research, their preferences should be more heavily weighted....

It would be easy to conclude based on the current record, that human experimentation in prisons should be abolished. But to do so would violate one important principle: the right of inmates, subject to strict safeguards, to make real choices. To force the inmate, effectively or directly, to participate, or to prohibit the inmate from participating, both violate this principle....

The importance of prisoner attitudes cannot be underestimated. In any calculus, the views of inmates should be given as much, if not more, weight than the sage opinion of disinterested experts, and certainly more than the assuagements of researchers.⁴⁰

It seems to me, on the contrary, for the reasons I have shown above, that the views of inmates point to a need for a consciousness-raising program. Given the limited range of options for time-use projects, given also the conditions of prison life, the preferences indicated by prisoners need not be construed as sacrosanct.

The second part of the question at hand focusses on the motives of researchers. We raise this question because, as argued earlier, the ethicality of human experimentation turns upon not only the subject being experimented upon but upon the experimenter as well. Researchers are commonly said to be motivated by a desire to further medical progress (and/or the public good). How far this is a genuine motive, divorced from interest in advancement of personal careers, we need not attempt to determine. The increasing emphasis on Peer Review Committees apropos research proposals may be taken as an acknowledgement of the fact that pure altruism alone is not a sufficient safeguard of the experimental subject insofar as ethical and scientific requirements are concerned. There may be, in fact, though not necessarily, a direct connection between zealous commitment to medical progress and moral myopia in regard to means--end considerations.

Our scrutiny of the motives of researchers favoring the prison setting must not blink the fact that in the words of Drs. Hodges and Bean, already cited, "the use of prison volunteers for medical research....permits the conduct of human investigation under ideal circumstances." Drs. Jonsen and Lee make the same point as follows:

Prisoners and prisons offer to research something rarely found elsewhere: constancy of experimental variables. Life in the prison is simple and rudimentary. All prisoners eat the same fare, participate in roughly the same programs, and share approximately the same quarters. The living conditions of most prisoners are comparable to those of experimental animals. Consequently, when introducing an experimental variable--a cosmetic or a medication--only a few factors have to be controlled for research purposes. For this reason prisons have been natural targets for experimentation requiring human subjects. Based on fragmentary data, most of the activity appears to have been bio-medical in nature; but food, personal products, and cosmetic interests have also been involved.⁴¹

If it is morally acceptable to carry out human experimentations within the prison setting, researchers are extremely fortunate indeed to have available such ideal (and not easily duplicatable) conditions under which to conduct their experiments; if on the other hand, it is not morally acceptable, the ethical requirements for conducting such experiments may always be bent.

Finally, on the subject of motives, we may observe that whereas it is important to consider motives if we are to under-

stand why we are faced with this problem in the first instance, it is not important to consider motives as pivotal to the question of ethical requirements governing human experimentation in prisons, unless they meet the specification of those requirements in Section I. Whatever position we take on this larger question, motives such as we have discussed here are likely to keep the question a live issue. I trust that I have indicated some possible interpretations to put upon known prisoner protests against declared moratoria on human experimentation in prisons.⁴²

2. Benefits: What benefits, if any, redound to the prisoners themselves?

We may treat very briefly the question of prisoner benefits, in view of our extended discussion of motives. Motives, after all, imply ends-in-view--in this case benefits to the prisoners. A number of benefits to prisoners have been pointed out, including relief from boredom, personal satisfaction stemming from contributing to a worthy cause, improved self-esteem, money with which to purchase cigarettes from the commissary and so on.

Most of these benefits, I should think, are not inextricably connected to participation in biomedical research. If prisons afford very little opportunity for gaining these benefits by some means short of participation in experiments, so much the worse for prisons, or more pointedly, so much the worse for the public

that countenances prison systems. Here I shall dwell upon the alleged benefit of the prison resulting from his participation in decision-making so far as biomedical research is concerned.

Again I am citing Jonsen and Lee: "...a more important "benefit" [than financial compensation] may be inmate decision-making. Prison drastically reduces the number and quality of decisions for the inmate. Prison life is routine and regimented--the only "real" decisions are often rebellious."⁴³

A real decision these authors argue, is made concerning whether or not to participate in biomedical research. Moreover these authors and others as well contend that prisoners have a right to decide for themselves whether they shall participate in experiments.

The question of the prisoner's right surfaces again and again in the present debate. It is implied that the exercise of this right is precisely what brings about benefits such as improved self-esteem. The devoted advocacy of prisoners' rights (in the limited context we have in mind here) from such quarters as we have seen (mainly from research-minded persons) in undoubtedly without parallel in the annals of the American Medical Association.

We now raise the hard question: does the prisoner have a right to participate in biomedical experimentation? I have no intention of entering into the centuries' old discussions among philosophers

as to the nature of rights. Suffice it to notice that we should be wary lest we are forced into what I consider to be an untenable position, namely, that of construing human experimentation in prisons as obligatory on the one hand or construing prisoner's rights as unenforceable on the other hand. As I see it, although human experimentation may be desirable in some contexts, we must reject the notion that human experimentation is necessary in any context, except in the sense identified by Dr. Beecher when he wrote that "Every act of a doctor soundly to relieve or cure a given patient is experimentation of an easily justifiable kind."⁴⁴

It may well be that writers who support the notion of a prisoner's right to participate in biomedical research actually are thinking of a privilege rather than a right. For whereas rights are thought of as entitlements to press claims and to obligate, privileges have no such standing.

We must conclude, I think, that prisoners at most may have a privilege, not a right, to participate in biomedical research. Since privileges, unlike rights, are conferred upon persons and may be revoked at will, it is not clear to me that prisoners, by deciding to offer themselves as experimental subjects are exercising the degree of autonomy some writers have attributed to them in this context. Drs. Jonsen and Lee have contrasted the

decision to participate in experiments with the decision prisoners make concerning whether to learn to paint, finding the latter to fall outside the category of "real" choices. In the light of our distinction between privilege and right, the same finding may apply to the decision to participate in biomedical research. I would go so far as to suggest that the dangling of such a privilege in front of prisoners is itself an inducement on a par with inducements such as escape from intolerable conditions. Nor can I think of a better way to insure a sufficient supply of prison "volunteers" than to encourage prisoners to think they have rights to volunteer. Of course, if it should be demonstrated that I am wrong, then prisoners who volunteer but who are not selected for participation in a given experiment may legitimately seek redress.

How then to summarize my position on the alleged benefits of prisoner participation in biomedical research, considering such participation to presuppose privilege rather than rights? In a word--prisoners should beware of Greeks bearing gifts!

3. Volunteers--What interpretation shall we put upon the notion of prisoners' volunteering themselves as experimental subjects in biomedical research?

Privileges, no less than rights, are exercizable with or without restraint. The institutional setting in which prisoners

live is regarded by a number of writers as intrinsically coercive. Hence they argue that prisoners cannot be said to give voluntary consent to their use as experimental subjects.⁴⁵ In Section I we observed that consent may be willing or reluctant. Reluctant consent does not satisfy the ethical requirement. Shall we construe the "quality" of consent obtained from prisoners as willing or reluctant?

Again prisoner's testimony may have some bearing on the question although it remains to be seen whether such testimony ought to be taken at face value. The acid test appears to me to lie in isolating the motive to serve society or medical progress. I have already argued that this altruistic motive should be discounted in the determination of the fate of human experimentation in prisons.⁴⁶ Here I might add the observation that the very existence of multiple motives having no intrinsic connection with the purpose of the experiment reveals the extent to which the decisions of prisoners to participate in experiments are made under pressure and, hence, do not meet the ethical requirement of free or willing consent.

Martin Miller reports the testimony of one prisoner as follows:

When I went to the [parole] board last time I tol' them I was doing research, but they said they didn't care---like it wasn't nothin' to them. I didn't dig it man; didn't they want me to...I mean, wasn't it helping no one?

A second prisoner is quoted:

This doctor, I think he was, asks me to sign the 'release' and I say could I read it, and he says, there's a long line of guys waiting and if I want to read it, it's perfectly all right, but I'll have to get out of the line and take it back to the cell. Then if there is any room next week, I might be able to get on it. I need the dough, so I signs it.⁴⁷

To be sure, there is testimony of different tenor, as for example, to quote one inmate,

Medical research is one of the very free choices a man has in prison. Where his every action is governed by a mass of rules and regulations. ...he is allowed...to pursue a program that benefits society, his family, and himself.⁴⁸

Even this apparently conflicting testimony about the quality of choice is conjoined with a pointed indication to the coercive environment that is the backdrop for such choices.

Recognizing the weight of pressures upon prospective volunteers, Professor Jones has argued that the research community itself, ideally speaking, should supply volunteers in the first instance and that "one should look for additional subjects where a maximum of identification, understanding, and spontaneity can be expected -- that is, among the most highly motivated, the most highly educated, and the least 'captive' members of the community."⁴⁹ As we have

noted Jonas would exclude prisoners from the class of captive persons, but having set aside his double penalty theory, we would include prisoners when he observes that

"The ruling principle in our considerations is that the 'wrong of reification [becoming a thing/object for the purposes of the experiment] can only be made "right" by such authentic identification with the cause that it is the subject's as well as the researcher's cause -- whereby his role in its service is not just permitted by him but willed. That sovereign will of his which embraces the end as his own restores his personhood to the otherwise depersonalizing context. To be valid it must be autonomous and informed.⁵⁰

Volunteering is genuine (willing) volunteering only if the end to be pursued in the experiment is an end to which the volunteer is devoted. Wherever motives operate for ends other than those pursued in the experiment, there is no devotion to redeem the depersonalization of the experiment. Given the extraneous motives of prisoners who "volunteer" for biomedical experimentation we must conclude that most prisoner "volunteers" give reluctant consent and hence are volunteers in name only.

Before leaving the subject of volunteering I should like to meet one objection raised by Lasagna and others, to the effect that some form of coercion, for all we know, may infect the decisions of all volunteers, not just the decisions of prisoners. It may well be true that a twin to use Lasagna's example, is under more coercion to donate a life-saving kidney to his twin

sibling, than is a prisoner in volunteering as an experimental subject in biomedical research.⁵¹ However, the twin's motive to save a particular life is not extraneous to the procedure to which he submits and hence escapes the criticism noted above.

4. The Ultimate Question: Is the use of prisoners in biomedical experimentation consistent with the ethical requirements outlined in Section I?

To answer the question that introduces this part of the paper we have to reiterate the ethical requirements outlined in Section I and to summarize our findings in regard to prisoners' motives, benefits, and volunteer status. In Section I we noted that

- 1) the principle of informed consent may be construed as a proposal for regulating the conduct of interested parties in the context of experimenting on human beings,

and that

- 2) the principle of informed consent is a proposal to ensure that the intrinsic value of persons acting and being acted upon in biomedical experimentation shall not be compromised,

furthermore, that

- 3) the principle of informed consent is a proposal to legitimize on ethical grounds the experimenter's intrusion upon the inviolability of the personhood of the experimental subject.⁵²

Professor Jonas comes very close to admitting that this principle cannot, by itself, ensure the ethicality of human experimentation when he writes as follows:

the mere issuing of the appeal, the calling for volunteers, with the moral and social pressures

it inevitably generates, amounts even under the most meticulous rules of consent to a sort of conscripting. And some solliciting is necessarily involved. This was in part meant by the earlier remark that in this area sin and guilt can perhaps not be wholly avoided. And this is why "consent," surely a non-negotiable minimum requirement, is not the full answer to the problem.⁵³

Thus Jonas is led to direct the appeal for volunteers to the research community itself. "With the fact of self-sollicitation the issue of consent in all its insoluble equivocality is bypassed per se....By himself, the scientist is free to obey his obsession, to play his hunch, to wager on chance, to follow the lure of ambition."⁵⁴

Criteria for selection of volunteers, if based on Jonas' description of the ideal pool of volunteers, include being highly educated, highly motivated to the point of being able to identify with research aims, and being free from coercion as far as possible (unless being touched with the divine madness is itself a form of coercion). The profile of the average prisoner seems a long distance away from the profile of the dedicated scientist. Far from being highly educated, prisoners have been reported to have a low verbal ability.⁵⁵ As Jonsen and Lee have put it, "some inmates lack even rudimentary skills."⁵⁶ Citing Miller's study, they hold that "rarely do the high ideals of research held by experimenters permeate prisoners' perceptions,"⁵⁷ and further, that "Inmates are generally less likely to be literate, many research protocols and accompanying consent forms could as well be Sanskrit."⁵⁸

In the light of these considerations, as well as those put forth above in regard to prisoners' motives and expected benefits, it seems to me that it would be the rare prisoner indeed who would by his participation meet the ethical requirements we have outlined. Thus, as I see it, the appeal for volunteers from prison populations ought not generally to be made; I would go so far as to hold the experimenter morally responsible for issuing his appeal to the "right" persons--that is, to persons who enjoy the perquisites of personhood. On the other hand, if the experimenter can identify with the subject in accordance with the principle of equality defended by Pappworth and cited above,⁵⁹ then he is being morally responsible in issuing his appeal; otherwise, not.

Finally we should here recall that the prison environment casts suspicion upon the very concept of authentic consent, insofar as the latter implies autonomy. If experimentation intrudes upon personhood, the prisoner's inviolability as person (a moral, not a legal concept) is already intruded upon by his being a prisoner.

This strikes me as penalty enough for the kinds of crimes that pass the screening test of prison officials for prison volunteers, not to mention the American Medical Association.⁶⁰ Certainly if informed consent as an ethical principle is seen to derive from the moral concept of a person, the loss of perquisites of personhood should also be seen as the most severe penalty, short of death and possibly physical torture, exactable from persons. In a word, prisoners are diminished persons and as such should not be solicited or permitted to give most to a society from which they have gained least.

III. INFORMED CONSENT: Special Difficulties in Behavioral Research

Our discussion thus far has referred specifically to biomedical research, but one area in which experimental subjects are human beings. Another area, behavioral research, poses special difficulties in its use of human subjects. We cannot here explore all such difficulties, not even the majority. Given that our problem is still that of informed consent, and our focus on the special groups enumerated in the preceding section, we shall here point out the nature of the difficulty of meeting ethical requirements as far as some kinds of psychological research are concerned.

Of the ten ethical principles adopted by the Council of Representatives of the American Psychological Association in December 1972, we cite two here that seem to enunciate a principle of informed consent.⁶¹

3. Ethical practice requires the investigator to inform the participant of all features of the research that reasonably might be expected to influence willingness to participate and to explain all other aspects of the research about which the participant inquires. Failure to make full disclosure gives added emphasis to the investigator's responsibility to protect the welfare and dignity of the research participant.
4. Openness and honesty are essential characteristics of the relationship between investigator and research participant. When the methodological requirements of a study necessitate concealment or deception, the investigator is required to ensure the participant's understanding of the reasons for this action and to restore the quality of the relationship with the investigator.

Close attention to the wording of these principles (as well as to the other eight and to the commentaries accompanying them) reveals that the principle of informed consent is given a qualified endorsement only. On the one hand, "ethical practice requires the investigator to inform the participant..." on the other hand, "failure to make full disclosure gives added emphasis to the investigator's responsibility to protect...."

Similar left-handed giving and right-handed taking away may be seen in the statement of other "principles" as well, e.g., in Principle

8. After the data are collected, ethical practice requires the investigator to provide the participant with a full clarification of the nature of the study and to remove any misconceptions that may have arisen. Where scientific or humane values justify delaying or withholding information, the investigator acquires a special responsibility to assure that there are no damaging consequences for the participant.⁶²

The first sentence of Principle 8 clearly takes for granted that the participant will not be provided with a full clarification of the nature of the study before he consents to participate. To appreciate the full force of this claim, we must recall that, whereas in psychological experimentation as in all experimentation the outcome cannot be foreseen in every detail, the nature of the study is assured by the research design. Thus, Principle 8 is a continuation of Principle 4-- the Principle of Informed Deception.⁶³

Admittedly, to attempt to conform to the principle of informed consent as we have outlined it in Section I would be to imperil much psychological research of designs so far conceived of by psychologists. Of course, no one knows what ingenuity might produce if informed consent were to be accepted as a requirement for experiments on human beings. The framers of the ethical principles concede as much when they observe that "Practices such as those just mentioned (failure to obtain informed consent, deception, exposure to stress and possible harm, invasion of privacy, withholding of potentially beneficial experiences from members of a control group) raise important ethical issues. Responsible psychologists will obviously avoid using them in pointless and unnecessary ways. They will invest their ingenuity in discovering ways of conducting research that avoid or minimize these problems.⁶⁴ (Emphasis added)

Far from being a requirement for psychological research using human subjects, the principle of informed consent, as we have seen is tentatively endorsed. The rationale for this tentative endorsement appears in the following statement:

Many psychologists believe (although some question this) that to obtain valid and generalizable data, it is often essential that the research participants be naive. The requirements of research may thus seem to demand that the participants be unaware of the fact that they are being studied, or unaware of what is being studied or of the hypotheses under investigation. Or deception may appear to be necessary if a psychological reality is to be created under experimental conditions that permit valid inference.⁶⁵

Here we have a double appeal to the end-justifies-the-means

principle. First, the requirements of research (as end) justify the withholding of information or providing misinformation (as means). Second creating a psychological reality (as end) may necessitate deception ("unreality" as means). In fact, the end-justifies-the-means clearly emerges as the overriding principle--I hesitate to call it an ethical principle. This may be seen to beat the principle of informed consent into hasty retreat throughout the detailed discussion of the ethical guidelines for psychological research using human subjects. "The general ethical question always is," the manual claims, "whether there is a negative effect upon the dignity and welfare of the participants that the importance of the research does not warrant."⁶⁶

The framers of these "Ethical Principles in the Conduct of Research with Human Participants" take care to disavow advocacy of ethical absolutes.⁶⁷ It becomes apparent, however, that the end of benefitting all mankind serves as an ethical absolute wherever the end-means principle is invoked. A number of assumptions are made. I shall pass over the contention that ethics is an empirical science,⁶⁸ a point I have touched upon earlier on. This assumption allows the psychologist to pass easily between speaking of their scientific obligations and their ethical obligations: "...for psychologists, the decision not to do research is in itself a matter of ethical concern since it is one of their obligations to use their

research skills to extend knowledge for the sake of ultimate human betterment."⁶⁹

Again, under the heading The Scientific Obligation, they report,

We begin with the commitment that the distinctive contribution of scientists to human welfare is the development of knowledge and its intelligent application to appropriate problems. Their underlying ethical imperative, thus, is to carry forward their research as well as they know how.⁷⁰

I submit that there is a gross confusion exhibited in these statements. Ethical imperatives, I should have thought, address themselves to men qua men--to persons qua persons--not to men qua psychologists, or to men qua medical researchers, or to men qua philosophers. Professional obligations are one thing; ethical obligations, another.

Apart from offering themselves as the saviors of mankind, the psychologists make a further assumption that people generally want to know the truth about human behavior, or that those who want to know it, want to know it at any cost. Many ethicists who argue for the inviolability of persons would demur to the following statement, "on the one hand, there is the contribution that the research may ultimately make to human welfare, on the other, there is the cost to the individual research participant. Put in these stark terms, the essential conflict is between the values of science to benefit all mankind and the values that dictate concern for the research participant."⁷¹

Finally, I would note that some of the ethical dilemmas faced by psychologists doing research--they say "with", I say "on"--human participants may be traced to core assumptions under-

lying much of the enterprise of psychology. Because psychologists believe there is often a difference between the unobserved behavior and the observed behavior of a given participant, and because they wish to be able to "observe the unobserved behavior" of participants, they sometimes use deception. But the problem may pose not only an ethical but a logical dilemma as well. A participant is deemed "naive" provided he does not know the exact nature of an experiment; lacking this knowledge, he may not be so naive after all, if he happens to know something about the practices of psychologists.

Moreover, insofar as informed (willing) consent is concerned, psychologists ask:

What does it mean to speak of the research participant's "freedom of choice" when one considers that such choices are the lawful psychological consequences of past and present influences in the environment? And how can we propose that a person deciding whether or not to participate in research should be free from coercion and at the same time maintain that all decisions are motivated and that they are affected by forces that act upon the decision maker?⁷²

We juxtapose to these questions that statement of Principle 5, which seems to blink the determinism implied in this passage and raises another point of logical consistency:

5. Ethical research practice requires the investigator to respect the individual's freedom to decline to participate in research or to discontinue participation at any time. The obligation to protect this freedom requires special vigilance when the investigator is in a position of power over the participant. The decision to limit this freedom increases the investigator's responsibility to protect the participant's dignity and welfare.⁷³

Research on prisoners is singled out as an example of the investigator's being in a position of power over the participant and although the guidelines exhort vigilance against extreme coercive measures to gain the prisoner's participation in research, they find it acceptable for investigators to attempt to persuade the prisoners that such research is for their own benefit.⁷⁴

Quite unintentionally, in the next but last passage cited, the psychologists have lent support to my contention argued in the previous section that the coercive setting of a prison spawns motives extraneous to the ends of biomedical research, motives that ought not to count in the debate over whether to continue biomedical research in prisons. For if the psychologists are right that "freedom of choice" is a nonsensical notion, on the grounds that choices are "the lawful psychological consequences of past and present influences in the environment," the case against inmate experimental subjects in biomedical research may be reformulated. Coercion in the prison setting consists precisely in the fact that choices--they mean options--are too much the product of present influences and not enough the product of past influences. For if the motive to serve the public good is the product of past influences, how does the prisoner come to be in prison in the first instance; but if the motive to serve the public good is the product of present influences, meaning prison influences, has not the prisoner been rehabilitated to the point of deserving release from prison?

We cannot advance the same case in regard to psychological research designed to benefit the prisoner-participant himself. But we will raise this question: If the end of the research in question is to rehabilitate the prisoner are we not implicitly acknowledging that prisons are institutions for socially ill persons? Pappworth, among others, has pointed to this problem by observing that the "basic problem of the essential purpose of prisons and punishments has not been solved."⁷⁵

IV. CONCLUSIONS AND RECOMMENDATIONS

Our statement of the principle of informed consent has received three formulations, that are offered to show the intent rather than the letter of a moral principle. We have reasoned that it is easier to cover myriad cases if we are quite clear about the intent of the principle and less easy to handle diversity if we try to apply the letter of the principle.

The first formulation refers to interested parties, and is broad enough to include the public interest as well as interests of researchers and experimental subjects or their legal guardians. By defining the principle of informed consent as a proposal, we have intended to reflect the widespread view in ethics that there are no rationally justifiable ethical ultimates. Basic ethical values are arbitrary.

The second formulation postulates the intrinsic value of persons thus setting itself against a consequentialist ethics or an ethics based on the end-justifies-the-means principle. Finally, the third principle imposes on researchers who comprise the inviolability of personhood an obligation to legitimize their action by obtaining the informed (willing) consent of their experimental subjects.

These are not to be thought of as three separate principles, but as successive elaborations of a single principle. By considering the concept of informed consent, we also should have

indicated the nature of the content of the principle of informed consent. In this connection, we noted the shift from the expression "voluntary consent" to "informed consent" and we reiterate our recommendation that the former expression be adopted, not only because it escapes the redundancy of the expression "informed consent," but more important than the point of logic, because it emphasizes the intent of the principle of informed (willing) consent to ensure the ethical legitimacy of any intrusions upon the inviolability of persons.⁷⁶

We have attempted to apply this principle of informed consent to special groups, focussing on prisoners. By appeal to the principle of informed consent as herein outlined, we would exclude, as a general rule, from biomedical experimentation all healthy persons qualified by special circumstances of institutionalized settings or minority age. Exceptions might be made depending upon close scrutiny of motives, in the case of prisoners, and competence of parent/guardian as well as sincerity of their own commitment (as indicated by their own history of participation as experimental subjects) to the cause of medical progress.

As far as behavioral research is concerned, we stopped short of anything more than tentative directions pointing to the moral admissability of research that directly benefits participants, where the benefits are consistent with the ends of the research in question. We expressed criticisms of the

American Psychological Association's guidelines for experimentation on human subjects, noting their divergencies from the principle of informed consent.

Our most important finding is that, given the extraneous motives of most prison volunteers in biomedical research and given also the ethical requirement of informed (willing) consent experimentation on prisoners ought to be abolished. Where the money motive predominates among prisoners, experimenters may be seen as solicitors of human flesh and prisoners may be viewed as prostitutes. We have argued that only the altruistic motive of benefitting society through medical progress can redeem the de-personalizing context of becoming an experimental subject and we have queried whether prisoners, having been divested of the perquisites of personhood can in their coercive environment make the morally redemptive act of informed (willing) consent.

We have said very little about the risks of experimentation, since to appreciate the ethical question is to focus elsewhere in the discussion. Nor have we said much about a minority perspective for the same reason. By this I mean to imply that if certain kinds of experimentations are morally offensive in certain contexts, they are offensive regardless of whether the subjects are blue, green, yellow or what have you. At this juncture, however, we shall permit ourselves the following observation. One writer, after noting that human experimentation is necessary for medical progress to be made, notes that risks of research "cannot be evenly distributed among the members of society, the many will continue to benefit from the contributions of the few."⁷⁷

It seems to me that historically when the few have contributed to the many, they have been treated as heroes not to be denied rewards of a grateful public. But a double standard seems to be in effect on this issue, insofar as prisoners' contribution to medical progress are concerned. Such money as prisoners are paid for being human guinea pigs is deliberately kept small in order to discourage the money motive. Yet the sums, however, paltry, do provide incentive nonetheless to impecunious prisoners. Thus a supply of volunteers is ensured.

There is an overwhelming irony, it seems to me that on the experimenter's table, no less than on the autopsy table, true equality is achieved, for the experimental subject, like the corpse is to use Jonas' words, "a token object for token action." For my part, I should like to see equality first in the free-living world, and secondly, may it filter into the prisons.

In view of the foregoing considerations, I should like to recommend for the scrutiny of this body,

1. That biomedical experimentation on prisoners be abolished.
2. That experimentation on healthy children be subjected to public scrutiny.
3. That behavioral research on prisoners be conducted in hospital wards and be limited to therapeutic treatment or procedures.
4. That behavioral research on the institutionalized mentally infirm be limited to therapeutic treatment or procedures.

FOOTNOTES

1. Jay Katz, Experimentation with Human Beings (New York: Russell Sage Foundation, 1972), p. 1030; Hans Jonas, "Philosophical Reflections on Experimenting with Human Subjects," in Paul A. Freund, ed., Experimentation with Human Subjects (New York: George Braziller, Inc., 1970), p. 5; A. R. Jonsen and P. R. Lea in unpublished manuscript, "Coercion and Choice: Human Experimentation in the Prison," December 1974, pp. 2, 23ff; also testimony before Senate Health Subcommittee and House Subcommittee on Public Health and Environment Hearings Concerning Biomedical and Behavioral Experimentation Involving Prison Inmates.
Dr. M. H. Pappworth, in Human Guinea Pigs, London: Routledge & Kegan Paul, 1967) makes the telling observation that "In fact, the ethical problems associated with the use of prison inmates as subjects for medical experiments are largely of artificial creation, because the basic problem of the essential purpose of prisons and punishments has not been solved." (p. 64). Nonetheless, we must consider the general case before proceeding to the special groups of experimental subjects.
2. cf. Dr. H. K. Beecher's statement that "an experiment is ethical or not at its inception. It does not become ethical post hoc--ends do not justify means." Dr. Beecher summarizes 22 experiments which he contends violate ethical principles. My point is that it is the experimenters, not the experimentees, who may be said to violate ethical principles. (H. K. Beecher in New England Journal of Medicine, 1966, 274, 1354. Cited in Pappworth, op. cit.
3. See Pappworth's list in Human Guinea Pigs, op. cit., p. 189.
4. Ibid.
5. Hans Jonas, op. cit., p. 18.
6. P. L. 93-348; 88 Stat. 349; Sec. 202 (a) (1) (B) (iv).
7. Louis Lasagna, "Special Subjects in Human Experimentation," in P. A. Freund, op. cit., p. 274.
8. Herbert W. Richardson, "What Is the Value of Life," in D. A. Cutler, ed., Updating Life and Death. Essays in Ethics and Medicine. Boston: Beacon Press, 1969. p. 169.
9. Pappworth, op. cit., pp. 60-61.
10. Ibid., p. 194.

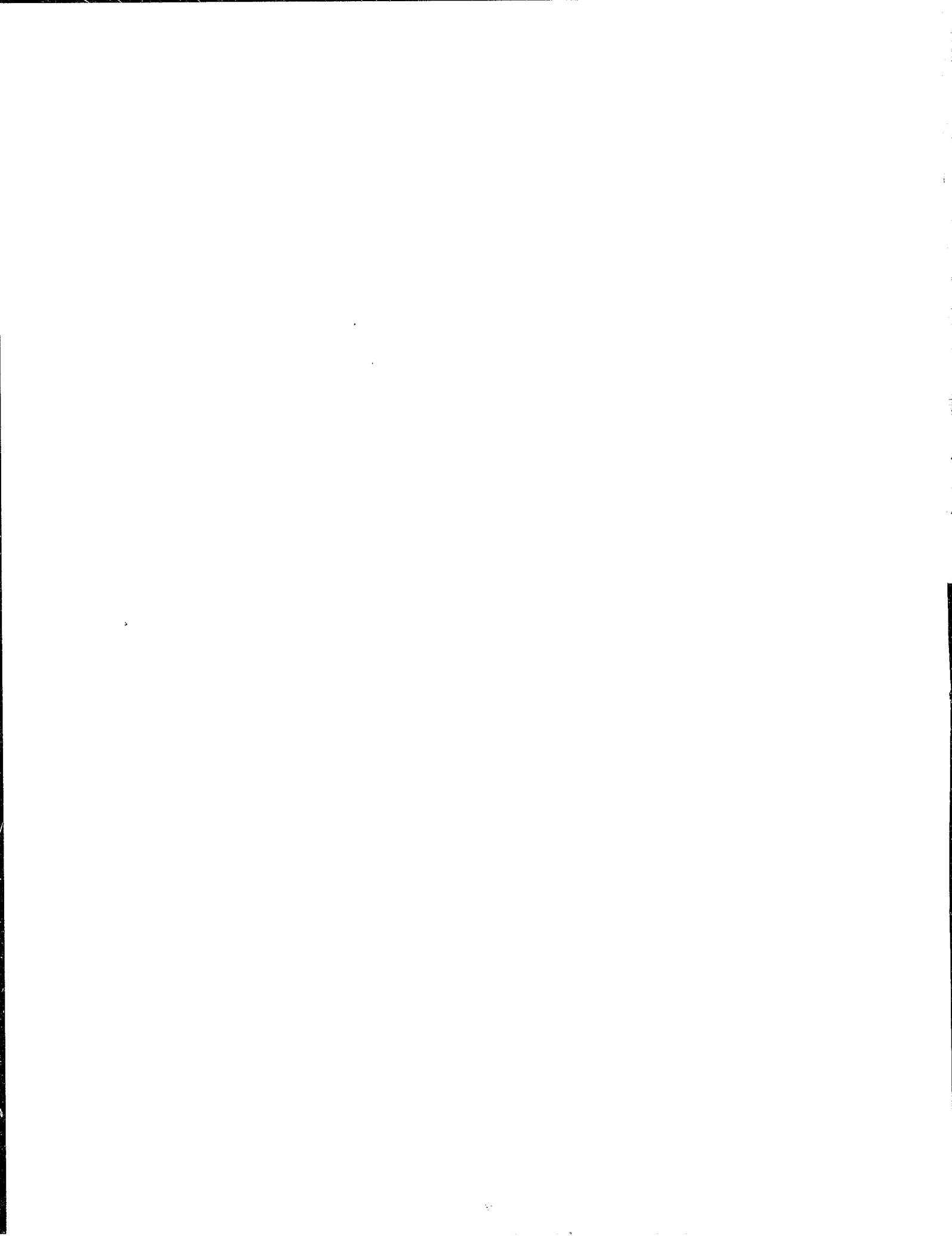
11. Cited in Jonsen and Lee, op. cit., p. 31 as excerpted from John Romano, MD., "Reflections on Informed Consent," Arch. Gen. Psychiatry 30 (Jan. 1974), p. 130.
12. Cited in Pappworth, op. cit., p. 188.
13. Ibid., 189.
14. Ibid., p. 63.
15. Pappworth quotes Dr. McCance, former president of the Royal Society of Medicine, "All experiments involve some risk. It may be an infinitesimally small one, but it is always there. If the experiment involves special techniques, then the risk is considerably enhanced." Op. cit., p. 19.
16. On my analysis, so-called "misinformed consent" turns out not to be consent at all. If, for example, I say that I consent to x, but I mistakenly take y for x, then I have consented to y, not to x.
17. Melvin Heller, "Problems and Prospects in the Use of Prison Inmates for Medical Experimentation." Prison Journal 47 (Spring-Summer 1967): 21-38. Cited from Jonsen and Lee, op. cit., p. 29.
18. Jonas, op. cit., p. 3.
19. The term "violence" is used here in a broad sense that includes, e.g., the puncturing of the skin with a needle.
20. See page 5 above.
21. I concur with Jonas also in his point that we are not to assume that the more medical progress the better, certainly not if medical progress is bought at the price of corroding the moral fabric of society.
22. A case can be made for construing minor children as captive groups. Among authors I have read, Jonas is the only one who excludes prisoners when he speaks of captive groups. See below, p. 28.
23. The ethically redeeming principle here is the well-being of the patient.
24. Lasagna, op. cit., p. 271.
25. Here I agree with Richardson that the "mark of a caring person or society is the protection and special advantages it accords to the weak, to those unable to fend for themselves." Op. cit., p. 170.

26. S. Kierkegaard, Fear and Trembling (New Jersey: Princeton University Press)
27. Pappworth, op. cit., p. 60.
28. Jonsen and Lee, op. cit., p. 62.
29. Robert E. Hodges, M.D., and William B. Bean, M.D., "The Use of Prisoners for Medical Research," Journal of the American Medical Association (JAMA), Vol 202, No. 6 (Nov. 6, 1967), p. 515.
30. Ibid.; see also John C. McDonald, "Why Prisoners Volunteer To Be Experimental Subjects," JAMA, op. cit., pp. 511-12. McDonald writes that "The inmate does not volunteer because he expects his sentence to be shortened, nor does he volunteer for financial reward. Actually he does so for much more immediate reasons, which are quite apparent to him and which seem quite sound (p. 511). Among other "reasons" McDonald reports thrill-seeking and he notes that some inmates felt justified "in accepting risks for the common good which they themselves would not accept if they were outside."
31. Reported by Hodges and Bean, op. cit.
32. Ibid.
33. Jay Katz, op. cit., p. 1023.
34. Jonsen and Lee, op. cit., p. 10, p. 35, p. 50.
35. Jonas, op. cit., pp. 9-10.
36. Ibid., fn 9, p. 30.
37. For a careful analysis of the historical connections between the concept of responsibility and accounting terms, see William Kneale, "The Responsibility of Criminals," in Moral Problems, ed. James Rachels (N.Y., etc.: Harper & Row Publish., 1971).
38. Jonas, op. cit., p. 3
39. In Section I, I have argued along lines suggested by Jonas that the moral wrong posed by human experimentation lies in the loss of personhood on the part of the experimental subject. In effect this means a surrendering of what is the source of all personal values. But a prisoner, by virtue of his status as prisoner, has already lost his autonomy to a very great extent. Thus it is not clear to me that he has sufficient moral autonomy for so momentous a moral act--his toehold on personhood lacks sufficient redemptive power to offset the action of the experimenter upon him.

40. Jonsen and Lee, op. cit., pp. 48, 55, 59.
41. Ibid., p. 1.
42. Ibid., p. 14.
43. Ibid., p. 47.
44. Cited in Pappworth, op. cit., p. 9.
45. See Response from States of Vermont and Oregon to survey conducted by Jonsen and Lee, op. cit., p. 11; see also, Ibid., pp. 15 and 26-27.
46. The public, it seems to me, ought to be prepared to see early releases of those prisoners who have truly reformed to the point of genuinely having altruistic motives. Having such motives puts them a cut above most free-living mortals.
47. Jonsen and Lee, op. cit., 35-35.
48. Ibid., p. 47.
49. Jonas, op. cit., p. 18.
50. Ibid., p. 19.
51. Lasagna, op. cit., p. 268.
52. See pages 9-10; 10, 15 above.
53. Jonas, op. cit., pp. 16-17.
54. Ibid., p. 17.
55. Katz, op. cit., p. 1020.
56. Jonsen and Lee, op. cit., p. 29.
57. Ibid., p. 34.
58. Ibid., pp. 48-49.
59. See pages 3-4, above.
60. In 1952 the American Medical Association, House of Delegates, adopted the following resolution: "Resolved, that the House of Delegates of the American Medical Association express its disapproval of the participation in scientific experiments of persons convicted of murder, rape, arson, kidnapping, trea-

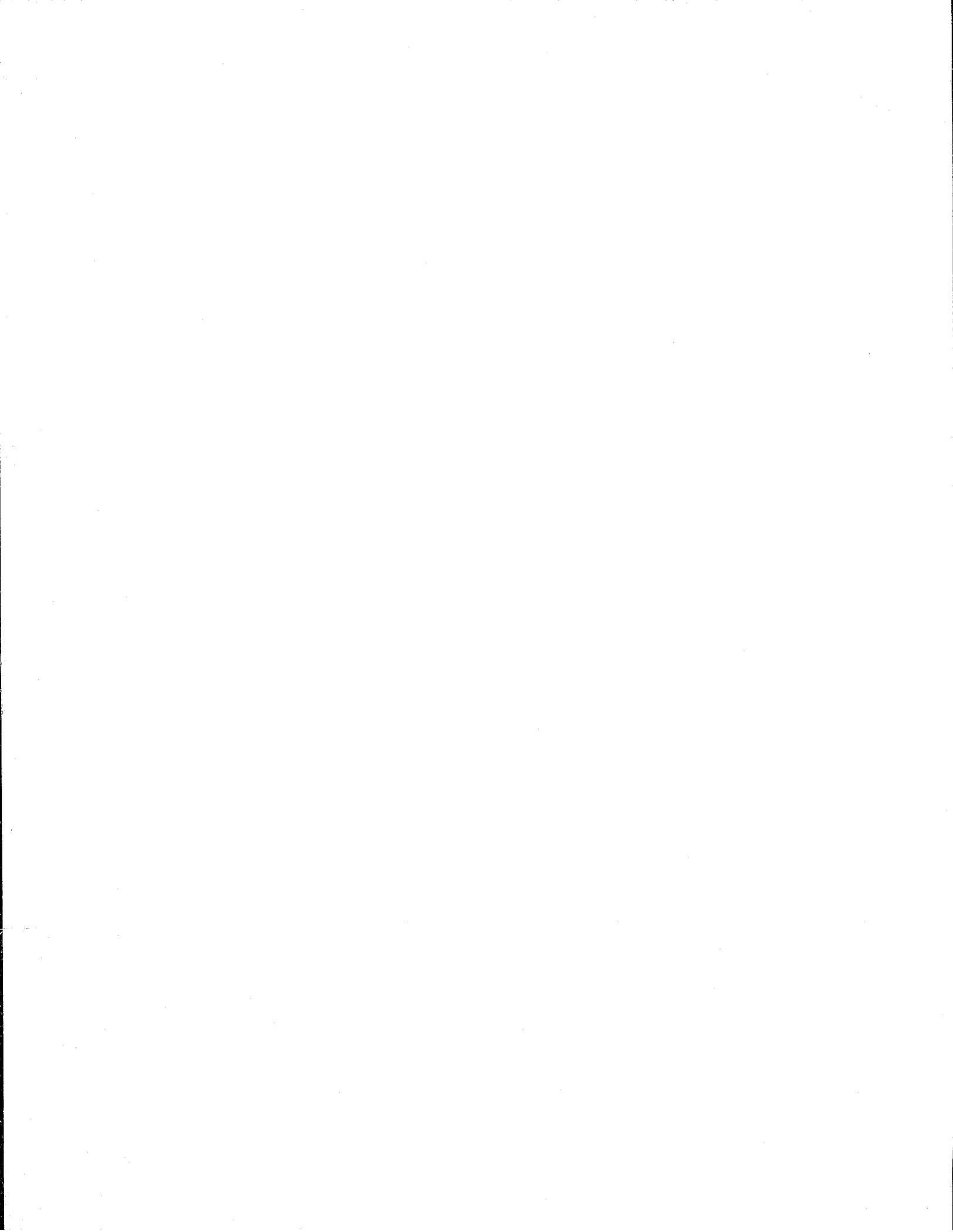
son, or other heinous crimes, and also urges that individuals who have lost their citizenship by due process of law be considered ineligible for meritorious or commendatory citation." Quoted from Katz, op. cit., p. 1025.

61. Ethical Principles in the Conduct of Research with Human Participants (Published by the American Psychological Association, Inc., 1200 Seventeenth Street, N. W., Washington, D. C., 20036). Drafted by the Ad Hoc Committee on Ethical Standards in Psychological Research, consisting of Stuart W. Cook, Chr., Leslie H. Hicks, Gregory A. Kimble, William T. McGuire, Phil H. Schoggen, M. Brewster Smith. Hereafter abbrev. APA; p. 1.
62. APA, p. 2.
63. The drafters of APA distinguish, wrongly I think (see p. 13 above and note 16 above) between a participant's being uninformed and misinformed. As I have urged earlier on, consent to x implies knowing x. Thus where the participant is misled as to the nature of the research, I would say that he has not consented to participate in the research at all (unless he is one of our not-so-aive participants who is on to the ways of some psychological research on human beings and thus does give blanket consent (see page 50).
64. APA, p. 9.
65. Ibid.
66. APA, p. 11
67. Ibid.
68. APA, p. 3-4
69. APA, p. 7.
70. Ibid.
71. APA, p. 10.
72. APA, p. 39.
73. APA, APA, p. 2.
74. APA, pp. 39-42.
75. Pappworth, op. cit., p. 64.
76. See esp. pp. 10-13 above
77. Lasagna, op. cit., pp. 273-74.



BIOMEDICAL AND BEHAVIORAL RESEARCH ON PRISONERS:
PUBLIC POLICY ISSUES IN HUMAN EXPERIMENTATION

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INTRODUCTION

Our increasing awareness and uneasiness about the course of biomedical and behavioral research in this country has led to the establishment of yet another National Commission. The creation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to study the "problem" and make recommendations can be interpreted as a national statement that we have a problem of enormous complexity. Ordinarily such national self-recognition should be applauded. However, our most recent attempts to resolve our national problems such as "crime" or "violence" through the commission process should make us question the efficacy of our present approach. If we think the ability of the nation to face the fundamental issues and to increase the nation's understanding of the "problems" is the purpose of the commission process, some of our previous attempts at commissioning a "problem" should be termed failures.¹ The reasons for failures by this standard are numerous and extremely complex, but I will suggest two explanations. Perhaps those participating in the debates of the previous national commissions failed to ask themselves what the "problem" was that led to the creation of the commission. Or perhaps those participating in the debate and the nation as a whole looked too quickly for "solutions" without a firm grasp of the enormity of their tasks.

By these standards the potential for "failure" looms large for this National Commission, this Conference, and my special topic. We are going to discuss basic ethical issues of "biomedical and behavioral research"² without any working consensus as to the meaning of those terms. In other words, we are faced with the question of what is the "problem"? Furthermore, we have added the present confusion surrounding public policy considerations inherent in any topic on prisoners to the murkiness surrounding the ethical issues. Finally, by trying to ascertain the special perspective of minority communities, this Conference has added to our other two difficulties, the social, psychological, economic, and moral ambiguity that race, nationality, and religion engender in this country. If these three inherent difficulties are not faced explicitly in our discussion, we are in danger of not even developing a dialogue and not coming forward with any recommendations.

Rather than offer a solution to our first difficulty of defining the "problem" before us, I will face the issue through a frank acknowledgment of its existence and enduring power. The terms used in the Commission's statutory mandate, "biomedical and behavioral research", could be narrowly or broadly defined. In its broadest sense, behavioral research could include certain sociological investigations that involve graduate students doing participant observation or prisoner responses to a simple questionnaire. In a more narrow sense, behavioral research

might be interpreted to mean certain types of psychological experiments that are designed to change the behavior of the prisoners. Such experiments in "behavior modification" could include the use of "token economies" in prisons. The term biomedical research is full of similar difficulties since the term might include everything from the testing of new drugs to psychosurgery on prisoners. There is nothing in the statutory language that argues for either a broad or a narrow definition of these terms. The confusion inherent in these terms is exacerbated by the statute's specific instruction to the Commission to distinguish between biomedical and behavioral research and the "accepted and routine practice of medicine".³ Rather than attempt to give definitional contents to the terms, "biomedical and behavioral research", or distinguish these terms from something else we would have to define, I propose to use terminology that encompasses all of these ambiguities.

The term used by the Conference organizers--human experimentation--is broad enough to encompass all of the widely diverse issues we might want to consider.

Clearly within the Conference's consideration are the testing of new drugs on prisoners. Non-therapeutic medical research on prisoners that is not related to drugs such as cures for malaria are also within the notion of human experimentation. Testing new cosmetics, bandaids, or hand lotions is perhaps less clearly within our concern but certainly

contains some of the risks of harm to the subject inherent in the notion of human experimentation.⁴ In addition we must include methods of "treating" prisoners to cure their criminality within our discussion, since these methods raise the question of the distinction between routine medical practice and biomedical and behavioral research. Examples of known proposed experiments utilized so far on prisoners include "aversion" therapy for "acting out" prisoners, and social experiments involving early release for some prisoners.⁵ Perhaps farthest removed from the core meaning of the notion of human experimentation is a sociological study of prison life. Nonetheless, such studies must be included since they are representative of the pervasiveness of the scientific or research ethos in this society. I will thus employ the term human experimentation to describe certain phenomenon knowing that at the perimeters we will have disagreement.

I will also discuss human experimentation as a process involving various actors and events. Looking at human experimentation as a process means that I will attempt to identify the participants, their purposes, and the values they seek to uphold in western man's desire to increase knowledge about the world and to ensure respect for individual worth and autonomy. The actors in the human experimentation process may include, for instance, drug manufacturers, investigators, physicians, hospitals, prisoner-volunteers, and ultimately the

recipients of their services--members of the general public. I will be keenly aware of ways in which the various participants in the process may have conflicts with regard to their purposes and values. I will also pay close attention to how these conflicts are and should be resolved.

Besides helping to illuminate value conflicts within my specific topic, my approach to human experimentation allows for a division of our discussion into functional stages where the decisions and underlying values of the participants can be analyzed more fully. For the purpose of this paper, the process of human experimentation is divided into three distinct but interrelated stages.⁶ These stages are:

- (1) the formulation of research policy;
- (2) the administration of research;
- (3) the review of research and its consequences.

If for some reason these functional stages are inadequate ways of addressing the problem, other divisions are possible. Regardless of the analytical framework adopted, you will have to resolve the value conflicts that I identify, and decide if the process method of dealing with the issues is sufficient to meet your own definitions of the problems before this Conference.

The other major advantage of the process approach is that the explicit assumptions that I bring to the other two difficulties in my topic--prisoners and minorities--can provide a means of stimulating discussion and furthering much needed dialogue.

Since a large percentage of human beings incarcerated in prisons in this country are members of minority groups,⁷ we might assume that the issues of prisoners and race are merged for the purposes of our discussion. Yet both issues are so inflammatory that we should be explicit rather than implicit about the relationship of race and prisoners within the process of human experimentation. The explicit assumption that guides the following discussion is that the fact that a large percentage of prisoners are members of minorities means we should not try to separate out the "minority issues". There are two reasons for my assumption. First, the most determinative factors in guiding the actions and decisions of the investigators, prisoner administrators, courts, and prisoners are the public policy decisions that are explicitly and implicitly made about human experimentation in prisons. Therefore, this Conference cannot ignore the difficult issues of what kinds of research, if any, should public and professional authorities allow in prison? Second, and ironically, in order to make explicit the moral lessons we have learned or failed to learn about minorities and human experimentation, we must first see the public policy issues. The relationship of the issue of race, religion, and nationality and scientific experiments on human beings looms large in our western consciences because of the Nazi Concentration Camp experiments on captives during World War II.⁸ A careful

examination of those horrifying experiments convinces me that we must understand the process of human experimentation and the allocation of public, professional, and subject decision-making authority within that process to avoid such future holocausts. It is also too easy for the participants in this Conference to evoke the Judgment in the Nuremberg Case without giving any explicit guidance to the persons involved in the decision-making process that leads to the use of minority prisoners as subjects of experiments. Rather than build special mechanisms for the control and promotion of experimentation on minority prisoners, my assumptions lead me to argue that the special methods are needed for experimentation on all prisoners.

I will thus use a process method to identify three major issues that must be resolved in order to design the necessary kinds of special mechanisms of control for research involving prisoners. I will first develop some guidelines surrounding the formulation of research policy for studies involving prisoners as human subjects. The policies that determine how and why the human experimentation is started are important to the manner in which value conflicts are resolved, and whether the process can achieve the desired degree of social control. Second, I will propose that we look critically at how research involving prisoners is administered. At this point, I will be particularly concerned with who should participate in these administrative

decisions. Within this discussion, I will be able to address the issue of the "consent" of prisoners to human experimentation as required by the Commission's statutory mandate. ⁹ Thirdly, I will address the question of how the decisions and consequences of research on prisoners can be reviewed. Review mechanisms, however, are not the only means of control that will be included in my recommendations. Within these discussions I will include my overall recommendations, derived from my process approach. These recommendations will avoid absolutist positions on the various issues that I raise. By the time I conclude this short discussion of an enormously complex problem, I hope you will see that this Conference is a part of the process of human experimentation.

I.

The Formulation of Research Policy for
Research Involving Prisoners as Subjects

First, we should insist upon a careful examination of the purposes of any research that proposes to involve prisoners as human subjects. Examination of the purposes of research before it is implemented will increase our awareness of the value conflicts inherent in any proposed human study. Such a requirement has the additional purpose of helping those engaged in

research to become more articulate about how their own values and goals are furthered by the proposed research. Such general scrutiny of research rather than assuming research should go forward, will help us understand the powerful social forces that lead humans to experiments with other humans. We should not be surprised that without such an approach prisoners were used in experiments to develop vaccines ¹⁰ long before our present heightened awareness of the issue of prison research.

The purpose of the requirement of careful scrutiny is to alert all the participants--individual investigators, the sponsoring agencies, and the prison administrators--in the research formulative stages that the use of prisoners as subjects is a special case of human experimentation with high risks to fundamental values. This level of scrutiny should lead those engaged in research policy formulation to ask and resolve for themselves in a satisfactory fashion three issues. First, are prisoners the appropriate subjects for this particular proposed form of human experimentation? Second, what are the societal interests to be gained from the proposed experiment and how do these relate to other pressing societal needs? Third, what are the possible types of risk of harm that may flow from the experiments and what steps have been taken to minimize those risks of harm to the subjects? Ideally, unsatisfactory answers to these inquiries could lead to the decision

not to implement some proposed human experiments. An examination of previous cases will demonstrate, however, that too often research involving prisoners goes forward without this type of "strict scrutiny" before implementation.

The participants in research policy formulation should begin with a presumption that prisoners should not be chosen as subjects of experiments. For instance, the investigator might ask if there are others in a non-captive setting who are willing to volunteer as healthy subjects to help find a cure for malaria. In point of fact we know there are few, if any, "free world" volunteers for such non-therapeutic biomedical research endeavors. Despite the "fact" that prisoners are the only potential subject pools, our method of strict scrutiny should alert us to the research policy implications of our limited knowledge about why prisoners volunteer. One study indicates that prisoners who volunteer for non-therapeutic biomedical research may view longterm and shortterm risks in a different manner than that of the free population in general.¹¹ On the other hand, another study indicates that the social position of prisoners within the institution was more determinative in the decision to volunteer, than was their attitude towards risks.¹² While the studies tell us different things about why prisoners volunteer, they are nonetheless useful in developing policy on how prisoner-subjects are recruited. First, the study makes the decision-maker go beyond the issue of the boredom and general

level of fear in most of our state prisons and jails in deciding whether or which prisoners to attempt to recruit as subjects. Second, depending upon what is known about the particular institution as research policy is developed, we might try to eliminate certain prisoners from the potential subject pool according to the studies' criteria. The investigators, sponsors, and prison administrators would try to determine, for instance, if the level of fear of harm is so high in the particular institution that all "loners" without protection are likely to volunteer. Or the participant may try to develop a means of eliminating those prisoners with the least aversion to risk from the potential subject pool. ¹³ I am not suggesting that such tasks are easy, but they are better means of developing subject pools in prisons than those previously suggested in the literature. Investigators should not eliminate prisoners as "unworthy" of participating in the "great" scientific enterprise as was suggested by one professional organization. ¹⁴ Nor should the subject pool be developed by categories of offense, for instance, "eliminate those convicted of rape, murder, arson, kidnapping, treason, or other heinous crime". ¹⁵ If, for instance, we concentrated on "aversion" to long-term risk as our criterion of selection, we might well discover that the persons convicted of violent crimes are more averse to longterm risk than a repeated petty thief incarcerated in a jail facility. The formulators of research policy must face directly the issue that incarcerated prisoners generally want most research

to continue, regardless of the prisoner motivations. If the prisoners are to be denied the opportunity to participate--be it to relieve boredom, earn money, etc.,--that decision should be as explicit as possible. In general the value conflicts inherent in using prisoners as subjects is made more clear if the volunteer pool is developed so as to ensure that the subjects are those with the maximum opportunity to refuse to participate. In general, researchers should be required to explain why prisoners were chosen as subjects. The failure to develop an adequate subject pool for the proposed study according to the method of criterion chosen by the investigators and administrators should lead to a decision not to proceed with the experiment.

The process of requiring those engaged in research to decide about societal interests and priorities will lead to the rejection of certain research under certain circumstances. This process further forces the investigators, sponsoring agencies, and prison administrators to articulate their own values about the purposes of incarceration, and their attitudes towards the human beings who are incarcerated. Two kinds of examples can highlight the usefulness of the second stages of decision-making about proposed research. First, it was once suggested that those sentenced to capital punishment be given the opportunity to volunteer for medical experimentation instead of receiving the

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death penalty. At one level it might be deemed more "worthy" to die in the pursuit of some scientific advance rather than suffer a "useless" death in the gas chamber. But if the issue is phrased in another manner, we will see that some serious questions of personal and professional morality must be faced before the project is undertaken. Does the investigator agree with the apparent social decision that the condemned person's life is useless? Are the administrators of the prison entitled to authorize such an experiment if the public's attitude about capital punishment and the purposes of punishments in general are in doubt?¹⁹ A more likely example involves the use of inmates at a city jail facility, for the purposes of conducting a controlled experiment involving "heroin maintenance".²⁰ If the purposes of legal confinement of heroin addicts is to "treat" them,²¹ would a jail administrator of the city jail be justified in deciding that a pilot program might be tried? I will not answer this question since the answer depends upon one's theories of heroin addiction, upon one's attitude towards the prevailing ethos of "treatment of prisoners" which is under heavy attack, and upon one's attitude about the efficacy of the alternatives--jail, methadone treatment²² or outright release.

The third part of designing research policy that uses prisoners is to decide about harm. Here it is useful to articulate as precisely as possible the types of harm--psychological, physical,

privacy and self-determination, etc.--involved in any proposed research. The purpose of this inquiry is to force the investigator and the sponsoring agency to identify the kinds of additional risks of harm involved in the proposed research, so as to minimize those risks. However, it is important in dealing with prison research not to romanticize the harm that the proposed experiment adds to the prisoners' life. Moreover, it is never possible to eliminate all risk of injury. Nonetheless, greater care could be taken to provide, for instance, for psychological counseling in the research design, if the threat of psychological harm was recognized before the project began. Similarly, biomedical research should include backup medical facilities for the prisoners. These kinds of precautions have often not been taken because of the failure of the researchers to engage in the type of strict scrutiny proposed here.

II.

Administration of Research Involving Prisoners As Subjects

We need not go back to Nazi Germany to realize that the administration of experiments on human captives should include persons other than individual investigators. Several well publicized incidents in this country in recent years indicate that we cannot

leave Phase I testing of drug or blood plasma testing to the
discretion of individual investigators. ²³ The essential
question then becomes--who besides the individual investigator
should participate in the administration of research on human
subjects in prison? There are four basic issues that must be
resolved before we can answer the essential question. First,
in response to these well publicized abuses on captive popu-
lations, we are naturally inclined to look to state regulation
as one solution. But that question is still essentially--who
among the variety of state officials with the power to regulate
research should administer the process? Second, we will address
the question of who should participate in the professional
regulation of research in prison since professional controls
are possible alternatives or complements to state regulation
of research in prisons. Thirdly, we will discuss whether the
special status afforded prison research in the research formu-
lation stage should lead to a process of monitoring and evaluating
the design and scientific merits of any project that is implemented.
Finally, we will discuss whether the consent of the prisoners to
the experiments should be supervised in ways that are distinct.
In general, we will find that the elements of "consent" are not
the overwhelming issue in prison research that we might assume
from the statutory mandate to the National Commission. Rather,
defining the functions of consent in the human experimentation

process in prison will remain the most difficult issue to resolve once the research design has been implemented.

State regulation of the administration of prison research might ordinarily be a matter of ensuring that volunteers for research projects are not given special institutional advantages such as better chances for parole as a reward for participating in the project. But two larger issues loom in the public eye today. First, whether the legislatures should prohibit all research in prisons. Second, whether the legislatures should require special kinds of administrative structures for certain kinds of human experimentation in prisons.

As to the first issue, I would urge this Conference to refrain from recommending a complete prohibition on all research involving prisoners. Not only would such a position not deal adequately with what we do and do not know about the complexities of the situation, but also the prohibition is likely to lead to the recruitment of new subjects. Such subjects, for instance, for Phase I drug testing, are likely to be "disadvantaged" by some standard. It has been suggested that the drug manufacturers would be encouraged to seek volunteers in poor and less developed countries if there were a complete prohibition in this country.²⁴ In other words, a complete prohibition in this country will simply displace the value conflicts we already have about research on prisoners, but not eliminate those conflicts.

As to the second issue of whether some form of legislation is needed for certain types of special treatments utilized in prisons, I agree with the growing consensus that such legislation would be useful to the proper administration of these types of experiments. These types of experiments, usually called treatment, aversion therapy, or organic therapy, ²⁵ are crucial to this Conference because of the statute. These types of experiments are the prisoner's version of the distinction between "biomedical and behavioral research" and "routine medical treatment". Even though aversion therapy has been utilized on free world population, in our discussion the label "treatment" might hide the potentially extra coercive effect of these kinds of biomedical and behavioral interventions. We should bear in mind that the definition of prison used in the statute includes "... any place for the confinement or rehabilitation of ... individuals charged with or convicted of criminal offenses". ²⁶ Thus the treatment or rehabilitation aspects of the definition of potential subjects means that our area of concern should include a host of treatment programs. We might need to consider whether any treatment offered or forced upon individuals confined in a specialized institution for "defective delinquents" should have special administrative mechanisms for what the officials call ordinary treatment. At the other extreme we should consider whether "social experiments" such as a decision to conduct a controlled experiment on early

release should also be the subject of special legislation, or left to the administrators of the prison and parole boards. At this stage of our development I would suggest only special legislation for "organic therapies" such as psychosurgery, a special topic addressed by others at this Conference. I would be wary of relying on legislatures to develop effective legislation that singled out "aversion therapy" or organic therapies for special treatment. The present state of public awareness ought to lead correctional officials to question whether any proposed therapy to cure the prisoners of their criminality is authorized without special legislative authority. We must also insist that other regulatory bodies, such as the Federal Drug Administration, share responsibility for research in prisons.

Our apparent public posture that more state regulation of prison research is needed ought to alert us to the need for professional regulation to control those areas where state regulation is likely to be ineffective. As an adjunct to state regulation, we might easily agree that all professional organizations whose members do any research involving prisoners ought to develop guidelines for their investigators. But a more controversial question is whether prisoners, as a source of potential subjects, ought to be included as part of the professional regulation of research involving prisoners. For instance, is it not possible that a sociologist engaged in certain types of

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"advocacy research" in prison might come to conclusions that are "harmful" to prisoners? What if his honest scientific conclusions were that more frequent use of "isolation" would in fact eliminate certain types of prisoner behavior deemed undesirable? Would not an even greater claim for prisoner participation in the research project be made by an assertion by the advocacy researcher claiming that his research would "benefit" prisoners?

The claim for prisoner participation in the professional regulation of at least some research in prison becomes more plausible if we consider that the prisoner as volunteer ought to be viewed as a participant in the human experimentation process. In addition, we should be skeptical of those professionals who would resent any prisoner participation since professionals are protective of themselves when it comes to the risks of human experimentation. It is noteworthy that some of the leading medical schools prevent the use of their own medical students-professionals--in experiments that involve "risks to health and well beings".²⁸ Why shouldn't the prisoners--the professional subjects for vast numbers of experiments--be allowed to develop some means of self-protection that is binding on the other professionals in experiments? While I have no specific suggestions as to the form that prisoner participation in professional regulation should take, I can point



CONTINUED

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to a tentative direction from a combination of the two guidelines.

Investigators who claim that the research will "benefit" the prisoners as a group should be required to include some prisoners in the administration of the research. Prisoners are in some sense the best determinators of what is a "benefit". On the negative side prisoners are also in the best position to see the adverse social, psychological, or moral consequences of race in the appropriate institutional setting. If professionals are unwilling to see the prisoner-subjects as true participants in cases of alleged benefits to prisoners, we might begin to question the meaning of the supposed "benefit". On the other hand, with regard to non-therapeutic research on prisoners, for example, the malaria experiments, ironically might be conducted without prisoner participation since there is no claim of benefit to prisoners as a primary justification for these experiments.

Every prison experiment must involve a stage where either state or professional participants evaluate the research design and the scientific merits of each project. One purpose of this stage is to see if the violation of the explicit guidelines developed should lead to cessation or modifications. As mentioned earlier, a lack of sufficient volunteers could lead to termination of a project. ²⁹ Another purpose of the evaluation of the design and scientific merits of prison experiments is to develop over time some sense of the kinds of research that should be conducted in prison. We will find that those experiments most in need of research design evaluation because of their public policy impli-

cations--social experiments--are the most difficult to evaluate because of our ethical doubts. For instance, to do a controlled experiment on early release, it might be necessary for the correctional officials and the investigators to employ the technique of "deception".³⁰ And yet the requirement of evaluation should not frighten off the researcher seriously interested in these kinds of empirical tests, provided he can meet the ethical objections or doubts. More importantly, we should insist that the evaluation of both the research design and the scientific merits of other kinds of research be undertaken, e.g., the evaluation of Phase I drugs tests in prison. Not only is such evaluation relatively easy, but the results of such tests have wide social implications since the marketing of a new drug or product is dependent on the prison experiments. Again our awareness of past abuses and our interest in self-protection indicates that research design and scientific merits of prison research should be prophylactic requirements.

Our final issue in establishing a structure for the proper administration of experiments involving prisoners--whether consent should be supervised--is the most confused. Congress apparently thought the National Commission should determine the "requirements" of consent for prisoners.³¹ Unfortunately, we cannot identify the elements of consent for prisoners because we have not understood the notion of consent in human experi-

mentation generally. Our public discussion indicates, for instance, that some notion of voluntary consent can eliminate issues such as whether there is sufficient scientific merit in the experiment to allow any human being to consent. Second, we forget that "consent" is not a well developed legal doctrine in therapeutic settings.³² Thus the functional relevance of "consent" to the human experimentation process generally, and prison experiments in particular, ought not to be assumed. Third, we often fail to realize that there are inherent limitations to the function of "consent".

The issue of whether consent should be supervised is best seen if we concentrate on the "informed" portion of the notion of "informed consent". Essential to this notion is a willingness on the part of participants to share knowledge with the subject.³³ The imparting of knowledge to the prisoner-subject thus requires certain preliminary measures of maximum information-gathering and dissemination to the prisoners-subject pool. In practical terms these notions require diagnostic screening of all subjects. For instance, in a drug test, one of the requirements of an informed consent is that the prisoner knows his present medical condition. The medical diagnosis should be documented and given to the potential subject in both written and oral form before his "consent" can be deemed informed. The dialogue would thus include a discussion of the risks vis-a-vis what is known about this particular person rather than simply the general risks.

These rather elaborate process will help to alert the investigator to whether their facilities are adequate to take care of all known risks. Besides hospitals or medical resources, in some experiments the investigator would be required to provide and inform the prisoners of psychotherapeutic aids if there were psychological risks apparent in a particular experiment. All of these remedial measures for handling the risks must be offered to all prisoners without charge so as to avoid their possible use as an inducement to volunteer.

We must then delineate the consent issues very carefully in prison research so as to further the purposes of consent. Prisoner consent cannot authorize an experiment but it is a necessary ingredient to the ethical legitimacy of prison research. Nor should we be afraid to face the possibility that consent is limited and not determinative of all issues. Before the question of consent is even presented to any prisoners, a host of other issues should have been resolved in the formulation of research policy, and in the administration of research.

The supervision of consent in the context of prison research thus plays an important part in the proper conceptualization of human experimentation. Consent does not, however, categorize a legal relationship between the prisoner-subjects and the public authorities and investigators. Rather consent seeks to assure that the subject is a full participant in the process of human experimentation.

III.

Reviewing the Decisions and Consequences of Human Experimentation in Prisons

The major method of reviewing the decisions throughout the process of human experiments in prisons and the consequences of such experiments is through public scrutiny. This Conference and the National Commission is an important part of the review mechanism governing experimentation with human beings. It is apparent that we need more public scrutiny of the current experimentation being carried out in prisons. One way to subject this experimentation to public scrutiny would be to require all prison administrators to make public all the research that they have authorized in the various institutions that they administer. Other governmental agencies such as the Federal Drug Administration or HEW should develop means of reviewing research in prisons where they have some means of controlling or regulating such research. For instance, each prison should be required to have an institutional review board for all experiments. ³⁴ Such boards could include prisoners who are not subjects, as well as various types of professionals some of whom are not connected with the correctional system or with human experimentation.

The other method for reviewing the consequences of experimentation is a willingness to allow the subject access to legal process for the vindication of all claims of injury. While it is noteworthy that a few courts have insisted that lower courts consider

the claims of prisoners subjected to "experimental therapy" by public officials for damages against those officials,³⁵ these decisions have not eliminated all issues of access to court and the public. It is more important to focus upon the emerging issues of whether the state can incarcerate a person for the purposes of "treatment" without adequate treatment. However, the "right" to be out of state control may be more important to the subject-captive than whether or not he receives treatment.

Included in these discussions of giving access to the courts is the notion that all research in prison should be done on a "non-fault" basis.³⁶ That is, the prisoner need not assume the risks of physical injury and need only prove his participation in the experiment and the resulting injury. Such proof should be relatively easy to establish if there is adequate screening and documentation of the subject's physical condition before the experiment is undertaken. As to psychological or emotional injury, I am not as certain that such matters ought to be subject to suit. But HEW and all federal agencies should require that as a condition of obtaining funds for an experiment in prisons there be a special contract proviso prohibiting the waiver of defenses, and requiring an authorization to bring suit on the basis of any injury without regard to consent. In other words, consent will not be used as a "defense" to any lawsuit.³⁷ In order to prevent the non-fault proviso from creating a "moral hazard" and in effect increasing the amount of experimentation, the first issues of access to court to question the public officials is the more important means of public scrutiny.

IV.

Summary

My general recommendation is for this Conference to avoid absolutist positions. There is little justification for a complete ban on all research in prison at this time. On the other hand, I should reiterate that our experience with race and human experimentation means that we should similarly eschew the position that we can leave the ethical issues to the individual investigator. The forces that led to the abuses of the Nazi concentration camp experiments are deeply engrained in our culture. It is not just that "racism" is so endemic, as it surely is in this society, but that the need to experiment with human beings is also so endemic. With such a positive force to contend with, we must understand that force in order to evaluate the kinds of risk of danger to prisoners in the experimentation process. Then finally, we must articulate the dangers to minorities inherent in the process of experimentation on prisoners. Values about race, religion, and nationality are part of the value conflict that must be resolved in prison research.

From my process approach, I would recommend that the Commission be instructed to inform Congress and the society at large that the decision to experiment on prisoners requires very careful scrutiny because of the subject's status and because of the minority status of most prisoners. I would further recommend that we avoid trying to scrutinize the "ethnic authenticity" of investigators in order

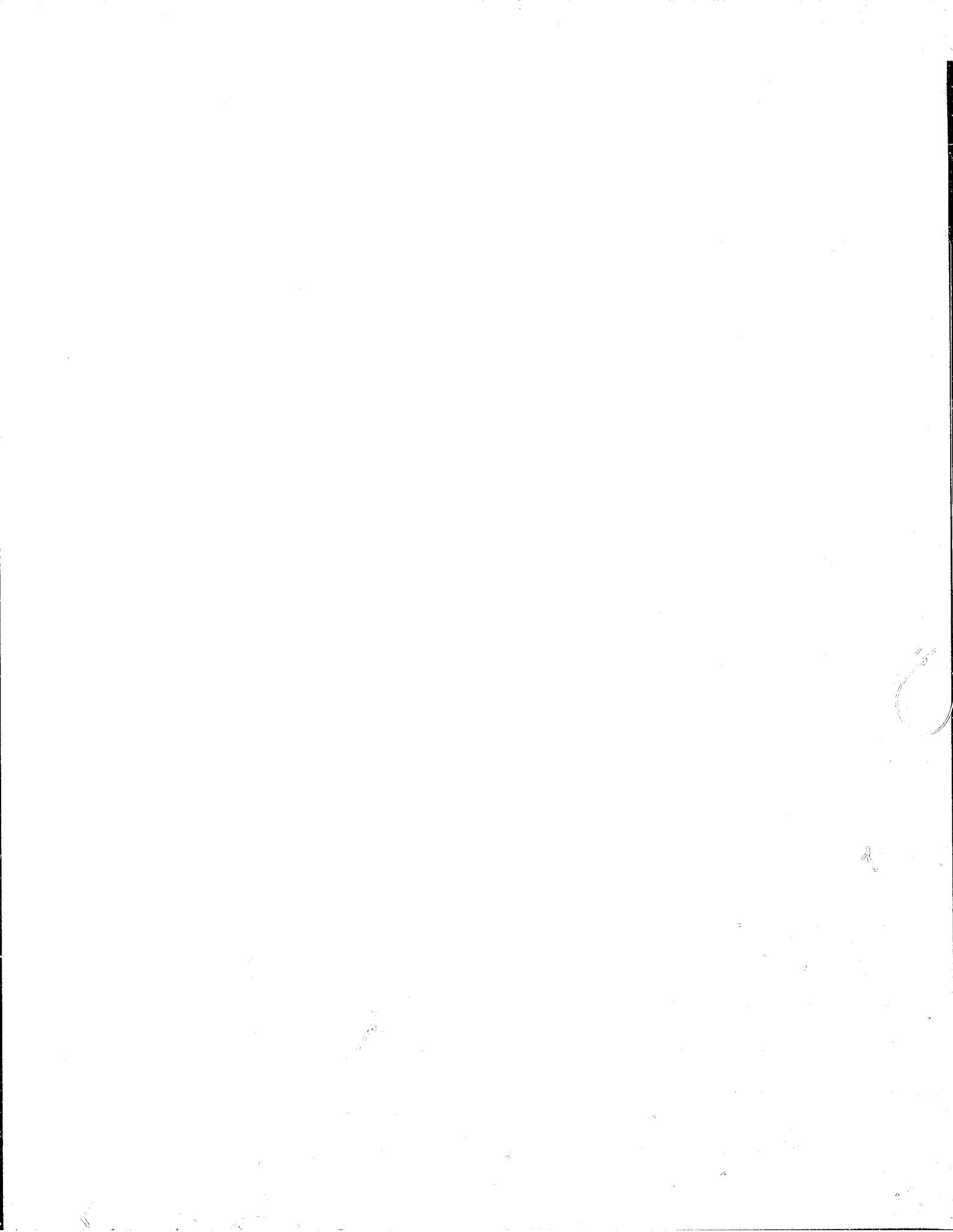
to deal with this problem. Just because the investigator gives assurances of his "civil rights" background or his own minority status does not adequately deal with the problem. Rather the process of scrutiny of the values involved in the fashion that I have proposed is the only remedy I can suggest at the present time. Thus, along with the policy statement on the experimentation on prisoners, I would suggest that all persons sponsoring research in prison require from the investigator a statement explaining why prisoners are chosen for this particular experiment rather than "free world" volunteers. Such a statement should include a clear delineation of the kinds of harm, and the measures taken to insure that harm can be avoided. The statement should also require an explicit discussion about the societal interests and priorities for the particular research project, as well as a discussion of how consent is to be supervised. Finally the public officials and professionals should readily grant the prisoner the right to question in court of law and other public forums any harm resulting from the experiment. Such prisoner access will help to assure the kind of public scrutiny of human experimentation that we are engaged in at this Conference.

FOOTNOTES

1. For an excellent critique of the National Commission on Crime, see generally, Lehman, Crime, The Public and the Crime Commission: A Critical Review of the Challenge of the Challenge of Crime in a Free Society, 66 MICH. L. Rev. 1487 (1968).
2. Pub. Law 93-348, §202(a)(1)(A).
3. Pub. Law 93-348, §202(a)(1)(B)(i).
4. See, Mills and Morris, Prisoners as Laboratory Animals, 11 Society 60 (July/August 1974).
5. N. Morris, Impediments to Penal Reform, 33 U. Chic. L. Rev. 627, 646-653 (1969).
6. See generally, Katz, Experimentation with Human Beings, 1972 [hereinafter Katz].
7. The adequacy of the statement depends upon how one defines minority. In New York, for instance, if we take Black and Puerto Ricans as our definition for minority, 70% of the prisoners are members of minorities. Sostre v. Rockefeller, 312 F.Supp. 863, 876-877. In California Blacks and Chicanos constitute nearly 40% of the prison population. Ridenour, Who is a Political Prisoner?, 1 Black Law Journal 17 (1971). If we use "poor" or "socially disadvantaged" to define minority, the percentage would be probably larger. I am unable to document the exact percentage of "minorities" in prison. For the purposes of this paper, the exact figure is irrelevant.
8. See United States v. Karl Brandt, reprinted in Katz at 292-311.
9. Pub. Law 93-348, §202(a)(2).
10. As early as 1906, there are reported instances of prisoners being used to test a vaccine against the plague. Katz at 1014-1016.
11. Katz at 1022.
12. Katz at 1024-1025.
13. The formulators of research policy would have to decide if some form "testing" of volunteers is ethical. For instance, a general questionnaire on "risk-aversion" might be administered to all volunteers. Would it be ethical to administer the proposed questionnaire without telling the volunteers that its purpose was to eliminate some volunteers from the study?

14. See, e.g., a statement from the American Medical Association that expressed disapproval of "citations" to prisoner-subjects, in 1952 as well as criticized "early release" for volunteer reprinted in Katz at 1025.
15. Id.
16. See supra note 4.
17. In the well known psychosurgery case of Kaimowitz v. Department of Health, Civil No. 73-194 34-AW (Cir. Ct. Mich., July 10, 1973), the research protocol called for at least 24 subjects. When only one subject meeting the investigators' own criteria could be found, shouldn't the investigation have stopped?
18. Kevorkian, Capital Punishment or Capital Gain, 50 J. of Criminal Law, Criminology, and Police Science, 50 (1959) reprinted Katz at 1027-1028.
19. The nine opinions in the Supreme Court's first decision on the Death Penalty in the United States represents great disagreement about the purposes of punishment. See, Furman v. Georgia, 408 U.S. 238 (1972).
20. Such an experiment was proposed in recent years by the Vera Institute in New York City, but dropped after public criticism.
21. See generally, Robinson v. California, 370 U.S. 660 (1962).
22. The efficacy of methadone programs is under some attack. Epstein, Methadone: The Forlorn Hope, The Public Interest.
23. Katz, at pp. 1041-1050.
24. See supra note 4.
25. See generally, Shapiro, Legislating the Control of Behavior Control of Behavior: Autonomy and the Coercive Use of Organic Therapies, 47 S. CALIF. L. REV. 237 (1974).
26. Pub. L. 93-348, §202(a)(2) refers to 42 U.S.C. §3781 for a definition of correctional institutions.
27. I do not mean to imply that this type of research is necessarily good scientifically.
28. Harvard Medical School Rules Governing the Participation of Medical Students as Experimental Subjects, reprinted in Katz at 1036.

29. See supra note 17 and accompanying text.
30. See supra note 5.
31. See supra note 9.
32. Katz at 523.
33. For a discussion of consent in a therapeutic and experimental situation see Capron, Informed Consent in Catastrophic Disease Research and Treatment, 123 U. Pa. L. Rev., 340 (1974).
34. See supra note 4.
35. See, e.g., 1141 Knecht v. Gillman, 488 F.2d 1136 (8th Cir. 1973); Mackey v. Procunier, 477 F.2d 877 (9th Cir. 1973).
36. See, e.g., People ex rel. Blunt v. Narcotic Addition Control Commission, 295 N.Y.S. 2d 276, aff'd, 296 N.Y.S. 2d 533 (1968); portion reprinted in Katz at 1050-1051.
37. Cf. O'Connor v. Donaldson, 43 U.S.L.W. 4928 (1975).
38. See supra note 4.

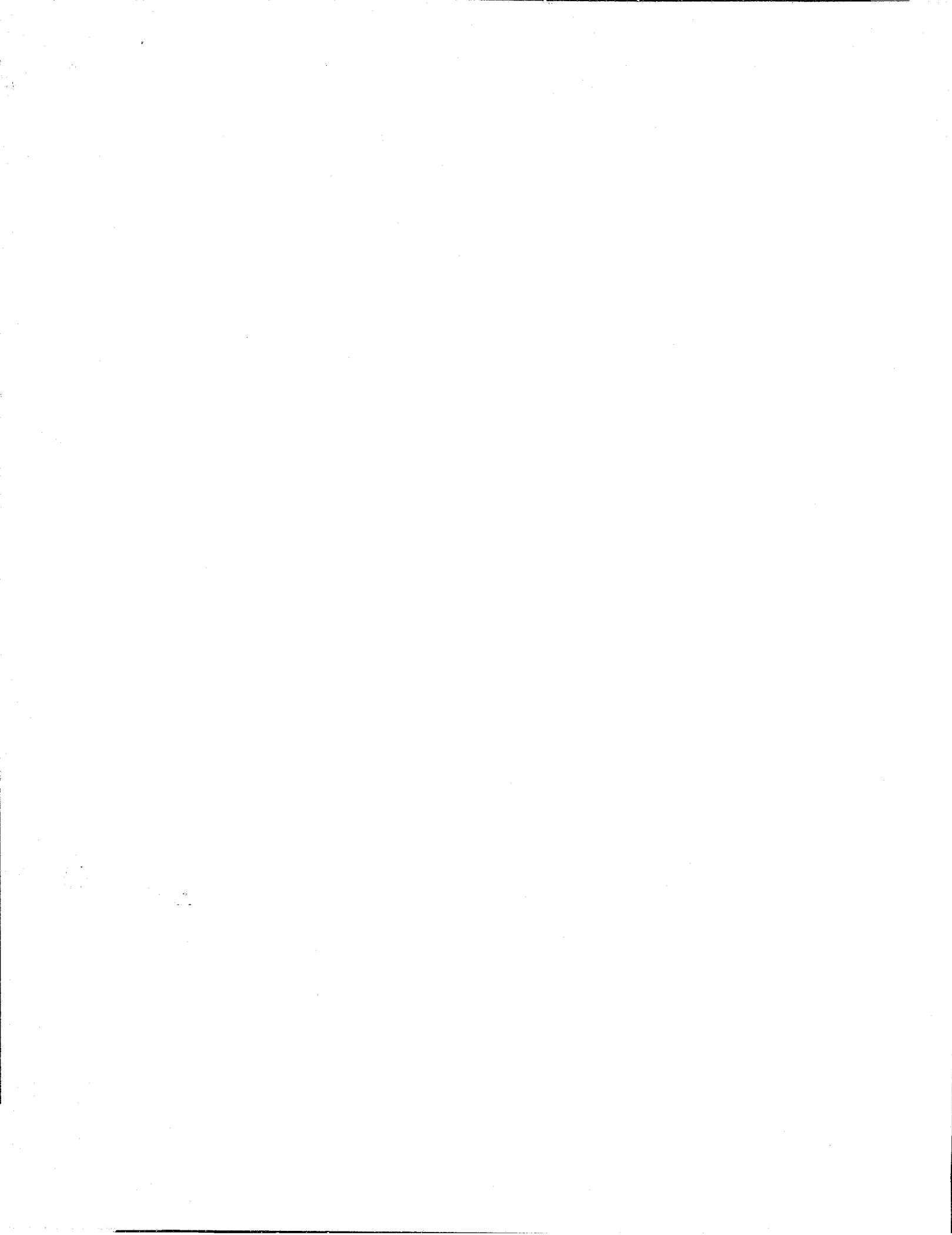




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ETHICAL ISSUES IN RESEARCH AND
EXPERIMENTATION IN PRISONS

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Ethical Issues in Research and Experimentation in Prisons

Historically, the prison as an institution in society has been a place for the research activities of many social and behavioral scientists. Some have not concerned themselves with an immediate practical result but rather with investigating fundamental facts, processes, and phenomena. On the other hand, there are those social and behavioral scientists who have established research projects within the prison which were designed to answer specific questions usually for control purposes, that arise within the prison system in the process and pursuit of administrative goals. Those who have been innovative and have produced progressive ideas have for the most part, left their findings to the discretion of prison and state officials to interpret, translate into policy and apply.

Research in prison has traditionally been undertaken under the guise of determining the causes of criminal behavior, and the development of approaches and programs that would assist the inmate to live more successfully in society. Because most researchers attempted to locate causes in the individual "offenders" the program and approaches have focused on changing the personalities of the offenders. The problem here is that the approaches were generally applied to selected offenders who had to follow certain programs regardless of the true nature of their guilt.

In the last 30 years the Federal Government and private foundations have developed an interest and concern in research in corrections. So much so that an enormous amount of money has been spent in an effort to develop plans and programs to deal more successfully with "criminals." Not only has research been undertaken to add to our fund of knowledge about criminal behavior and society's response, but to evaluate the effectiveness of the new techniques and approaches in the programs in corrections.

A considerable amount of cooperation has always been extended by institutional administrators to researchers who seem to recognize the need for involving social and behavioral scientists in applied research and solving problems in correction. More recently, a more important and practical reason for institutional administrators interest in research is their concern for enhancing the effectiveness of rehabilitation programs. Somehow, this defined need has been recognized by officials, working professionals, and social and behavioral scientists. Sellitz and others have argued that:

Historically, the scientific enterprise has been concerned both with knowledge for its own sake and with knowledge for what it can contribute to practical concerns.¹

The real question is whose concerns have social and behavioral scientists served and what is the principle ideological guide for research in prisons? When we engage in research we must concern ourselves with our particular concerns and the ideological principle that undergirds the research.

The Prison Condition

To deal adequately with the issue of research in prison we must first look at the relationship between the needs of the state and the prison system. Almost everyone who has visited prisons agree that they are probably the worst places in all the world for human habitation. Guards have been oppressive and repressive and have created certain conditions which forced some inmates to carry out atrocities such as beatings and floggings against those inmates who defied their presence in prison in political terms, and attempted to organize political action against oppressive conditions. Inmates are required to work every work day and the labor is practically free to the state. Inmates do not benefit from their labors which bring income and profits to the prison system and to the state. The inmates did not wear clothes from the cotton they grew, neither did they eat any of the fresh vegetables they grew on the prison farms. Instead, they ate leftovers and rotten potatoes. No money went to the inmates or their families, and very little money was spent to improve the living conditions in prison. Slave labor, brutal treatment, and inhuman living conditions, inadequate medical attention and insufficient dental care, characterize the majority if not all of America's prisons.

These conditions have persisted because the prison system serve the same purpose today as it did thirty years ago - that

of exploiting the labor of poor and working-class people who have been judged by state officials to have violated the criminal law for which they have been convicted.

Prison conditions are the function of the definition of inmates as subjects of the state and prison officials as agents of the state in terms of the needs of the state and the powerless nature of the presence of inmates in the prison system. It is within this context that research in prison may be understood and the associated ethical issues discussed. Research by social and behavioral scientists within the prisons must take as its concern exposing oppressive conditions and the material and psychological needs served by prisons, and the relationship between the prison system and the state.

Consequently, the aim and major objective of research in prison must be to promote the basic ideological principle of human liberation. Under the basic concept there are certain issues to be addressed in prison research:

- 1) Exposing the nature of colonization in prison.
- 2) Exposing racial practices and policies in prison.
- 3) Exposing the capitalist nature of the prison system.
- 4) Translating theoretical knowledge into methods for change.
- 5) Exposing the parasitical relationship between the prior subsystems of the criminal justice system and the prison system.

To provide state and prison officials with information to oppress powerless people and the exploitation of prisoners' labor is unethical to the basic principle of freedom. Consequently, it is unethical to violate the basic ideological principle of human liberation for a system which is oppressive against powerless people who are in prison.

Prior to 1957, so called minorities in the prisons were model prisoners who submitted to the power arm of the state through prison officials. Since 1957, however, we have witnessed the rise of a powerful people's movement outside of and inside the prison for equality, justice, and an end to oppressive condition, repressive racial policies and exploitation. The liberation movement in the United States and the Third World movement in general have influenced events in prisons in America. The struggle included young students and other working-class people who attempted to change the way in which the society conducted its business against oppressed people and the way prisons conduct their business against confined inmates. The response of the rulers was to resort to force through the use of the police, attorneys, courts, and prisons. Open oppression of the most militant individuals characterized the earlier stages of the movement, but as more people got involved in the struggle, and the economic situation reached crisis proportions for working-class people the prisons became overcrowded with blacks, browns and other poor people who had become more

critical of society and its oppressive apparatus, including the criminal justice system. More importantly, many of these new breed of inmates had developed a political conscience which afforded them an understanding of their presence in prison in political terms. Some had even suggested that if oppressed people defined their presence and conditions in the American society as oppressive, then anything done by such people to change those conditions should not be defined as criminal.

Control of prison inmates became more difficult to achieve and the concern for control increased. As the prison population increased the prison conditions got worse. Consequently, those who were involved on the outside began to involve themselves in bringing about change on the inside. However, some have come to realize that no real change will come to prison conditions if there is no real change in the nature and function of the American system of racism and capitalism. These systems establish a need relationship between the police and the state and a need relationship between the prison system and the state. These relationships translate themselves into repressive action against the oppressed and are facilitated by the powerlessness of racially oppressed groups in American Government agencies and commissions. These agencies have suggested certain liberal and conservative changes; courts have issued decrees, and other private organizations and individuals have made certain recommendations for change,

however, these recommendations, suggestions and decrees have not been implemented or complied with. Instead the State through its agents - prison officials - have allowed social and behavioral scientists to conduct research in prisons which is designed to control the behavior of the politically conscious and active prisoners who are defined as "trouble makers." In this sense social and behavioral scientists are used by state agents to facilitate control of prisoners who are critical of the State, prisons and prison officials and who define their presence in prison in political and economic terms.

Although some researchers would argue that social science research has in some sense enhanced a more liberalized climate in the American society, oppressed people who have had to intensify their struggle for liberation and freedom would argue that social science research has been a part of the colonial relationship which exist between institutional power and oppressive control over the prison population.

To the prison population of inmates, in the presence of their raising consciousness, social and behavioral scientists have begun to look like other agents of the power structure. They are perceived to be outsiders who entered the prison system to advance personal and institutional goals that are defined and determined outside of the interests of the prison population of inmates. The "new" consciousness demanded self definition, the rejection of officials definition as "criminals"

and "trouble makers;" self-determination and the move to decolonize research. These moves made it apparent that the norms of pure disinterested scientific investigation were inadequate. Moreover, prison officials recognized that the scientist's control over the research enterprise, including all the intergroup interaction which he/she sets in motion, is supported by the norms of professional autonomy and expertise and may be organized to support and enhance institutional power and control over prisoners. Within this context, the view is held that only the social scientist can define a suitable problem for research because he alone knows the theories of the field and the methods by which theories are tested. In this model of science there is no place for the prison community of those studied to share in the determination and the outcome of research objectives. This stance is unethical and contrary to the basic ideological principle of human liberation. The life problems and needs of the prison community affect us directly and indirectly and should be the starting point for all prison research. Therefore, the traditional gulf between the researcher's purposes and the subject's awareness of what the investigator and his research instrument is all about can be closed.

The in-depth interview is used in prison research and "it is expected that the respondent will spill his guts about various aspects of his personal life and social or political beliefs. The interviewer is supposed to be a neutral recorder

revealing nothing in return about his own life, feelings and opinions."² The attempt to avoid "bias" in the data and its interpretation has also produced certain questions of ethical proportions. "The monopoly, domination and control continues through the stages of analyzing and publication of the results of the studies."³ The prisoners unique outlook and specific responses are typically lost in the aggregate of data which are subjected to standardized statistical summaries, ideal type classifications, or some other operation. Because social and behavioral scientists write for other scholars and "experts," those who are studied usually cannot make head or tail of the research report toward which their own responses contributed. Whenever there is a markedly unequal exchange between two parties and this inequality is supported by a discrepancy in social power, exploitation is manifested.⁴

In social research, subjects give up some of their time, energy and trust. In the process they get nothing from the transaction. Social scientists get grants and research awards which pay part if not all of their salary. Their professional status is enhanced and through the publication they are advanced in status, income, and rank.⁵ The gap is further widened between the subjects and the scientists. It is unethical to exploit the subjected in or out of the prison in this manner. Because it is unethical to use oppressed people as objects, things, and as means only to our own ends in our research projects means that there is need for change.

The poor and racially oppressed in prison have been promised much from social science, but these groups with their pragmatic sense and sensitivity to phoneness know before the social scientists that no tangible change will be achieved in those conditions which oppress them.

Pay off must come from closing the distance between the theoretical and empirical concerns of research activities and the life problems and situations of the inmate population, and from the organization of power to implement and influence change.⁶

Research in the prison, therefore, must begin with the idea of building into it specific strategies that might permit the social and behavior scientist to transcend the exploitive dynamics of the research process. One principle to follow is to pay the respondents for the time they spend talking with researchers or otherwise involved in the research. The money should be defined as a wage for labor-time not a bribe for information. The other principle is that funded research on oppressed communities, including the prison inmate population, should include sizeable grants to the prison population and their organization for development and the enhancement of their programs.

Another principle is for social and behavioral scientists to be honest about the nature and purposes of the research and the difference it would make. Because prisons have been a

complete failure by most definitions, it must be clear that there is dissatisfaction with the way social and behavioral scientists have approached research of oppressed people especially in the prison. We cannot change the total situation through research and we should not make such promises. Nonetheless, every effort must be organized to expose the relationship between the state and the criminal justice system, especially the prison system of which the inability to realize significant liberating changes is a function.

It is unethical for social and behavioral scientists to take sides with those who are defined by inmates as their enemies since they see themselves in a life-and-death struggle with prison officials and the state. Within the context of the principle of liberation it is also unethical to create labels of inmates that distort or humiliate and place them in insidious categorical bags. The principle of human liberation for inmates requires that the gaps between research and action be bridged. This means that certain positions must be taken, and the social and behavioral scientist may also become partisan. Consequently, such scientists cannot consider themselves dispassionate researchers without responsibility for possible misuse of their research findings and recommendations.

More Specific Issues

There is turmoil in corrections today concerning more specific unethical issues which are secondary to the issues of the need relationship between the state and corrections.

Although most of us, if not all, experience some degree of behavior modification in the process of development and growth, the individual takes the initiative and makes the decisions as to which behavior would be changed or challenged.

Behavior modification in the prison are activities instituted by correction officials for the defined purpose of changing the so-called "criminal" behavior patterns of those incarcerated. It is defined so that most of the efforts are focused on repeated offenders and the so-called "trouble makers." It must be understood that the first offender is most vulnerable to being a repeat offender whether guilty or not, and the subjects most subjected to behavior modification techniques are the politically active who have defined their behavior and presence in the prison in political and economic terms.

Various methods to alter behavior in prison fall under the broad categories of surgical and psychological techniques. Group therapy, drug dosages, reward and punishment conditioning, psychosurgery and shock therapy constitute the major approaches. These techniques are used in human experimentation programs in the prison to change behavior as well as to test new medical

techniques. Prison officials and the state, through their agents, (social and behavioral scientists) have defined the involvement of certain inmates as informed consent. That is, the prisoners had been given all of the necessary information concerning the experimentation before consent is requested. However, by definition no informed consent is possible within the context of confinement in prison. The very fact that certain prisoners are defined and selected to be informed about the techniques and programs are developed to alter the behavior patterns of prisoners suggest that informed consent does not exist in prison and is not possible given the nature of coercion in prison.

The essential issue is the ability of the individual to exercise the fundamental right of freedom of choice and the freedom of man to make decisions which affect her/his own body and life. What is unethical is the imposition of the will of the state through prison officials and social and behavioral scientists, by manipulating the will of prisoners within the context of incarceration. To operate in prison in this manner violates the ethical principle of integrity and makes void the dignity of man especially in prison.

It is also unethical to use these techniques and procedures for disciplinary or punitive purposes. It is cruel and inhuman to practice dehumanizing experimentation in prison by

psycho-surgical behavior modification methods. The attempt to alter the behavior of selected persons in prison cannot solve the socio-psychological and political-economic problems which are basic to the nature of the society and related to those incarcerated.

Special programs are established in America where those defined as "aggressive" by the state through their agents in correctional institution, attempt to take short-cuts to the problems of crime by victimizing the victims who are exploited, oppressed and repressed in a system which places more emphases on property rights than human rights. The right to read, have visitors, have exercises daily, have certain personal property, to take a shower more than once per week are basic and fundamental constitutional rights. Punishment is implicit in the sentence to be imprisoned upon conviction for an accused violation of certain moral values upheld by legal principles. Therefore, to use strategies and techniques in the absence of informed consent (which is impossible to obtain in the prison context), to attempt to alter the behavior of selected prisoners is cruel and unethical.

It is also unethical to force the oppressed and exploited to accept responsibility for their behavior in a society that has been violent to them; a behavior which has not been defined by the legal system as criminal.

Most programs in the prison which attempt to alter the behavior of prisoners are anti-resocialization and anti-rehabilitation because they seem to suggest that behavior can be changed permanently without altering the very nature of the American society and the socially developed attitudes of individuals. More importantly, is the force used through these programs of experimentation to facilitate the adjustment of inmates to the prison environment which is contrary to the principle of human liberation and the goal of self-respect, self worth, independence, and the development of the individual's ability to cope with the responsibilities of society. Consequently, the goal of submission, and the destruction of initiative is cruel and unusual punishment.

Another question in prison research and experimentation is the question of the definition of subjects. In order to establish certain tests, or determine sets of relationships or correlations, the definition of "uncontrollable aggression" is applied to rapists and those who have been convicted for murder. Now it must be understood that the tests do not establish causation. If they are organized correctly, the researchers can show correlations and relationships regardless of how significant. From such, most researchers also talk about causation. It is dishonest to talk about causation or give the impression that the correlations are the causal factors to explain the behavior. Most rape is political since

men attempt to gain power and control of the body of women. This is why resistance is so essential to a rape and the rapist. This behavior is an extension of the behavior in the general society where power and control is used against people defined as powerless. Most murders by black people are secondary acts to robbery, burglary and the like. They are secondary crimes to the primary crimes of survival. This is also behavior which is an extension of the historical crimes of exploitation, oppression, violence and racism, employed by white power elites and their agents who talk about these crimes in the history books with pride. However, they have not defined them in criminal terms, and those against whom the criminal acts were perpetuated have never had the power to define them as such or to put their definitions into operation. The danger to the oppressed communities is that once their subjects are used as guinea pigs to determine whether or not there is a relationship between electrical discharges in the brain, and aggressive behavior, their communities which lack the power to defend themselves, are the natural subjects for the exercise of control. For every twelve personality types in prison today, there are twenty-four similar personality types in the so-called free society.

It was after the 1967 riots that it was suggested by a few white scholars that "psychosurgery might be an appropriate way for society to deal with violent-prone dumb young male

participants." The riot participants in the Detroit and Harlem riots were black. However, the participants in the 1917 East St. Louis riots, and those who initiated the Chicago riots were white. In fact, we have not since witnessed a riot as destructive to human life and property as the 1917 East St. Louis riot. The question is whether or not this procedure (psychosurgery) restores the individual to the community? No, its design is to make him more manageable in the prison. There is no answer in these procedures to the essential principle of human liberation. A further question is who would make the decisions if it were found that the procedures can restore the individual to the community? Clearly, the use of these behavior altering procedures within the prison context is evidently for political purposes and points out the danger to the American society as a whole.

There is no question in my mind that most scientific research in America is politically determined, controlled and manipulated in order to repress healthy dissent and legitimate disagreement in a society which has used violence to solve its problems and only condemn it when others resort to it.

The American society, because of its very capitalist nature to exploit and oppress the powerless, limits achievement and advancement in employment, education and politics for this group. The prison is a manifestation of the failure of society and reflects its inability to address the basic needs of powerless people who are racially and economically oppressed.

Summary Issues

1. Any technique or procedure that invades the inmates body and/or his personality involuntarily within the context of imprisonment is unethical and cruel.
2. The prison system is inherently coercive, consequently, it is not possible for an inmate to freely consent to risky procedures to alter his/her behavior. Therefore, informed consent is a myth in the context of confinement in prison.
3. To intrude upon the brain through experimentation to alter the behavior is unethical because it violates the inmates right to privacy. Further, it violates the rights of the individual of free speech and impairs the individual's power to create and generate ideas.
4. Psychosurgical and biomedical research on violence to pacify, and other experimental techniques which curtail the individual's initiative, independence and freedom of thought are repressive and oppressive.
5. Labeling individuals in the prison as violence-prone and aggressive for the purpose of experimental research is dishonest, dangerous and serves the same purpose of political control as the definitions of militant, radical and subversive.
6. Constitutional liberties are seriously in danger when certain behavior modifying techniques are allowed to be operative in a closed setting as the prison system where these liberties should be protected.
7. In a custodial setting where coercion is operative, due process and voluntary participation is impossible. Behavior modifying techniques erode the right to privacy and individual dignity and destroys the development of self-respect and self-esteem.
8. Research which does not promote human liberation, independence and freedom is oppressive, repressive and destructive to human growth and the progress of society.

FOOTNOTES

¹Claire Sellitz, Marie Jahoda, Morton Deutsch and Stuart W. Cook, Research Methods in Social Relations (New York: Holt Rinehart and Winston, 1961), p. 4.

²Blauner, Robert and David Wellman. "Towards the Decolonization of Social Research." in Racial Oppression in America. Harper and Row, 1972.

³Ibid. p. 6.

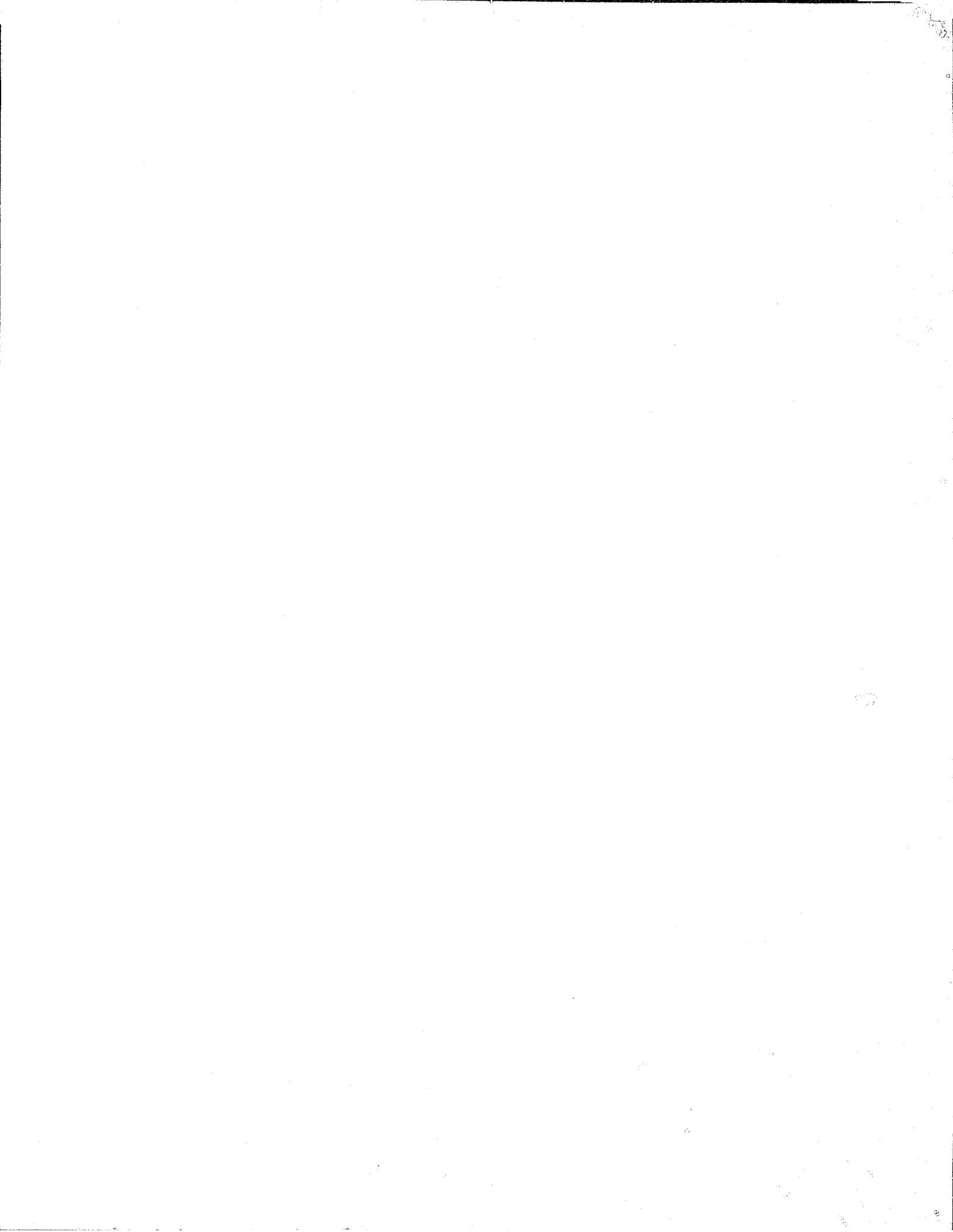
⁴Ibid. p. 7

⁵Ibid. p. 8.

⁶Ibid. p. 8.

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Part III

STAFF PAPERS AND REPORTS

16

PRISONERS AS RESEARCH SUBJECTS

OCTOBER 31, 1975



PRISONERS AS RESEARCH SUBJECTS

I. Introduction

Research activities involving prisoners in the United States are primarily of two kinds: 1) nontherapeutic research, which is mainly the evaluation of new drugs as to safety (and sometimes, by first inducing a disease, efficacy), and 2) research involving new approaches to behavioral therapy or rehabilitation. The history of the use of prisoners in nontherapeutic research, and of the concern about such use, is long. By contrast, the use (and the concern regarding the use) of prisoners in innovative approaches to therapy and rehabilitation is relatively recent.

The circumstances under which nontherapeutic biomedical research and therapeutic behavioral research are conducted in prisons differ sufficiently that the the two areas should be examined separately. The issues raised by the participation of prisoners in nontherapeutic biomedical research revolve around the question whether prisoners are in an environment which is so restrictive or coercive that voluntary consent is impossible. The issues raised by participation of prisoners in therapeutic behavioral research include not only the question of coercion but also the extent to which an individual retains the right to refuse treatment for deviant behavior, or to refuse to be rehabilitated, following conviction by a court or commitment (as an alternative to criminal penalty) based upon psychopathy, insanity or drug addiction. Articles about one kind of research in prisons generally do not express concern about the other kind.

II. History: Nontherapeutic Biomedical Research in Prisons

The use of prisoners for nontherapeutic research has a long history.^{1/} Ancient Persian kings and the Ptolemys of Egypt are said to have employed the practice. It is attributed, as well, to Fallopius (in Tuscany, in the sixteenth century) and to Queen Caroline (wife of George IV, in eighteenth century England). At the turn of this century, criminals under sentence of death in the Phillipines were infected with plague (without their knowledge) by Richard P. Strong, who later became Professor of Tropical Medicine at Harvard. Colonel Strong used another group of Phillipine convicts to study beri-beri, reportedly rewarding them with tobacco in return for their submitting to a disease which caused paralysis, mental disturbance and heart failure. In 1915, Goldberger induced pellagra in twelve white Mississippi convicts in an attempt to develop a cure. In this instance, formal contracts for subsequent parole were written with the assistance of the prisoners' attorneys. In 1934, a program was established at Leavenworth Prison to assess the abuse potentiality of narcotic analgesics (analogues of morphine, codeine, etc.). These studies are continuing at the Addiction Research Center in Lexington, Kentucky.^{2/}

During World War II prisoner participation in research increased considerably in this country. Hundreds of inmates in Chicago and New Jersey prisons volunteered to be infected with malaria to test the safety and efficacy of experimental drugs in treating that disease. This involvement of prisoners in research was considered acceptable and even praiseworthy, since malaria was a serious threat to

our military men during the war, and the research project afforded the prisoners an opportunity to contribute to the war effort.^{3/} Nathan Leopold, who (with Richard Loeb) committed what became known as the "crime of the century," was one of the participants in the malaria project.

Of that experience, he wrote:

The coming of the malaria project was probably the most stirring and exciting event of my prison term. Here, without any question, was a real chance to be useful The length of the war in the Pacific could be very well affected by those who got the answer to malaria first In some not too farfetched sense our bodies would be the battlefield in a not unimportant war

There were some who, I am convinced, went into the thing entirely on an idealistic basis. They didn't want the money . . . and they had little hope of getting their sentences reduced. But they saw a chance to do something decent and worthwhile for a change. They were more than willing to undergo the necessary discomfort and run the necessary risk in order to make their tiny contribution to humanity. . . .

4/

It was, of course, during the same war that the Nazi concentration camps became the site of infamous medical experimentation, which was at issue in the Nuremberg Trials and led to the enunciation of the Nuremberg Code, the archetype of codes for research involving human subjects. The German physicians who were accused of performing brutal experiments on nonconsenting inmates of the concentration camps cited in their defense the studies conducted in this country on prisoners.^{5/} The first principle of the Nuremberg Code addresses the problem of research on unconsenting individuals,^{6/} but does not distinguish between therapeutic and nontherapeutic research and never states explicitly

whether or not prisoners should be considered acceptable subjects of biomedical, let alone behavioral, research:

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion. . . .

7/

The central issue regarding the use of prisoners in nontherapeutic research is whether or not they can be considered to be "so situated as to be able to exercise free power of choice . . .".

In the years following the Nuremburg Trials, a number of countries decided that prisoners are not acceptable subjects for certain kinds of experimentation. Thus, in 1955, the Public Health Council of the Netherlands stated that:

Experiments on children; in institutions for children, old people, etc.; on the insane; or on prisoners, which involve dangerous risks, inconvenience or pain are not approved.

8/

The Draft Code of Ethics on Human Experimentation which was presented to the World Medical Association in 1961 stated that:

Persons retained in prisons, penitentiaries, or reformatories - being "captive groups" - should not be used as subjects of experiment; nor persons incapable of giving consent because of age, mental incapacity, or of being in a position in which they are incapable of exercising the power of free choice.

9/

It is reported that pressure from the United States resulted in deletion of this provision from the final version of the code which was adopted in Helsinki in 1964.

10/

Renée Fox has described a number of factors which contributed to the interest of the United States in continuing its use of prisoners in nontherapeutic research.^{11/} In the decade following the war, clinical research came into its own. The United States enthusiastically supported biomedical research through government and private grants, and the establishment of prestigious university positions, in a manner which was apparently unique to this country. We were committed heavily (both emotionally and financially) to clinical research. In 1953, the National Institutes of Health (which was already supporting research through grants and contracts) opened its 500 bed Clinical Center hospital, which Fox called "a colossal version of the growing number of research wards specifically designed to carry out studies in American hospitals."^{12/}

Prison research was also endorsed during this period. Governor Green of Illinois convened a committee to study the ethical issues surrounding the participation of prisoners in projects such as the malaria study. In 1948 that committee reported that:

Since one of the purposes of the parole system is reformatory, the reformatory value of serving as a subject in a medical experiment should be considered. Serving as a subject in a medical experiment is obviously an act of good conduct, if frequently unpleasant and occasionally hazardous, and demonstrates a type of social consciousness of high order when performed primarily as a service to society.

13/

In like manner, the Deputy Commissioner of Institutions and Agencies of New Jersey said, of the prisoners who had participated in research during the war, that:

All prisoners who had participated in medical experiments were given certificates of merit, copies of which were put into their records and called to the special attention of the Court of Pardons or the Board of Managers when parole was under consideration. Apparently no definite policy was ever formulated, and the participation in a medical experiment was considered only as one favorable factor in the whole case.

14/

In 1949, after a prisoner from an Iowa penitentiary was enlisted by chance as a subject for their metabolic research ward, two investigators set up a formal arrangement with the Iowa state board of control to provide inmates on a regular basis for their research. When a state attorney general questioned the legality of their arrangement, they suspended operation for two years while they obtained enactment of legislation specifically permitting inmates to participate in medical research at the University Hospitals. 15/ They report, in retrospect, that:

We feel that the use of prison volunteers for medical research is justified and highly desirable for the investigator, for the subjects, and for society.

16/

Prisoner participation in research appeared to be such a salutary experience that the American Medical Association's House of Delegates passed a resolution in 1952 expressing its disapproval "of the participation in scientific experiments of persons convicted of murder, rape, arson, kidnapping, treason or other heinous crimes" 17/ The concern was that such prisoners might receive a pardon or parole through their participation in research, and they were deemed to be unworthy of such consideration.

Impetus was also provided by the Kefauver-Harris amendments to the Food and Drug Act in 1962, which established additional requirements for testing the safety and efficacy of all drugs to be sold in interstate commerce. Phase I of such testing involves evaluation of the safety of new drugs in normal volunteers. The Deputy Director of the FDA's Bureau of Drugs has been quoted as saying that "virtually all" of Phase I tests involve prisoners.^{18/} (Prisoners may also participate in Phase II tests, by submitting to a disease in order to test the effectiveness of a new drug in combatting the illness, as in the malaria studies of the 1940's). The business arrangements between large pharmaceutical manufacturers, individual investigators, and state prisons have been described in detail by Jessica Mitford.^{19/} She suggests that biomedical research in prisons is a big business, precipitated in large part by the requirements of the Food and Drug Administration and perpetuated by the economic self-interest of the drug firms, the investigators, the prison authorities, and the inmates, themselves.

The use of prisoners in research in this country was first seriously challenged by several articles in the anthology edited by Irving Ladimer and Roger W. Newman for the Law-Medicine Research Institute of Boston University, in 1963.^{20/} Next came the classic "exposé" (Human Guinea Pigs) by H. M. Pappworth, in 1967, cataloging questionable research activities. Hans Jonas and Louis Lasagna critically examined the problem in the Daedalus special issue on human experimentation in the Spring of 1969. In January, 1970, the New York Academy of Sciences published the proceedings of a conference on legal and ethical concepts in human research, chaired by Irving Ladimer.^{21/}

In all of these, the arguments for and against research in prisons may be found. The conference published by the N.Y. Academy of Sciences, however, was supported largely by four major drug firms,^{22/} which may explain the preponderance of articles in that symposium which support the participation of prisoners in drug research. Nevertheless, included among the articles is a classic in the field by John Arnold and others, which identifies the important factors contributing to prisoners' decisions to participate in research.^{23/}

III. History: Therapeutic Behavioral Research in Prisons

... [I]n the Future, when the Courts convict a prisoner, ... he may have to undergo a course of treatment varied according to his special need, which may, or may not, be painful in its operation. ... They will inflict no moment of unnecessary suffering; if they have to give any pain, there will be purpose in it, and a friendly purpose. [G. Ives, A History of Penal Methods, 266, 335 (1914).]

24/

In the late 19th century, the theory of retribution or punishment for criminal deeds was replaced by theories of rehabilitation. The original rehabilitation concept was that isolation from the temptations of the community, and subjection to a highly disciplined existence, would themselves transform the criminal into a well-behaved citizen.^{25/} Later, fixed sentences based upon the nature of the crime gave way to a system of flexible sentencing which adjusted the "treatment" to the physical, mental, or social shortcomings of the offender. The idea of a conditional and therapeutic sentence was described by Ferri, in 1917:

The application of a conditional sentence ... is a wise concession to practical utility, being in perfect theoretical accord with the doctrines of anthropology and of criminal sociology... As the sick person is kept in the hospital just as long a time as is necessary for his cure, and the insane patient remains in the asylum all of his life unless cured and leaves it when he is cured, so it should be with the delinquent....

26/

The theory of curing the offender was applied, in this country, by creating a class of "defective delinquents". The first legislation was passed by Massachusetts in 1911, followed in the next three decades by similar legislation in over half the states and the District of Columbia. 27/ Such legislation provides for the indefinite commitment of persons either accused or convicted of criminal acts, so that treatment may be provided and they may be released, when cured. These statutes apply generally to sexual offenders and habitual miscreants, or both. Maryland's law, for example, is aimed at the individual who "evidences a propensity toward criminal activity and who is found to have either such intellectual deficiency or emotional unbalance so as to require... confinement and treatment." 28/ The states differ as to whether individuals may be committed before or after conviction, and as to whether they still may be convicted and imprisoned even following their release from treatment. Psychopaths are not generally considered "insane" nor are they acquitted on the basis of their defects. 29/

The relevance to research of legislation based upon the concept of rehabilitation is first, that the concept itself is uncertain, 30/ and second, that it provides the framework for applying new and unproven approaches to treatment.

Throughout the first half of this century, it was widely thought that behavioral scientists could explain, diagnose, and treat the criminal offender. Psychiatrists became actively involved in the correctional programs 31/ at the

same time that psychiatry, as a profession, was doubling its membership every ten years. ^{32/} Psychologists, having mastered the art of behavioral testing and classification for the military during World War I, applied their techniques to civil prisoners, following the war. ^{33/} In 1909, a psychologist (William Healy) had founded the Juvenile Psychopathic Institute in Chicago, a clinic which gave advice to the new Juvenile Court and offered therapy to youngsters under its jurisdiction. ^{34/}

In the 1950's and 60's, behavioral scientists interested in criminology organized formally. The American Association of Correctional Psychologists (now, 300 members) began in 1951, and published the Journal of Correctional Psychology (now, Criminal Justice and Behavior) three years later. In 1968, two more societies were formed: the American Psychology and Law Society, and the International Academy of Forensic Psychology. A year later, the American Academy of Psychiatry and the Law (350 members) was founded.

Courts and legislatures were impressed by the promise of the behavioral sciences. Legislatures repealed fixed sentences and gave the courts wide discretion to base sentences upon detailed personal information. Parole boards were given similar discretionary powers to release a convict upon demonstration of rehabilitation. Probation was another alternative made available to, and utilized by, the courts. ^{35/} It was assumed that the practitioners knew what they were doing. As one noted jurist optimistically observed:

The criminal law cannot fulfill its function as a social tool if it continues to ignore the complexity of causation.... Though there are great gaps in our knowledge about the causation of behavior, this does not mean that we have no such knowledge from psychiatry, sociology, anthropology, physiology and other disciplines. We are not morally justified in ignoring what we know.

^{36/}

Eight years later, that same judge noted that "our entire correctional process is a shambles," and chastised correctional psychologists for failing

to realize their limitations. Noting that most crime in this country is committed by individuals "at the bottom of society's barrel," he said:

I fear that we may be trying to rehabilitate these offenders with techniques that can work, if at all, only on the middle class. Poor, black offenders are not necessarily sick. They may simply be responding to an environment that has impoverished them, humiliated them and embittered them.... Have we, perhaps, been focusing our attention on the wrong part of the problem the offender and his mental condition instead of the conditions which produce him?

37/

IV. Other Kinds of Research Involving Prisoners.

Although nontherapeutic biomedical research and therapeutic behavioral research are the most publicized (and cause the most controversy and concern), other research is being conducted in prisons. Most of the projects may be characterized as nontherapeutic behavioral research. They include, for example, studies of the factors contributing to criminal behavior (such as cytogenetic anomalies or socio-economic and psychological stress), comparison of effectiveness of various rehabilitative programs in reducing recidivism, psychological assessment of criminals as compared with non-criminal counterparts, tracking the outcome of judgments concerning "dangerousness", and evaluating standards for determining competency to stand trial. In addition, NIMH has been directed by Congress to study the factors contributing to homosexual rape in prisons.

38/

Therapeutic biomedical research is also conducted in prisons. Examples are studies to reduce the spread of infections in crowded environments, or to develop new methods of treating drug addiction. Other research may involve investigations to increase understanding of the nature and causes of narcotic or alcohol addiction. (These studies may or may not be therapeutic.) Therapeutic biomedical research has not been the focus of public concern, however, compared to nontherapeutic biomedical research programs or experimental programs for treatment or rehabilitation.

V. Issues: Nontherapeutic Biomedical Research in Prisons

As indicated earlier, the central question concerning the participation of prisoners in nontherapeutic research is whether or not they are so situated as to be able to volunteer, or whether the nature of a prison is such that free choice is impossible. Much has been written on this subject, and the issue does not simply position the ethicists against the scientists. Rather, reasonable people from various disciplines see the same conditions differently.

Hans Jonas believes that those who are poorer in knowledge, motivation, and freedom of decision (the "captive" in various senses) should be the last candidates for research. This, he explains, is the opposite of a standard of availability.^{39/} On the other hand, Paul Ramsey has written that it is possible to arrange matters so that prisoners "may be as free in volunteering as persons in normal life."^{40/} Agreeing that there are circumstances in which their participation may be unacceptable (for example, when prison authorities are corrupt), he still concludes that with proper precautions, "since we have deprived a prisoner of a large number of his consents, we should yield to his consent to do good if it is an understanding, voluntary consent."^{41/}

Similarly, Paul Freund has written :

The basic standard ought to be that [the prisoners'] will should not be overborne either by threats of punishment or by promises of reward. Within those limits, although some investigators rule out prisoners as subjects, there seems to be no good reason for depriving this group of the satisfactions of participation on an informed basis, satisfactions that to them are often great, indeed, bolstering their self-esteem and furnishing links to the general community and its values.

42/

Others see the prison setting itself as so coercive and dehumanizing that the promise of better food, more comfortable quarters, additional contact with outsiders, and relief from the boredom (and fear) of the cell block all constitute coercion. This is said to be true even if no reduction in sentence is promised, and even if the payment for participation is comparable to that of other jobs in the same facility.

In a study of why prisoners volunteer to participate in research, John Arnold and his colleagues found that over 50% of the prisoners volunteered, at least in part, out of a desire for better living conditions. Moreover, many of them were "loners", and sought membership in "the only group that would take them - the research project."^{43/} Altruism and patriotism have also been cited by prisoners as motivating factors. In addition, the relative security of the research ward has been cited, but on the other hand, the research (at least in the perception of the inmate) seemed to offer the status and personal satisfaction associated with risk-taking. Finally, it appeared that money had great appeal, for paying legal fees, supporting families, purchasing items at the canteen or for savings to use after discharge.^{44/}

Jessica Mitford has described in detail the business arrangements through which, she says, the pharmaceutical manufacturers and the physicians profit from the use of prisoners in research. She claims that even when paying rates which are greatly disproportionate to other pay available in the prison (\$30 per month as against \$2 to \$10 per month), the drug firms are paying a prisoner roughly one tenth of the compensation which would be required on the outside (although this is true of all prison jobs). Mitford says that through their contracts with

drug companies doctors conducting research in prisons may gross \$300,000 per year, and participating physicians may double or triple their regular incomes. 45/

A complicating factor in the prison setting is the hope for early release or parole resulting from participation in research. As already noted, some research projects have incorporated this possibility in their negotiations with the prisoners. In other projects, even when reduction of sentence is explicitly not a consideration, the prisoners apparently continue to hope that it may be. Thus, as Leopold has written:

There was no assurance whatever that volunteers would be rewarded by having their time cut. Of that fact each group was solemnly and emphatically reminded before they were allowed to sign their contracts. But the possibility did exist that there would be time cuts. And that was a chance I could not afford to miss... I had some reason to hope that public opinion in my regard might be softened to some degree...

46/

Perhaps this hope is sustained by the ambiguity reflected by Hodges and Bean (two investigators):

...for their participation in research activities [prisoners] receive no reduction of their sentence nor any favoritism regarding paroles. We do, however, send a letter to the warden at the termination of each experiment expressing our appreciation for the inmate's participation in the study. It is possible that this letter in the prisoner's file may favorably influence the parole board.

47/

Striking the proper balance may be difficult. On the one hand, prisoners should not be offered so much (either in the form of pay or through favorable consideration) that the offer itself constitutes undue inducement. On the other hand, not to compensate prisoners for discomfort

and risk is to take advantage of their captive state and availability; it is to capitalize on the factors of deprivation which might make the induction of illness, for example, appear to be an improvement over the prevailing conditions of the cell block.

An additional problem is that of the freedom to withdraw without prejudice. This is an integral aspect of informed consent, for consent is a continuing process. The right of withdrawal may be difficult to exercise in a prison setting, however, particularly in those facilities which limit access to the outside. If telephone calls are difficult or impossible to make, and if outgoing mail is censored, then a complaint to an advocate, or an appeal for help, may be unachievable. In addition, the purpose of the communication may be frustrated if the reply never reaches the prisoner because it is "Refused by the Censor"^{48/}.

Some research involving prisoners may be counter-therapeutic. If prisoners who have a documented history of drug addiction are offered money to leave prison and enlist in a program where they will be given narcotic drugs over a period of a year or so, this conflicts with detoxification. To the extent that research in drug addiction utilizes anyone to test the addictive potential of drugs, this should be considered counter-therapeutic if the participants are drug-free when enlisted. Even the testing of drug antagonists is counter-therapeutic if narcotic drugs must first be administered to a detoxified inmate in order to evaluate the efficacy of the antagonist.

A current operations manual of the Addiction Research Center in Lexington, Kentucky refers to the "statutory responsibilities" under the Narcotics Manufacturing Act of 1960 (now incorporated in P.L. 93-351) for the Secretary, DHEW, to identify the drug abuse potential

of strong analgesics. The manual describes the procedures for induction of prisoners (who must have a history of two or three treatments for drug abuse to qualify) in tests of this sort. If a prisoner is over 25, in good health, with "no major psychiatric disorders in and above sociopathic or neurotic personality," and with at least 18 months of a sentence left to serve, he may qualify for unrestricted participation. Unrestricted participation, according to a 1968 memorandum of understanding with NIMH, "means that the subject can participate in any experiment involving narcotic analgesics, sedative-hypnotics, marijuana, cocaine, alcohol, or psychotomimetic agents as well as other centrally acting drugs."^{49/} For such participation, the prisoner will receive both good time and cash awards "commensurate with awards given to comparable prisoners by the Bureau of Prisons."^{50/} Although there is some indication that involvement of prisoners in tests of this sort is being phased out at Lexington, the testimony of HEW officials at a recent congressional hearing endorsed the participation of prisoners in studies to determine the addictive potentiality of new narcotic analgesics, saying: "there is no alternative way this information can be obtained at this time."^{51/}

An additional complication is that prisoners are not always adults, nor are they always free of mental disabilities. In fact, according to a survey conducted in the mid 1960's, approximately 9.5% of the individuals in all correctional institutions in this country (except local jails and workhouses) had I.Q.'s below 70. The actual number of retarded individuals (based on the total prison population at that time) would have been 20,000.^{52/} Similarly, 1.6% of the surveyed population had I.Q.'s below 55, which would indicate a total number of approximately 3,300 moderately to severely retarded inmates. (The range of I.Q.

scores reported for 90,477 inmates was from 17 to 145.) The first critical issue identified by the NIMH report for which the survey was undertaken is "the lack of awareness of the complex legal, sociological and psychological problems of the mentally retarded offender."^{53/} This factor must be kept in mind when considering the competence of prisoners to consent to participation in research.

VI. Alternative Solutions

There are two alternatives to the present use of prisoners in non-therapeutic biomedical research: 1) to control the practice more vigorously and uniformly through careful regulations and monitoring; or 2) to prohibit the practice through legislation or administrative policy.

A. Restricting and Regulating Research in Prisons

In November 1973, the Department of Health, Education and Welfare proposed the first alternative, i. e., strict supervision of prison research through a combination of additional monitoring by IRB's and close supervision by Protection Committees.^{54/} Mechanisms to ensure comparability of pay, access to members of the Protection Committee, and protection of the right to withdraw without prejudice were to be reviewed and approved as part of the grant or IND application. In addition, prisons were to be accredited for research purposes on the basis of the general living conditions, opportunities for other employment, and standards of medical care

available in the facility. The Department also proposed to apply the regulations to research conducted pursuant to FDA regulatory requirements in addition to research conducted or supported by DHEW. The latter two provisions were omitted from a subsequent DHEW proposal (August 23, 1974).

At least two states have attempted to implement some DHEW controls. The state of Washington wrote the Department that it had established an IRB which was constituted according to DHEW requirements and was charged with determining the appropriateness of all research proposals involving prisoners. It is noteworthy that the end result was an unofficial moratorium on prison research in that state, inasmuch as the IRB has not been able to approve any applications for research in prisons because of a failure to resolve the ethical problems.^{55/}

Connecticut adopted the November 1973 proposals in full and wrote, a year later, that "typically about 24 studies are cleared by the system in a year and it is not unusual to have five or more studies in process at one time in our largest facility."^{56/} Another year has gone by, and it now appears that no research is being conducted in the Connecticut correctional facilities, although the mechanism still exists.^{57/} The Pharmaceutical Manufacturers Association has endorsed review mechanisms and standards similar to those proposed by HEW in November 1973, including on-site review by an institutional review committee and prisoner representation on that committee.^{58/}

B. Prohibiting Research in Prisons

It has been claimed that the only way to demonstrate the safety and efficacy of new drugs is to test them on prisoners. It has further been claimed that to prohibit such testing in prisoners would be to introduce unsafe drugs into clinical practice or to discourage the development of new drugs.

It is sometimes suggested, in addition, that prisoners should not be deprived of the right to earn money, contribute to society, and have some contacts with the outside, through participation in biomedical research. Finally, it is claimed that prohibiting research on prisoners in this country would drive research overseas. These arguments will be examined in turn.

The Question of Safety

At an interdisciplinary conference on the regulation of new drugs held in December 1972, many comparisons were made between the British system and our own.^{59/} The primary purpose of drug testing in Britain is to establish safety; it is assumed that a determination of efficacy will emerge through scientific literature and debate after a drug is introduced into clinical practice.^{60/} In fact, the British require that all adverse reactions be reported by physicians to a special branch of the safety of drugs committee; and it was this system of reporting that picked up the blood-clotting effects of oral contraceptives.^{61/} The British also test for addictive properties (without using prisoners for that purpose) and until very recently, "the incidence of addiction to potent narcotics in Britain was so rare as to be a matter of almost incredulous envy in other parts of the world."^{62/}

Most of the participants in the conference agreed that the British system, by all evidence, was as safe as ours and required much less time for the introduction of new drugs.^{63/} In fact, Sam Peltzman, an economist, calculated that the FDA would have to catch a hazardous drug like Thalidomide more than once each year in order to offset the direct cost (in lives) of a two-year delay imposed on a once-perdecade innovation such as TB drugs.^{64/} In addition, James L. Goddard (then Commissioner of FDA) estimated in 1968 that in a five year period, 1.4 million people in this country (300,000 each year) will

be involved in the testing of drugs which never reach the market.^{65/}
These reasons have prompted a number of people to suggest that the United States revise its system of drug evaluation to approximate that of the British, that we shorten considerably the amount of testing required prior to the introduction of drugs into clinical practice, and have strict requirements for monitoring and reporting adverse reactions after a drug is in general use.^{66/} As Lasagna observes, controlled clinical trials give no indication of how a drug will affect sick people, or how it will interact with other drugs such as cold pills, contraceptives and similar medications which people take as a matter of course in this country.^{67/}

Alternative Populations

On the other hand, the Thalidomide incident was a close call, and there is a consumers' movement in this country which is pushing for better scrutiny of drugs, both for safety and for efficacy. It appears that such scrutiny may be possible without the participation of prisoners in research, by utilizing alternative populations. The idea is not new. In World War II, conscientious objectors fulfilled their service obligations by participating in research programs in the Public Health Service. At one time it was estimated that "4000 Quakers, Mennonites, members of the Assemblies of God and Church of the Brethren, or other pacifist sects . . . choose this course each year."^{68/} It would be hard to characterize participation under the Selective Service Act as volunteering; but individuals not subject to the draft have also participated as a means of fulfilling the public service obligations of their sect. The National Institutes of Health Clinical Center has, since its beginning, had a permanent corps of normal volunteers drawn from these religious sects. The government may actually contract with a university or other organization to enlist volunteers, and then to arrange for their transportation to Bethesda and nominal compensation.^{69/} A

large proportion of the volunteers at the Clinical Center are students, especially during the summer months. They may spend several months in the hospital participating in studies of normal behavior and physiology (perception, sleep, metabolism, circulation, etc.) and the development of new instruments for monitoring body functions, as well as some testing of new drugs. These studies may require 24-hour blood pressure measurements, special diets, monitoring blood or urine, recording EEG's during sleep, and the like. Often arrangements are made for the volunteer students to work with scientists in career development programs during their free time. Thus, they may acquire experience in basic laboratory sciences, computer programming, medical arts, public information, photography, or library science. Volunteers are provided with room and board, laundry service, entertainment, television sets and modest stipends in addition to the experience and education gained from their participation. Currently, normal volunteers comprise nearly 15 per cent of the new admissions to the Clinical Center. A similar program is conducted, on a smaller scale, at an NIH metabolic research facility in Phoenix, Arizona. ^{70/}

Others have tried using alternate populations with similar success. The University of Maryland, under a contract with the National Institute of Allergy and Infectious Diseases, is testing strains of respiratory viruses and microorganisms for possible use in vaccines, using normal volunteers. They are paid \$20 a day for their participation in the study, which may last from 15 and 30 days. During this time, they are confined to an isolation ward, but ample provision is made for their comfort and recreation. It is interesting to note that in one group of 15 subjects (most in their mid or early 20's, only two over 30), a majority of the men had

been arrested and most of those had served prison sentences, some for resisting the draft. Several of the subjects were high school dropouts; three had college degrees. ^{71/}

John Arnold, former director of the Truman Research Laboratory in Missouri, who conducted malaria research (with prisoners as subjects) for 27 years, is now advocating and using normal volunteers as an alternative population. In 1974, he used 200 such subjects in both metabolic and drug studies. They are paid the local minimum wage and learn to negotiate their contracts with skill. ^{72/} In recent testimony before a House Subcommittee, Arnold said:

The prediction that alternate populations were not available has been wrong. . . . We no longer need to propose that important programs be dismantled if we discontinue use of prison volunteers. ^{73/}

In addition, he suggested that the use of alternative populations would, in fact, be an improvement since their commitment to research is stronger, the quality of their consent is better, there are fewer problems with contraband drugs, the research staff is better (in prisons, inmates often serve as staff), and the subjects are less dependent upon the investigator (which means that the option to withdraw is more realistic). He added that it is easier to develop systems for follow-up care and compensation for these populations, and the research is more open to public inspection. Arnold estimated that changing to alternative populations will increase the cost of new drug development by only 1%, while improving the credibility of clinical research as well as its product. ^{74/}

Prisoners' Rights

A number of states have already prohibited the use of prisoners in research. At last count, one state (Oregon) prohibits the participation of prisoners in biomedical research by state legislation. Seven other states and the District of Columbia have written regulations or

departmental policy prohibiting such research. One state (Illinois) has declared an official moratorium. Of the 20 states which specifically permit it, only seven (and the Federal Bureau of Prisons) seem to be conducting such research at this time. No research is currently being conducted in states which have no written policy or regulation. ^{75/}

Prisoners have protested such bans; ^{76/} but whether or not prisoners have a right to participate in research, or an interest in doing so which must be protected, is a matter yet to be resolved.

It is clear that at least some prisoners perceive participation in research to be an infringement of their constitutional rights. In a class action suit brought against officials of the state of Maryland, DHEW, and the Department of Defense, prisoners at the correctional facility at Jessup have challenged the validity of consent given under the conditions of deprivation which exist there. In addition, they charge that prisoners who are not participating in studies of infectious diseases are infected by those who are, because of the crowded conditions in the prison and the fact that the subjects of research are not isolated from the others. They complain also about the absence of follow-up care, and charge that in at least one instance, a former prisoner was unable to obtain treatment for recurrent malaria (with which he was infected as part of the research project) and as a consequence, incurred large debts for treatment which he had to obtain on his own. The petitioners request, inter alia, a declaratory judgment "that the use of prisoners in nontherapeutic biomedical experimentation of this type is unconstitutional per se, because of the impossibility of truly voluntary consent and because confronting prisoners with such a choice is cruel and unusual punishment and subjects them to involuntary servitude." ^{77/}

A second case which is pending in New York charges the Federal government with negligence, and charges individual doctors with negligence, malpractice, and misrepresentation. The plaintiff states that while he was a federal prisoner, he participated in research sponsored by NIMH at the Addiction Research Center in Lexington, Kentucky. The research involved a study to determine the effectiveness of a drug thought to prevent the euphoric and dependency effects of narcotic drugs. The plaintiff claims that he suffered a heart attack as a direct result of having received an injection of the experimental drug, and that whereas the doctors knew the drug was dangerous, they told him that the dosage involved was too small to cause harm. The U.S. District Court dismissed the case on several technical grounds, including a finding that the plaintiff had no real cause of action. The Appellate Court reversed that decision, saying that the complaints "alleged a callous disregard for the safety of human subjects in medical experimentation, a problem which has drawn increasing public and governmental attention". Referring to the creation of the National Commission for the Protection of Human Subject of Bioemdicall and Behavioral Research, and the legislative history of the charges to that Commission, the court held that "in view of these expressions of public policy, a court should not be quick to dismiss on pleading technicalities an action involving experimentation on humans." The Appellate Court therefore reversed the decision of the District Court with directions that the case be heard. ^{78/}

Shifting Drug Research Overseas

Prohibiting research on prisoners might deflect drug research overseas, but it appears that it would only cause an increase over a considerable amount which is already being conducted abroad.^{79/} Furthermore, it is unclear why, or even whether, this would be disadvantageous in and of itself with respect to protecting human subjects. It cannot be that the result would be to involve prisoners overseas in research, for none of the European countries seem to allow it;^{80/} and it is yet to be demonstrated that research conducted overseas is either less reliable or conducted less ethically than research conducted in this country. It should be possible to control for all such contingencies by rigorous standards governing all research submitted to FDA, whether it is conducted in the United States or abroad.

The real problems with an increase in overseas research may be peripheral. For example, to what extent would it be ethical to shift the risks to subjects in other countries, when the benefits would be distributed in the United States? Or, to what extent is it ethical to conduct research abroad simply because it may cost less to do so? Would we not, in that case, be taking advantage of people living in the economically depressed countries? These are questions of policy which should be kept in mind when considering the possible effects of a limitation or prohibition of such research in this country.

VII. Issues: Therapeutic Behavioral Research

Perhaps the earliest "experiment" in behavior modification in prisons was an attempt mandated by the New York legislature in 1821, to test the effectiveness of total isolation.^{81/} Eighty prisoners were placed in solitude; and the results were less than successful. Before a year had elapsed, five men died, at least one went insane, and so many became depressed that the Governor pardoned twenty-six, and permitted the rest to leave the project. As to the rehabilitative effects, the warden reported "not one instance of reformation".^{82/} Severity and ineffectiveness are still major issues.

Between 1950 and 1960, disillusionment with standard rehabilitative methods and the emergence of procedures to alter the behavior of individuals through methods based on theories of learning coalesced.^{83/} The application of these procedures in the correctional system raises a number of questions concerning: 1) the rights of prisoners to refuse to participate, and 2) the appropriateness and effectiveness of such programs in a prison setting. Central to the consideration of the rights of prisoners in programs designed to modify their behavior are questions regarding the purpose of incarceration, the severity of the techniques involved in the program, and the extent to which the program is experimental.

Criminologists list four possible reasons for imprisonment: punishment, the protection of society, deterrence, and rehabilitation. As noted earlier, the stated purpose of the "correctional" system in this country, since 1900, has been rehabilitation; and the introduction of programs designed to alter behavior is consistent with that purpose. Problems arise, however, when the design includes either the application of organic therapy (such as surgery, electric or chemical shock, psychotropic drugs, or drugs to induce extreme

discomfort) or the deprivation of basic amenities.

Concern about this problem is not confined to any one profession.

Ralph Schwitzgebel, a lawyer, has written:

...[T]herapists should not be permitted to do under the label of treatment or behavior modification that which cannot also be done under the label of discipline. Ultimately, the justification of discipline or behavior modification is the safety of the community and not a supposed benefit to the offender...

84/

This concern is reiterated by David Rothman (an historian) who writes:

...[A] willingness to accept the promise to do good as the equivalent of the ability to do good is certain to legitimate a network of intervention schemes which would otherwise be suspect....[W]e cannot debate preventive detention if it calls itself rehabilitation. And if we are incarcerating people for treatment purposes, then let us measure the effectiveness of the treatment....

85/

Similarly, Gerald Klerman (a psychiatrist) has taken correctional psychologists to task for redefining basic rights as privileges which may be withdrawn in order to serve as incentives in a behavior modification program;

86/

and a professor of law and ethics, Benjamin Freedman, suggests:

...[T]here are certain basic freedoms and rights which we possess which entitle us (morally) to certain things (or states of affairs)....When the "reward" is such as only to give us the necessary rights and freedoms - when all the reward does is bring us up to a level of living to which we are entitled, and of which we have been deprived by man - then the "reward," I think, constitutes duress.

87/

A more dramatic approach was taken by a research psychologist cataloguing instances of "Psychiatric Violence Against Prisoners: When Therapy is Punishment".

88/

On the other hand, a number of writers suggest that a convicted felon, at least, has no standing to refuse to be rehabilitated. Two sociologists ask: "How can we justify asking a man to consent to behavior modification when he is not asked to consent to all the prison brutality to which he is

subjected when imprisoned?" ^{89/} They distinguish between therapy as part of the criminal justice system and therapy as a health service:

We cannot use the criminal law to enforce therapy for health and welfare purposes, but we can use the law to prevent harm to others and to prevent crimes. Treatment can be a function of criminal law... ^{90/}

James V. McConnell, a professor of psychology, has been quoted as saying:

I don't believe the Constitution of the United States gives you the right to commit a crime if you want to; therefore the Constitution does not guarantee you the right to maintain inviolate the personality it forced on you in the first place [sic] if and when the personality manifests strongly antisocial behavior. ^{91/}

In a paper submitted to the Law and Psychiatry Seminar at the University of Pennsylvania Law School, a student stated the case with brevity:

The community need not protect a man's right to be a criminal by refusing to change his criminal mind (and through it, his criminal behavior) without his consent. ^{92/}

Several courts, speaking of compulsory treatment for drug addiction, have agreed:

When a subject is within the proper scope of the State's police power, any exercise of that power is constitutional if there is a rational basis for the legislative act, even where the state of knowledge is uncertain and conflicting theories exist as to the problem's solution. [Emphasis added] ^{93/}

Other courts have upheld the state's power to impose therapy when it is "recognized as appropriate by recognized medical authorities", but not when it is experimental; ^{94/} and the involuntary injection of a disturbed prisoner with a tranquilizer has withstood constitutional challenge. ^{95/} By contrast, the Attorney General of Hawaii ordered that a prisoner's right to refuse anti-psychotic medication (on religious grounds) be honored. ^{96/}

In 1944, a U. S. Circuit Court had said that a prisoner "retains all the rights of an ordinary citizen except those expressly, or by necessary implication, taken away from him by law."^{97/} (The case involved interference with the personal liberty of an inmate who claimed to have suffered "injuries and indignities" in the Public Health Service facility at Lexington, Ky.). The problem, of course, is in defining those rights which a prisoner retains, and those rights which he or she may forfeit, as a consequence of conviction.

Emerging Definition of Prisoners' Rights

Recent cases have begun to delineate those rights. In 1973, a U. S. Circuit Court held that aversive conditioning for undesirable behavior in prison is cruel and unusual punishment unless the prisoner has consented (Knecht v. Gillman).^{98/} Similarly, the claim that a prisoner was subjected, without his consent, to aversive conditioning in Vacaville was held to "raise serious constitutional questions respecting cruel and unusual punishment or impermissible tinkering with mental processes" (Mackey v. Procunier).^{99/} Deprivation may also be unconstitutional. A Federal District court held, in 1973, that it is cruel and unusual punishment to segregate prisoners for sixteen months, for 23 hours a day, in a cell eight by six feet (Adams v. Carlson).^{100/} (The case involved 36 men who were transferred into a "control unit treatment program" in the federal penitentiary in Marion, Illinois, following a work stoppage.)^{101/} The implications of this decision for behavior modification programs are clear when one observes that the design of the program S. T. A. R. T. (in the Federal Bureau of Prisons), for example, called for segregation (up to one year) in small cells, with no prison privileges, and only two showers and two hours of recreation, each week.^{102/} When the constitutionality of S. T. A. R. T. was challenged, the court held only that

the transfer of prisoners into such segregation without a proper hearing violated the right to due process. The court did not reach the question of the constitutionality of enforced participation in such a program, or of the deprivations involved (since the project had been terminated by the time of hearing, and the questions were therefore deemed moot), nor did it elaborate on its observation that "a prisoner may not have a constitutional right to prevent such experimentation".^{103/} It did, however, say that the labeling of a program as treatment instead of punishment "is not a relevant factor in determining the due process question involved".^{104/}

It appears, then, that the rights of prisoners with respect to behavior modification may depend not on a distinction between treatment and punishment, but on the distinction between research and routine or accepted practice. There is a wealth of literature on the effectiveness (or, to be more precise, the ineffectiveness) of behavior modification techniques in reducing recidivism in prisoners, or even in producing enduring alterations in behavior.^{105/} In fact, there is some laboratory evidence that aversive conditioning may increase the rate of undesirable behavior either from a paradoxical effect, or because of the anxiety and deception associated with it.^{106/} The Jefferys observed that "at this point in history we do not possess the necessary knowledge to alter criminal behavior",^{107/} and the President's Crime Commission concluded that "there is probably no subject of comparable concern to which the nation is devoting so much effort with little knowledge of what it is doing".^{108/} That being so, it is possible to argue that behavior modification is not a proven or effective technique for rehabilitating prisoners, and its application should be considered experimental.

A suit filed by the ACLU National Prison Project has challenged the aversive conditioning of sex offenders in Somers state prison, in Connecticut, on the grounds that it is unproven as to effectiveness and is therefore experimental. In addition, the suit claims that when prisoners "are encouraged to believe that their parole depends upon their participation" any consent they may give is involuntary. ^{109/} By contrast, it was recently reported that a prisoner went to court for permission to enter an experimental drug therapy program from which he had been barred by the hospital's IRB because he was a prisoner. ^{110/}

Consent and Benefits in the Institutional Setting

The question of the voluntariness of consent in an institutional setting is especially important when it involves procedures which the confined individual may believe will improve his or her chances for release. The fact that an inmate is willing to cooperate to the extent of participating in the program may seem to be important (to the inmate, if not to the staff) in a setting where release from confinement is contingent upon demonstrating appropriate behavior. These factors were discussed at length by the court in Kaimowitz v. Department of Mental Health which challenged the validity of consent for psychosurgery by an individual who was being held under sexual psychopath laws. ^{111/} The court held that involuntarily confined mental patients cannot give voluntary consent to hazardous experimental procedures because of the coercive nature of institutional life and the inherent inequality of their bargaining position. ^{112/} (It is important to note that the court specifically held, on the other hand, that such individuals can give voluntary consent to accepted neurosurgical procedures.) ^{113/} Although the case involved surgical intervention, the

language of the opinion stands for the protection of privacy, per se:

Intrusion into one's intellect, when one is involuntarily detained and subject to the control of institutional authorities, is an intrusion into one's constitutionally protected right of privacy. If one is not protected in his thoughts, behavior, personality and identity, then the right of privacy becomes meaningless.

114/

Frank Ervin, a psychiatrist, has said that "programs of all kinds labeled psychotherapeutic in the correctional system are a sham, insofar as they are coercive either explicitly or implicitly."^{115/} Similarly Hugo Bedau, a professor of philosophy, concludes that prisoners probably cannot give voluntary consent (as an empirical, rather than an a priori, matter) but rejects the conclusion that therefore they cannot be subjected to interventions designed to make them less dangerous. Rather, he believes that there may be some conditions under which even physical intervention may be undertaken without consent.^{116/}

The idea of rehabilitation or treatment deserves further scrutiny, however, especially if it is categorized as therapeutic research. A number of writers have cautioned that the correctional psychologist or therapist acts as a double agent, serving the needs of both the inmate and the society; and when the two roles conflict, the demands of society for controlling deviant behavior usually override the needs of the "client".^{117/} In addition, the needs of the correctional institution, itself, may supervene; and the inmate may be made "better" only with respect to being more manageable. Just as with therapeutic research in institutions for the mentally disabled the question must be asked in the prison: who benefits?

VIII. Summary

A. Nontherapeutic Biomedical Research.

Although there is a long history of the use of prisoners in nontherapeutic biomedical research, the practice was not widely endorsed in this country until World War II, when it was considered patriotic for prisoners to participate, as research subjects, in the military effort. Following the war, although the European countries apparently rejected such participation, prisoners continued to be involved in even greater numbers in the United States due to our increased commitment to clinical research and our increased concern with evaluating the safety of new drugs. Only in the last decade have questions been raised regarding continuation of this practice.

The central issue is whether conditions within a prison permit a prisoner to give voluntary consent to participate in research. Even if it is possible to create conditions in some prisons under which the right to participate, or refuse to participate, can be protected, other questions must still be faced. To what extent are abuses still possible elsewhere? Should the potential for abuse in some prisons override the possibility for valid consent in others and require that research be prohibited in all correctional facilities? Should research in prisons be prohibited on principle, whatever the facts of the case?

Additional questions come to mind. Do prisoners have a right to participate in nontherapeutic research? If the presence of a research program in a prison provides the only opportunity for public scrutiny (or for an inmate's access to outsiders), would withdrawing that opportunity produce more problems than it would solve? Are those problems the proper concern of this Commission?

If research in prisons is to be prohibited, what are the alternatives? Shall we modify our requirements for testing the safety and efficacy of drugs, or shall the tests be conducted on other populations? How free from coercion are the alternative populations?

If research in prisons is to be permitted, what conditions should be imposed to protect the prisoners? How should these be enforced? Will the conditions, themselves, prove so burdensome that the net effect will be to end research in prisons, after all?

The first question the Commission must answer is whether to decide the matter on principle, or on the basis of evidence. Do the expressed wishes of prisoners matter? Do the conditions in the prisons have any bearing? If so, then the answers must be empirically based. If not, then the issue can be decided on the basis of a general principle that (for example) no individual involuntarily confined in an institution should be the subject of research unless that research is for the direct benefit of that individual, or unless the research is designed to increase our understanding of the conditions for which the individual is confined.

B. Therapeutic Behavioral Research.

The involvement of prisoners in therapeutic behavioral research is a different matter. There is agreement in much of the literature that aversive conditioning, without consent, is unacceptable. Other methods of behavioral modification are equally unacceptable if they depend upon deprivation of basic human rights. Because the right of a prisoner to

refuse treatment may depend upon whether or not the treatment is experimental, some mechanism for making that determination may be essential.

A number of suggestions advanced in the literature merit consideration:

1. Basic human rights, to which all prisoners are entitled, must be clearly defined.
2. No research should be permitted which depends upon deprivation of those basic rights.
3. No research involving behavior modification should involve a prisoner without his or her consent.
4. Mechanisms should be developed to determine whether a program for rehabilitation is research or accepted practice.
5. No prisoner should be subjected to aversive conditioning or organic therapy without his or her consent and, in addition, an administrative or judicial hearing to determine the validity of that consent.
6. Behavioral research in prisons should be subject to the same community scrutiny and accountability as biomedical research, especially with respect to risks and benefits (including the question of who benefits) and all aspects of informed consent.
7. No procedures should be permitted in the name of "treatment" or "rehabilitation" which are impermissible as punishment.

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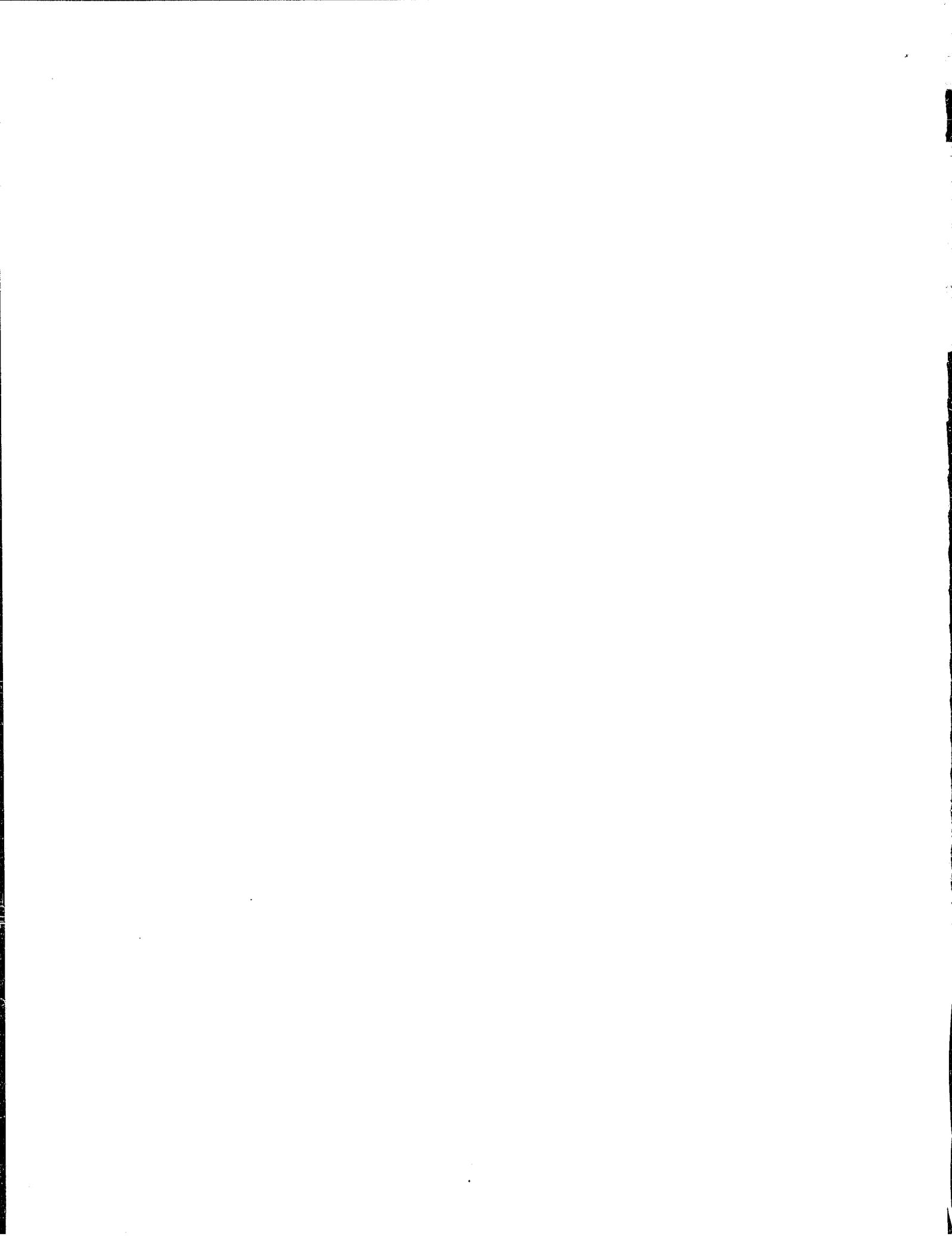
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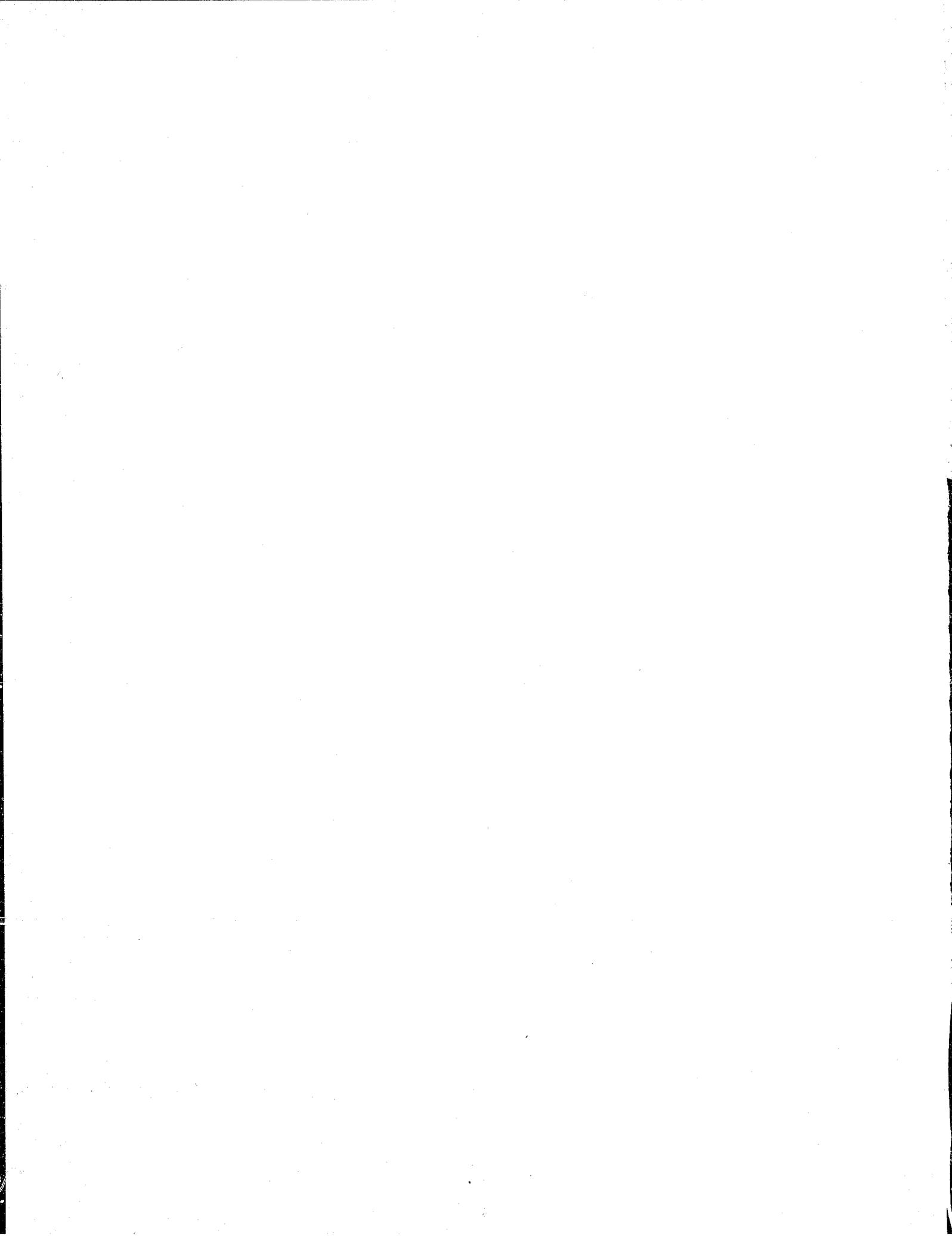
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17

SURVEY OF PRESENT STATUS OF PRISON INMATE INVOLVEMENT
IN BIOMEDICAL AND BEHAVIORAL RESEARCH
IN STATE CORRECTIONAL FACILITIES

November 12, 1975



PRISON INMATE INVOLVEMENT IN BIOMEDICAL AND BEHAVIORAL RESEARCH IN STATE CORRECTIONAL FACILITIES

Purpose

The present study was conducted at the request of the National Commission for the Protection of Human Subjects in order to ascertain the current status of state law and regulation pertaining to biomedical and behavioral research involving prisoners, and the states in which such research is presently being conducted.

Methods

Between July and October, 1975, the directors of state correctional agencies, or their immediate subordinates, were contacted by Commission staff and asked whether biomedical or behavioral research was permitted in their jurisdictions, the legislation or departmental policy basis for permitting or prohibiting such research, and whether any such research was currently being conducted. Research was further categorized as to whether it was therapeutic or nontherapeutic in nature.

For the purposes of this survey, biomedical research was defined as any program instituted on an experimental basis involving innovative drugs, devices or medical procedures intended to deal with some medical problem and not primarily to modify behavior. Therapeutic biomedical research included any program from which an inmate might be expected to benefit personally (e. g., experimental plastic surgery to correct certain defects). Nontherapeutic biomedical research included any programs from which no apparent benefits might be expected to accrue to that subject (e. g., Phase I drug and cosmetic testing). Behavioral research was defined as any program instituted on an experimental basis involving innovative behavior modification or other behavior-related techniques.

Survey (cont'd.)

Therapeutic behavioral research included any innovative program intended to ameliorate a preexisting psychological condition. Nontherapeutic behavioral research included any innovative program from which no apparent benefits might be expected to accrue to the subject.

All fifty states and the District of Columbia were contacted by telephone, as was the Federal Bureau of Prisons. Constraints of time and resources did not permit extending this survey to the county and municipal level. Those jurisdictions with legislation or written policies regarding biomedical or behavioral research were requested to forward copies of these documents. Verbal responses were verified from these documents, which are maintained on file in the Commission office. No further documentation was required of those jurisdictions reporting that there was no legislation or written departmental policy concerning biomedical or behavioral research. However, in comparing such responses with the results of three other surveys (1), further clarification was sought whenever the responses were inconsistent. Every jurisdiction that reported it was conducting biomedical or behavioral research also indicated that legislation or written departmental policy existed regulating such research.

Results

The results of the survey are summarized in Tables I and II. The

1/ See Jessica Mitford, Kind and Usual Punishment: The Prison Business (New York: Vintage Books, 1974), pp. 183-84; Rick Carlson, et al., "Biomedical Experimentation on Prisoners: Practices, Problems and Possible Solutions," unpublished paper, Health Policy Program, University of California, San Francisco, 1975; and Urban Information Interpreters Inc., "State Policy with Regard to Medical Experimentation Using Prisoners as Human Subjects: Revised," Medical Research on Prisoners (College Park, MD: Urban Information Interpreters Inc., 1975), p. 11.

Survey (cont'd.)

following observations are based on the information that was reported to the staff of the Commission:

1. Of the 21 states which presently permit biomedical research and the 23 which permit behavioral research, studies are presently being conducted in only 7 and 5 states, respectively. These figures represent a decline from numbers reported in earlier surveys. (2)

2. Of those 7 states in which biomedical research is presently conducted, all of the programs are nontherapeutic, primarily involving drug and cosmetic testing.

3. Of those 5 states in which behavioral research is presently conducted, all of the programs are therapeutic except in one state in which both nontherapeutic and therapeutic behavioral research are conducted.

4. Only 8 states have chosen to prohibit biomedical research outright: one by legislation, 6 by departmental policy, and one by moratorium.

5. Only 5 states have chosen to prohibit behavioral research outright: one by legislation, 3 by departmental policy, and one by moratorium.

6. Research is presently being conducted only in states which have specific legislation or departmental policies permitting and regulating it.

Information provided by the Federal Bureau of Prisons indicated that both biomedical and behavioral research are permitted by departmental

2/ In 1973, Jessica Mitford reported that "medical experiments" were being conducted in 25 states based on information provided to her by the U.S. Food and Drug Administration (see Mitford, op. cit.).

A 1974 survey conducted by Rick Carlson, et al. indicated that "human experimentation" was permitted in 16 states and actually conducted in 8 of the 45 states responding to the questionnaire (see Carlson, et al., op. cit.).

In its June 1975 newsletter, the Urban Information Interpreters Inc. note that 10 states reported "medical research or plasma procurement in one or more of its facilities" in a 1974 survey (see Urban Information Interpreters Inc., op. cit.).

Survey (cont'd.)

policy. Nontherapeutic biomedical and therapeutic behavioral research projects are presently being conducted.

More detailed information is provided in Appendices I and II, which categorize information in Table I by type of research (Appendix I - Biomedical; Appendix II - Behavioral), type of policy, and the number and names of the states falling into each of the eight policy subcategories.

TABLE I

Reported Prison Inmate Involvement in Biomedical and Behavioral
Research in State Correctional Facilities by Policy and Current Practice

| STATE | PRESENT WRITTEN POLICY | | RESEARCH CURRENTLY BEING CONDUCTED | |
|----------------|------------------------|---------------|------------------------------------|------------|
| | Biomedical | Behavioral | Biomedical | Behavioral |
| Alabama | 0 | 0 | -- | -- |
| Alaska | + (P) | + (P) | -- | -- |
| Arizona | + (L) | + (L) | -- | -- |
| Arkansas | + (P) (2) | + (P) (2) | -- | -- |
| California | + (P) | + (L) (1) (3) | NT | -- |
| Colorado | 0 (2) | 0 (2) | -- | -- |
| Connecticut | + (P) | + (P) | -- | -- |
| Delaware | 0 | 0 | -- | -- |
| D. of C. | 0 (2) | 0 (2) | -- | -- |
| Florida | + (P) (1) | + (P) (1) | -- | -- |
| Georgia | + (P) | + (P) | -- | -- |
| Hawaii | 0 | 0 | -- | -- |
| Idaho | 0 (2) | 0 (2) | -- | -- |
| Illinois | - (P) (4) | - (P) (4) | -- | -- |
| Indiana | + (P) | + (P) | NT | -- |
| Iowa | + (L) | + (L) | -- | -- |
| Kansas | 0 | 0 | -- | -- |
| Kentucky | + (P) | + (P) | -- | -- |
| Louisiana | + (L) | + (L) | -- | -- |
| Maine | 0 (2) | 0 (2) | -- | -- |
| Maryland | + (P) | + (P) | NT | T |
| Massachusetts | - (P) | + (P) | -- | -- |
| Michigan | + (P) | + (P) | NT | -- |
| Minnesota | 0 | 0 | -- | -- |
| Mississippi | 0 | 0 | -- | -- |
| Missouri | - (P) | - (P) | -- | -- |
| Montana | + (L) | + (L) | NT | -- |
| Nebraska | 0 (2) | 0 (2) | -- | -- |
| Nevada | 0 (2) | 0 (2) | -- | -- |
| New Hampshire | 0 | 0 | -- | -- |
| New Jersey | + (P) (1) | + (P) (1) | -- | -- |
| New Mexico | 0 | 0 | -- | -- |
| New York | - (P) | + (P) | -- | -- |
| North Carolina | + (P) | 0 (2) | -- | -- |
| North Dakota | 0 | 0 | -- | -- |
| Ohio | + (L) | + (L) | -- | T |
| Oklahoma | 0 (2) | 0 (2) | -- | -- |
| Oregon | - (L) | - (L) | -- | -- |
| Pennsylvania | - (P) | - (P) | -- | -- |
| Rhode Island | 0 | 0 | -- | -- |
| South Carolina | - (P) (5) | + (P) | -- | T & NT |



CONTINUED

6 OF 8

TABLE I (cont'd.)

| <u>STATE</u> | <u>Biomedical</u> | <u>Behavioral</u> | <u>Biomedical</u> | <u>Behavioral</u> |
|---------------|----------------------------------|----------------------------------|-------------------|-------------------|
| South Dakota | 0 (2) | 0 (2) | -- | -- |
| Tennessee | + (L) | + (L) | -- | -- |
| Texas | + (L) | + (L) | NT | -- |
| Utah | 0 | 0 | -- | -- |
| Vermont | - (P) | - (P) | -- | -- |
| Virginia | + (L) | + (L) | NT | T |
| Washington | + (P) | + (P) | -- | T |
| West Virginia | 0 (2) | 0 (2) | -- | -- |
| Wisconsin | 0 | 0 | -- | -- |
| Wyoming | 0 (6) | 0 (6) | -- | -- |
| TOTALS | + 21 - 8 <u>0 22</u> 51 | + 23 - 5 <u>0 23</u> 51 | NT 7 T 0 | NT 1 T 5 |

1/ Therapeutic research only.

2/ Unwritten departmental policy prohibits such research.

3/ Except "organic" therapy (e.g., psychosurgery or the use of drugs, electric shocks, electronic stimulation of the brain, or infliction of physical pain when used as an aversive or reinforcing stimulus in a program of aversive, classical, or operant conditioning).

4/ A moratorium has been declared until new guidelines are developed.

5/ Exceptions may be granted under certain conditions.

6/ Unwritten departmental policy permits such research.

TABLE II

Summary of Current Status of Reported Prison Inmate Involvement
in Biomedical and Behavioral Research in State Correctional Facilities

BIOMEDICAL RESEARCH

| Written Policy | Presently Conducting Research | | Total |
|--|-------------------------------|----|-------|
| | Yes | No | |
| Legislation or departmental policy permits | 7 | 14 | 21 |
| No legislation or departmental policy | 0 | 22 | 22 |
| Legislation or departmental policy prohibits | 0 | 8 | 8 |
| Total | 7 | 44 | 51 |

BEHAVIORAL RESEARCH

| Written Policy | Presently Conducting Research | | Total |
|--|-------------------------------|----|-------|
| | Yes | No | |
| Legislation or departmental policy permits | 5 | 18 | 23 |
| No legislation or departmental policy | 0 | 23 | 23 |
| Legislation or departmental policy prohibits | 0 | 5 | 5 |
| Total | 5 | 46 | 51 |

APPENDIX I

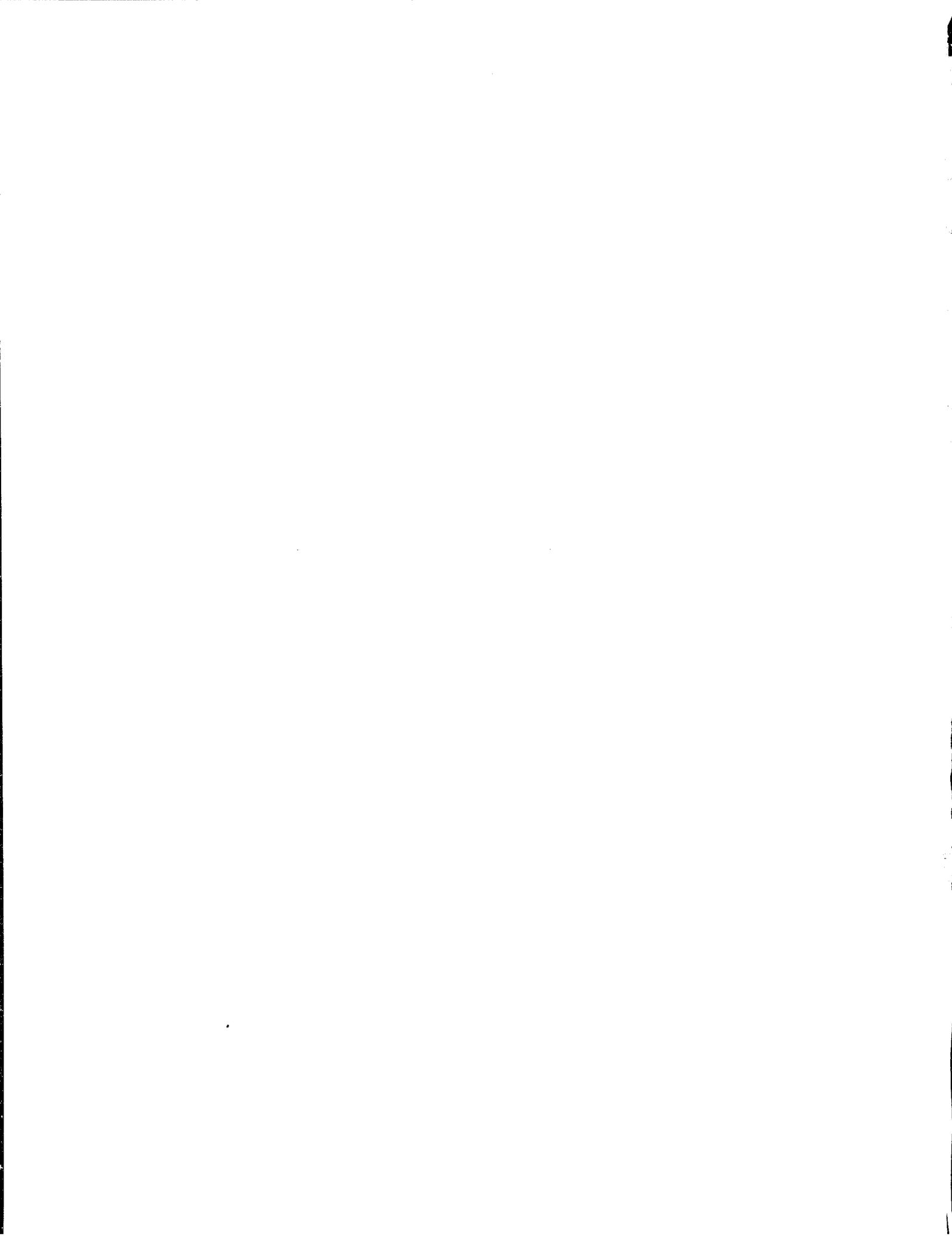
Reported Prison Inmate Involvement in Biomedical Research in State Correctional Facilities by Type of Policy, Number, and State

| | <u># of States</u> | <u>States</u> |
|--|--------------------|---|
| I. State law permits the use of prisoners in biomedical research, and it is being conducted. | 2 | Montana, Virginia |
| II. State correctional agency permits the use of prisoners in biomedical research, and it is being conducted. | 5 | California, Indiana, Maryland, Michigan, Texas |
| III. State law permits the use of prisoners in biomedical research, but none is being conducted. | 5 | Arizona, Iowa, Louisiana, Ohio, Tennessee |
| IV. State correctional agency permits the use of prisoners in biomedical research, but none is being conducted. | 9 | Alaska, Arkansas, Connecticut, Florida (therapeutic only), Georgia, Kentucky, New Jersey (therapeutic only), North Carolina, Washington |
| V. Neither state law nor correctional agency permits or prohibits the use of prisoners for biomedical research, and none is being conducted. | 12 | Alabama, Delaware, Hawaii, Kansas, Minnesota, Mississippi, New Hampshire, New Mexico, North Dakota, Rhode Island, Utah, Wisconsin |
| A. However, an unwritten departmental policy prohibits research. | 9 | Colorado, District of Columbia, Idaho, Maine, Nebraska, Nevada, Oklahoma, South Dakota, West Virginia |
| B. However, an unwritten departmental policy permits research. | 1 | Wyoming |
| VI. State law prohibits the use of prisoners in biomedical research. | 1 | Oregon |
| VII. State correctional agency prohibits the use of prisoners in biomedical research. | 6 | Massachusetts, Missouri, New York, Pennsylvania (imposed by Dept. of Justice), South Carolina, Vermont |
| VIII. State correctional agency has declared a moratorium on prisoner participation in biomedical research. | 1 | Illinois |

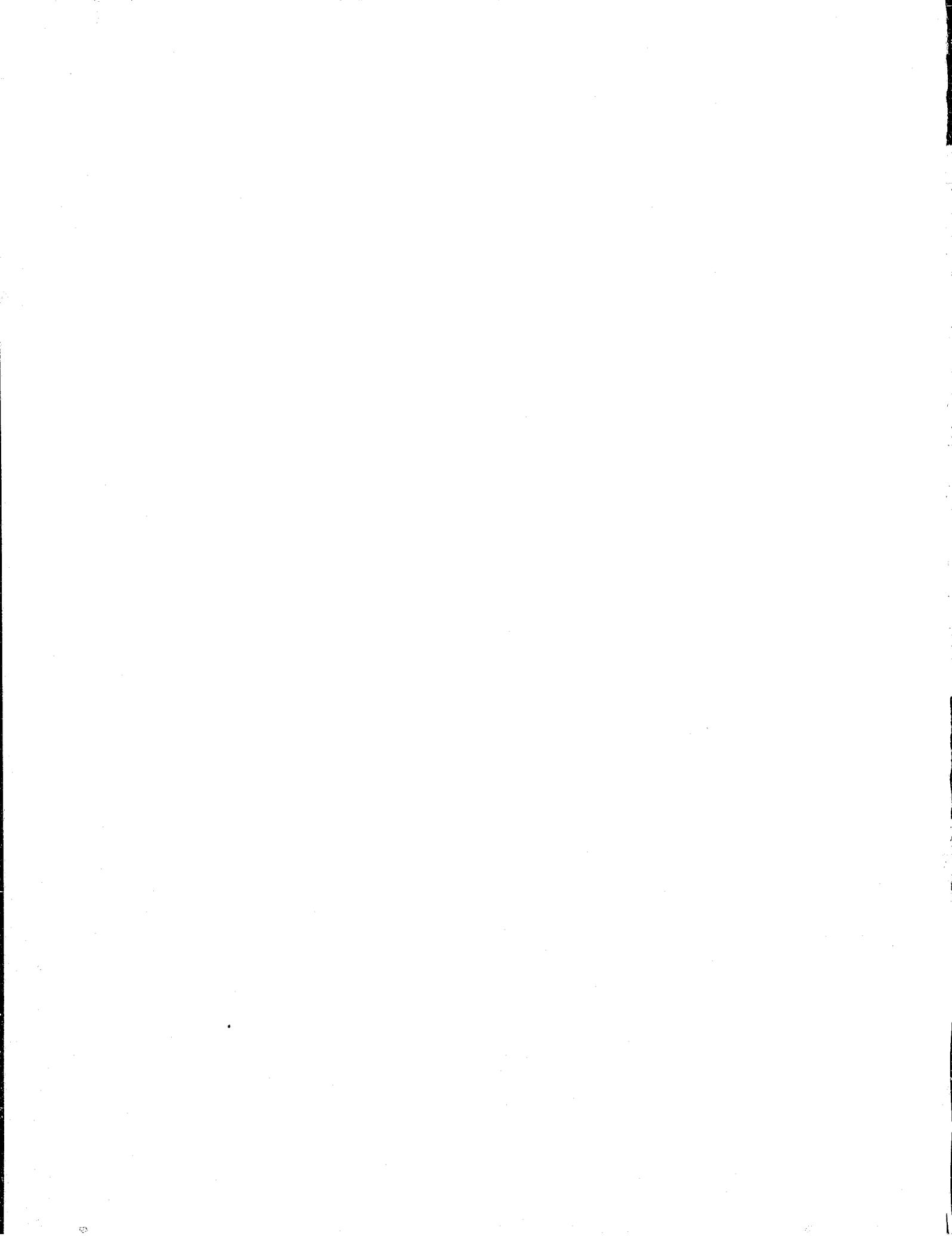
APPENDIX II

Reported Prison Inmate Involvement in Behavioral Research in State Correctional Facilities by Type of Policy, Number, and State

| | <u># of States</u> | <u>States</u> |
|--|--------------------|---|
| I. State law permits the use of prisoners in behavioral research, and it is being conducted. | 2 | Ohio, Virginia |
| II. State correctional agency permits the use of prisoners in behavioral research, and it is being conducted. | 3 | Maryland, South Carolina, Washington |
| III. State law permits the use of prisoners in behavioral research, but none is being conducted. | 7 | Arizona, California (therapeutic only), Iowa, Louisiana, Montana, Tennessee, Texas |
| IV. State correctional agency permits the use of prisoners in behavioral research, but none is being conducted. | 11 | Alaska, Arkansas, Connecticut, Florida (therapeutic only), Georgia, Indiana, Kentucky, Massachusetts, Michigan, New Jersey (therapeutic only), New York |
| V. Neither state law nor correctional agency permits or prohibits the use of prisoners for behavioral research, and none is being conducted. | 12 | Alabama, Delaware, Hawaii, Kansas, Minnesota, Mississippi, New Hampshire, New Mexico, North Dakota, Rhode Island, Utah, Wisconsin |
| A. However, an unwritten departmental policy prohibits research. | 10 | Colorado, District of Columbia, Idaho, Maine, Nebraska, Nevada, North Carolina, Oklahoma, South Dakota, West Virginia |
| B. However, an unwritten departmental policy permits research. | 1 | Wyoming |
| VI. State law prohibits the use of prisoners in behavioral research. | 1 | Oregon |
| VII. State correctional agency prohibits the use of prisoners in behavioral research. | 3 | Missouri, Pennsylvania (imposed by Dept. of Justice), Vermont |
| VIII. State correctional agency has declared a moratorium on prisoner participation in behavioral research. | 1 | Illinois |



REPORT OF A SITE VISIT: LILLY RESEARCH UNITS,
PENDLETON REFORMATORY AND WISHARD MEMORIAL HOSPITAL,
PENDLETON AND INDIANAPOLIS, INDIANA, MARCH 24, 1976



Report of Site Visit
Lilly Research Units
Pendleton Reformatory and Wishard Memorial Hospital
Pendleton and Indianapolis, Indiana
March 24, 1976

The Lilly research units which employ prisoners as subjects were visited at the request of the Commission to obtain information on their operation, particularly on the prisoner unit at the Wishard community hospital in Indianapolis.

Prisoner volunteers from Pendleton State Reformatory, a maximum security facility housing 1400-1800 men and located 30 miles northeast of Indianapolis, participate in pharmaceutical research in the Lilly units at the prison and at the hospital. Tests involving the first administration of a drug to humans, or requiring use of a radiolabeled substance or sophisticated monitoring equipment, are done only at the hospital; other types of tests may be done either at the prison or the hospital. The same review procedure for protocols applies to both units, and consists of an initial review by a Lilly committee, a secondary review by the IRB (a subcommittee of the Indiana University - Purdue University at Indianapolis School of Medicine IRB that reviews all protocols for Wishard hospital and the studies at the prison), and a final review by the chief medical officer and warden at the prison. There are no prisoners on the review committees.

Procedures for the recruitment of subjects are the same for both units. There is no active recruitment by Lilly, and recruitment by

prison staff is prohibited. All recruitment is by word-of-mouth; inmates learn of the program from other inmates and file an "interview request" form with the Lilly unit, just as they request a prison job or education interview. When volunteers are needed for a study, interview request slips are pulled in chronologic order, and the men come for an explanation of the study along with blood tests and physical examinations to determine if they are qualified. Those who qualify return for a complete explanation of the study from the physician conducting it; consent is obtained at that time. After completion of a study, an inmate must file a new request form in order to be considered for another study.

In order to qualify for participation in a study in the hospital unit outside the prison, a prisoner must meet a number of requirements. In general, either his parole date or hearing date before the parole board must be established, although the warden may permit exceptions. This requirement is imposed because prisoners with parole or hearing dates are considered less likely to try to escape or misbehave in the hospital setting. In addition, the prisoner must have one year of good behavior and specific permission from the warden. Prisoners convicted of violent crimes are not allowed to go to the Lilly hospital unit. These conditions are essentially the eligibility requirements for a work-release program; thus, the hospital research unit is one option for a prisoner on work-release. Inmates may participate in a test at the hospital only once and always return to the prison before parole. Approximately 90% of the volunteers for the hospital program are former participants in the prison research program.

The Hospital Unit

Lilly has operated a research unit at the Marion County General Hospital (now renamed the Wishard Memorial Hospital) since the 1920's. The hospital has recently changed from a county hospital to a unit of the Indiana University - Purdue University at Indianapolis (IUPUI) School of Medicine. Lilly donated several million dollars for construction of a new building 10 years ago and in return uses the 6th and 7th floors of the building for research operations, paying the hospital for central services. Use of prisoners in this unit began in the mid-1960's, about the same time that the unit was started at Pendleton.

The 7th floor has offices and laboratories, and also houses an outpatient clinic where phase III studies are conducted on patients and some phase I studies are conducted on Lilly employees and their families. The 6th floor has inpatient wards on three wings, one housing a 20-bed patient unit, one a 12-bed nonprisoner normal volunteer unit, and one 16-bed prisoner normal volunteer unit, all served by the same Lilly nursing staff. The patient unit is used primarily for phase II studies, with patients coming from the outpatient specialty clinics Lilly operates at the hospital or on referral from outside physicians. The nonprisoner normal volunteer unit is used for phase I studies of the same type as those in which prisoners participate, but prisoners and nonprisoners usually do not participate in the same protocol. The primary reason for this is apparently logistical. Whether prisoners or nonprisoners are chosen for a particular study depends upon the preference of the physician supervising the study and the number of volunteers needed and available at the time. Nonprisoner volunteers are men off the street who learn of the

program by word-of-mouth and ask to participate. These men are virtually all unemployed and many seem to be derelicts whose liver function tests still permit them to qualify for research. They are paid \$7 a day, plus varying fees for each test performed. Most enroll as research subjects frequently. Lilly does no recruiting of subjects for this program; all subjects are self-referred.

The prisoner volunteer wing is physically no different from the other wings and is a typical (but plain) hospital floor, with two- and four-man rooms. There is a small recreation room with a color TV and some hobby materials. Volunteers are considered hospital patients, and are assigned a hospital number and a permanent hospital chart. The full range of hospital emergency equipment and staff is available at all times.

Prisoners are not allowed to leave the research ward at any time, except when accompanied by a Lilly staff member to go for a test elsewhere in the hospital. Otherwise there are no special security precautions on the prisoner ward. The prisoners appear to value the Lilly experience enough that they enforce the rules themselves. Only four men have escaped in 10 years, a marked contrast to the higher escape rate in the prison's other work-release programs. There have been no incidents of personal injury or threats to nursing staff, and problems with illicit drugs or alcohol on the ward are extremely rare.

The requirement to stay on the ward does present some problems, however. The men, who stay from 2 weeks to 3 months, tend to get bored; in fact, boredom is the major reason men drop out of the research program-- they miss their friends and activities at Pendleton, and ask to return to the prison to escape from the boredom of research. The other main

reason for leaving the program is receipt of another work-release job. It appears that while men may sometimes choose research in preference to other work-release jobs, they may also do so because few other work-release jobs are available. Other jobs pay more than the \$3 per day they are allowed by the prison to receive on the Lilly unit, and the prisoners are allowed to keep half of what they earn at other jobs. Another advantage of other work-release jobs is that the men are free to move about outside, and can visit with friends and family for more than the one hour per day permitted at the hospital. However, other work-release opportunities at Pendleton are dwindling due to public outcry following several rapes and murders by prisoners in these programs, and consequently the desirability of the research program is increasing. In contrast to other work-release programs, the Lilly facility appears to enjoy good community acceptance.

The Prison Unit

The Lilly unit at Pendleton Reformatory consists of a refurbished wing of the prison hospital (really an infirmary, much like at Jackson) which the prison allows the company to use without charge. There is a large dormitory room with bunks, a small lounge with color TV, examining/testing rooms, and office space. The studies are all done on an inpatient basis to the extent that the prisoners, while participating in research, must sleep and eat (regular prison food) in the Lilly unit, but during free time they may participate in regular prison activities or even continue to work on their prison jobs. They are paid only for their research participation, not for their prison jobs, while they are on

studies. Their pay is a flat rate of \$1.50 per day; Lilly provides an additional \$1.50 per day in "matching funds" to the prisoner recreation fund, managed primarily by the prison administration, with input from prisoners, and used for movies, sports equipment, etc. The research payment schedule is established by the prison authorities and is the same as the best pay a prisoner can earn at a prison job. Other prison job opportunities, such as furniture making, construction work, automobile shop, yard work, kitchen work, or clerking on the Lilly unit, pay from \$0.30-\$1.50 per day. Prisoners must apply and compete for jobs as they would on the outside. Over half the prisoners have a job. They do not lose their job or seniority by participating in research.

Length of stay on the unit varies from two to twelve weeks, averaging six weeks. Volunteers are not allowed to participate in consecutive studies and must reapply each time they complete a study if they want to continue in the research pool.

The prison population is approximately 40% black; the percentage of blacks among prisoners volunteering for research averaged 20% for a number of years. However, after the prison administration was told by the federal government that in order to qualify for federal funds, racial representation in all jobs in the prison would have to approximate the racial makeup of the total prison population, Lilly was advised by the warden that the research program would have to meet this federal requirement. Black volunteers in the research program were made aware of this directive, and began on their own to recruit additional volunteers among the black population. They were quite successful, and the numbers of black and white volunteers now are nearly equal. Present practice

to select volunteers for each study so that 40% of the participants are black.

The prisoners elect a council which provides some self-government and presents grievances and problems to the prison administration. Two ombudsmen for the prisoners are appointed by the governor; all correspondence to them, as well as to lawyers and the clergy, is uncensored. Prisoners with good time are allowed one collect phone call to the outside per month; other phone calls can be made only in emergencies. Visits are restricted in number and time due to space constraints. Education programs through the college level are available.

A physician is on the prison grounds and on call at all times. Some emergency equipment is available at the prison hospital, but any prisoners with serious illnesses are taken to an outside hospital for care. No serious adverse effects from the drug testing program have occurred since the program began. Lilly provides free medical care for any adverse effect.

Advantages and Disadvantages of the Hospital Research Setting

Lilly officials cite a number of advantages of bringing prisoners to the hospital setting for research. The hospital setting, with its full range of emergency equipment and round-the-clock staff, is unquestionably safer than the prison infirmary in case of an adverse reaction. On the other hand, the total absence of severe adverse reactions in 10 years would seem to reduce the absolute necessity for the degree of protection offered by the hospital. Other advantages are the convenience, pleasant surroundings and more secure environment offered to the investigator, who can walk down the hall from his hospital office

to see his subjects in a hospital ward instead of driving out of town to the prison setting. Diet control and environmental control are also better in the hospital setting. The major disadvantage to the company and the prisoners is the limited number of prisoners who qualify as subjects - only a few men at a time (presently around 55) qualify for work-release, and approximately 60% either are assigned to state jobs to meet quotas, or choose other jobs because of their advantages (freer movement, better pay, more opportunity for family contact). Lilly investigators feel the hospital may be slightly more open to public scrutiny than the prison, but that it would be impossible to cover up or hide an adverse occurrence (even if they wanted to) in either setting.

Documents detailing the regulations and procedures governing the operations of these two research units are attached.

OPERATING PRINCIPLES FOR CLINICAL STUDIES UTILIZING
VOLUNTEER SUBJECTS AT PENDLETON REFORMATORY AND
PENDLETON VOLUNTEER SUBJECTS AT THE LILLY LABORATORY
FOR CLINICAL RESEARCH (MARION COUNTY GENERAL HOSPITAL)

1. The protocol for any proposed study involving inmate volunteers will be prepared by a member of the medical staff of Eli Lilly and Company, who in each instance will be the principal investigator. Co-investigators should be listed on the protocol.
2. The attached Declaration of Helsinki-Recommendations Guiding Doctors in Clinical Research will serve as the principles to be followed.
3. Drug investigations conducted at the Pendleton Reformatory will be limited to marketed items and/or new drugs which have been the subject of human pharmacology tests elsewhere. Qualified Pendleton inmates may volunteer for initial human pharmacologic testing of investigational new drugs to be conducted in the Lilly Laboratory for Clinical Research at Marion County General Hospital.
4. The Institutional Review Committee, appointed by the Dean of IUPUI School of Medicine has been designated as the official group responsible for initial and continuing review and approval of clinical studies involving volunteers from the Pendleton Reformatory. This committee requires that the attached checklist (Attachment B) be executed, signed, and submitted with the study protocol.

Eight copies of the protocol for a proposed study should be submitted first to the Lilly Protocol Review Committee. This committee meets on the 2nd and 4th Thursdays of each month. If the protocol is approved, then it will be placed on the agenda of the next meeting of the Institutional Review Committee (1st and 3rd Thursdays). The principal investigator should plan to attend the meetings of these two committees to discuss his proposed study when the protocol for that study is being considered.

5. The approved protocol will be submitted to the Superintendent of the Reformatory with sufficient copies for distribution to his staff physician and others he may designate.
6. The Superintendent or his staff physician will advise the secretary of the Institutional Review Committee if there are any objections or suggested changes in the proposed study or protocol.

7. The staff physician at the Reformatory will be kept informed of the details of each phase of the drug study. A copy of the Project Status Report for the Institutional Review Committee (Attachment C) will be forwarded to the staff physician by the secretary of the Institutional Review Committee.
8. Personnel will be provided at no cost to the Reformatory to carry out those aspects of the research project which would otherwise constitute an increased work load on Reformatory personnel. Laboratory tests will be performed either in the Lilly Laboratory or by Lilly personnel, temporarily assigned for such purposes, in the Reformatory Laboratory.
9. Subjects will be limited to those 21 years of age or older. A signed informed consent form as designated in the study protocol will be obtained.
10. Inmate volunteers will be remunerated in accordance with a plan and fee schedule mutually satisfactory to Lilly's and the Reformatory staff.
11. Consultation service will be available to the Reformatory physician by the clinical and laboratory staffs of the Lilly company.
12. Scheduling of clinical studies involving Pendleton volunteers will be done through the office of the chairman of the Lilly Protocol Committee. If priority problems arise, the Director of Clinical Research will be consulted. In requesting volunteers, the attached form should be utilized. (Attachment D)
13. The Guidelines for the Recruitment of Prisoner Volunteers will be followed (Attachment E).
14. For Pendleton volunteers admitted to clinical studies on the Lilly ward at Marion County General Hospital, the Provisions and Guidelines for Patients and Guidelines for Physicians and Staff are applicable (Attachments F and G).
15. A Weekly Census Report will be available in the office of the Director, Lilly Laboratory for Clinical Research. This report will identify the inmate volunteers by name, number and birthdate, study protocol, date admitted to study and date discharged from the study.

George W. Orend

Superintendent, Indiana Reformatory
(Pendleton)

2-20-73

Date

W.R. Kutten MD

Director, Lilly Laboratory for
Clinical Research

Feb 19 1973

Date

Robert B. Forney

Chairman, Institutional Review
Committee

March 1, 1973

Date

L.D. Bechtel M.D.

Chairman, Lilly Protocol Review
Committee

19 Feb 73

Date

GUIDELINES FOR THE RECRUITMENT OF WELL PRISONER VOLUNTEERS

1. Under no circumstances shall any corrections employee assist in recruiting prisoner volunteers for drug experimentation except for allowing recruiters to use corrections facilities.
2. Recruiters shall avoid any appearance of acting for or on behalf of the Department of Corrections or any employee thereof.
3. Preliminary notices or requests for volunteers should avoid any element of persuasion such as recitation of benefits involved.
4. It is permissible to transfer a volunteer to an infirmary or hospital either in or out of the institution for the duration of the experiment and to compensate a volunteer in a reasonable amount but no other inducements to participate shall be made and under no circumstances shall a promise of parole, pardon or other clemency be made.
5. All volunteers shall be given a physical examination appropriate to the risks involved in the proposed experiment prior to participation.
6. In all cases of response to a preliminary request for volunteers, the responder shall be given the following:
"Eli Lilly and Company is recruiting volunteers to participate in the study of a new drug related to (here state relief of pain, antibiotics or relevant description in lay language). There are varying degrees of physical risk involved in any new drug as yet untested for human beings (where this is the case). You will be asked to use the new drug and the risks will be discussed fully between you and the administering physician or physicians before you give your consent to participate. Details of the experiment will also be furnished at that time. Probably not all of those volunteering will qualify or be needed. If you wish to volunteer sign below." (Public sign up sheets are to be avoided)
7. Every volunteer will be read the following:
"In order that progress and improvement be made in medicine it is important that new drug discoveries which may help people be fully tested before they are put on the market. If people cannot be found who are willing to experiment with new drugs this would slow medical progress. On the otherhand, if anyone were to believe that people were

being forced or improperly persuaded to test the drugs, this would be just as harmful. So it is important that you be sure you are not under pressure to consent to experimental testing upon you nor are unduly influenced by promises of rewards. If you have any doubts about either, it is best that you not participate in this experiment. It is very important that you do this of your own free will after all the risks and benefits both to you and the public have been explained. Your decision not to participate will not affect your present situation nor be held against you in any way. The reason for not using any volunteer is confidential between you and the Eli Lilly and Company and will not be told to others."

8. An Informed Consent Form will be designed for each specific study and will be read and signed by each volunteer participating in the study. The individual investigator is responsible for the execution of the Informed Consent Form. Among other requirements in the form it is desirable to include the following statement:

"I am over 21 years of age and, as far as I know, am in good health."

A statement should also be included indicating any volunteer subject can withdraw from the study at any time for any reason.

9. Volunteers should not be advised that if they withdraw from a study after it is initiated, other volunteer participants necessarily also must be withdrawn from the study.

2/8/73

Provisions and Guidelines for Patients
from
Indiana Reformatory Admitted to Lilly Ward
Marion County General Hospital

The following points are listed to provide you with an understanding of specific information essential for your participation and cooperation in research projects at the Lilly Clinic. Proper adherence is necessary to complete the study for which you have volunteered.

Since your participation in a study is completely voluntary, you are free to withdraw at any time. When your participation in the study is terminated, you will be returned to Indiana Reformatory.

While at the Lilly Clinic chaplain service is available to you from Indiana Reformatory.

If a problem occurs that is not covered by the guidelines, the supervisory nursing staff, Dr. Bechtol, or Mr. Walker will determine the guidelines to control the situation. The success of the project will depend upon your cooperation with the Lilly personnel as well as with other patients on the ward.

Provisions Made by Lilly Clinic

1. You will receive \$3.00 per day as long as you are participating in a clinical study. The total amount earned, minus deductions for commissary orders, will be sent to you by check within two weeks of your release from the ward.
2. You will be provided with one pack of cigarettes per day or the equivalent in money that will be added to your account if you do not smoke.
3. Writing paper and envelopes will be provided once a week in a container in your lounge.
4. Letters will be posted for you by the nursing staff. Please have your mail addressed to:
Your name
Lilly Clinic
Marion County General Hospital
960 Locke Street
Indianapolis, Indiana 46202
5. You will be furnished hospital clothing which includes pajama bottoms, gowns, and robes. (All other personal clothing worn by you on admission will be stored and returned to you upon release from the ward.)

6. Laundry of your personal articles of clothing is done routinely on Mondays and Thursdays when time permits by the nursing staff unless Monday or Thursday is a holiday.
7. You will be provided with hobby-craft materials each week to help keep you occupied. Should you desire not to order supplies at any time, the amount allotted cannot be added to your account.
8. You will be provided public library service; a bookmobile makes rounds twice weekly when possible.
9. Volunteer barber service is available to our area through Marion County General Hospital. The barbers are fairly consistent in providing service once a week. However, there are times when they may not be able to be here for two or three weeks in a row due to changes in their schedule.
10. A newspaper is left for you each day in the lounge.
11. You will be able to send in a weekly commissary order. (See instructions under Guidelines.)

Guidelines at the Lilly Clinic

1. On admission you are to bring your own toilet articles (toothbrush, toothpaste, razor, etc.) and allotted sundries (lighters, flint, matches, etc.). You may bring underclothing, socks, shoes, houseslippers, pictures of family and friends, radios, letters and five books or magazines, but other personal articles should be left at the Reformatory.
2. You are to remain in the immediate ward area at all times which will be defined by the nursing staff. We ask that you not linger in the hallway because noise tends to carry into other areas of the ward and disturbs sick patients. (Lingering includes standing or sitting in the hallway or end of hall and standing in your doorway.)
3. If it is necessary that you travel to another department or area (such as X-ray), you will be escorted and remained in attendance by the physician or nursing staff.
4. Smoking in hallways or in bed is strictly forbidden (Fire Marshal Regulation).
5. In the interest of other patients who may be ill:
 - a.) Showers and baths are to be taken between 7:00 a.m. & 9:00 p.m.
 - b.) Noise making projects that you may be working on should be confined to the above hours unless otherwise notified.
 - c.) Radios, T.V.'s, conversations, etc. should be kept to a minimum noise level.
 - d.) If situations arise causing other problems for sick patients, the nursing staff will inform you and ask your cooperation in solving the problem by following instructions.
6. The doors to your rooms are to be left open at all times. At bedtime, the night shift personnel will partially close them after they make their first rounds. (On the nights you are permitted to watch the late show, you may partially close them upon retiring). The doors can remain closed for the night, but should be open each morning at least by breakfast time (approximately 8:00 a.m.).
7. The rooms not occupied by you are to have the doors closed and should not be entered unless someone is admitted.

8. TV - Radio - Bedtime Policies:

- a.) Sunday through Thursday nights - You are to be in bed with lights out, TV & Radios off, and absolute quiet at 11:00 p.m.
- b.) Friday and Saturday nights - You will be permitted to watch the "Late Show" (Not the late late show) which is over at approximately 1:00 - 1:30 a.m. At the conclusion of the Late Show you are to be in bed with lights out, TV & radios off, and observe absolute quiet.
- c.) If you do not wish to watch TV on any of the above nights you are to remain quietly in your room and observe the same bedtime policies as above.
- d.) Choice of TV program to be seen will be voted on by you, with the majority ruling.

9. Visiting regulations:

- a.) Prior to your admission, you will be given the opportunity to select four names from your visiting card of persons you wish to visit you while at the Lilly Clinic. A special visiting card will be provided the nursing staff indicating the four names of your choice. Four visitors names, originally indicated, may not be changed until permission is obtained from Tom Collins.
- b.) Visiting hours are from 2:00 p.m. to 3:00 p.m. daily without exception.
- c.) Not more than two visitors can see you any given day, and they must be 14 years old or older.
- d.) Visitors are requested to sign in at the nursing station giving their name, address, and name of patient they are visiting.
- e.) All packages brought in by a visitor must be left at the nursing station while visiting and must be picked up upon their departure.

10. In accordance with the rules of your institution you will not be permitted to make telephone calls. In case of an emergency the manager of administrative services can be reached through the nurse and he must approve and place the call in the privacy of an office, with him present.

11. Weekly Commissary Ordering:

- a.) Each Monday you will be given the opportunity to hand in a list of articles required for your personal use.
- b.) The selection of items must be taken off the commissary list posted on the Bulletin Board in your lounge. If you order an item or brand name article that is not on the list, you will not receive it.
- c.) Your order is not to exceed \$8.00 each week. The total amount of your weekly order will be deducted from your pay.
- d.) If you require and order additional cigarettes other than the pack a day you receive, these also will be deducted from your pay.
- e.) No cosmetics, food, or articles containing alcohol will be permitted.
- f.) Your order will be delivered sometime during the week and is usually done by Friday at the latest.

12. You will be served a regulated diet at mealtime as specified by your physician. The dietary and nursing staff cannot make any changes or substitutions for your food or beverages that may be requested by you unless a written order is received from your doctor (and/or) approval is given by the dietician. No other food or beverages will be served between meals unless you are on a specific study requiring that this be done. You are not to accept from visitors, patients, or anyone else anything that your physician has not approved.

13. No gambling is permitted at any time.

14. Windows are to be kept closed and screens left in place at all times. A total malfunction of the heating and cooling system occurs if windows are opened.

15. No packages are to be received by mail, through visitors or other available sources. (The only exception is that a radio may be brought to you by a visitor.)

16. Handicraft items made by you if not given away beforehand should be packaged for mailing. On your return to Pendleton Mr. Collins will stop at the post office where you can mail your package.

17. No money or money orders are to be brought with you, sent by mail, or accepted from visitors or others.
18. You will be individually responsible for keeping your room in neat order. Special emphasis is to be placed on your lounge room which should be cleaned daily before 2 p.m.
19. Willful damage to the building or furnishing is strictly forbidden. Items are not to be hung or placed on top of light fixtures or brackets. No pictures or other articles are to be placed on wall or door surfaces.
20. You will be expected to conduct yourself as gentlemen at all times. Disrespect towards any personnel or abusive language or physical violence is not permitted.
21. You must remember that Indiana Reformatory rules still apply while you are a volunteer patient at the Lilly Laboratories for Clinical Research.

Violation of the above guidelines will be discussed with your physician, Dr. Bechtol, Mr. Walker, and the nursing staff; and where misconduct is involved, a major offense report may be submitted to your superintendent along with your return to Indiana Reformatory.



W. R. Kertley, M.D.
Director, Lilly Laboratory
for Clinical Research

12-4-72
George W. Phend
Superintendent
Indiana Reformatory

12/1/72

Guidelines for the Physicians and Staff
Using
Volunteer Patients from Indiana Reformatory
on
Lilly Ward, Marion County General Hospital

The following points are listed to provide you with an understanding of the agreement we have between the Superintendent of Indiana Reformatory and the Lilly Laboratories for Clinical Research.

1. The attached provisions and guidelines for volunteer patients will be discussed with the individual by a Lilly representative during the preliminary screening process at Indiana Reformatory. Each volunteer will be given a copy to bring with him to the Lilly ward. The Lilly staff will review the guidelines with the volunteer upon arrival at the Lilly Clinic.
2. No patient will be admitted to the Lilly ward until the study is approved by the Protocol Review Committee and discussed with Dr. Bechtol. He will then inform Mr. Collins and the nursing staff of our needs.
3. The medication must be available at the Lilly Clinic before the volunteer arrives from the Reformatory.
4. No repeaters to the Lilly Clinic should be authorized without the approval of the responsible physician, Dr. Bechtol, the nursing staff, and the Reformatory staff. This same approval applies to extending the study time beyond that initially approved and/or switching the protocol.
5. All senior scientists performing drug studies with inmate volunteers must be consistent in interpreting the rules. Before an exception is authorized, Dr. Bechtol, Mr. Walker, and the nursing staff must be informed and agree that we can live with the exception.
6. If an inmate volunteer fails to conform with established rules, he may be returned to Indiana Reformatory immediately. The decision will be made after consulting with the monitor, the nursing staff, Dr. Bechtol, and Mr. Walker.
7. No volunteer from Indiana Reformatory is permitted to leave the designated ward area unless accompanied by Lilly personnel who must remain with him while he is outside the Lilly area.

8. Volunteers will be returned at the completion of their studies and will not be permitted to remain on the ward until their parole date or for other personal reasons.

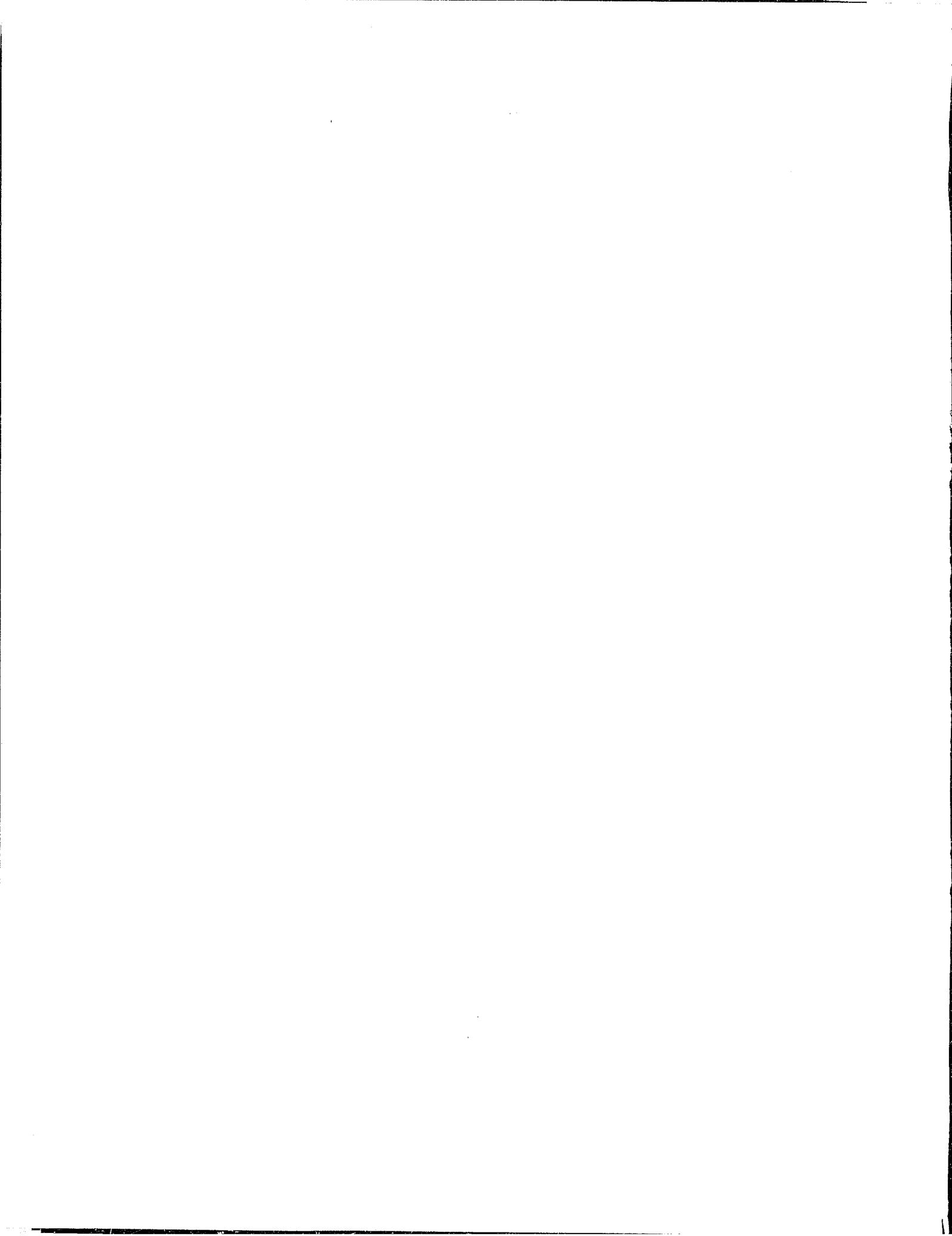
It is important that we work together in making our Indiana Reformatory volunteer research program a tremendous success.

W.R. Kirtley M.D.
Director, Lilly Laboratory
for Clinical Research

12-4-72
George W. Shend
Superintendent
Indiana Reformatory

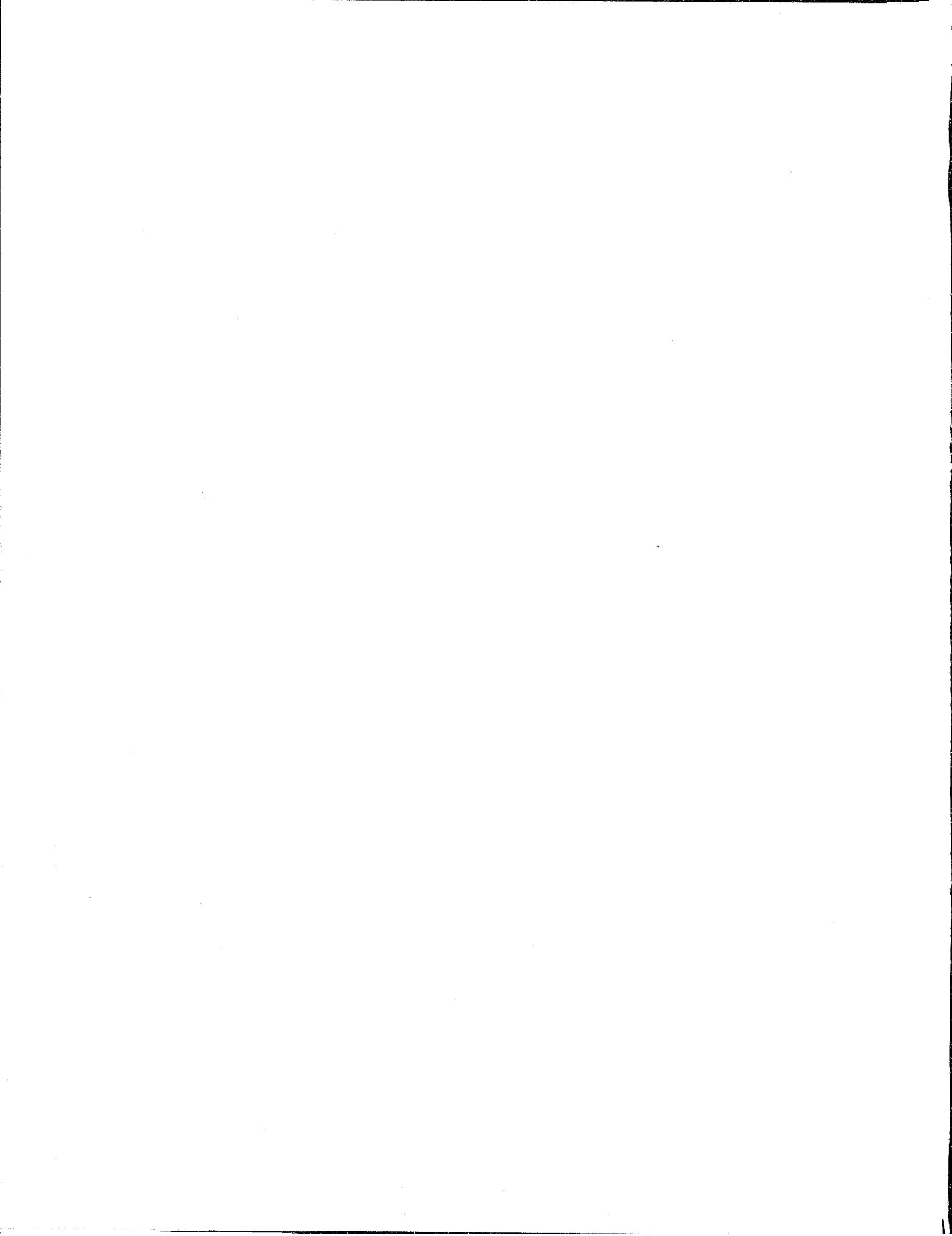


12/1/72



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REPORT OF A SITE VISIT: ADDICTION RESEARCH CENTER,
LEXINGTON, KENTUCKY, MAY 3, 1976



REPORT OF SITE VISIT

Addiction Research Center
Lexington, Kentucky
May 3, 1976

The Addiction Research Center was visited by staff of the National Commission for the Protection of Human Subjects to obtain information on operations and conditions at the Center, which utilizes prisoners as subjects in drug addiction research. This report is based on information obtained from that site visit, and includes the views expressed by investigators and prisoner subjects there in interviews with the Commission staff.

Historical Background. Establishment of a research program in drug addiction grew out of recommendations from studies in the 1920's that a solution to the problem of drug addiction in the United States required research to develop a nonaddictive analgesic. Some of the prominent physicians conducting research in this field were in the Public Health Service, which at that time had full responsibility for providing medical care in federal prisons. Consequently, these investigators established a research program in addiction at Leavenworth Prison in 1934, using imprisoned addicts there as subjects for their human studies. In 1935 a facility was opened in Lexington as a "prison hospital" for treatment of addicted prisoners, operated by the Public Health Service in conjunction with the Bureau of Prisons. The research program was transferred from Leavenworth to a wing of the Lexington facility at that time, and eventually became the Addiction Research Center (ARC), continuing to use prisoners at Lexington as subjects. For a number of years Lexington continued as a prison hospital, housing approximately 500 federal prisoner addicts and 500 "volunteer" addicts who came to Lexington for detoxification and treatment.

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When the Department of Health, Education, and Welfare was established and the Public Health Service (PHS) was transferred from the Treasury Department to HEW, the PHS remained administratively responsible for the Lexington prison hospital and the research program. After passage of the Narcotic Addict Rehabilitation Act in 1966, the Lexington PHS prison hospital was converted to a Clinical Research Center for narcotic addiction administered by the National Institute of Mental Health (NIMH). Thereafter addicts only came to Lexington either pre-conviction or on self-referral for treatment of their addiction and for research related to that treatment; post-conviction addicts (prisoners) were sent to the regular prison system. This situation created a crisis for the ARC, because the types of patients coming to Lexington as a result of this change were considered to be inappropriate for the kinds of studies the ARC performed, as the research (narcotic administration) would interfere with the therapy (keeping the patients off all drugs). Consequently, an agreement was reached in 1968 between the Bureau of Prisons and NIMH (see attachment) whereby prisoners who were formerly addicts could volunteer for the ARC research program at Lexington and be transferred there for studies. This agreement constitutes the basis for present operations of the ARC.

In 1974 an additional change occurred: the NIMH, apparently disenchanted with operations of the Clinical Research Center, transferred the building to the Bureau of Prisons, which renovated the facility and converted it to a Federal Correctional Institution (FCI) that houses approximately 800 male and female young offenders, primarily serving short terms for relatively minor offenses, and operating as a "model prison" with an unlocked main entrance,

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extensive educational and vocational programs, and special units for dealing with alcoholism and drug abuse. The ARC, transferred from NIMH to the National Institute on Drug Abuse (NIDA) when the latter was established in 1975, operates in a wing of the hospital-turned-model prison, connected by a locked corridor to the FCI.

Although the initial research efforts at the ARC were directed toward developing a nonaddictive analgesic (to avoid the disastrous experience with heroin and morphine), emphasis changed somewhat over the years to testing the addictive potential of drugs developed by others. Development of meperidine (Demerol) in World War II was followed by synthesis of a host of other non-narcotic analgesics which were screened by the ARC for their addiction potential. The facility, faced with being overwhelmed by sheer numbers of drugs, developed animal models for testing drug dependence; consequently, any analgesic drug inducing dependence in animals (mainly dogs and monkeys) is not even studied at the ARC in humans. Further, new analgesics are not studied at the ARC until all phase I studies are completed and efficacy has been demonstrated in phase II studies. Passage of new drug abuse laws and institution of drug scheduling helped to establish and formalize the role of the ARC in providing the data used by the Secretary, DHEW, in advising the Attorney General as to the abuse potential of drugs and the degree of control needed. The research performed at the ARC forms the basis for decisions on drug scheduling and control not only for the United States but also for the World Health Organization. This research has prevented errors both in overcontrolling and undercontrolling drugs. For example, chlorphentermine (an appetite suppressant) would have been

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scheduled with amphetamines based on its structure, but ARC studies showed dependence of the amphetamine type did not develop. On the other hand, ARC studies resulted in phenazocine, profadol, and tilidine either not being introduced or being scheduled, rather than being freely used as they would have been otherwise.

Several types of research involving human subjects have been done at the ARC. Some involve questionnaires or psychologic tests, both with and without drug administration. Others involve short-term administration of various drugs to measure psychologic and physiologic response; this is usually done in a blind cross-over protocol. Other studies have involved developing improved methods of treating narcotic addiction and withdrawal and studies of prolonged abstinence. Finally, some studies involve chronic drug administration, in which a drug is given for several weeks and then withdrawn to see if dependence develops, or a subject is made dependent on morphine and then an experimental drug is substituted for it to see if it can block the effects of morphine withdrawal (reportedly the most precise test of addictive potential).

The decision to use prisoners who are ex-addicts for these studies was not a matter of chance or convenience; rather they were selected because experienced addicts were considered to be the best possible reporters of the subjective effects of new drugs in comparison with narcotics, and best able to understand what administration of these drugs meant in order to give informed consent. Non-addicts were considered unacceptable subjects for tests involving administration of narcotics. Using prisoners rather than non-prisoners has been done because the studies require cloistered conditions to provide a stable environment and eliminate access to other drugs, as well as long-term drug

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administration and withdrawal, and it has been considered impossible to cloister free-living addicts for a long enough time to conduct the studies. Further, only use of hard-core addicts (in practice, those who have been withdrawn and become readdicted three times or more) was considered acceptable for chronic studies, and only prisoners have records to document such status. Because studies have shown that the likelihood that such persons will stay off drugs after release from prison approaches zero, ARC researchers have considered conducting studies on volunteers with this documentable history ethically acceptable, in that they are not doing anything to the subjects that the prisoners wouldn't do to themselves if they had a chance. In addition, the long-term availability of prisoners permits cross-over studies, so that significant results can be obtained by using far fewer human subjects than in a study design restricted to short-term studies.

Present Operations. The Addiction Research Center operates as an intramural research program of the National Institute on Drug Abuse. Research involving human subjects is conducted according to specific protocols, reviewed initially by staff and then by an Organizational Review Committee (equivalent to an IRB) to assess both scientific merit and design as well as adequacy of protection of the subjects (see attachments). Ongoing studies are monitored closely and are terminated before completion if ever it becomes clear that adverse effects are occurring from the drug.

Nearly all the subjects are prisoners, although some free-living persons have been used as controls in psychologic tests. Prisoners are recruited from federal correctional institutions; 90% of the subjects are from Atlanta and Leavenworth

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(the prisons housing recidivist addicts), the rest from Lewisburg and Terre Haute. Several times a year notices are put in the prison paper or bulletin board informing prisoners of the nature of the studies, the qualifications required, the method of application (a request through their caseworker to the Chief of Classification and Parole), and the date a recruiter will come to discuss the program in a group meeting. Most of the men have heard of the program from fellow prisoners, and some write the ARC directly and ask to come. In the meeting the concept of the operation and examples of studies are explained; prisoners are recruited to the concept of the program, rather than for a particular study. Persons who volunteer for the ARC program after the explanation at the recruiting meeting are screened by the ARC to be sure they meet the requirements of the program (good physical health, history of narcotic addiction, at least 25 years old, at least 18 more months of sentence to serve, no major psychiatric disorders other than sociopathic or neurotic personality) and that they could behave acceptably on the unit. They are then screened by the prison system (warden, medical officer, and Medical Director of the Bureau of Prisons) to eliminate those considered unacceptable security risks, incompatible mixes, and those believed by their drug abuse therapist to be inappropriate for the ARC. Prisoners approved in this screening process are then allowed either restricted or unrestricted participation, the difference being that the latter have a history of at least three previous treatments for addiction, and therefore may participate in studies involving opiates, cocaine, or chronic administration of hypnotics, alcohol, marijuana, or their synthetic equivalents, which restricted subjects cannot participate in. Approved prisoners are then transferred to the ARC, signing a non-binding agreement to stay there for a year, which may be extended to two years (or longer in exceptional circumstances). All prisoners are transferred back to their prison of

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origin after their stay at the ARC, at least six months prior to the time they are paroled or released from prison.

Prisoners are advised by ARC recruiters that their participation will not affect their chances for parole or for transfer to another prison. The benefits are a single-occupant cell to live in, with opportunity to have a TV or stereo in the cell if the prisoner buys one, and opportunity to earn meritorious compensation and good time based on the same schedule as elsewhere in the federal prison system (see attachment). Meritorious or industrial good time is awarded at a rate of up to 3 days per month in the first year and up to 5 days per month thereafter, based on good performance at a prison job and good behavior, and is subtracted from the length of sentence. Meritorious compensation is limited to a maximum of \$50 per month and is paid for prison jobs done other than those in the capital industry of that prison (a cotton mill in Atlanta, shoe factory in Leavenworth, and print shop at Lexington) which are recompensed separately. Research participation is recompensed as a prison job, at a rate of \$5 per study day (maximum \$30/month) for single dose studies and \$40 per month for chronic studies. The average pay at the ARC is \$21/month in research, \$25/month in the print shop, and \$12/month in other jobs (cleaning the ward, mowing grass, etc.).

At the ARC each prisoner is assigned to a one-man, 6 x 10 foot cell on one of three wards. The facility can house up to 50 men at a time; the overall volunteer population has been approximately 1/3 white, 1/3 black, and 1/3 chicano. Living conditions are plain, but not austere. There is freedom of movement on the ward, and the men are allowed outdoors in a grassy fenced exercise yard or basketball and handball courts when the guards are willing. A library, billiards, weights, and other light recreation is also available, and movies are shown once

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a week. The men go as a group to the commissary or to church at the adjoining Lexington FCI, but are allowed no contact with its inmates. There is no educational or vocational program available to ARC residents. Medical care needs beyond those which can be met by the ARC staff are provided by the FCI.

"Prisoners rights" are essentially the same at the ARC as in the federal prison system. The mail censorship is identical (spot censorship and monitoring with some exceptions), as is visiting policy. A recent rule change permits free access to the telephone, but calls may be monitored. Access to any lawyer by mail or phone is permitted without censorship or surveillance.

When a new study is being initiated, available qualified subjects are told about its nature and purpose, the type and exact name of the drugs being given and their known effects, the duration of the study, the test procedures involved, and how much they may earn by participating. They are given a consent form to read, and then it is read to them. Questions are answered, and in a subsequent session the consent form is signed and witnessed. Participants are advised that they can withdraw at any time without prejudice. As a matter of policy, they are never misinformed about what drug they are taking or its effects, and are never offered drugs as a reward for participating in a study, although drugs may be used therapeutically in treating a bad reaction or in aiding narcotic withdrawal. If a subject wishes to withdraw from a study investigators may talk with him to ascertain the reasons and see if he would be willing to continue, but do not pressure

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subjects not to withdraw. If a subject repeatedly refuses studies or withdraws from them, the investigators stop offering studies to the subject (as data collection depends on cooperation), but the investigators state that unless the subject requests it, he is not returned to his prison of origin until his agreement expires, as long as he otherwise makes a good institutional adjustment. Medical care is provided for any adverse effects of the drugs. Prior to discharge to the prison of origin, prisoners receive a complete medical reevaluation and psychologic testing, and total withdrawal from any drugs is accomplished.

The recent decision by the Bureau of Prisons to terminate the agreement by which prisoners are transferred to the ARC has forced consideration of other means of continuing the research, which is viewed as essential. Although still convinced that prisoners are the best subjects for such studies, for the reasons stated previously, the ARC investigators are planning an effort to recruit street addicts applying for enrollment in a methadone maintenance program to come to the ARC to participate in research and then return to go on the methadone program. Using these subjects would avoid many of the criticisms related to coercion and readdiction associated with using prisoners; the unanswered questions are whether people would volunteer and whether they would remain at the ARC long enough for meaningful studies to be performed.

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Interviews with subjects. Each of the sixteen prisoner-volunteers in the ARC on May 3 was interviewed individually by one of two Commission staff members. Although the interviews were unstructured, they dealt with the same basic topics of reasons for coming to the ARC, consent-related issues, and life in the ARC.

Various and multiple reasons were given for decisions to come to the ARC. Most men cited reasons related to the conditions of their imprisonment. These reasons included, in about equal proportion, the desire to be located closer to families, the belief (apparently erroneous) that transfer to more desirable prisons could be more easily arranged at the ARC than at their prisons of origin, and dissatisfaction with living conditions at their prisons of origin. Regarding the latter, mention was made of individual cells at the ARC and the resulting privacy, although not all men were specific about what conditions they had hoped would be better in Lexington.

About half of the men indicated that they believed that participating in the research program at the ARC would have a positive effect on their chances for parole or release. When questioned on this point, nothing they said contradicted the researchers' statement that such an effect is never promised or even hinted at. Rather, the belief is passed by word of mouth in the prisons of origin or is supported, not by statistical evidence, but by knowledge of particular men who made parole after returning from the ARC. The belief is fed by the men's conviction that participation in research is considered to be a socially beneficial thing to do, and their knowledge that, since their participation involved

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a transfer from one facility to another, the fact that they participated will be part of their prison record. (Federal regulations issued in June 1974 prescribing factors to be considered in parole decisions may, when they are understood by prisoners, eliminate their belief that participation in research will improve parole chances.)

A few men cited their belief in the importance of the research as a factor in their decisions, although only one indicated that this was his primary reason for participating. Only one man indicated that he found the program attractive because of his specific interest, as a former addict, in drugs. Only one of the men questioned indicated that he would have participated in the research program if it had been located at his former prison and if he were sure participation would not improve his chances for parole or transfer.

The men offered few complaints about particular studies, and indicated that they were treated properly, that adequate precautions were taken in selection of subjects and in the conduct of research, that they were given adequate information on which to base decisions, and that they understood that they were free to decline to participate in any study and that they could withdraw at any time.

Many of the men indicated that they participated selectively in research (avoiding certain kinds of studies, such as those involving hallucinogens or opiates or injections directly into the veins). In addition, many reported having withdrawn from particular studies before they were complete. With one exception, it was indicated that there had been

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no interference with such decisions. One man, however, said that on one occasion he had been strongly urged to delay his desired withdrawal from a study in which he had been addicted until after a particular visit of outsiders to the facility, because, he said, the researchers did not want on display a man going through drug withdrawal. (The Commission staff has no independent knowledge of the validity of this report.)

Despite the fact that there was general agreement that they had been explicitly informed about the voluntary nature of participation, most men stated the belief that if they declined participation too often or withdrew from too many studies they would be returned to their prison of origin. This, they believe, would be a black mark on their record, and would hurt parole or release chances. (It should be recalled that many men entered the program because of a belief that it would improve such chances.) In support of their belief that a pattern of refusal or withdrawal would result in removal from the ARC, they appealed to logic ("if we all refused, you know they would not keep us here") or they cited the fact that men are commonly returned to their prisons of origin on very short notice or without explanation. None of the men could identify any particular case where a refusal to participate, per se, resulted in a man's removal from the ARC; they did point out that if the researchers found a man to be unsatisfactory for any reason, he would be gone soon. Even if there is, in fact, a link between nonparticipation and removal from the unit--a fact not established--interpretation would need to be very careful. The researchers pointed out that

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men sometimes become dissatisfied with being located at the ARC and that this dissatisfaction may be manifested in a number of ways of "acting out." When a man becomes a discipline problem within the unit, he is usually removed; the behavior which actually results in removal may be accompanied by uncooperativeness in the research which, by itself, according to the researchers, would not result in a man's removal.

Nevertheless, the particular combination of factors described above--the fact that the same people who are responsible for the research are also responsible for decisions regarding the circumstances of the men's incarceration at the ARC, and that decisions to remove a prisoner from the ARC are viewed by prisoners as having a negative impact on chances for parole--suggest the presence of a significant coercive element in the unit. The problem is partly due to the fact that, since changes of facilities are involved, "failure" at the ARC inevitably is reflected in a man's record, and he knows it. The problem also seems to be due to the fact that the researchers, not distant prison officials, are responsible for discipline and order within the unit. The maintenance of such order requires having the power to "motivate" men to behave according to the rules; it is not surprising that the prisoners are unable to ignore completely the fact of this power when they are asked to participate in a particular study.

While there were few, if any, complaints about particular studies, there were four complaints about the general program at the ARC. All of these complaints were frequently repeated. First, men complained

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about the low amount of money received in the tests and at other jobs. Many said they could make much more money at the prison of origin. Money, incidentally, was never mentioned among the reasons why the men had decided to come to the ARC. A conscious decision has been made by the administration of the program to keep the pay rate at a level sufficiently low that it will not be an important motivating factor for subjects.

The second complaint concerned the lack of educational, training, therapeutic (i.e., counseling or psychotherapy), entertainment and recreational programs at the ARC. Exercise facilities regularly available at the ARC were limited, and the men apparently had little access to the recreation facilities at the neighboring FCI. The men had no access to educational or training programs. There is available one prison industry--a print shop--but only two men in the ARC were currently working there. As for entertainment, only one occasion was cited at which the men attended a program at the neighboring FCI; entertainment at the ARC itself is confined to television and a weekly movie. The lack of educational, training, therapeutic, recreation, or entertainment provisions again reflects a conscious decision not to make the ARC unduly attractive to potential residents. This decision reflects a sensitivity to some criticisms which have been made of prison research, but, from the standpoint of the prisoner-subjects, it is very unfair not to have access to facilities comparable to their prison of origin, particularly since they view themselves as making sacrifices for the good of society. They consider their existence dull and opportunities limited compared with

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their prison of origin, and feel that their meritorious behavior is being penalized.

The third criticism, closely related to the previous one, pertains to their segregation from the FCI next door. In addition to not being allowed to participate in FCI programs, they are segregated on the occasions that they enter that facility, primarily to go to the commissary (twice a week) and to attend church services (men from the ARC sit in a reserved area). From the standpoint of the administrators of the ARC, these restrictions are necessitated by factors of security and cost. Men come to the ARC from maximum security federal prisons, and have the criminal backgrounds implied by this fact. The FCI next to the ARC is a facility run for a very different population, so much so that during daylight hours, there is no locked door between many inmates there and the outside world. To allow the ARC residents greater access to the FCI would require special security for which funds are not available, and which would be counter to the concept of that FCI. Furthermore, since the FCI is relatively open and houses a substantial population of people incarcerated for drug-related offenses, the ARC officials expressed concern that contact between the FCI and the ARC would bring contraband drugs into the ARC and interfere with the studies therein.

The fourth complaint concerned the lack of what was uniformly called "aftercare." As this concern was expressed, the men saw themselves as taking drugs with unknown effects, drugs they feared might have after-effects or cause "flashbacks." Thus, they expressed a belief that "after-care" of some sort was necessary. The researchers expressed doubt that

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this was a genuine issue, indicating a belief that the need for "after-care" was a lever the men were trying to use in order to be transferred to desired facilities such as a Bureau of Prisons hospital. The researchers indicated that all effects on subjects of the research program are now being studied, and they expressed lack of knowledge as to what such "aftercare" would entail.

Between Bureau of Prisons and the
National Institute of Mental Health

Concerning transfer of prisoners from Bureau of Prisons
for research studies at the NIMH Addiction Research Center

This is a memorandum of understanding between the Bureau of Prisons and the National Institute of Mental Health concerned with the transfer of patients to the NIMH Addiction Research Center from the Bureau of Prisons to participate in psychopharmacological studies, and more particularly, to participate in studies concerning the assessment of the abuse potentialities of opiate-like analgesics. The assessment of the abuse potentiality of narcotic analgesics by the U. S. Public Health Service using prisoner subjects of the Bureau of Prisons has been ongoing since 1934, at which time Dr. C. K. Himmelsbach established the program at Leavenworth Prison. The studies have continued at the Clinical Research Center (formerly U. S. Public Health Service Hospital) at Lexington, Kentucky. The Secretary of Health, Education and Welfare has statutory responsibilities outlined in the Narcotics Manufacturing Act of 1960 for advising the Secretary of the Treasury concerning the abuse potentiality of strong analgesics. In this Act,

"The word 'opiate,'...shall mean any drug...or other substance found by the Secretary (of the Treasury) or his delegate and proclaimed by the Secretary or his delegate (after considering the technical advice of the Secretary of Health, Education, and Welfare, or his delegate, on the subject) to have been so found in the Federal Register, after due notice and opportunity for public hearing, to have an addiction-forming or addiction-sustaining liability similar to morphine or cocaine or to be capable of conversion into a drug having such addiction-forming or addiction-sustaining liability, where, in the judgment of the Secretary or his delegate, the relative technical simplicity and degree of yield of such conversion create a risk of improper use of the drug or other substance."

A Federal prisoner would be eligible for these studies when:

1. He has volunteered for the studies and for transfer to the Addiction Research Center.
2. The application has been reviewed and mutually approved by (a) the warden and medical officer of the prison in which he is incarcerated, (b) the Medical Director of the Bureau of Prisons or his delegate, (c) the Assistant Director, Division of Institutional Services or his delegate, and (d) the Chief of the NIMH Addiction Research Center or his delegate.
3. He has a history of narcotic addiction.
4. He is in good physical health.

5. He has no major psychiatric disorders in and above sociopathic or neurotic personality.
6. He must be over 25 years of age.
7. He must have at least 18 months of sentence to serve at the time of volunteering.

Patients who satisfy these criteria would be then classified by the mutual agreement of the warden of the prison or his medical director, the Medical Director of the Bureau of Prisons or his delegate, Assistant Director of Institutional Services or his delegate, and the Chief of the Addiction Research Center or his delegate into one of several categories of participation:

1. Unrestricted participation. Unrestricted participation means that the subject can participate in any experiment involving narcotic analgesics, sedative-hypnotics, marihuana, cocaine, alcohol, or psychotomimetic agents, as well as other centrally acting drugs. Criteria for unrestricted participation are: (a) Patient must be at least 25 years of age, and (b) have at least three previous treatments of addiction. Unrestricted participation is further divided into two subcategories: Those patients who are eligible for chronic drug studies, and those patients who are eligible for single dose studies. No hard criteria can be established for this distinction which depends on the judgment of the Chief of the Addiction Research Center or his delegate and is based on the relative therapeutic prospect of the subject and medical considerations.
2. Restricted participation. Restricted participation means that the patient cannot participate in studies involving opiates, cocaine or the chronic administration of hypnotics, alcohol, marihuana, or the synthetic equivalents of these drugs. Criteria for restricted participation are: (a) The subject be at least 25 years of age, and (b) that there be no contraindication to participation in experiments.

Approval or renewal of eligibility. Approval for participation in research studies will be made for a period of one year or less. Approval can be renewed yearly with the approval of the Chief of the Addiction Research Center and the Medical Director of the Bureau of Prisons. Except in special instances, it is not anticipated that subjects will continue to participate in studies in excess of two or three years.

Transfer. When a subject has been approved for transfer to the Addiction Research Center for participation in research studies, the patient and both his administrative and medical jackets will be transferred to the Clinical Research Center. The transfers to the Clinical Research Center and from the Clinical Research Center to Federal prisons will be arranged by the Bureau of Prisons; however, the costs of transfer will be assumed by the Addiction Research Center.

Admission and prisoner care. The admission of the inmate to this Center would be the responsibility of the Clinical Research Center. The Medical Records Section would obtain all necessary information at the time of admission and would take the responsibility for maintaining the administrative records on each inmate and determining the number of days that the inmate is earning, as well as keeping an accurate account of the length of sentence, eligibility for parole, and other administrative details concerned with his sentence and release. The Clinical Research Center will provide services to the inmates related to housing, food, clothing, laundry, infirmary care including laboratory, x-ray, physical therapy and dental care, as well as recreational facilities, religious counseling and psychotherapy that are consistent with the program and facilities of the Clinical Research Center.

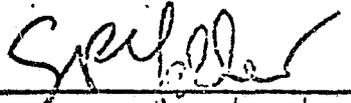
The Clinical Research Center will assume the responsibility for the custody, security and discipline of the patients. The Addiction Research Center will have the responsibility for recommending meritorious and research good time. The Clinical Research Center will have the responsibility of recommending industrial good time awards. Further, the Addiction Research Center will have the responsibility for funding and awarding any cash awards that will be given for participation in research studies.

Incentives. Incentives will include both good time and cash awards and will be given not only for participation in research studies but meritorious and industrial good time awards will also be made. The nature and magnitude of the awards shall be commensurate with awards given to comparable prisoners by the Bureau of Prisons.

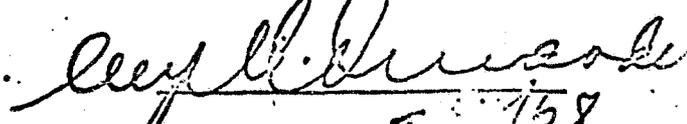
Participation in experiments. Prior to participation in each study, each subject will undergo a complete history and physical examination, as well as having appropriate laboratory tests done, and will execute a separate and informed consent form. Participation in any study is voluntary and the patient is free to withdraw at any time during the course of the study. All study plans will have been previously reviewed by the local research committee of the Addiction Research Center and will in every respect conform to the regulations for clinical experimentation established by the Surgeon General. Copies of all research protocols will be forwarded to the Medical Director of the Bureau of Prisons for his information.

Records. The Addiction Research Center will provide semi-annually to the Bureau of Prisons a summary of patient participation. This will include the patient's name, registration number, prison of origin, home address, short time release date, research classification, study number, date of admission to the Addiction Research Center, as well as a record of all good time and cash awards.

For the
National Institute of Mental Health


Date: 1/27/58

For the Bureau of Prisons


Date: 2/1/58

OPERATIONS MANUAL
ORGANIZATIONAL REVIEW COMMITTEE

2. The Organizational Review Committee reviews all clinical study plans. The study plans of each experiment conducted on the wards of the ARC are circulated to all committee members. They review the study plan and either, (a) approve it, (b) approve it but make suggestions concerning the experimental design and conduct of the experiment, or (c) do not approve it, and indicate to the investigator in writing their reasons for not approving it. No study is initiated without the approval in writing of the entire Organizational Review Committee of the ARC.

B. Method of selection

The Organizational Review Committee is selected by the Director of ARC. Several criteria are used in the selection of this Committee. (1) A substantive portion of the committee must have technical expertise such that they can assess the soundness of the experimental designs to be employed, the risks to the health of the patients, and the efficacy of procedures taken to avoid or treat toxic or adverse reactions. (2) Other members of the committee are selected because of their knowledge and background concerning the relevance of the particular experiments and general experimental program of the ARC to the common good. (3) Other members of the committee are selected on the basis of their knowledge and experience to provide guidance to the Director, ARC, on issues concerning the humane treatment of prisoner-patients and ethical questions concerning the conduct of experiments.

The committee will make determinations of whether subjects will be or not be at risk as defined in Part II, "Protection of Human Subjects" Regulations:

"Subject at risk" means any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service."

The committee will also determine that the sum of benefits so outweigh the risk to the subject that allow the subject to accept these risks.

C. Organizational Review Committee composition

Members

Harris Isbell, M.D.
417 Foch Street
Eastland, Texas 76448

Abraham Wikler, M.D.
Professor of Psychiatry
University of KY Medical Center
Lexington, Kentucky 40506

Robert Straus, Ph.D.
Professor and Chairman
Dept. of Behavioral Sciences
Univ. of Kentucky Medical Center
Lexington, Kentucky 40506

Qualifications

Paid Consultant; Board Certified Internal Medicine; Clinical Pharmacologist; Professor of Medicine, Univ. of Ky.; Formerly Director of ARC

Paid Consultant; Board Certified in Neurology; Board Certified in Psychiatry; Professor of Psychiatry and Pharmacology, Univ. of KY

Paid Consultant; Fellow, American Public Health Association; Member, National Advisory Commission of Alcoholism

Members

T. Z. Csaky, M.D.
Professor and Chairman
Department of Pharmacology
Univ. of Kentucky Medical Center
Lexington, Kentucky 40506

Charles W. Gorodetzky, M.D.
Chief, Section on Drug Metabolism
and Kinetics
NIDA Addiction Research Center
P.O. Box 12390
Lexington, Kentucky 40511

Donald R. Jasinski, M.D.
Chief, Clinical Pharmacology Section
NIDA Addiction Research Center
P.O. Box 12390
Lexington, Kentucky 40511

David C. Kay, M.D.
Chief, Section on Experimental
Psychiatry
NIDA Addiction Research Center
P.O. Box 12390
Lexington, Kentucky 40511

John D. Griffith, M.D.
Chief, Stimulant and Hallucinogen Unit
NIDA Addiction Research Center
P.O. Box 12390
Lexington, Kentucky 40511

William R. Martin, M.D.
Director, NIDA Addiction Research Center
P.O. Box 12390
Lexington, Kentucky 40511

Qualifications

Paid Consultant; Member, American
Society for Pharmacology and
Experimental Therapeutics; Member,
American Physiological Society

Full Time Employee; Clinical
Pharmacologist

Full Time Employee; Clinical
Pharmacologist

Full Time Employee; Board
Certified Psychiatrist; Neuro-
psychopharmacologist

Full Time Employee; Board
Certified Psychiatrist; Clinical
Pharmacologist

Full Time Employee; Clinical
Pharmacologist; Neuropsychopharmacologist

SCHEDULE FOR MERITORIOUS COMPENSATION

A. Research Participation

1. Single dose studies generally

(a) \$5 per study day not to exceed 6 study days per month

(b) In instances approved in advance by Chief, Clinical Pharmacology Section, \$6 per study day not to exceed 5 study days in any one month.

2. Chronic Studies

\$40 per month

B. Job Assignment

1. Routine job and satisfactory behavior

\$12 per month

2. Printing trades

Schedule attached

C. Conclusion of Stay at ARC

At time of return to the Bureau of Prisons, patients may receive a bonus of \$50 for each year of participation in program at the ARC with a maximum of \$100.

*Prisoner patients cannot earn both meritorious compensation for job assignments and Printing Trades pay.

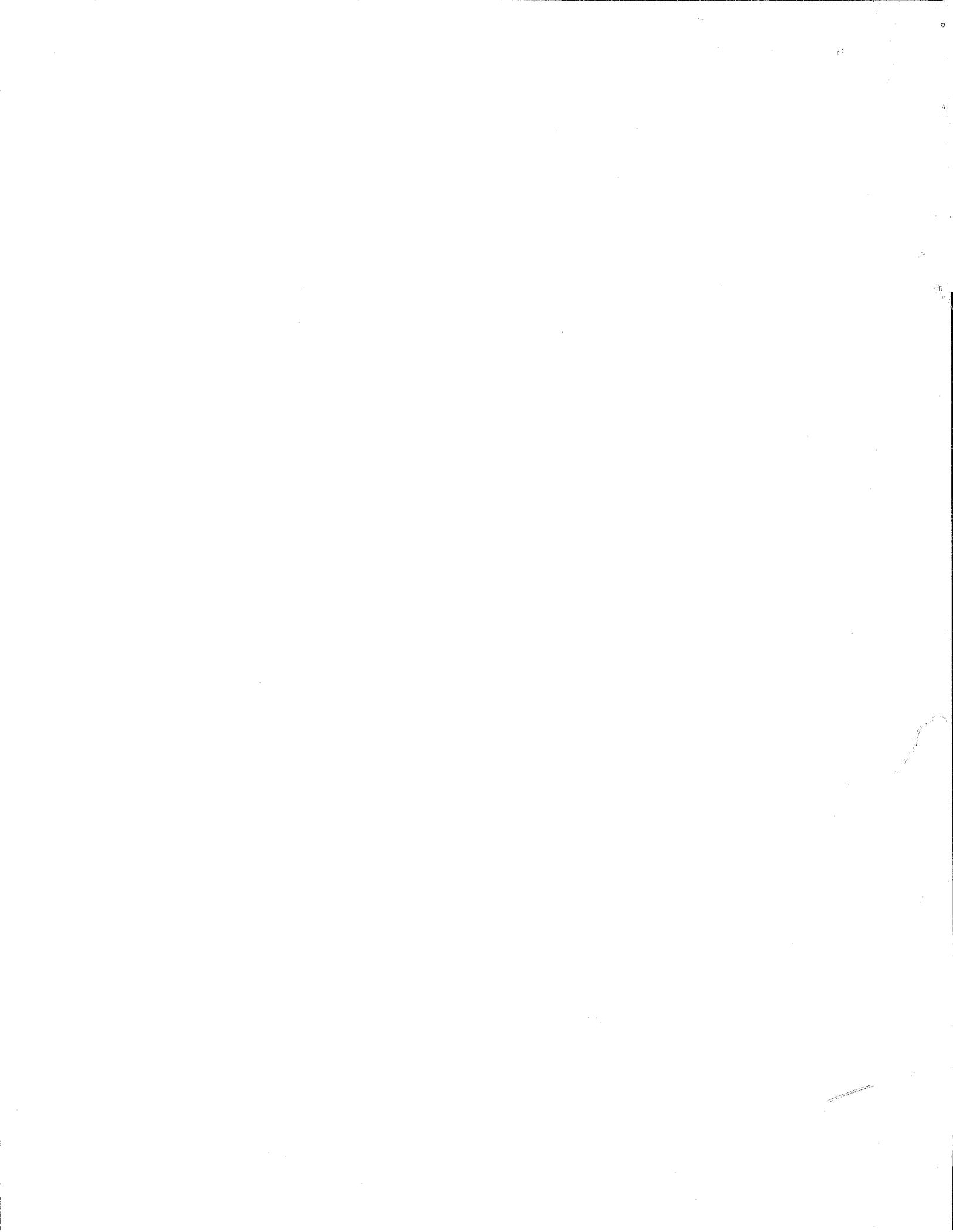
Schedule for Compensation Printing Trades ARC

the following will be used as a step rate method of payment to patients assigned to Printing Trades.

| CLASSIFICATION | Hour Rate | After | After |
|--------------------------|-------------------|--------------------------|--------------------------|
| | Step 1 | 6 Mo. Training Step 2 | 1 Yr. Training Step 3 |
| Janitor | <u>New</u> .27 | <u>New</u> .32 | <u>New</u> .37 |
| Shipping Clerk | .27 | .32 | .37 |
| Clerk | .27 | .32 | .37 |
| Stuffing Envelopes | .27 | .32 | .37 |
| Zip Coding | .27 | .32 | .37 |
| Hand Assembly | .27 | .32 | .37 |
| Purchasing (Clerk-Steno) | .27 | .32 | .37 |
| Binding | .27 | .32 | .37 |
| Stapling | .27 | .32 | .37 |
| Graph-O-Type Operator | .27 | .32 | .37 |
| Addressograph | .27 | .32 | .37 |
| 11 x 14 Press | .28 | .33 | .38 |
| 11x17 & 15x18 Press | .29 | .34 | .39 |
| 17 x 22 Press | .30 | .35 | .40 |
| Relief Press Operator | .30 | .35 | .40 |
| Collator Operator | .29 | .34 | .39 |
| Paper Cutter Operator | .28 | .33 | .38 |
| Photo-Lithographer | .28 | .33 | .38 |

Patients must have worked a minimum weekly average of 20 hours and performed in a satisfactory manner in order to be eligible for the next higher step.

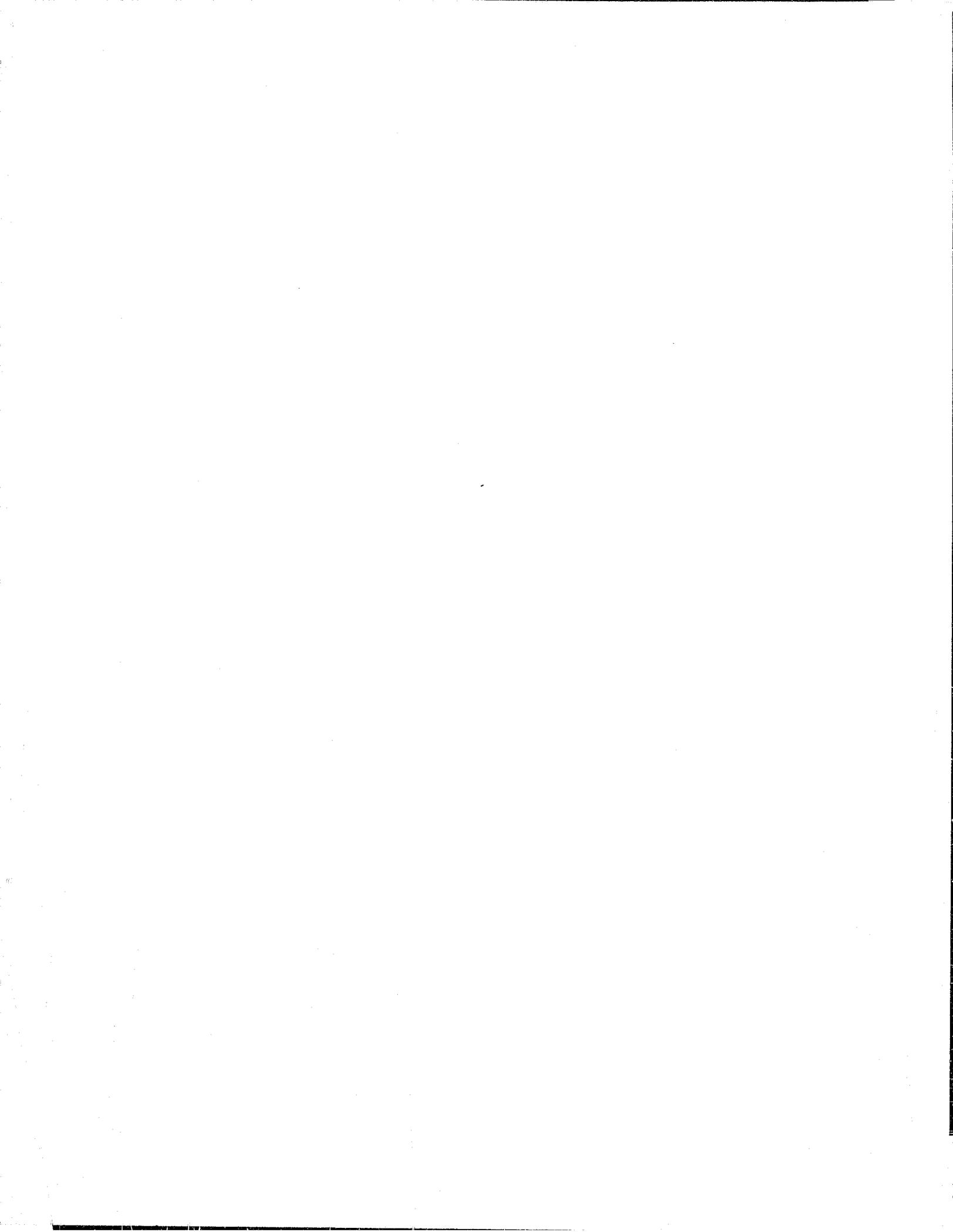
Patients will work a maximum of 4 days per week unless they have permission to work longer.



Part IV

SUPPLEMENTAL RESOURCE INFORMATION

THE NUREMBERG CODE OF ETHICS
IN MEDICAL RESEARCH



The Nuremberg Code of Ethics in Medical Research

(1) The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent: should be so situated as to be able to exercise free power of choice without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

(2) The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

(3) The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

(4) The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

(5) No experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subject.

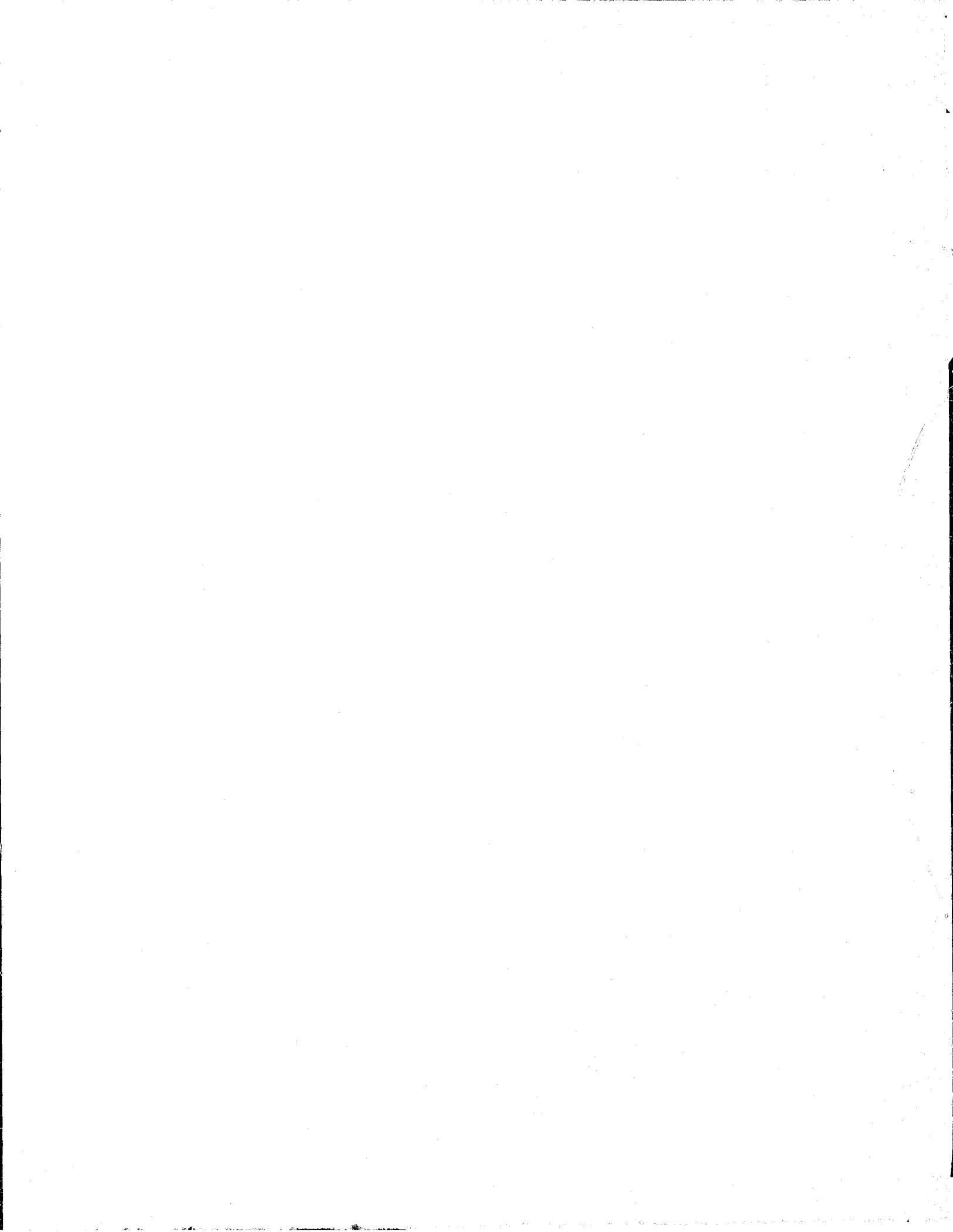
(6) The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

(7) Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

(8) The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

(9) During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

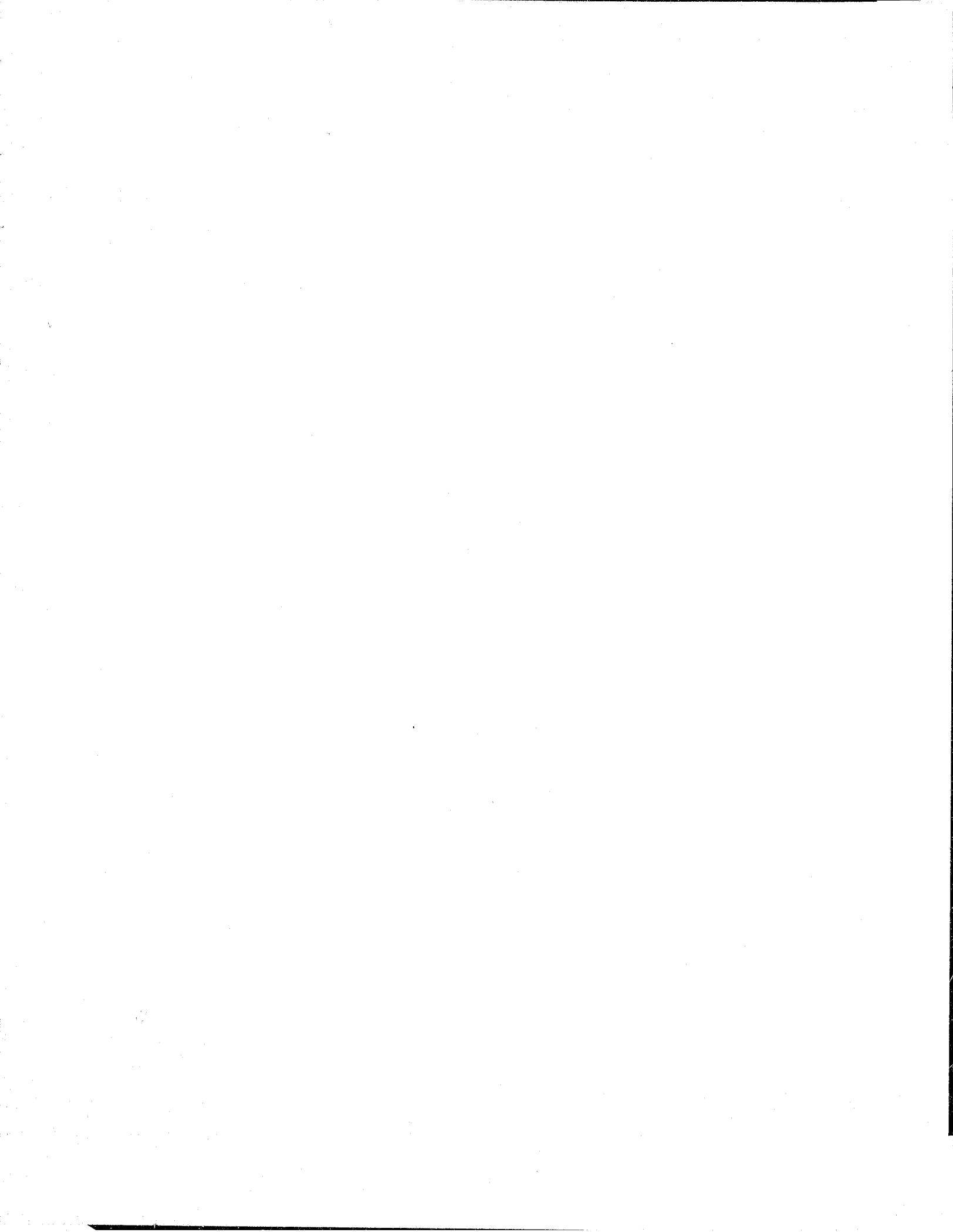
(10) During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill, and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.





21

DECLARATION OF HELSINKI



Declaration of Helsinki

INTRODUCTION

It is the mission of the doctor to safeguard the health of the people. His knowledge and conscience are dedicated to the fulfillment of this mission.

The Declaration of Geneva of The World Medical Association binds the doctor with the words: "The health of my patient will be my first consideration" and the International Code of Medical Ethics which declares that "Any act or advice which could weaken physical or mental resistance of a human being may be used only in his interest."

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, The World Medical Association has prepared the following recommendations as a guide to each doctor in clinical research. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Doctors are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

In the field of clinical research a fundamental distinction must be recognized between clinical research in which the aim is essentially therapeutic for a patient, and the clinical research, the essential object of which is purely scientific and without therapeutic value to the person subjected to the research.

I. BASIC PRINCIPLES

1. Clinical research must conform to the moral and scientific principles that justify medical research and should be based on laboratory and animal experiments or other scientifically established facts.
2. Clinical research should be conducted only by scientifically qualified persons and under the supervision of a qualified medical man.
3. Clinical research cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.
4. Every clinical research project should be preceded by careful assessment of inherent risks in comparison to foreseeable benefits to the subject or to others.
5. Special caution should be exercised by the doctor in performing clinical research in which the personality of the subject is liable to be altered by drugs or experimental procedure.

II. CLINICAL RESEARCH COMBINED WITH PROFESSIONAL CARE

1. In the treatment of the sick person, the doctor must be free to use a new therapeutic measure, if in his judgment it offers hope of saving life, reestablishing health, or alleviating suffering.

If at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent after the patient has been given a full explanation. In case of legal incapacity, consent should also be procured from the legal guardian; in case of physical incapacity the permission of the legal guardian replaces that of the patient.

2. The doctor can combine clinical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that clinical research is justified by its therapeutic value for the patient.

III. NON-THERAPEUTIC CLINICAL RESEARCH

1. In the purely scientific application of clinical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom clinical research is being carried out.

2. The nature, the purpose and the risk of clinical research must be explained to the subject by the doctor.

3a. Clinical research on a human being cannot be undertaken without his free consent after he has been informed; if he is legally incompetent, the consent of the legal guardian should be procured.

3b. The subject of clinical research should be in such a mental, physical and legal state as to be able to exercise fully his power of choice.

3c. Consent should, as a rule, be obtained in writing. However, the responsibility for clinical research always remains with the research worker; it never falls on the subject even after consent is obtained.

4a. The investigator must respect the right of each individual to safeguard his personal integrity, especially if the subject is in a dependent relationship to the investigator.

4b. At any time during the course of clinical research the subject or his guardian should be free to withdraw permission for research to be continued.

The investigator or the investigating team should discontinue the research if in his or their judgment, it may, if continued, be harmful to the individual.

We, the undersigned medical organizations, endorse the ethical principles set forth in the Declaration of Helsinki by the World Medical Association concerning human experimentation. These principles supplement the principles of medical ethics to which American physicians already subscribe.

American Federation for Clinical Research
American Society for Clinical Investigation
Central Society for Clinical Research
American College of Physicians
American College of Surgeons
Society for Pediatric Research
American Academy of Pediatrics
American Medical Association





21-5

Recommendations of the World Medical Association

Guiding Medical Doctors in Biomedical Research Involving Human Subjects

RECOMMENDATIONS

The World Medical Association

*Comprising the Declaration of Helsinki
as revised in the Declaration of Tokyo*

INTRODUCTION

It is the mission of the medical doctor to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfillment of this mission.

The Declaration of Geneva of the World Medical Association binds the doctor with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "Any act or advice which could weaken physical or mental resistance of a human being may be used only in his interest."

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

in current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies *a fortiori* to biomedical research.

Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

In the field of biomedical research a fundamental distinction must be recognized between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific

and without direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, The World Medical Association has prepared the following recommendations as a guide to every doctor in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Doctors are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

1. BASIC PRINCIPLES

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.

2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment and guidance.

3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.

4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.

6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

7. Doctors should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Doctors should cease any investigation if the hazards are found to outweigh the potential benefits.

8. In publication of the results of his or her research, the doctor is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The doctor should then obtain the subject's freely-given informed consent, preferably in writing.

10. When obtaining informed consent for the

research project the doctor should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a doctor who is not engaged in the investigation and who is completely independent of this official relationship.

11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.

12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II. MEDICAL RESEARCH COMBINED WITH PROFESSIONAL CARE (CLINICAL RESEARCH)

1. In the treatment of the sick person, the doctor must be free to use a new diagnostic and therapeutic measure, if in his or her judgement it offers hope of saving life, reestablishing health or alleviating suffering.

2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.

3. In any medical study, every patient - including those of a control group, if any - should be assured of the best proven diagnostic and therapeutic method.

4. The refusal of the patient to participate in a study must never interfere with the doctor-patient relationship.

5. If the doctor considers it essential not to obtain

informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (1, 2).

6. The doctor can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III. NON-THERAPEUTIC BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (NON-CLINICAL BIOMEDICAL RESEARCH)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom biomedical research is being carried out.

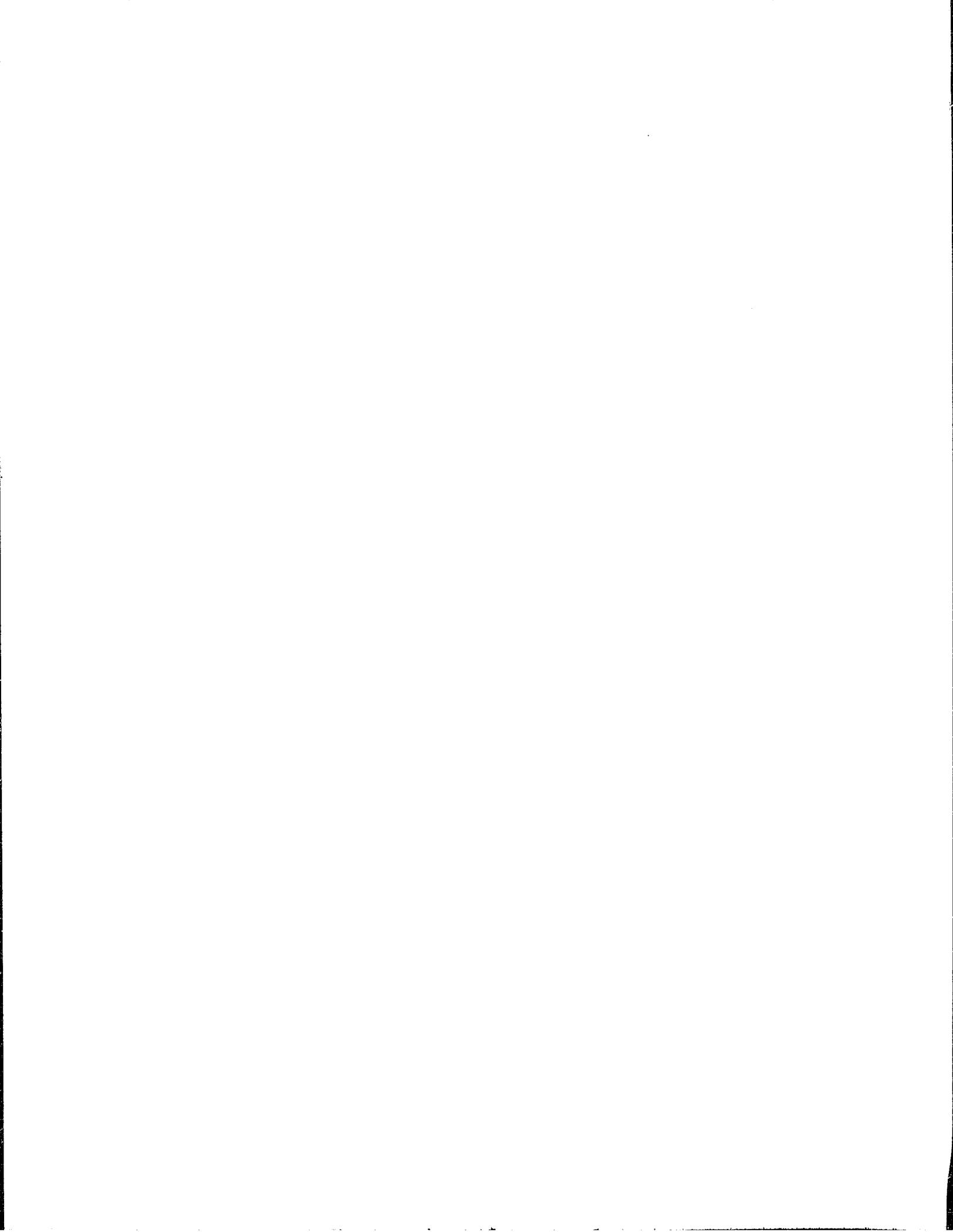
2. The subjects should be volunteers - either healthy persons or patients for whom the experimental design is not related to the patient's illness.

3. The investigator or the investigating team should discontinue the research if in his/her or their judgement it may, if continued, be harmful to the individual.

4. In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.

Adopted by the 18th World Medical Assembly, Helsinki, Finland, 1961, and as revised by the 29th World Medical Assembly, Tokyo, Japan, 1975.

Distributed by
Office for Protection From Research Risks
Office of the Director
National Institutes of Health



POSITION STATEMENT: THE USE OF PRISONERS AND DETAINEES
AS SUBJECTS OF HUMAN EXPERIMENTATION

The American Correctional Association



POSITION STATEMENT --- THE AMERICAN CORRECTIONAL ASSOCIATION

THE USE OF PRISONERS AND DETAINEES AS
SUBJECTS OF HUMAN EXPERIMENTATION

The American Correctional Association has long viewed with concern the use of prisoners as subjects of medical, pharmacological experimentation. This concern is shared by many--the courts, legislatures, administrators, professional bodies, and the community at large. The Association is aware that many state correctional systems have already adopted policies precluding, or sharply limiting, such experimentation. It now urges that efforts to eliminate such practices be undertaken by responsible bodies at the Federal, State, and local levels.

(1) While it is recognized that such experimentation can make a contribution to the health and well-being of all people and contribute to the achievement of legitimate objectives and goals of correctional systems, and

(2) Although it can be argued that the elimination of human experimentation from correctional institutions may deny the offender a measure of freedom of choice in determining the extent to which he may offer himself for experimental purposes;

(3) We have concluded that:

(a) A person confined in a correctional institution is incapable of volunteering as a human subject without

hope of reward;

(b) It is very doubtful that prisoners who volunteer can be said to do so on the basis of fully informed consent;

(c) The assessment of risks attached to human experiments is ordinarily beyond the competence of those who bear the ultimate responsibility for approving human research projects.

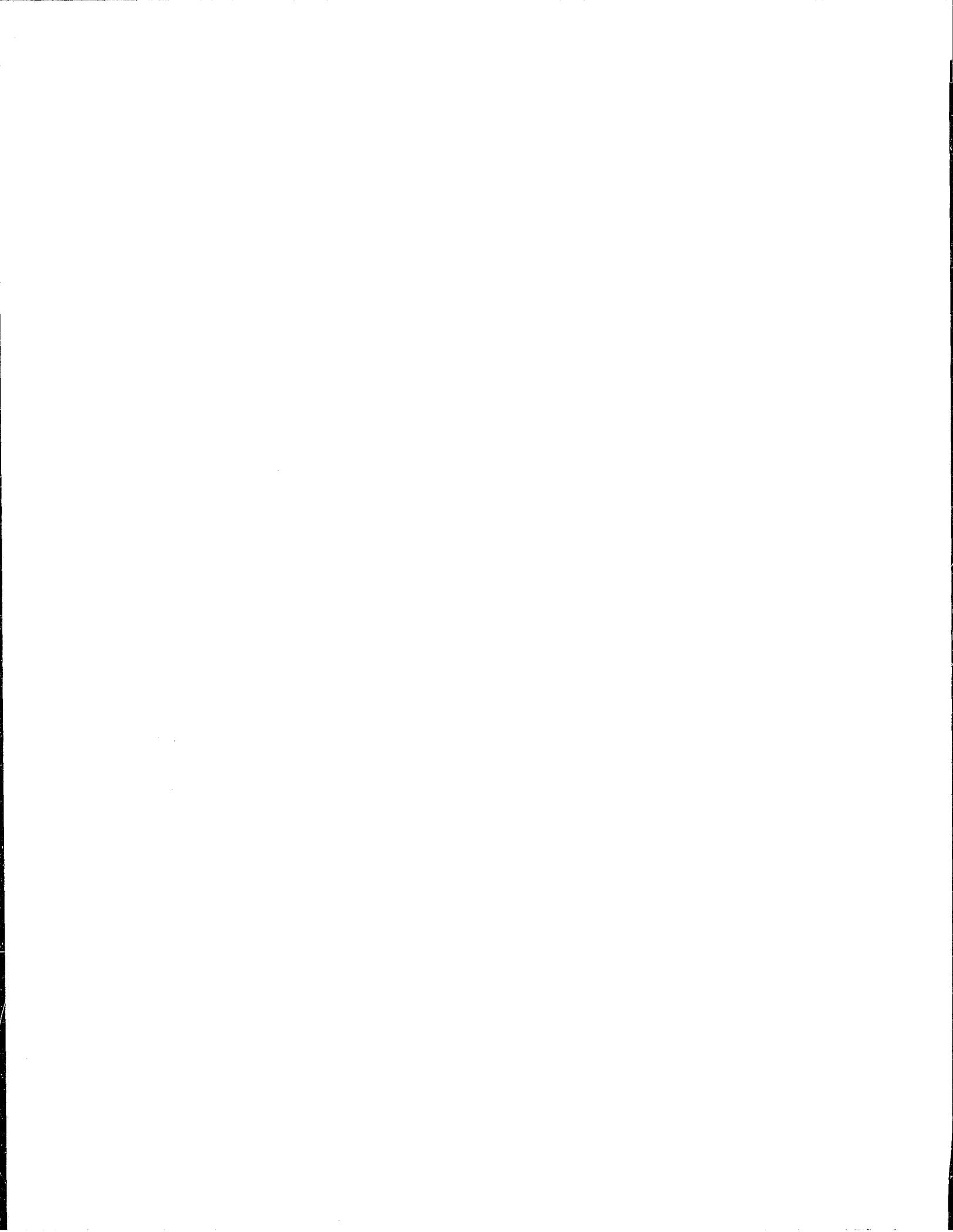
(d) No fully effective protection against injury or death can be provided to prisoner volunteers in human experimentation programs.

(e) Nor can there be assured the necessary guarantee of adequate therapeutic or remedial services to prisoner volunteers who, as the consequence of participation, may require long-term medical assistance.

In the light of the foregoing, it appears that the authority which authorizes or permits prisoners to become subjects of human experimentation ignores his historic obligation as a custodian to protect and safely keep those for whom he assumes a legal responsibility.

Officially Adopted--Board of Directors
American Correctional Association
St. Louis, Missouri
February 20, 1976

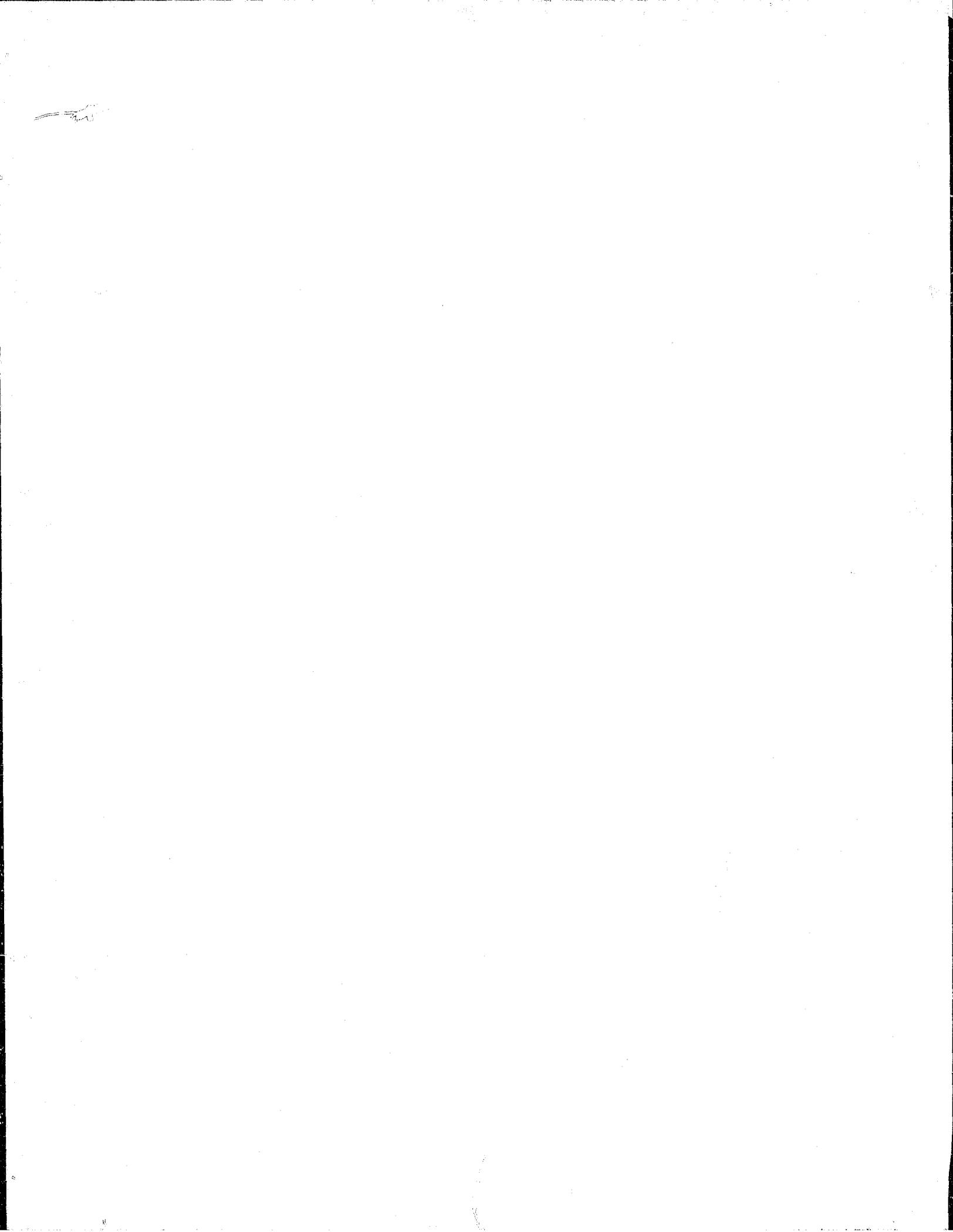




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CORRESPONDENCE FROM THE NATIONAL PRISON PROJECT OF
THE AMERICAN CIVIL LIBERTIES UNION FOUNDATION

MAY 28, 1976



THE NATIONAL PRISON PROJECT

of the American Civil
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May 28, 1976

National Commission for the Protection of
Human Subjects
Westwood Building, Room 125
5333 Westbard Avenue
Bethesda, Maryland 20016

Dear Commissioners and Members of the Commission staff:

I have carefully reviewed the "Iberia Draft" prepared by the Commission staff on May 15, 1976 which is intended to act as a guide to the Commission in determining the conditions of confinement which it will recommend as a prerequisite to the certification by the Ethical Advisory Council of a penal institution for a particular biomedical research project in order to ensure that the degree of openness on the part of institutions and voluntariness on the part of prisoners recommended by Commissioner Jonsen's proposal exist. After listening to the discussions during the Commission meeting on May 14 and May 15, I believe that certain additions to or clarifications of the "Iberia Draft" are necessary to ensure the fulfillment of the Commission's intent. While the standards issued by the Commission should be sufficiently broad to allow for a flexible approach to situations which may arise, the standards must be specific enough to guide future decisionmakers.

The additions to the proposed draft and its accompanying comments which are suggested in this letter are based on our office's extensive experience as a prisoner advocate, judicial decisions, various correctional commission reports and model prison regulations proposed by various prestigious correctional organizations. After the proposed recommendations on "Standard of Living" I have included a brief discussion of the authorities on which the suggestions are based. Wherever possible, specific citations to supporting authority are included and several of the references are enclosed to assist you in your consideration of these proposals.

The following are our suggestions:

"A. Public Scrutiny. Prisoners are able to communicate, both by mail and in person, without censorship and without their communication being monitored or read, with persons outside the prison. Mail from prisoners to the following persons must be permitted to leave the prison unopened and mail

Steering Committee
William H. Allen
Ben Bagdikian
Roach Brown
Haywood Burns
Patricia M. Derian
John M. Ferren
Monroe Freedman
Philip J. Hirschkop
Edward Katkin
Robert B. McKay
Herman Schwartz
Mervin L. Wulf

from the following persons may be opened by prison officials only in the presence of the prisoner and may only be inspected for contraband: attorneys, legal organizations which assist prisoners, courts, state and federal public officials, members of the news media, the organization of elected prisoner representatives referred to in Paragraph B. below, the Human Subjects Review Committee of the Institutional Review Board referred to elsewhere in this document, the Ethical Advisory Council referred to above and any prisoner advocate appointed or recognized by the Ethical Advisory Council of the Human Subjects Review Committee.

Each of the individuals or organizations listed above must be able to conduct private, confidential interviews with any prisoner who so desires. Members of the outside organization of elected prisoner representatives and the Human Subjects Review Committee are able to tour the entire prison upon request.

Research should not be conducted in prisons in which the security needs curtail the conditions set forth above.

Comment: The Commission has concluded that biomedical research in prisons should occur only where meaningful public scrutiny is possible. Prisoners must be able to communicate freely, confidentially and without fear of reprisal. The Commission recognizes that the standards set forth in certain respects exceed the constitutionally minimum standards set forth by the Supreme Court of the United States in Procunier v. Martinez, 94 S.Ct. 1800 (1974); Pell v. Procunier, 94 S.Ct. 2800 (1974) and Wolff v. McDonnell, 94 S.Ct. 2963 (1974). In particular the Commission recognizes that the standard set forth above requires that prisoners and media be given freer access to each other and that prisoners be able to communicate privately with a broader range of individuals than is constitutionally required where no research is being conducted.

C. Standard of Living: Living conditions in the prison are sufficiently adequate so that the desire to improve one's living condition is not a consideration in the decision to become a subject in biomedical research. Compliance with the following standards is essential:

(1) The prison population does not exceed capacity and each prisoner has at least 60 square feet of living space.

(2) There are only single occupancy cells equipped with an operable toilet which can be flushed from the inside, a sink with hot and cold running water, ventilation, noise control and lighting which meet the minimum standards of the United States Public Health Service.

(3) Offenders are classified and separated according to age, sex, offense, prior criminal record, physical and mental health requirements and vocational and educational needs.

(4) There are operable cell doors, emergency exits and fire extinguishers. State and local fire and safety codes are met as certified by state and local fire officials.

(5) Articles of personal care are regularly issued, without charge, including but not limited to soap, toothpaste, toothbrushes, shampoo, shaving utensils, clean clothing and clean linen.

(6) The prison meets institutional environmental health standards promulgated by the United States Public Health Service, the American Public Health Association and State Public Health officials as certified by United States Public Health Officials and applicable state officials. Prisoners are allowed to shower daily. The prison food service meets the standards established by the United States Public Health Service Code for Food Service Operation and all state food service institutional food service regulations. The diet should be of quality, kind and amount to meet the recommended daily dietary allowances of the Food and Nutritional Board of the National Research Council and all rations should be prescribed by a qualified nutritionist.

(7) There are adequate recreational facilities and activities directed by a full time trained and qualified staff person. Every prisoner is allowed at least one hour of recreation outside daily.

(8) The racial and cultural disparity between the staff and prisoners is less than 20%. There is sufficient custodial staff to provide prisoners reasonable protection against violence.

(9) There are first rate medical facilities in the prison, adequately staffed and equipped and licensed by the appropriate state or federal agency. Such medical care should be comparable in quality and availability to that obtainable by the general public. No prisoner who seeks medical assistance should be denied permission to see a physician by a member of the custodial staff or another prisoner. Each medical facility with over 10 hospital beds or which on the average treats over 60 patients a day should maintain accreditation by the Joint Commission on Accreditation of Hospitals.

(10) There are adequate mental health services and professional staff, including not less than the number of mental health professionals recommended in the Manual of Correctional Standards of the American Correctional Association.

(11) Each prisoner who is eligible to participate in biomedical research is able to do meaningful non-research related work for remuneration comparable to that received for participation in research.

(12) Each prisoner who is eligible to participate in biomedical research is eligible and able to participate in a broad range of vocational and educational programs.

(13) A prisoner's parole, date of release, standard of living or opportunity to participate in vocational, educational or work programs is in no way affected by his participation or non-participation in biomedical research.

(14) Prisoners are afforded privacy with their visitors. Visitors are excluded only where they present a clear danger to the security of the institution. Prisoners are permitted no less than two visits per week.

(15) The prison does not house more than 400 prisoners and is not more than 25 miles from a major metropolitan area.

Comment: Biomedical research should not be conducted in institutions in which conditions are such that prisoners become subjects in order to improve their living conditions, to escape from intolerable living conditions, to enhance their chance for an early release, to obtain needed medical care or to obtain money which is not otherwise available to them. The Commission is aware that prison conditions in a number of states have recently come under the scrutiny of the Courts and that, after determining that incarceration in one state's prisons violated the prisoners' constitutional right to be free from cruel and unusual punishment, at least one Court has enunciated a detailed list of minimum constitutional standards for that prison system. [James v. Wallace, 406 F. Supp. 319 (M.D. Ala. 1976)]. Conditions of confinement which are adequate to overcome a legal challenge to their constitutionality where no biomedical research is being conducted may not be adequate to permit biomedical research. As a general rule, confinement within a particular prison violates the constitutional prohibition against cruel and unusual punishment only where the confinement is characterized by conditions and practices "so bad as to be shocking to the conscience of a reasonably civilized people." Holt v. Sarver, 309 F. Supp. 362, 372-373 (E.D. Ark. 1970) affirmed, 442 F.2d 304 (8th Cir. 1971). The

standard established by the Commission as a prerequisite to the use of prisoners as subjects in biomedical research is substantially more stringent."

The suggestions concerning public scrutiny are designed to guarantee free public access to the prison and information about biomedical research being conducted there. Media access is fundamental, but at present prisons not conducting biomedical research are not constitutionally required to permit the media to interview willing prisoners, Pell v. Procunier, *supra* in the Comment. Similarly, the range of individuals with whom prisoners are constitutionally guaranteed the right to correspond with confidentially is very limited. Experience teaches us that this base must be broadened to ensure adequate public scrutiny of prisons in which biomedical research is being conducted. Wolff v. McDonnell, *supra* in the Comment; Procunier v. Martinez, *supra* in the Comment. Neither of these suggestions should create undue hardships for progressive correctional administrators. Much of what is suggested was recommended several years ago by the National Advisory Commission on Criminal Justice Standards and Goals, Report on Corrections, Standard 2.17 (a copy of which is enclosed). The Federal Bureau of Prisons has also recently altered its policy to permit media interviews with prisoners. Finally, these standards must not be permitted to be weakened by a correctional official's subjective determination of security needs. Adequate public scrutiny is critical when biomedical research is being conducted in closed institutions. Where the institutional needs prevent this scrutiny from taking place, no research should be conducted.

The fifteen suggested "Standard of Living" standards by and large are derived from constitutionally minimum standards for prisons established by the courts, United States health officials and organizations of correctional officials. The most detailed set of standards for minimally acceptable prison conditions was recently enunciated by the Federal Court in Alabama in a case entitled James v. Wallace, 406 F. Supp. 318 (M.D.Ala. 1976), a copy of which is enclosed for your assistance. The only area not covered by the James decision is prison medical care. However, the same Court laid down standards to cover prison medical care a couple of years ago in a case entitled Newman v. Alabama, 349 F. Supp. 278 (M.D.Ala. 1972), affirmed 503 F. 2d 1320 (5th Cir. 1974).

There have been innumerable cases in addition to James v. Wallace which have ordered that the prison population must not exceed rated capacity, e.g., Costello v. Wainwright, 397 F. Supp. 20 (D.Fla. 1975), affirmed 525 F.2d 1239 (5th Cir. 1976); Williams v. McKeithen, C.A. No. 71-98 (M.D.La. 1975); Campbell v. McGruder, C.A. No. 1462-71 (D.D.C. Nov. 1975). Several courts have also found that a prisoner will suffer severe consequences if he or she is not given a certain amount of living space and have so ordered. E.g., James v. Wallace, *supra*; Costello v. Wainwright, *supra*; Campbell v. McGruder, *supra*;

The National Clearinghouse for Criminal Justice Planning and Architecture requires that in order to receive federal assistance in construction new prisons must guarantee that each prisoner has no less than 70 square feet of living space.

Standards 2, 4 and 6 relate to the physical conditions of confinement. They are designed to provide for minimally healthful and humane surroundings and are derived directly from James v. Wallace, supra; Campbell v. McGruder, supra, the American Correctional Association's Manual of Correctional Standards, the American Public Health Association's Basic Principles of Healthful Housing, the U. S. Public Health Service Code for Food Service Operations, Walton, G., Institutional Sanitation, U.S. Public Health Service, prepared for the Federal Bureau of Prisons and the National Advisory Commission, Standards 2.5, 11.1 and 11.2. Reference to these professional organizations gives the standards flexibility and places continuing development and enforcement of these standards in the hands of the most qualified individuals.

Additional factors have been included in Standard 3 concerning the classification and separation of prisoners. Each of these factors have been found to play an important role in decreasing tension and violence and enhancing the opportunity for a more successful rehabilitation. The opinion and the order in James v. Wallace point out the need for consideration of these factors. See also, National Advisory Commission Standards 6.1, 6.2. This standard will also assist in identifying, separating and aiding those prisoners requiring special medical, mental health, educational or vocational attention.

Standards 5 and 7 seek to make more specific identical provisions in the "Iberia Draft." Both have been mandated by judicial decision as constitutional minimums and have been recommended by the National Advisory Commission, Standards 2.5 and 11.8. The daily exercise requirement has substantial support in both judicial decisions and the literature as being necessary to maintain one's physical and mental health and as one of the few constructive outlets that a prisoner has for his or her pent up energy and tension. E.g., James v. Wallace; Campbell v. McGruder; Rhem v. Malcolm, 371 F. Supp. 594, 626-627 (S.D.N.Y. 1974), affirmed 507 F.2d 333 (2d Cir. 1974); Miller v. Carson, 392 F. Supp. 515, 520-521 (M.D.Fla. 1975); Hamilton v. Landrieu, 351 F. Supp. 549 (E.D. La. 1972).

Standard 8 concerning the racial and cultural disparity between guards and prisoners was not included in the "Iberia Draft." However, the racial and cultural disparity between guards and prisoners has been cited as one of the primary causes of the tension that led to the riot in Attica four years ago. Attica - The Official Report of the New York State Special Committee on Attica, Bantam Book Co., 1972. When this occurs guards and prisoners become unable to relate to or understand each other and each other's lifestyles, they become insensitive to each other's feelings and eventually the guards begin to treat prisoners as less than human and inferior. Hostility,

distrust, tension, anxiety, frustration and violence all arise. An atmosphere is created from which a prisoner will do anything to escape and in which abuse of that which can be abused will occur. National Advisory Commission; James v. Wallace.

Standard 9 leaves the specifics of determining the adequacy of medical care to professional organizations with some basic guidelines. The section providing for accreditation by the Joint Commission on Accreditation of Hospitals will guarantee adequate medical care. Those institutions desiring to permit biomedical research should be required to comply. As of January 1973 the Federal Bureau of Prisons was in compliance with this requirement. A copy of the Federal Prison Medical Program report demonstrating their compliance is attached. The section prohibiting research where custodial personnel and other prisoners are able to prevent a sick prisoner from seeing a physician is adopted from the constitutionally minimum requirement enunciated in Newman v. Alabama, 349 F. Supp. 278 (M.D.Ala. 1972), aff'd 503 F.2d 1320 (5th Cir. 1974).

The "Iberia Draft" does not discuss mental health requirements. The inclusion of Standard 10 represents a recognition of the serious need for mental health delivery services in prison, their present inadequate state and their relationship to the problems of voluntariness. One court has found that as many as 50% of those in large penal institutions would benefit substantially from professional mental health care, Newman v. Alabama, *supra*, and all agree that the impact of incarceration in most prisons today is detrimental to a prisoner's mental health and ability to cope. The standards suggested by the American Correctional Association represent the bare minimum needed and, if anything, this standard should be strengthened. A copy of the relevant portion of the A.C.A. Manual is attached.

Standards 11, 12 and 13 are simply clarifications of the "Iberia Draft" and do not require further discussion. The last two sentences of Standard 14 are additions designed to ensure the free flow of information between the prisoner and the outside and to assist the prisoner to maintain some minimal contact with the community from which he or she came. The requirements for visiting in some prison systems at present are vague and subjective. The inability of prisoners to visit with people whom they desire to see is one of the most frequent complaints received at our office. This provision is particularly important for the maintenance of public scrutiny and for the prisoner's rehabilitation. The strength of a prisoner's contact with the community upon his release is one of the few factors which has been identified as having a positive impact on recidivism.

Finally, standard 15 recognizes the impossibility of ensuring adequate public scrutiny or maintaining community contact in isolated, rural institutions. It also recognizes the problems which exist in large institutions. In 1973 the noted corrections expert William Nagel wrote at the conclusion of his study of over 100 new prisons

for the Law Enforcement Assistance Administration:

"The penitentiary did not start big but became big. By the middle of the 19th century all the idealism and hope that went into the invention of the penitentiary was replaced by a pragmatism that held that confinement was a valid end in itself. Prisons could not correct or reform, but they could separate the offender from the rest of mankind. A kind of warehousing developed. Prisoners were stuffed into tiny cubicles stacked tier upon tier. Movement was tightly scheduled and regimented. Human needs were ignored. Economy of operations became the essential element of prison management. The bigger the prison, the more economical the operation. And prisons grew. Penitentiaries to house between 2,000 and 5,000 men were built in Texas, Oklahoma, Pennsylvania, Tennessee, New York, Virginia, Georgia, Florida, California, Illinois and Michigan (the biggest). Many small states such as Delaware, Hawaii, Maine, Montana, North Dakota, Rhode Island, South Dakota, and Wyoming built prisons no larger than 500 and as small as 250 to house their smaller inmate populations. In spite of these exceptions the average prison for men built prior to 1960 was constructed to hold 1,100 inmates. The extremes were 250 and 4,800.

The inevitable consequence is the development of operational monstrosities. It is impossible to remove large numbers of men from the free world, isolate them together in the unnaturalness of huge prisons, and not have management problems of staggering dimensions. The tensions and frustrations inherent in prisons of any size are magnified by the herding together of large numbers of troubled people. The result is the evolution of a prison goal that, when stripped of all the correctional rhetoric, is simply, 'Keep the lid on.' Regimentation, discipline, control - not treatment - have become the correctional preoccupations. Dehumanization is one of the major results."

p. 55

Nagel, William, The New Red Barn: A Critical Look at the Modern American Prison, the American Foundation, Walker and Company, 1973.

In recognition of this situation the National Clearinghouse for Criminal Justice Planning and Architecture has established a policy against prisons with a capacity over 400. The problems of obtaining the requisite degree of voluntariness in an institution where regimentation, discipline and depersonalization strip many prisoners of the power to make most decisions affecting their lives warrants the addition of this Standard.

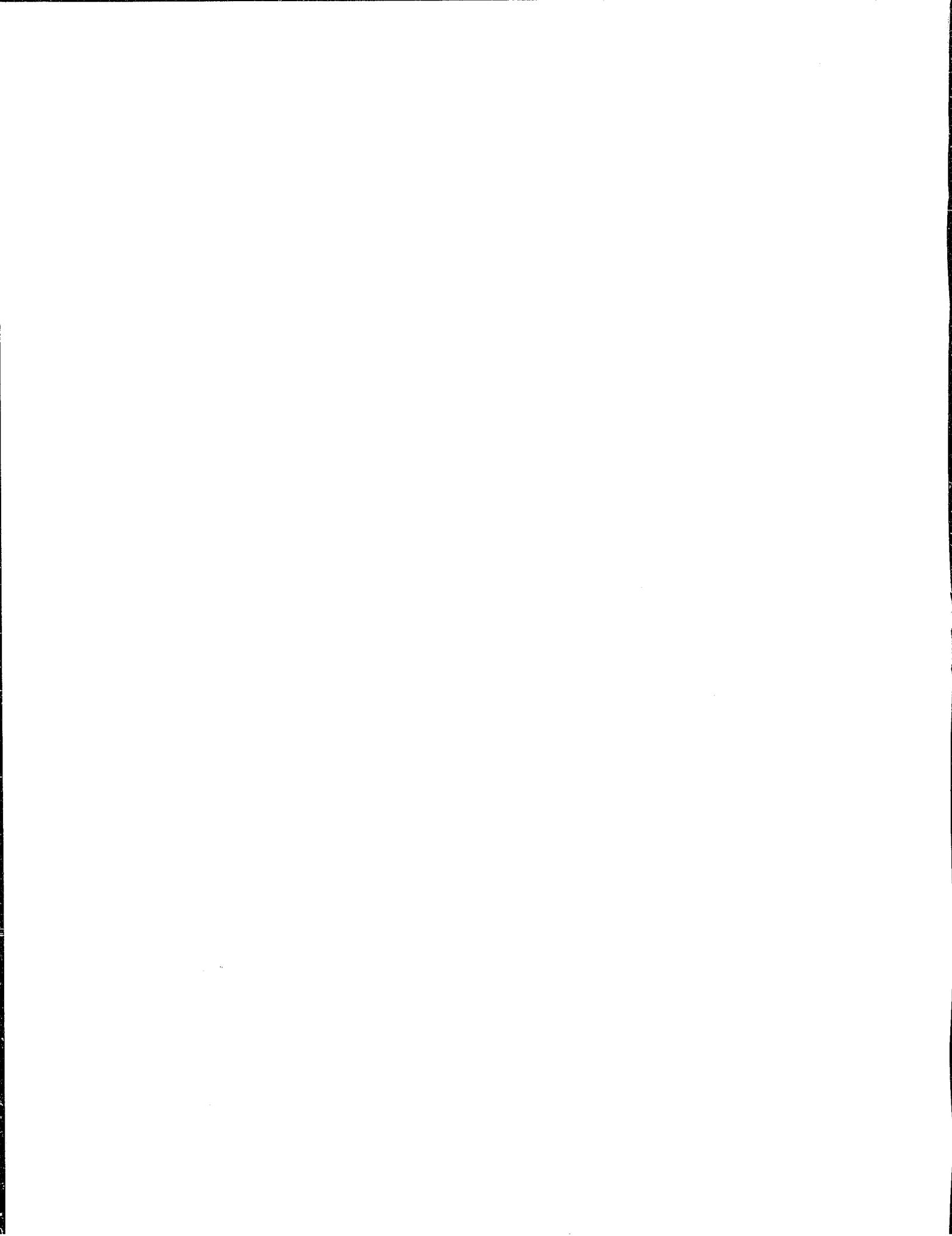
In conclusion, I believe the additions to or clarifications of the "Iberia Draft" which I have suggested are necessary to make the Commission's recommendations meaningful. If you desire additional information or supporting material, I will be glad to furnish it. I appreciate your consideration of these suggestions.

Sincerely,

Matthew L. Myers

Matthew L. Myers

MLM;jb



DHEW PROPOSED REGULATIONS ON PRISONER RESEARCH:

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
NATIONAL INSTITUTES OF HEALTH, "PROTECTION OF HUMAN SUBJECTS:
POLICIES AND PROCEDURES," FEDERAL REGISTER,
PART II, 38 (NOVEMBER 16, 1973), 31738-49.

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
OFFICE OF THE SECRETARY, "PROTECTION OF HUMAN SUBJECTS:
PROPOSED POLICY," FEDERAL REGISTER,
PART III, 39 (AUGUST 23, 1974), 30648-57.



federal register

FRIDAY, NOVEMBER 16, 1973
WASHINGTON, D.C.

Volume 38 ■ Number 221

PART II

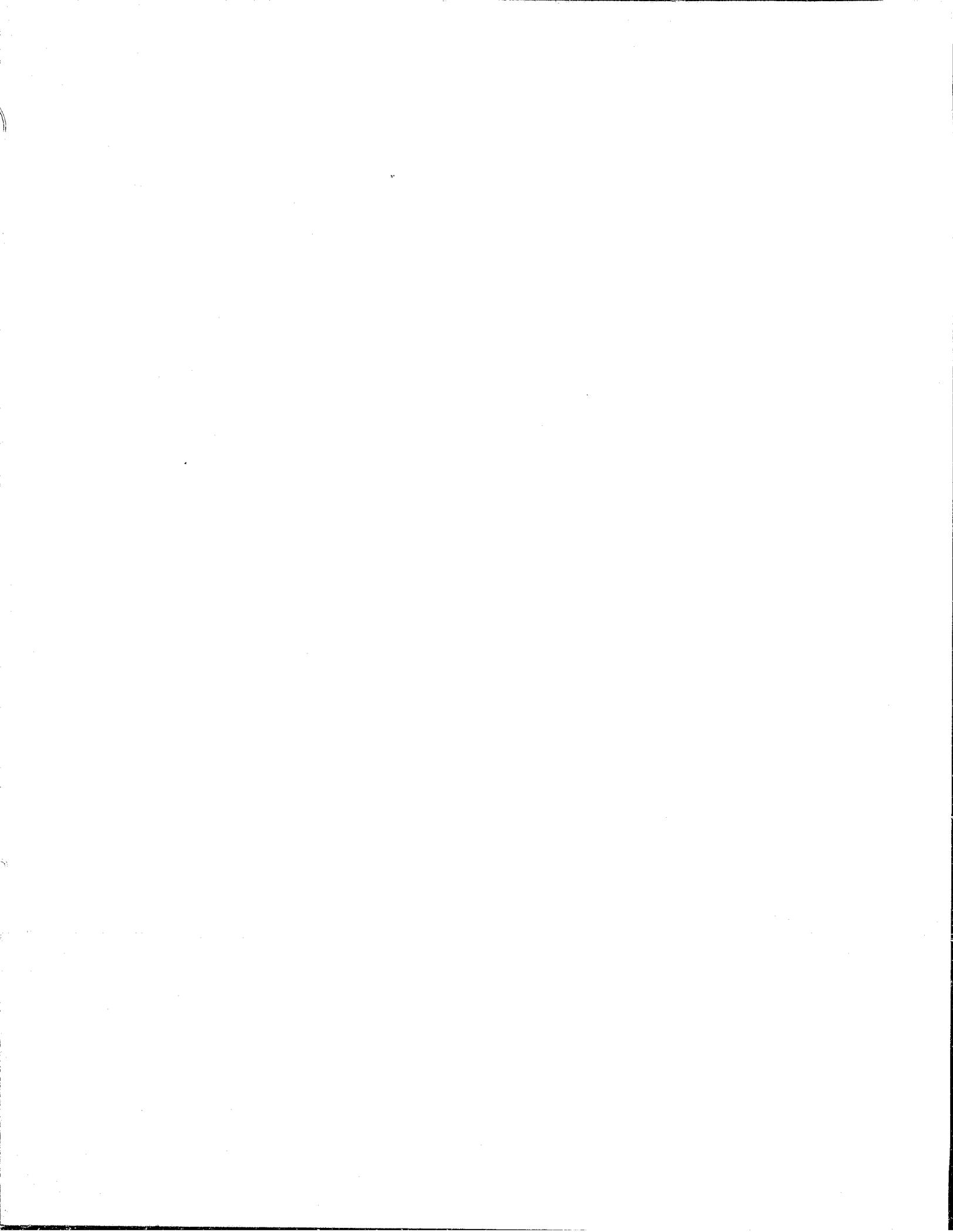


DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

NATIONAL INSTITUTES OF HEALTH

Protection of Human Subjects

Policies and Procedures



CONTINUED

7 OF 8

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

National Institutes of Health

PROTECTION OF HUMAN SUBJECTS

Policies and Procedures

In the FEDERAL REGISTER of October 9, 1973 (38 FR 27882 et seq.), the Secretary of Health, Education, and Welfare issued a notice of proposed rulemaking concerning the protection of human subjects and mentioned that DHEW through the National Institutes of Health, had appointed a special study group to review and recommend policies and special procedures for the protection of children, prisoners, and the institutionalized mentally infirm in research, development, and demonstration activities. The report of this study group has been completed in draft form and reviewed by the Director, NIH.

There may well be elements in the recommendations which will provoke debate and controversy. We recognize that public consideration and comment are vital to the development of our final recommendations to the Secretary and are inviting such comment now even though the materials are still pending final review and completion. The product of our effort after considering public comment will be transmitted to the Assistant Secretary for Health, HEW to recommend to the Secretary, HEW that it appear again in the FEDERAL REGISTER as proposed rulemaking for further public comment. Such a procedure is consistent with long established DHEW policy for permitting extensive public opportunity to affect the promulgation of DHEW regulations.

It must be clearly understood by the reader that the material that follows is not proposed rulemaking in the technical sense, and is not presented as Departmental, Public Health Service, or NIH policy. Rather it is a draft working document on which early public comment and participation is invited.

Please address any comments on these draft policies and procedures to the Director, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20014. All comments should be received by January 4, 1974.

Additional copies of this notice are available from the Chief, Institutional Relations Branch, Division of Research Grants, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20014.

Dated: November 6, 1973.

ROBERT S. STONE,
Director,

National Institutes of Health.

RESEARCH, DEVELOPMENT, AND DEMONSTRATION ACTIVITIES: LIMITATIONS OF INFORMED CONSENT

SPECIAL POLICY CONSIDERATIONS

Summary

NOVEMBER 5, 1973.

The mission of the Department of Health, Education, and Welfare includes

the improvement of the health of the Nation's people through research, development, and demonstration activities which at times involve human subjects. Thus, policies and procedures are required for the protection of subjects on whose participation these activities depend.

Informed consent is the keystone of the protection of human subjects involved in research, development, and demonstration activities. Certain categories of persons have limited capacity to consent to their involvement in such activities. Therefore, as a supplement to DHEW policies, special protections are proposed for children, prisoners, and the mentally infirm who are to be involved in research, development, and demonstration activities.

Agency "Ethical Review Boards" are to be established to provide rigorous review of the ethical issues in research, development, and demonstration activities involving human subjects, in order to make judgments regarding societal acceptability in relation to scientific value. "Protection Committees" are to be established by the applicant to provide "supplementary judgment" concerning the reasonableness and validity of the consent given by, or on behalf of, subjects. The intent of this policy is that institutions which apply for DHEW funds or submit research in fulfillment of DHEW regulations, must be in compliance with these special protections, whether or not particular research, development, or demonstration activities are Federally activities.

1. *Children.* If the health of children is to be improved, research activities involving their participation is often essential. Limitation of their capacity to give informed consent, however, requires that certain protections be provided to assure that scientific importance is weighed against other social values in determining acceptable risk to children. Therefore, research, development, and demonstration activities which involve risk to children who participate must:

a. Include a mechanism for obtaining the consent of children who are 7 years of age or older;

b. Include the applicant's proposal for use of a Protection Committee which is appropriate to the nature of the activity;

c. Be reviewed and approved, in conformity with present DHEW policy, by an Organizational Review Committee; and

d. Be reviewed by the appropriate agency Primary Review Committee, the Ethical Review Board, and the appropriate secondary review group.

2. *Special categories.*—a. *The Abortus.* No research, development, or demonstration activity involving the non-viable abortus shall be conducted which:

1. Will prolong heart beat and respiration artificially solely for the purpose of research;

2. Will of itself terminate heart beat and respiration;

3. Has not been reviewed by the agency Ethical Review Board; and

4. Has not been consented to by the pregnant woman with participation of a Protection Committee.

(An abortus having the capacity to sustain heart beat and respiration is in fact a premature infant, and all regulations governing research on children apply.)

b. *The fetus in utero.* No research involving pregnant women shall be conducted unless:

1. Primary Review Groups assure that the activity is not likely to harm the fetus;

2. the agency Ethical Review Board has reviewed the activity;

3. a Protection Committee is operating in a manner approved by the agency; and

4. the consent of both prospective legal parents has been obtained, when reasonably possible.

c. *Products of in vitro fertilization.* No research involving implantation of human ova which have been fertilized *in vitro* shall be approved until the safety of the technique has been demonstrated as far as possible in sub-human primates, and the responsibilities of the donor and recipient "parents" and of research institutions and personnel have been established. Therefore, no such research may be conducted without review of the Ethical Review Board and of a Protection Committee.

3. *Prisoners.* Research, development, and demonstration activities involving human subjects often require the participation of normal volunteers. Prisoners may be especially suitable subjects for such studies, although there are problems concerning the voluntariness of the consent of normal volunteers who are confined in institutions. Certain protections are required to compensate for the diminished autonomy of prisoners in giving voluntary consent. Research, development, and demonstration activities involving prisoners must:

a. Include the applicant's proposal for use of a Protection Committee which is appropriate to the nature of the activity;

b. Be reviewed and approved by an Organizational Review Committee which may already exist in compliance with present DHEW policy or which must be appointed in a manner approved by the appropriate DHEW agency;

c. Be reviewed by the agency Primary Review Committee; and

d. Be conducted in an institution which is accredited by the Secretary of Health, Education, and Welfare.

4. *The mentally infirm.* Insofar as the institutionalized mentally infirm might lack either the competency or the autonomy (or both) to give informed consent, their participation in research requires additional protection:

a. Research, development and demonstration activities involving the mentally infirm will be limited to investigations concerning (1) diagnosis, etiology, prevention, or treatment of the disability from which they suffer, or (2) aspects of institutional life, *per se*, or (3) information which can be obtained only from such subjects.

All research, development and demonstration activities involving such persons must:

1. Include the applicant's assurance that the study can be accomplished *only*

with the participation of the mentally infirm;

2. Include the applicant's proposal for use of a Protection Committee which is appropriate to the activity; and

3. Be reviewed and approved by an Organizational Review Committee, in conformity with present DHEW policy.

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INTRODUCTION

The mission of the Department of Health, Education, and Welfare includes the improvement of the health of the Nation's people through biomedical research. This mission requires the establishment of policy and procedures for the protection of subjects on whose participation that research depends. In DHEW policy, as well as in ethical codes pertaining to research in human subjects, the keystone of protection is informed consent.

An uncoerced person of adult years and sound mind may consent to the application of standard medical procedures in the case of illness, and when fully and properly informed, may legally and ethically consent to accept the risks of participating in research activities. Parents and legal guardians have authority to consent on behalf of their child or ward to established therapeutic procedures when the child is suffering from an illness, even though the treatment might involve some risk.

There is no firm legal basis, however, for parental or guardian consent to participation in research on behalf of subjects who are incompetent, by virtue of age or mental state, to understand the

information provided and to formulate the judgments on which valid consent must depend. In addition, current policies for clinical research afford such subjects inadequate protection. Nevertheless, to proscribe research on all such subjects, simply because existing protections are inadequate, would be to deny them potential benefits, and is, therefore, inequitable. Knowledge of some diseases and therapies can be obtained only from those subjects (such as children) who suffer from the disease or who will be receiving the therapy. Their participation in research is necessary to progress in those fields of medicine. When such subjects participate in research, they need more protection than is provided by present policy.

There are other individuals who might be able to comprehend the nature of the research, but who are involuntarily confined in institutions. Insofar as incarceration might diminish their freedom of choice, and thus limit the degree to which informed consent can be freely given, they too need additional protection. Current policies do not recognize the limitations on voluntariness of consent which may emanate from incarceration.

This addition to existing policy is offered as a means of providing adequate protection to subjects who, for one reason or another, have a limited ability to give truly informed and fully autonomous consent to participate in research. The aim is to set standards which are both comprehensive and equitable, in order to provide protection and, to the extent consistent with such protection, maintain an environment in which clinical research may continue to thrive.

1. *Definitions.* For purposes of this policy:

A. *Subject at risk* means any individual who might be exposed to the possibility of harm (physical, psychological, sociological, or other) as a consequence of participation as a subject in any research, development or demonstration activity (hereinafter called "activity") which goes beyond the application of established and accepted methods necessary to meet his needs.

B. *Clinical research* means an investigation involving the biological, behavioral, or psychological study of a person, his body or his surroundings. This includes but is not limited to any medical or surgical procedure, any withdrawal or removal of body tissue or fluid, any administration of a chemical substance, any deviation from normal diet or daily regimen, and any manipulation or observation of bodily processes, behavior or environment. Clinical research comprises four categories of activity:

1. Studies which conform to established and accepted medical practice with respect to diagnosis or treatment of an illness.

2. Studies which represent a deviation from accepted practice, but which are specifically aimed at improved diagnosis, prevention, or treatment of a specific illness in a patient.

3. Studies which are related to a patient's disease but from which he or she will not necessarily receive any direct benefit.

4. Investigative, non-therapeutic research in which there is no intent or expectation of treating an illness from which the patient is suffering, or in which the subject is a "normal control" who is not suffering from an illness but who volunteers to participate for the potential benefit of others.

It is important to emphasize that "non-therapeutic" is not to be understood as meaning "harmful." Understanding of normal processes is essential; it is the prerequisite, in many instances, to recognition of those deviations from normal which define disease. Important knowledge can be gained through such studies of normal processes. Although such research might not in any way benefit the subjects from whom the data are obtained, neither does it necessarily harm them.

Patients participating in studies identified in paragraph B-1, above, are not considered to be at special risk by virtue of participating in research activities, and this policy statement offers no special protection to them. When patients or subjects are involved in procedures identified in paragraphs B2, B3, and B4, they are considered to be "at risk," and the special policy and procedures set forth in this document pertain. Excluded from this definition are studies in which the risk is negligible, such as research requiring only, for example, the recording of height and weight, collecting excreta, or analysing hair, deciduous teeth, or nail clippings. Some studies which appear to involve negligible physical risk might, however, have psychological, sociological or legal implications which are significant. In that event, the subjects are in fact "at risk," and appropriate procedures described in this document shall be applied.

C. *Children* are individuals who have not attained the legal age of consent to participate in research as determined under the applicable law of the jurisdiction in which the proposed research is to be conducted.

D. *Pregnancy* encompasses the period of time from implantation until delivery. All women during the child bearing years should be considered at risk of pregnancy; hence, prudence requires definitive exclusion of pregnancy when women in this period of life are subjects for experimentation which might affect the fetus.

E. *Fetus* means the product of conception from the time of implantation to the time of delivery from the uterus.

F. *Abortus* means a fetus when it is expelled while, whether spontaneously or as a result of medical or surgical intervention undertaken with the intention of terminating a pregnancy, prior to viability. This definition, for the purpose of this policy, excludes the placenta, fetal material which is macerated at the time of expulsion, a dead fetus, and isolated

fetal tissue or organs excised from a dead fetus.

G. *Viability of the fetus*, means the ability of the fetus, after either a spontaneous delivery or an abortion, to survive to the point of independently maintaining vital functions; such a "viable" fetus is a premature infant. Determination of viability entails a subjective and objective judgment by the physician attending labor or examining the product of conception, and must be made by a physician other than the investigator wishing to use fetal tissue in research. In general, and all other circumstances notwithstanding, a beating heart is not sufficient evidence of viability. At least one additional necessary condition is the possibility that the lungs can be inflated. Without this precondition, no currently available mechanisms to initiate or maintain respiration can sustain life; and in this case, though the heart is beating, the fetus or abortus is in fact non-viable.

H. *In vitro fertilization* is any fertilization of human ova which occurs outside the body of the female, either through admixture of donor sperm and ova or by any other means.

I. *Prisoner* is any individual involuntarily confined in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, or individuals detained by virtue of statutes which provide alternatives to criminal prosecution.

J. *Mentally infirm* includes the mentally ill, the mentally retarded, the emotionally disturbed, the psychotic, the senile, and others with impairments of a similar nature, residing as patients in an institution, regardless of whether or not the individual has been determined to be legally incompetent.

K. *Informed consent* has two elements: comprehension of adequate information and autonomy of consent. Consent is a continuing process. The person giving consent must be informed fully of the nature and purpose of the research and of the procedures to be used, including identification of those procedures which are experimental, the possible attendant short or long term risks and discomforts, the anticipated benefits to himself and/or others, any alternative methods of treatment, expected duration of the study, and of his or her freedom to ask any questions and to withdraw at any time, should the person wish to do so. There must also be written evidence of the process used for obtaining informed consent, including grounds for belief that the subject has understood the information given and has sufficient maturity and mental capacity to make such choices and formulate the requisite judgment to consent. In addition, the person must have sufficient autonomy to choose, without duress, whether or not to participate. Both the comprehension of information and the autonomy of consent are necessary elements; to the extent that either of these is in doubt, the adequacy of informed consent may be in doubt.

L. *Supplementary judgment* is the judgment made by others to assent, or to refuse to assent, to procedures for which the subject cannot give adequate consent on his or her own behalf. For the purposes of this document, supplementary judgment will refer to judgments made by local committees in addition to the subject's consent (when possible) and that of the parents or legal guardian (where applicable), as to whether or not a subject may participate in clinical research. This supplementary judgment is to be confirmed by the signature of the Chairman of the Protection Committee on the consent form. In accordance with the procedures approved by the agency for the Protection Committee, the Chairman's signature may be affixed on a standard consent form, or may need to be withheld until the Committee approves the participation of the individual subject.

II. *General policy considerations*. In general, clinical research, like medical practice, entails some risk to the subjects. When the potential subject is unable fully to comprehend the risks which might be involved, or to make the judgment essential to consent regarding the assumption of those risks, current guidelines suggest obtaining the consent of the parents or legal representative.

Whereas it is clear by law that consent of a parent or legal representative is valid for established and generally accepted therapeutic procedures performed on a child or an incompetent adult, it is far from clear that it is adequate for research procedures. In practice, parental or guardian consent generally has been accepted as adequate for therapeutic research, although the issue has not been definitively resolved in the courts. When research might expose a subject to risk without defined therapeutic benefit or other positive effect on that subject's well-being, parental or guardian consent appears to be insufficient.

In the case of prisoners, confinement imposes limitations on freedom of choice which brings into question their ability to give voluntary consent. A prisoner's ability to give consent may be restricted by overt or potential coercion, or by the loss of personal autonomy generally considered to result from incarceration itself. Therefore, additional protection must be afforded this group even though an individual's competency to understand what is involved might not be in doubt.

The institutionalized mentally infirm are doubly limited: as with children, they might not be competent to make informed judgments, and, as with prisoners, they are confined under conditions which limit their civil freedom and autonomy. Therefore, their participation in research requires special protections.

The law is not clear on these issues. Even if the law were clear, however, ethical questions would remain; specifically, whether, and under what conditions research involving these subject groups may proceed. Resolution of these ethical questions requires judgments concerning

both the ethics of conducting a particular research project, and the adequacy of procedures for protecting the individual subjects who will be asked to participate. The intention of this policy is to broaden the scope of review, preclude or resolve conflicts of interest, and invoke social as well as scientific judgments to protect potential subjects who might have diminished capacity to consent.

The proposed mechanism for protecting subjects with limited ability to give informed consent culminates in a form of supplementary judgment, which is to be supportive and protective of the subject's best interests and wishes, to the extent that he or she is capable of formulating and expressing a judgment. In the case of children and the mentally infirm, it will supplement their judgment and that of their parents or guardians. In the case of competent individuals who have restricted autonomy, it will support and protect their wishes. Through this mechanism, these subjects will be protected as fully as possible by community review; however, the nature of some research procedures might be such that, in addition, court review ultimately will be required.

III. *Participation of children in research*—A. *Policy considerations*. Children have generally been considered inappropriate subjects for many research activities because of their inability to give informed consent. There are circumstances, however, which not only justify, but even require their participation. Children do differ from adults in their physiologic responses, both to drugs and to disease; if the health of children is to be improved, it is necessary to know the nature and extent of these differences, and to have a full understanding of normal patterns of growth and development, metabolism, and biochemistry in the perinatal, infant, early childhood, pubertal and adolescent stages of development. Studies of normal physiology and behavior can also provide significant benefit to children suffering from disease; children are the only subjects from whom these data can be obtained. Furthermore, there are diseases which cannot be induced in laboratory animals, and occur only rarely, if at all, in human adults. In such cases, children are the only subjects in whom the disease process and possible modes of therapy can be studied.

The Kefauver-Harris Act¹ requires that drugs be tested for safety, efficacy and dosage in children and pregnant women before being approved for use to treat illness in such patients. Food and Drug Administration (FDA) approval for the use of a new drug depends upon submission of proposed labeling for a new drug, which must include "adequate directions for use" and "adequate warnings" as to unapproved uses.² Acceptance of a new drug

¹ Federal Food, Drug, and Cosmetic Act, 1962 (FDC Act), 21 U.S.C. Sec. 301 et. seq.

² FDC Act Sec. 502(f), 21 U.S.C. Sec. 352(f).

rests on the adequacy of the research reports submitted with the application to support the proposed labeling.³ Thus, in order for a drug to be distributed in interstate commerce for use in children or pregnant women, sufficient testing must have taken place in children or pregnant women to substantiate claims on the label regarding safety, efficacy, and dosage for those groups. If the safe and efficacious dosage for children and pregnant women has not been determined, the label must so state. Thus, participation of children in drug research might be the only means of meeting licensing requirements for new drugs for use in children, just as studies in pregnant women might be the only means of meeting licensing requirements for new drugs for use in that class of patients.

When the risk of a proposed study is generally considered not significant, and the potential benefit is explicit, the ethical issues need not preclude the participation of children in biomedical research. However, the progression from innocuous to noxious, in terms of risk, is often subtle. Therefore, additional review procedures are necessary for research activities which expose children to risk, in order to provide sharp scrutiny, vigorous review, and stringent procedural safeguards for all subjects of such research.

Judgments concerning the ethical propriety of research depend partly upon the scientific assessment of the potential risks and benefits. Risk has several important elements: severity, probability, frequency, and the timing of possible adverse effects. While it might not always be easy to distinguish these elements, they must be evaluated in the assessment of risk, and in the determination of the acceptable limits of specific risk for an anticipated benefit. The first judgment to be made is whether it is possible to assess the risk. If studies in animals or adults do not provide sufficient information to assess these elements of risk, then the research should not be conducted on children. If the risks can be determined from studies in animal and adult human populations, application to children may be considered.

In addition to results from investigations on animals and adult subjects, there are unknowns which must be considered in the weighing of risk to children. These include: (1) differences in physiologic or psychologic response from adult patterns; (2) delayed expression of injury (for example, until puberty); (3) effects on developing organs (especially the central nervous system); (4) degree of interference with normal routine required by the study; and (5) possibility of misuse of data by institution or school personnel.

Once the severity and probability of risks in a particular study have been identified, a second judgment must be made: given potential benefits of described dimensions, what are the acceptable limits of risk to which children

ethically may be subjected? Value judgments which must be weighed here transcend scientific issues and suggest that the decision requires interaction among individuals in society with diverse training and perspectives. Further, given the complexity of the issues and the opportunity for conflict among the interests of several parties (the child, the parents or guardian, the attending physician, and the research personnel), decisions regarding participation of individual subjects in research activities involving children should not rest solely with persons directly involved in the research.

In order to provide both impartial ethical review of projects and maximum protection of individual subjects, two procedures are proposed in addition to those currently required: review by an Ethical Review Board at the sponsoring DHEW agency, and participation by a Protection Committee at the institution in which the research is to be conducted. Both groups will provide community involvement in decisions and attempt to balance scientific value and societal acceptability of proposed research involving children.

B. Ethical Review Board: Ethical review of projects. Each DHEW agency shall appoint an Ethical Review Board to provide rigorous review of ethical issues in research involving human subjects by people whose interests are not solely those of the scientific community. Its functions will include:

1. Advising the agency on ethical issues including review of questions of policy, and development of guidelines and procedures;
2. Fostering inter-agency coherence through cognizance of the policies and procedures of other agencies;
3. Reviewing specific proposals or classes of proposals submitted to the Board by the agency. These will include proposals stipulated herein as requiring review by the Board, as well as proposals submitted on an *ad hoc* basis by agency staff. In addition, the Board may recommend that certain additional classes of research be reviewed.

The acceptability of a research project rests on questions of scientific merit as well as on questions of ethics. The agency Primary Review Committees are responsible for evaluating scientific merit and experimental design. The Ethical Review Board will be concerned with ethical issues and questions of societal acceptability in relation to scientific value. In reaching its determination of acceptability, the Board will rely upon the Primary Review Committees for judgments on scientific merit and design, existence of prerequisite animal and adult human studies, estimated risks and benefits (taking into account the competence and experience of investigators and the adequacy of their resources), and scientific importance. It will review proposals received from these Primary Review Committees.

An investigator proposing research activities which expose children to risk must document, as part of the application for support, that the information to

be gained can be obtained in no other way. The investigator must also stipulate either that the risk to the subjects will be insignificant, or that although some risk exists, the potential benefit is significant and far outweighs that risk. In no case will research activities be approved which entail substantial risk, except in the case of clearly therapeutic procedures in which the benefit to the patient significantly outweighs the possible harm. The Ethical Review Board shall review all proposals approved by Primary Review Committees involving children in research activities, except when the Primary Review Committees determine that the subjects are not at risk.

In addition to reviewing ethical issues, the Board will review procedures proposed in the research application to be employed by the institution's Protection Committee (see below), and may suggest modifications of these procedures. The Board's recommendation may vary from a general concurrence with the proposal, as submitted by the investigator, to a recommendation that each parental and subject consent must be obtained with the concurrence of the full Protection Committee. Any specific recommendations for procedures to be followed by the Protection Committee will be included in the report of the Ethical Review Board which will be forwarded to the National Advisory Councils or other secondary review groups of the agency. Appropriate information will be provided by the agency to assist the Protection Committee.

Inasmuch as the articulation of decisions might clarify both the objectives and the assumptions on which they are based, records of testimony and deliberations, as well as final decisions, should be maintained pursuant to existing regulations. Such records will serve additionally as the basis for public accountability and will facilitate the review of any decision, should such action be requested.

Members of the Board, which shall number 15, shall be drawn from the general public, and shall include, for example, research scientists (including social scientists), physicians, lawyers, clergy, or ethicists, and other representatives of the public, none of whom shall be employees of the agency establishing the Board. Appointments shall be made by the agency, which will establish the terms of office and other administrative procedures of the Board. No more than 1/3 of the members of the Board may be actively engaged in research, development, or demonstration activities involving human subjects.

C. Protection Committee: Protection of individual subjects. The determination that it is justifiable to conduct a particular investigation in children, however, does not mean that all children are equally appropriate subjects for inclusion in that research. Numerous considerations might affect the proper choice of subjects. Therefore, the sponsoring institution shall designate a Protection Committee to oversee: (1) the process of

³ FDCA Act Sec. 505 (b), (d), 21 U.S.C. Sec. 355 (b), (d).

selection of subjects who may be included in the project; (2) the monitoring of their continued willingness to participate in the research; and (3) the design of procedures to permit intervention on behalf of the subject, should that become necessary. This Committee should consider the reasonableness and validity of the consent of the child participants (see below) as well as that of the parents, and should assure that the issue of risk and discomfort has been fully and fairly disclosed to parents and subjects. The procedure employed by the institution to achieve these goals will vary; the latitude for such procedures will be great since it will be related in part to the issue of risk. Investigators proposing research involving children shall include a description of their planned use of the Protection Committee in their research proposal; the proposed use of this Committee will be considered an integral part of the research proposal under review by the agency. Relevant information arising in the review process, including information about safety, risk, efficacy, and protection procedures, will be provided to the Protection Committee by the agency supporting the research.

One member of the Committee shall be designated a representative for the project to whom any participant (or parent of a participant) may go to discuss questions or reservations concerning the child's continued participation in the project.

The signature on the consent form of the Chairman of the Protection Committee, when all the stipulations and conditions identified above have been met, will constitute, for DHEW, *supplementary judgment* on behalf of the child subject.

The institution's Protection Committee shall be comprised of at least 5 members so selected that the Committee will be competent to deal with the medical, legal, social, and ethical issues involved in the research, and to represent the community from which the subject population is to be drawn. The Committee should include members of both sexes. No more than two of the members may be employees of the institution sponsoring or conducting the research. The Protection Committee may operate as a subcommittee of the Organizational Review Committee. The composition of the Committee must be approved by the awarding agency.

D. Special provisions—1. Consent of both parents. Even where State law may permit one parent alone to consent to medical care, both parents have an interest in the child, and therefore, consent of both parents should be obtained before any child may participate in research activities. Since the risks of research entail the possibility of additional burdens of care and support, the consent of both parents to the assumption of those risks should be obtained,⁴ except when the identity or whereabouts of either cannot be ascertained or either has been judged mentally incompetent. If the

consent of either parent is not obtained, written explanation or justification should be provided to the Protection Committee. Consent of school or institutional authorities is no substitute for parental concern and consent.

2. The child's consent. An important addition to the requirement for parental consent is the consent of the child subject. Clearly infants have neither the comprehension nor the independence of judgment essential to consent; older children might or might not have these capabilities. Although children might not have the capacity to consent on their own to participate in research activities, they must be given the opportunity (so far as they are able) to refuse to participate. The traditional requirement of parental consent for medical procedures is intended to be protective rather than coercive. Thus, while it was held to be unlawful to proceed merely with the consent of the child, but without consent of the parent or legal guardian,⁵ the reverse should also hold. Therefore, in addition to consent of both parents, consent of the child subject must also be obtained when the child has attained the common law "age of discretion" of 7 years, unless the agency Ethical Review Board specifically exempts a project from this requirement.

3. Exclusions. Despite all the protections afforded by these procedures, certain children are categorically excluded from participation in research involving risk. These include children with no natural or adoptive parents available to participate in consent deliberations, and children detained by court order in a residential facility, whether or not natural or adoptive parents are available.

E. The fetus. Respect for the dignity of human life must not be compromised whatever the age, circumstance, or expectation of life of the individual. Therefore, all appropriate procedures providing protection for children as subjects in biomedical research must be applied with equal rigor and with additional safeguards to the fetus.

The recent decision of the Supreme Court on abortion⁶ does not nullify the ethical obligation to protect the developing fetus from avoidable harm. This obligation, along with the right of every woman to change her decision regarding abortion, requires that no experimental procedures entailing risk to the fetus be undertaken in anticipation of abortion. Further, since the fetus might be at risk in research involving pregnant women, all research involving pregnant women must be reviewed by the Ethical Review Board, unless the Primary Review Committee determines that the research involves no risk to the fetus. Recruitment of pregnant subjects for research reviewed by the Board must involve the institution's Protection Committee in a manner approved by the Board, to provide supplementary judgment.

⁴ *Bonner v. Moran*, 75 U.S. App. D.C. 166, 126 F. 2d 121, 139 A.L.R. 1366 (1941).

⁵ *Roe v. Wade*, 410 U.S. 113 (1973).

The consent of both parents must be obtained for any research involving the fetus, any statutes to the contrary on consent for abortion notwithstanding. Both the mother and the father have an interest in the fetus, and legal responsibility for it, if it is born. Therefore, the father's consent must be obtained for experimental procedures involving the fetus; consent of the father may be waived if his identity or whereabouts cannot be ascertained, or if he has been judged mentally incompetent.

IV. Special categories—A. The abortus. Prematurity is the major cause of infant death in this country; thus, research aimed at developing techniques to further viability is of utmost importance. Such research has already contributed significantly to improvement in the care of the pregnant woman and of her fetus. In addition, knowledge of fetal drug metabolism, enzyme activity, and the development of organs is essential to progress in preventing or offsetting certain congenital defects. After thorough research in animal models, it often eventually becomes essential to undertake studies in the non-viable human fetus.

The decision of the Supreme Court on abortion does not eliminate the ethical issues involved in research on the non-viable human fetus. No procedures should be undertaken on the non-viable fetus which clearly affront societal values. Nevertheless, certain research is essential to improve both the chance of survival and the health status of premature infants. Such research must meet ethical standards as well as show a clear relation either to the expectation of saving the life of premature infants through the development of rescue techniques, or to the furthering of our knowledge of human development and thereby our capacity to offset the disabilities associated with prematurity. It is imperative, however, that the investigator first demonstrate that appropriate studies on animals have in fact been exhausted and that therefore the research in question requires that the work be done on the non-viable human fetus. Specific reasons for this necessity must be identified. A thorough review of the ethical issues in proposed research involving the non-viable fetus is of utmost importance.

It must be recognized that consent for abortion does not necessarily entail disinterest on the part of the pregnant woman in what happens to the product of conception. Some women feel strongly about what may, or may not, be done to the aborted fetus; others do not. In order to give every woman the opportunity to declare her wishes, consent of the pregnant woman for application of any research procedures to the aborted fetus must be secured at the time of admission to the hospital for the abortion.

Because research on the abortus involves ethical as well as scientific issues, all projects involving the abortus must be reviewed by the Ethical Review Board, and recruitment of individual pregnant women for such research must involve

⁶ 59 Am. Jur. 2d, Sect. 129, p. 229.

the institution's Protection Committee in a manner approved by the Board to provide supplementary judgment. In addition to the requirement for maternal consent, both the Ethical Review Board and the Protection Committee shall, in their deliberations, consider the ethical and social issues surrounding research on the non-viable fetus. The Protection Committee must be satisfied that maternal consent is freely given and based on full disclosure, each time approved research is conducted on an abortus.

In order to insure that research considerations do not influence decisions as to timing, method, or extent of a procedure to terminate a pregnancy, no investigator engaged in the research on the abortus may take part in these decisions. These are decisions to be made by the woman and her physician.

The attending physician, not the investigator, must determine the viability of the abortus at the termination of pregnancy. If there is a reasonable possibility that the life of the fetus might be saved, experimental and established methods may be used to achieve that goal. Artificial life-support techniques may be employed only if the physician of record determines that the fetus might be viable. If the physician determines that the fetus is not viable, it is not acceptable to maintain heart beat or respiration artificially in the abortus for the purpose of research. Experimental procedures which of themselves will terminate respiration and heart beat may not be undertaken.

This policy and these protections apply with equal force to the products of spontaneous abortions.

B. The products of *in vitro* fertilization. In the interest of improving human health and development, the biology of human fertilization and the early events surrounding this phenomenon, including implantation, should be studied. To the extent that *in vitro* studies of human fertilization might further this aim, they are permissible at the present time within the limits outlined below.

Current technology limits the *in vitro* development of the human fertilized ovum to a period of several days. This is a rapidly advancing field of biomedical research, however, and the time might come when it is possible to extend *in vitro* development beyond the stage of early cell division and possibly even to viability.

It is contrary to the interests of society to set permanent restrictions on research which are based on the successes and limitations of current technology. Still, it is necessary to impose restraints prospectively in order to provide reasonable protections, while at the same time permitting scientific advancements which might well benefit society. A mechanism is required to weigh, at any given time, the state of the art, a specific proposal, legal issues, community standards, and the availability of guidelines to govern the research situation. This mechanism is provided by the Ethical Review Board. Ultimately, the Board will determine the acceptability of a

project involving *in vitro* fertilization, and by recognizing the state of the art, as well as societal concerns, propose appropriate research policy.

Care must be taken not to bring human ova fertilized *in vitro* to viability—whether in the laboratory or implanted in the uterus—until the safety of the technique has been demonstrated as far as possible in sub-human primates. To this end:

1. All proposals for research involving human *in vitro* fertilization must be reviewed by the Ethical Review Board.

2. No research involving the implantation of human ova fertilized in the laboratory into recipient women should be supported until the appropriate scientific review boards are satisfied that there has been sufficient work in animals (including sub-human primates) to demonstrate the safety of the technique. It is recommended that this determination of safety include studies of natural born offspring of the products of *in vitro* fertilization.

3. No implantation of human ova fertilized in the laboratory should be attempted until guidelines are developed governing the responsibilities of the donor and recipient "parents" and of research institutions and personnel.

V. Prisoners—A. Policy considerations. Clinical research often requires the participation of normal volunteers; for example, in the early stages of drug or vaccine evaluation. Sometimes, the need for standardization certain variables, or for monitoring responses over an extended period of time, requires that the subjects of research remain in a controlled environment for the duration of the project. Prisoners may be especially suitable subjects for such studies, since, unlike most adults, they can donate their time to research at virtually no cost to themselves. However, the special status of prisoners requires that they have special protection when they participate in research.

While there is no legal or moral objection to the participation of normal volunteers in research, there are problems surrounding the participation of volunteers who are confined in an institution. Many aspects of institutional life may influence a decision to participate; the extent of that influence might amount to coercion, whether it is intended or not. Where there are no opportunities for productive activity, research projects might offer relief from boredom. Where there are no opportunities for earning money, research projects offer a source of income. Where living conditions are unsatisfactory, research projects might offer a respite in the form of good food, comfortable bedding, and medical attention. While this is not necessarily wrong, the inducement (compared to the deprivation) might cause prisoners to offer to participate in research which would expose them to risks of pain or incapacity which, under normal circumstances, they would refuse. In addition, there is always the possibility that the prisoner will expect participation in research to be

viewed favorably, and to his advantage, by prison authorities (on whom his other few privileges depend) and by the parole board (on whom his eventual release depends). This is especially true when the research involves behavior modification and may be termed "therapeutic" with respect to the prisoner. In such instances, participation inevitably carries with it the hope that a successful result will increase the subject's chances for parole. Thus, the inducement involved in therapeutic research might be extremely difficult to resist; and for this reason, special protection is necessary for prisoners participating in research, whether or not the research is therapeutic.

The first principle of the Nuremberg Code requires that subjects of biomedical research must be "so situated as to be able to exercise free power of choice" concerning their participation. Whether prisoners can be considered to be "so situated" is ultimately a matter for the courts and the legislatures to resolve. In the meantime, it must be recognized that where liberty is limited, and where freedom of choice is restricted, there is a corresponding limitation of the capacity to give truly voluntary consent. Although the prisoner might be adequately informed, and competent to make judgments, the voluntariness of the person's consent remains open to question. This policy statement is designed to provide additional protections to prisoners participating in research.

The mission of the Department of Health, Education, and Welfare does not include rendering judgments on the administration of justice or the management of the correctional system. At the same time, the Department should not support activities which take unethical advantage of those who are under the jurisdiction of the courts and who, for that reason, lack some of the usual defenses to their personal integrity. Participation of prisoners in the research activities of the DHEW in the pursuit of medical knowledge might be beneficial to all concerned, but the relationship which involves a class of persons with diminished autonomy requires careful supervision.

Many prisoners are strongly motivated to participate in research, and view as unfair suggestions that they be denied this opportunity. Unless society, through its judicial and legislative bodies, decides that such participation should be halted, it is essential to develop mechanisms to protect those who may participate, or who are now participating, from the coercive aspects of incarceration which diminish their capacity for voluntary consent. Pursuant to the obligation to protect the rights of all subjects participating in research conducted under its auspices, the DHEW is proposing special guidelines for the protection of prisoners as subjects in any biomedical or behavioral research.

Two aspects of research involving prison populations require special review and procedural safeguards in addition to those provided by current DHEW policies.

First, when research is conducted under the auspices of a commercial manufacturer or an individual investigator, it is not always subject to review by an Organizational Review Committee, as is required for similar research conducted at a hospital or a university. Thus, local review has not heretofore been required for ethical considerations or for specific problems related to the population or institution which is to be directly involved. Second, because of the loss of individual dignity, the limitations of personal freedom, and the possibility of real or potential coercion which may accompany confinement in an institution, special safeguards must be provided to mitigate the inequalities of bargaining power between the prisoners and those who are in positions of authority. While it is important that prisoners have the opportunity to participate in research, it is equally important that they not feel compelled to do so.

B. Organizational Review Committee. All research involving prisoners must be conducted at an accredited correctional facility (see Section F, below) and be reviewed initially, and on a continuing basis, either by the Organizational Review Committee of that correctional facility or by the Organizational Review Committee of the institution sponsoring the research. The Organizational Review Committee shall have the duties and responsibilities identified in current DHEW regulations. In addition, for each project, it shall determine the adequacy of clinic or hospital facilities for the particular activity to be conducted, assess the appropriateness of the subject population for that activity, and weigh the questions of scientific importance, social need, and ethical acceptability. In addition to the foregoing, the Organizational Review Committee shall have the following duties, with respect to research involving prisoners as subjects:

1. To review and approve or modify the process proposed by the principal investigator for involvement of the Protection Committee (see below) in overseeing the selection of subjects who may be included in the research, and the process of obtaining their voluntary and informed consent.

2. To set rates of remuneration, if any, consistent with the expected duration and discomfort or risk of the proposed study, and consistent with other opportunities for employment, if any, at the facility in question.

3. To monitor the progress of the research as required by the sponsoring DHEW agency.

The recommendations of this Committee, along with a report describing any site visits, shall be included with the investigator's application to the agency. For facilities which have filed no general assurance, composition as well as recommendations of the Organizational Review Committee will be considered an integral part of the proposal in the agency review.

C. Protection Committee. The primary function of the Protection Committee is to provide supplementary judgment by

overseeing the selection of subjects who may be included in a research project to assure that their consent is as voluntary as possible under the conditions of confinement.

Consent is a continuing process. To assure the voluntariness of consent, subjects must be able to withdraw from the research project without prejudice. Each Protection Committee shall establish such a withdrawal mechanism.

The duties of the Protection Committee, therefore, shall include:

1. Reviewing the information given the potential subjects, with special attention to: adverse effects, the importance of reporting all deviations from normal function, the continuing option of withdrawing from participation at any time, and the identification of a member of the committee who will be available, at reasonable intervals upon request, for consultation regarding the research project. All of this information shall appear on the consent form, a copy of which will be given to each participant. When oral representations are made procedures described under DHEW regulations shall be followed.

2. Overseeing the process of selection of subjects who may be included in the research, to the extent stipulated in the recommendation of the Organizational Review Committee. This may vary from overall approval of the recruitment process, to reviewing a sample of subject selections, to interviewing as a full Committee each individual subject to be included in the project.

3. Visiting the institution on a regular basis to invite questions, to monitor the progress of the research, and to assess the continued willingness of subject participation. The frequency of these visits will be determined by the nature of the research, and any recommendations of the Organizational Review Committee. Depending upon the circumstances and the number of subjects involved, these visits may be made either on a rotating basis by various members of the Committee, or by the full Committee.

4. Maintaining records of its activities including contacts initiated by subjects in the project between regular site visits. These records shall be made available to the agency upon request.

The Protection Committee shall be comprised of at least 5 members so selected that the Committee will be competent to deal with the medical, legal, social, and ethical issues involved. No more than 1/3 of the members shall be scientists engaged in biomedical research or physicians; at least 1 shall be a prisoner or a representative of an organization concerned with the prisoners' interests; no more than 1 (except prisoners or their representatives) shall have any affiliation with the prison facility or with the unit of government having jurisdiction over the facility, with the exception of persons employed by the department of education of a relevant jurisdiction in a teaching capacity. The composition and the investigator's proposed use of the Committee must be reviewed and approved by the DHEW agency.

D. Payment to prisoners. The amount paid for participation in research will vary according to the risks and discomforts involved, and the other employment opportunities in the facility in which the research is to be conducted. The specific amount for each project will be determined by the Organizational Review Committee, which will forward its recommendation as part of the application to the sponsoring agency. The amount paid shall provide a compensation for services, but shall not be so great as to constitute undue inducement to participate.

Any reduction of sentence as a consequence of participation in research shall be comparable to other opportunities at the facility for earning such a reduction.

Any subject who is required by the investigator or prison physician to withdraw, for medical reasons, before completion of the investigation, shall continue to be paid for a period to be determined by the Protection Committee in consultation with the investigator. This does not apply to subjects who withdraw for other reasons. Any disputes regarding certification of withdrawal for medical reasons shall be heard and resolved by the Protection Committee.

Prisoners who serve on the Protection Committee shall be paid an amount consistent with that received by the research subjects.

E. Accreditation. The Secretary, DHEW, shall establish standards for accreditation of correctional facilities offering to act as sites for the performance of clinical research, or offering to act as a source of volunteer subjects for clinical research when the research is supported in whole or in part by Departmental funds or the research is to be performed in compliance with requirements of Federal statutes.

The review for certification shall include, but not be limited to:

1. Standard of living in the prison facility.

2. Other opportunities for employment and/or constructive activity, either within the prison, or in a work-release program.

3. Adequacy of (a) medical care for the general prison population (so that participation in research is not the only means of obtaining medical attention), and (b) the proposed methods for maintaining medical records and for protecting the confidentiality of those records.

4. The nature, structure, function, and composition of the Organizational Review Committee (whether located at the prison or at the institution sponsoring the research) which is to review clinical research in that correctional facility.

The Secretary shall also set general guidelines to assist the Organizational Review Committees in determining rates of remuneration, and shall indicate groups who may be considered to represent the prisoners' interests for the purpose of appointment to membership on the Protection Committee. No institution shall be accredited if research, whether or not supported by funds from the DHEW, is conducted under its auspices,

or by members of its staff, which is not in conformity with these guidelines. No DHEW funds will be granted for research in institutions lacking such accreditation.

F. *Special provisions.* 1. Persons detained in a correctional facility while awaiting sentence, or in a hospital facility for pre-sentence diagnostic observation, are excluded from participation in research.

2. A child may not be included as a subject in research involving risk if he is detained in an institutional setting pursuant to a court order, whether or not the parents and the child have consented to the child's participation.

VI. *The mentally infirm.*—A. *Policy considerations.* The institutionalized mentally infirm are doubly limited with respect to participation in research activities. First, as with children, they might lack the clear capacity to comprehend relevant information, and to make informed judgments concerning their participation. Second, as with prisoners, they experience a diminished sense of personal integrity as a result of confinement in an institution. Such confinement restricts their freedom of choice and imposes elements of coercion, which limit their capacity to give truly voluntary consent. In addition, the mentally infirm who are confined in institutions have more pressures to cooperate with custodial authorities than do prisoners, for their release might depend entirely upon their behavior and on the impression they make upon those having the power to make decisions concerning termination of their confinement.

Legal guardians, who have authority to consent for medical treatment, might have interests in the matter which do not necessarily coincide with those of the patient. Long-term management of patients with mental disabilities is expensive and time-consuming. Any proposal which might reduce either the expense or the supervision required in caring for such persons might be appealing, whether or not there is correlative benefit to the patient. This is certainly the case in projects offering new therapy; it might also occur, albeit in a more subtle form, where free medical or custodial services are perceived to be contingent upon the patient's participation as a subject in research.

The courts have begun to recognize that persons confined in institutions might not be able to give truly voluntary consent in such matters. It is important to recognize, as well, that persons encumbered with the economic or custodial responsibility for the mentally infirm might not be sufficiently objective to make judgments which are fully in the best interest of the institutionalized person.

The circumstances are limited under which it is justifiable to include the mentally infirm as subjects in biomedical research. These circumstances include projects in which: the proposed research concerns diagnosis, treatment, prevention, or etiology of the disability from which they suffer; the necessary infor-

mation can be obtained only from those subjects; or the studies concern institutional life *per se*. With these exceptions, the general rule is that the participation of the mentally infirm as subjects in research is not acceptable.

B. *Ethical review of projects and protection of subjects.* In instances in which a research protocol requires the participation of mentally infirm subjects, the research must be overseen by a Protection Committee in the manner described in Section III-C, pertaining to children. This Protection Committee must be supervised on a continuing basis, as described in Section V-B, by the Organizational Review Committee of the institution in which the research is to be conducted or of the institution sponsoring the research.

VII. *General provisions.* These provisions apply to all research activities covered by this policy.

A. *Referrals to the Ethical Review Board.* Whenever a Primary Review Committee, secondary review group, or the agency staff perceives an apparent and significant question of ethics or an unusual element of risk—whatever the subject group involved—the research proposal in question may be forwarded to the Ethical Review Board for an opinion. In addition to offering an opinion of acceptability from an ethical viewpoint, the Board may choose to recommend the establishment of a Protection Committee, and suggest guidelines for its operation.

B. *Procedures requiring special consideration.* All other recommendations notwithstanding, DHEW may identify certain procedures which: (1) Require Protection Committee review of the selection of each individual subject; (2) are acceptable for stipulated subjects only if approved by affirmative declaratory judgment of a court of competent jurisdiction; or (3) are unacceptable.

C. *Research conducted in Foreign Countries.* All regulations governing research conducted in the United States apply to research conducted in foreign countries under DHEW auspices, and the ethical review must be of equal rigor.

There are sometimes special constraints encountered in foreign settings. Therefore, in addition to the requirement that consent procedures for research to be conducted abroad conform with the policy and regulations set forth in this document, there must be written assurance that the proposed research enjoys local acceptance, and offends no local ethical standards.

D. *Research submitted pursuant to DHEW regulatory requirements.* Research or testing which is performed pursuant to or in fulfillment of any regulation issued by any agency of the DHEW will be acceptable to the government only if conducted in compliance with these procedures and regulations.

E. *Clinical research not funded by DHEW.*

If, in the judgment of the Secretary, an organization has failed to comply with the terms of this policy with respect to a par-

ticular DHEW grant or contract, he may require that said grant or contract be terminated or suspended in the manner prescribed in applicable grant or procurement regulations.

If, in the judgment of the Secretary, an organization fails to discharge its responsibilities for the protection of the rights and welfare of the subjects in its care, whether or not DHEW funds are involved, he may, upon reasonable notice to the organization of the basis for such action, determine that its eligibility to receive further DHEW grants or contracts involving human subjects shall be terminated. Such disqualification shall continue until it is shown to the satisfaction of the Secretary that the reasons therefor no longer exist.

If, in the judgment of the Secretary, an individual serving as principal investigator, program director, or other person having responsibility for the scientific and technical direction of a project or activity, has failed to discharge his responsibilities for the protection of the rights and welfare of human subjects in his care, the Secretary may, upon reasonable notice to the individual of the basis for such action, determine that such individual's eligibility to serve as a principal investigator or program director or in another similar capacity shall be terminated. Such disqualification shall continue until it is shown to the satisfaction of the Secretary that the reasons therefor no longer exist.⁷

In reaching a determination on compliance, with respect to subjects with limited capacity for consent, the Secretary will consider the extent and the nature of the procedures by which the institution offers protection in all studies conducted in or by that institution regardless of the source of funds, with the expectation that there shall be an ethical review similar to that required of the agency Ethical Review Board (III-B). The existence of a Protection Committee, overseen by an Organizational Review Committee and acting to afford supplementary judgment, will be accepted as evidence of responsibility in this regard.

F. *Confidentiality of information and records.* Nothing in this policy shall be construed as permitting the release of confidential research protocols nor the violation of State law applicable to the confidentiality of individual medical records.

VIII. *Draft additions to proposed regulations* (See FEDERAL REGISTER, Vol. 38, No. 194, Part 2, Tues., Oct. 9, 1973, pp. 27882-27885).

To amend the proposed Part 46 of Subtitle A of Title 45 of the Code of Federal Regulations by deleting §§ 46.20 through 46.23, redesignating §§ 46.1 through 46.19 thereof as Subpart A, and adding the following new Subparts B through F:

SUBPART B—ADDITIONAL PROTECTIONS FOR CHILDREN INVOLVED AS SUBJECTS IN DHEW ACTIVITIES

| | |
|-------|--|
| Sec. | |
| 46.21 | Applicability. |
| 46.22 | Purpose. |
| 46.23 | Need for legally effective consent. |
| 46.24 | Definitions. |
| 46.25 | Ethical Review Board; Composition; Duties. |

⁷ FEDERAL REGISTER, Vol. 38, No. 194, Part 2, Tuesday, October 9, 1973, § 46.22, p. 27885.

- Sec. 46.26 Protection Committees; Composition; Duties.
- 46.27 Certain children excluded from participation in DHEW supported activities.
- 46.28 Activities to be performed outside the United States.

SUBPART C—ADDITIONAL PROTECTIONS FOR CERTAIN CLASSES OF DHEW ACTIVITIES

- 46.31 Applicability.
- 46.32 Purpose.
- 46.33 Definitions.
- 46.34 Duties of the Ethical Review Board.
- 46.35 Maternal consent to activities involving the abortion.
- 46.36 Additional conditions for activities involving the abortion.
- 46.37 Prohibition on certain activities involving pregnant women where the fetus may be adversely affected.
- 46.38 Parental consent to activities which may affect the fetus.
- 46.39 Activities to be performed outside the United States.

SUBPART D—ADDITIONAL PROTECTIONS FOR PRISONERS INVOLVED AS SUBJECTS IN DHEW ACTIVITIES

- Sec. 46.41 Applicability.
- 46.42 Purpose.
- 46.43 Definitions.
- 46.44 Additional duties of Organizational Review Committee where prisoners are involved.
- 46.45 Protection Committees; Duties; Composition.
- 46.46 Prohibition on participation in activities prior to conviction.
- 46.47 Remuneration to subjects.
- 46.48 Accreditation.
- 46.49 Activities to be performed outside the United States.

SUBPART E—ADDITIONAL PROTECTIONS FOR THE INSTITUTIONALIZED MENTALLY INFIRM INVOLVED AS SUBJECTS IN DHEW ACTIVITIES

- 46.51 Applicability.
- 46.52 Purpose.
- 46.53 Definitions.
- 46.54 Limitations on activities involving the institutionalized mentally infirm.
- 46.55 Additional duties of Organizational Review Committee where the mentally infirm are involved.
- 46.56 Protection Committees; Duties; Composition.
- 46.57 Activities to be performed outside the United States.

SUBPART F—GENERAL PROVISIONS

- 46.61 Applicability.
- 46.62 Organization's records.
- 46.63 Reports.
- 46.64 Early termination of awards; sanctions for noncompliance.
- 46.65 Conditions.

AUTHORITY: 5 U.S.C. 301.

SUBPART B—ADDITIONAL PROTECTIONS FOR CHILDREN INVOLVED AS SUBJECT IN DHEW ACTIVITIES

Section 46.21 *Applicability.* (a) The regulations in this subpart are applicable to all Department of Health, Education, and Welfare research, development, or demonstration activities in which children may be at risk.

(b) The requirements of this subpart are in addition to those imposed under subpart A of this part.

Section 46.22 *Purpose.* It is the purpose of this subpart to provide additional safeguards in reviewing activities to which this subpart is applicable inasmuch as the potential subjects in activities conducted there-

under might be unable fully to comprehend the risks which might be involved and are legally incapable of consenting to their participation in such activities.

Section 46.23 *Need for legally effective consent.* Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will necessarily result in a legally effective consent under applicable State or local law to a subject's participation in any activity; nor in particular does it obviate the need for court approval of such participation where court approval is required under applicable State or local law in order to obtain a legally effective consent.

Section 46.24 *Definitions.* As used in this subpart:

(a) "DHEW activity" means:
(1) The conduct or support (through grants, contracts, or other awards) of biomedical or behavioral research involving human subjects; or

(2) Research, development, or demonstration activities regulated by any DHEW agency.

(b) "Subject at risk" means any individual who might be exposed to the possibility of harm—physical, psychological, sociological, or other—as a consequence of participation as a subject in any DHEW activity which goes beyond the application of those established and accepted methods necessary to meet his needs.

(c) "Child" means an individual who has not attained the legal age of consent to participate in research as determined under the applicable law of the jurisdiction in which such research is to be conducted.

(d) "DHEW" means the Department of Health, Education and Welfare.

Section 46.25 *Agency Ethical Review Board; composition; duties.* (a) The head of each agency shall establish an Ethical Review Board, hereinafter referred to as the "Board," to review proposals for research, development, and demonstration activities to which this subpart is applicable, as well as to advise him or her on matters of policy concerning protection of human subjects. The Board shall be composed of research scientists (biomedical, behavioral, and/or social), physicians, lawyers, clergy, ethicists, and representatives of the public. It shall consist of 15 members appointed by the agency head from outside the Federal Government. No more than one-third of the members may be individuals engaged in research, development, or demonstration activities involving human subjects.

(b) It shall be the function of the Board to review each proposed activity to which this subpart applies, and advise the agency concerning the acceptability of such activities from the standpoint of societal need and ethical considerations, taking into account the assessment of the appropriate Primary Review Committees as to: (1) The potential benefit of the proposed activity, (2) scientific merit and experimental design, (3) whether the proposed activity entails risk of significant harm to the subject, (4) the sufficiency of animal and adult human studies demonstrating safety and clear potential benefit of the proposed procedures and providing sufficient information on which to base an assessment of the risks, and (5) whether the information to be gained may be obtained from further animal and adult human studies.

(c) The Board shall review the procedures proposed by the applicant to be followed by the Protection Committee, provided for in § 46.26 of this subpart, in carrying out its functions as set forth in § 46.26. In addition, the Board may recommend additional functions to be performed by the Protection Committee in connection with any particular activity.

(d) In decisions regarding activities covered by this subpart, the agency shall take into account the recommendations of the Board.

Section 46.26 *Protection Committees; composition; duties.* (a) No activity covered by this subpart will be approved unless it provides for the establishment by the applicant of a Protection Committee, composed of at least five members so selected that the Committee will be competent to deal with the medical, legal, social and ethical issues involved in the activity. None of the members shall have any association with the proposed activity, and at least one-half shall have no association with any organization or individual conducting or supporting the activity. No more than one-third of the members shall be individuals engaged in research, development, or demonstration activities involving human subjects. The composition of the Protection Committee shall be subject to DHEW approval.

(b) The duties of the Protection Committee, proposed by the applicant, and reviewed by the agency including the Ethical Review Board shall be to oversee: (1) The selection of subjects who may be included in the activity; (2) the monitoring of the subject's continued willingness to participate in the activity; (3) the design of procedures to permit intervention on behalf of one or more of the subjects if conditions warrant; (4) the evaluation of the reasonableness of the parents' consent and (where applicable) the subject's consent; and (5) the procedures for advising the subject and/or the parents concerning the subject's continued participation in the activity. Each subject and his or her parent or guardian will be informed of the name of a member of the Protection Committee who will be available for consultation concerning the activity.

(c) The Protection Committee shall establish rules of procedure for conducting its activities, which must be reviewed by DHEW, and shall conduct its activities at convened meetings, minutes of which shall be prepared and retained.

Section 46.27 *Certain children excluded from participation in DHEW activities.* A child may not be included as a subject in DHEW activities to which this subpart is applicable if:

(a) The child has no known living parent who is available and capable of participating in the consent process; *Provided*, That this exclusion shall be inapplicable if the child is seriously ill, and the proposed research is designed to substantially alleviate his condition; or

(b) The child has only one known living parent who is available and capable of participating in the consent process, or only one such parent, and that parent has not given consent to the child's participation in the activity; or

(c) Both the child's parents are available and capable of participating in the consent process, but both have not given such consent;

(d) The child is involuntarily confined in an institutional setting pursuant to a court order, whether or not the parents and child have consented to the child's participation in the activity; or

(e) The child has not given consent to his or her participation in the research; *Provided*, That this exclusion shall be inapplicable if the child is 6 years of age or less or if explicitly waived by the DHEW; or

(f) The Protection Committee established under § 46.26 of this subpart has not reviewed and approved the child's participation in the activity.

Section 46.28 *Activities to be performed outside the United States.* In addition to satisfying all other applicable requirements in

this subpart, an activity to which this subpart is applicable, which is to be conducted outside the United States, must include written documentation satisfactory to DHEW that the proposed activity is acceptable under the legal, social, and ethical standards of the locale in which it is to be performed.

SUBPART C—ADDITIONAL PROTECTION FOR CERTAIN CLASSES OF DHEW ACTIVITIES

Section 46.31 Applicability. (a) The regulations in this subpart are applicable to all Department of Health, Education, and Welfare research, development, or demonstration activities: (1) Involving pregnant women, unless there is a finding by DHEW that the activity will have no adverse effect on the fetus, or is clearly therapeutic with respect to the fetus involved; (2) Involving the abortion or the non-viable fetus, or (3) Involving in vitro fertilization of human ova.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will in any way render inapplicable pertinent State or local laws bearing upon activities covered by this subpart.

(c) To the extent the requirements of subpart A of this part are applicable to activities also covered by this subpart, the requirements of this subpart are in addition to those imposed under subpart A.

Section 46.32 Purpose. It is the purpose of this subpart to provide additional safeguards in reviewing activities to which this subpart is applicable to assure that they conform to appropriate ethical standards and relate to important societal needs.

Section 46.33 Definitions. As used in this subpart:

(a) "DHEW" means the Department of Health, Education, and Welfare.

(b) "DHEW activity" means:

(1) The conduct or support (through grants, contracts, or other awards) of biomedical or behavioral research involving human subjects; or

(2) Research, development, or demonstration activities regulated by any DHEW agency.

(c) "Board" means the Board established under § 46.25.

(d) "Protection Committee" means a committee referred to in § 46.26.

(e) "Pregnancy" means the period of time from implantation of a fertilized ovum until delivery.

(f) "Fetus" means the product of conception from implantation until delivery.

(g) "Abortus" means the fetus when it has been expelled whole, whether spontaneously or as a result of medical or surgical intervention to terminate a pregnancy, prior to viability. This definition, for the purpose of this policy, excludes the placenta, fetal material which is macerated at the time of expulsion, a dead fetus, and isolated fetal tissue or organs excised from a dead fetus.

(h) "Viability of a fetus" means capability given the benefit of available therapy, or independently maintaining heart beat and respiration.

(i) "In vitro fertilization" means any fertilization of human ova which occurs outside the body of a female, through admixture of human sperm and such ova.

Section 46.34 Duties of the Ethical Review Board. (a) It shall be the function of the Board to review each activity to which this subpart applies and advise the agency concerning the acceptability of such activities from the standpoint of societal need and ethical considerations, taking into account the assessment of the appropriate Primary Review Committees as to: (1) The potential benefit of the proposed activity, (2) scientific merit and experimental design, (3) the sufficiency of studies involving animals dem-

onstrating the clear potential benefit of the proposed procedures and (4) whether the information to be gained may be obtained from further animal or adult human studies.

(b) The Board may recommend the establishment by the sponsoring institution of a Protection Committee to carry out such functions as the Board deems necessary.

Section 46.35 Maternal consent to activities involving the abortus. (a) No activity to which this subpart is applicable may involve an abortus or a non-viable fetus unless maternal consent has been obtained.

(b) No activity to which this subpart is applicable may involve an abortus or a non-viable fetus unless: (1) Individuals involved in the activity will have no part in the decision as to timing, method, or extent of the procedure used to terminate the pregnancy, or in determining viability of the fetus at the termination of the pregnancy; (2) vital functions of the abortus will not be maintained artificially for purposes of research; and (3) experimental procedures which would terminate heart beat or respiration in the abortus will not be employed.

Section 46.37 Prohibition on certain activities involving pregnant women where the fetus may be adversely affected. The Board shall review all research, development, and demonstration activities involving pregnant women. No activity to which this subpart is applicable may involve a pregnant woman if the Primary Review Committee finds that the fetus might be adversely affected, unless the primary purpose of the activity is to benefit that fetus. In addition, no activity to which this subpart is applicable may involve pregnant women unless all the requirements of this subpart are satisfied.

Section 46.38 Parental consent to activities which might affect the fetus. No activity involving a pregnant woman which might affect the fetus but which nevertheless is permissible under § 46.37 shall be conducted unless maternal consent has been obtained, as well as the consent of the father if he is available and capable of participating in the consent process.

Section 46.39 Activities to be performed outside the United States. In addition to satisfying all other applicable requirements in this subpart, activities to which this subpart is applicable, which are to be conducted outside the United States, must include written documentation satisfactory to DHEW that the proposed activity is acceptable under the legal, social, and ethical standards of the locale in which it is to be performed.

SUBPART D—ADDITIONAL PROTECTIONS FOR PRISONERS INVOLVED AS SUBJECTS IN DHEW ACTIVITIES

Section 46.41 Applicability. (a) The regulations in this subpart are applicable to all Department of Health, Education, and Welfare research, development, and demonstration activities involving prisoners as subjects.

(b) The requirements of this subpart are in addition to those imposed under subparts A and B of this part.

Section 46.42 Purpose. It is the purpose of this subpart to provide additional safeguards for activities to which this subpart is applicable inasmuch as the potential subjects in activities conducted thereunder, because of their incarceration, might be under constraints which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate in such activities.

Section 46.43 Definitions. As used in this subpart:

(a) "DHEW activity" means:

(1) the conduct or support (through grants, contracts, or other awards) of biomedical or behavioral research involving human subjects; or

(2) research, development, or demonstration activities regulated by any DHEW agency.

(b) "Prisoner" means any individual involuntarily confined in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute and also individuals detained by virtue of statutes which provide alternatives to criminal prosecution.

(c) "DHEW" means the Department of Health, Education, and Welfare.

Section 46.44 Additional duties of Organizational Review Committees where prisoners are involved. (a) In carrying out its responsibilities under subpart A of this part for activities also covered by this subpart, the Organizational Review Committee provided for under subpart A shall also certify: (1) That there will be no undue inducements to participation by prisoners as subjects in the activity, taking into account among other factors, the sources of earnings generally available to the prisoners as compared with those offered to participants in the activity, (2) that the clinic and hospital facilities are adequate for the proposed activity, (3) that all aspects of the activity would be appropriate for performance on nonprisoners, and (4) that no prisoner will be offered any reduction in sentence or parole for participation in such activity which is not comparable to that offered for other activities at the facility not of a research, development, demonstration or similar nature.

(b) In addition, the Organizational Review Committee shall have the following duties: (1) To review, approve, or modify the procedures proposed for the Protection Committee in carrying out its functions as set forth in § 46.45; (2) To recommend any additional functions to be performed by the Protection Committee in connection with a particular activity; (3) To set rates of remuneration, if any, consistent with the anticipated duration, discomfort, and/or risk of the activity but not in excess of that paid for other employment generally available to inmates of the facility in question; and (4) To carry out such other responsibilities as may be stipulated by DHEW in the contract or grant award.

(c) Activities to which this subpart is applicable must provide for the designation of an Organizational Review Committee, where no such Committee has been established under subpart A.

Section 46.45 Protection Committees; duties; composition. (a) No activity covered by this subpart will be approved unless it provides for the establishment of a Protection Committee to carry out the following functions, as well as any others recommended by the Organizational Review Committee or by DHEW: (1) Reviewing the procedure for soliciting participation by prisoners in the research activity to determine that all elements of informed consent, as outlined in § 46.3, are satisfied; (2) overseeing the selection of prisoners who may participate in the activity; (3) monitoring the progress of the research and the continued willingness of subject participation; and (4) intervening on behalf of one or more subjects if conditions warrant. In addition, each subject will be informed of the name of a member of the Protection Committee who will be available to the subject for consultation concerning the activity.

(b) Each Protection Committee shall be composed of at least five members appointed by the applicant and so selected that the Committee will be competent to deal with the medical, legal, social, and ethical issues involved. At least one member of the Committee shall be either a prisoner or a representative of an organization having as a primary concern protection of the interests of prisoners.

No more than one-third of the members may be physicians or scientists engaged in biomedical or behavioral research, and no more than one member, other than a prisoners' representative, may have any affiliation with the prison facility or the legal entity having jurisdiction over the facility, except for persons employed by a Department of Education in a teaching capacity. Any prisoners serving on the Committee shall be compensated at a rate consistent with that set for prisoners participating as subjects in activities at the facility to which this subpart is applicable.

(c) The Protection Committee shall establish rules of procedure for conducting its activities which must be reviewed by DHEW, and shall conduct its activities at convened meetings, minutes of which shall be prepared and retained. The composition of the Committee shall be subject to DHEW approval.

Section 46.46 *Prohibition on participation in activities prior to conviction.* No individual confined pending arraignment, trial, or sentencing for an offense punishable as a crime may be used as a subject in any activity supported in whole or in part by a grant or contract to which this subpart is applicable.

Section 46.47 *Remuneration to subjects.* Where rates of remuneration are set pursuant to § 46.44 of this subpart, any subject who, for medical reasons, is required by a representative of the prison facility, grantee, contractor, or sponsor of the activity, to withdraw before completion of his or her participation in the activity shall continue to be compensated for a period to be set by the Protection Committee after consultation with the grantee or contractor.

Section 46.48 *Accreditation.* It is the intention of DHEW to accredit prison facilities as sites for the performance of activities to which this subpart applies. Accreditation will be based on certification of the acceptability of the facilities and compliance with the procedures required by this subpart, as determined by the Secretary. No activity covered by this subpart may involve prisoners incarcerated in a facility not accredited by Secretary of DHEW.

Section 46.49 *Activities to be performed outside the United States.* In addition to satisfying all other applicable requirements in this subpart, an activity to which this subpart is applicable, which is to be conducted outside the United States, must include written documentation satisfactory to DHEW that the proposed activity is acceptable under the legal, social, and ethical standards of the locale in which it is to be performed.

SUBPART E—ADDITIONAL PROTECTIONS FOR INSTITUTIONALIZED MENTALLY INFIRM INDIVIDUALS INVOLVED AS SUBJECTS IN DHEW ACTIVITIES

Section 46.51 *Applicability.* (a) The regulations in this subpart are applicable to all Department of Health, Education, and Welfare activities involving the institutionalized mentally infirm as subjects.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein, in connection with activities permitted under § 46.54 of this subpart will necessarily result in a legally effective consent under applicable State or local law to a subject's participation in such an activity; nor in particular does it obviate the need for court approval of such participation where court approval is required under applicable State or local law in order to obtain a legally effective consent.

(c) The requirements of this subpart are in addition to those imposed under Subparts A, B, and D of this part.

Section 46.52 *Purpose.* It is the purpose of this subpart to provide additional safe-

guards for the mentally infirm involved in research, development, and demonstration activities, inasmuch as the potential subjects in such activities are: (1) Confined in an institutional setting; (2) might be unable fully to comprehend the type risks which may be involved; and (3) might be legally incompetent to consent to their participation in such activities.

Section 46.53 *Definitions.* As used in this subpart:

(a) "DHEW activity" means:

(1) The conduct or support (through grants, contracts, or other awards) of biomedical or behavioral research involving human subjects; or

(2) Research, development, or demonstration activities regulated by any DHEW agency.

(b) "Mentally infirm" includes the mentally ill, the mentally retarded, the emotionally disturbed, the psychotic, the senile, and others with impairments of a similar nature, regardless of whether or not the individual has been determined to be legally incompetent.

(c) "Institutionalized" means confined, whether by court order or voluntary commitment, in an institution for the care and/or treatment of the mentally infirm.

Section 46.54 *Limitations on activities involving the institutionalized mentally infirm.* No institutionalized mentally infirm individual may be included as a subject in a DHEW activity unless:

(a) The proposed activity is concerned with: (1) The diagnosis, treatment, prevention, or etiology of the impairment with which he or she is afflicted; or (2) the proposed activity is concerned with the effect of institutional life on the subject and involves no risk of harm to the subject; or (3) the information can be obtained only from such subjects.

(b) The individual's legal guardian has given consent to the individual's participation in such activity;

(c) Where the individual has sufficient mental competency to understand what is proposed and to express an opinion as to his or her participation, the individual's consent to such participation has also been secured; and

(d) The Protection Committee, provided for in § 46.56 of this subpart, has reviewed and approved subject participation in the activity (by class or by individual).

Section 46.55 *Additional duties of Organizational Review Committee where the mentally infirm are involved.* (a) In addition to its responsibilities under Subpart A of this part, the Organizational Review Committee shall, with respect to activities to which subpart applies:

(1) Certify that all aspects of the activity would be ethically appropriate for performance on healthy individuals;

(2) Conduct at least one on-site visit to the institution and prepare a report of the visit, including discussion of such matters as living conditions, availability of medical care, and quality of food, to be submitted to DHEW along with the application;

(3) Review and approve or modify the procedures proposed by the applicant to be followed by the Protection Committee, provided for in § 46.56, in overseeing the recruitment of the mentally infirm subjects who may be included in such activity;

(4) Recommend any additional functions to be performed by the Protection Committee in connection with any particular activity; and

(5) Carry out such other responsibilities as may be recommended by DHEW.

(b) Activities to which this subpart is applicable must provide for the designation of

an Organizational Review Committee where no such Committee has been established under subpart A.

Section 46.56 *Protection Committees; duties; composition.* (a) No activity covered by this subpart will be approved unless it provides for the establishment of a Protection Committee to carry out the following functions, as well as any others prescribed by the Organizational Review Committee or by DHEW: (1) Overseeing the process of selection of subjects who may be included in the activity, (2) monitoring the progress of the activity with special attention to adverse effects on subjects, (3) intervening on behalf of one or more of the subjects if conditions warrant, (4) evaluating the process and reasonableness of consent of the legal guardian and (where applicable) of the subject, and (5) advising the legal guardian and/or the subject concerning the latter's continued participation in the activity if conditions warrant.

(b) The composition of each Protection Committee shall conform to the requirements set forth in § 46.26(a).

(c) The Protection Committee shall establish rules of procedure for conducting its activities, which must be reviewed by DHEW, and shall conduct its activities at convened meetings, minutes of which shall be prepared and retained.

Section 46.57 *Activities to be performed outside the United States.* In addition to satisfying all other applicable requirements in this subpart, an activity to which this subpart is applicable, which is to be conducted outside the United States, must include written documentation satisfactory to DHEW that the proposed activity is acceptable under the legal, social, and ethical standards of the locale in which it is to be performed.

SUBPART F—GENERAL PROVISIONS

Section 46.61 *Applicability.* The following regulations are applicable to all activities covered by this part.

Section 46.62 *Records.* (a) Copies of all documents presented or required for initial and continuing review by any Organizational Review Committee or Protection Committee and minutes, transmittals on actions, instructions, and conditions resulting from committee deliberations are to be made part of the official files of the grantee or contractor for the supported activity.

(b) Records of subject's and representative's consent shall be retained by the grantee or contractor in accordance with its established practice, or, if no practice has been established, in project files.

(c) Acceptance of any DHEW grant or contract award shall constitute consent of the grantee or contracting organization to inspection and audit of records pertaining to the assisted activity by authorized representatives of the Secretary.

(d) All documents and other records required under this part must be retained by the grantee or contracting organization for a minimum of three years following termination of DHEW support of the activity.

Section 46.63 *Reports.* Each organization with an approved assurance shall provide the Secretary with such reports and other information as the Secretary may from time to time prescribe.

Section 46.64 *Early termination of awards; sanctions for noncompliance.* (a) If, in the judgment of the Secretary, an organization has failed to comply with the terms of this part with respect to a particular Federal activity, he may require that said grant or contract be terminated or suspended in the manner prescribed in applicable grant or procurement regulations.

(b) If, in the judgment of the Secretary, an organization fails to discharge its responsibilities for the protection of the rights and welfare of the subjects in its care, whether or not DHEW funds are involved, he may, upon reasonable notice to the organization of the basis for such action, determine that its eligibility to receive further DHEW grants or contracts or participate in DHEW assisted activities, involving human subjects, shall be terminated. Such disqualification shall continue until it is shown to the satisfaction of the Secretary that the reasons therefor no longer exist.

(c) If, in the judgment of the Secretary, an individual serving as principal investigator, program director, or other person having responsibility for the scientific and technical direction of a project or activity, has failed to discharge her or his responsibilities for the protection of the rights and welfare of human subjects in his or her care, the Secretary may, upon reasonable notice to the individual of the basis for such action, determine that such individual's eligibility to serve as a principal investigator or program director or in another similar capacity shall be terminated. Such disqualification shall

continue until it is shown to the satisfaction of the Secretary that the reasons therefor no longer exist.

Section 46.65 Conditions. The Secretary may with respect to any activity or any class of activities impose conditions, including conditions pertaining to informed consent, prior to or at the time of the approval of any activity when in the Secretary's judgment such conditions are necessary for the protection of human subjects.

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PART III



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of the Secretary



PROTECTION OF HUMAN SUBJECTS

Proposed Policy

DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE

Office of the Secretary

[45 CFR Part 46]

PROTECTION OF HUMAN SUBJECTS

Proposed Policy

In the FEDERAL REGISTER of May 30, 1974 (39 FR 18914), regulations were published as Part 46 of Title 45 of the Code of Federal Regulations providing generally for the protection of human subjects involved in research, development, or related activities supported by Department grants or contracts. At that time it was indicated that notices of proposed rulemaking would be developed concerning minors, fetuses, abortuses, prisoners, and the institutionalized mentally disabled.

Coincidentally with the development of the notice of proposed rulemaking set forth below, both Houses of Congress reached agreement on the "National Research Act," and the President signed P.L. 93-348 into law. Among other things, the Act establishes an eleven-member National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research to " * * (i) conduct a comprehensive investigation and study to identify the basic ethical principles which should underlie the conduct of biomedical and behavioral research involving human subjects, (ii) develop guidelines which should be followed in such research to assure that it is conducted in accordance with such principles, and (iii) make recommendations to the Secretary (I) for such administrative action as may be appropriate to apply such guidelines to biomedical and behavioral research conducted or supported under programs administered by the Secretary, and (II) concerning any other matter pertaining to the protection of human subjects of biomedical and behavioral research."

This notice of proposed rulemaking is published today to continue the public dialogue begun in November 1973 when the Director of the National Institutes of Health published draft proposals on these issues in the FEDERAL REGISTER. The comments addressed in this preamble are the result of that issuance.

The comments received as a result of this notice of proposed rulemaking will not only assist the Department to develop final regulations but will also be available to the Commission for their use during the course of their deliberations over the next two years.

In the light of the 450 responses received as a result of the November issuance, largely from grantee and contractor organizations, the Department now proposes that, in addition to the protection afforded generally to all subjects of research, development, and related activities supported by the Department by virtue of Part 46, further protective measures should be provided for those subjects of research whose capability of providing informed consent is or may be absent or limited.

This would be accomplished by amending Part 46 to delete § 46.19 through 46.22, redesignating § 46.1 through 46.18 as Subpart A, and adding new Subparts B through F. If this proposal is accepted, the regulations would be structured as follows:

Subpart A would be the basic regulation, substantially as promulgated on May 30, 1974. This provides that no activity involving any human subject at risk shall be supported by a DHEW grant or contract unless the applicant or offering organization has established an organizational review committee which has reviewed and approved such activity and submitted to DHEW a certification of such review and approval. This subpart also provides that all grant and contract proposals involving human subjects at risk are to be additionally evaluated by the Secretary for compliance with the requirements of said subpart.

Subpart B is reserved for a separate, future proposed rulemaking providing additional protection for children.

Subpart C as described in the present proposed rulemaking would call for the utilization of two special mechanisms for the protection of the pregnant woman and unborn child or fetus, where the pregnant woman participates in a research, development, or related activity. While these mechanisms are designed to allow sufficient flexibility for the pursuit of new information about the perinatal process, they are also designed to provide additional safeguards to assure that the research is acceptable from an ethical standpoint.

Subpart D as described in the present proposed rulemaking would give added responsibilities to an organizational review committee where the contemplated research would involve prisoners as subjects and also would require in such instances that a consent committee be established to supervise the selection and participation of prisoners in the research. Prisoner groups are particularly valuable in properly conducted clinical trials since they provide a stable subject population which can be followed over a period of weeks or months rather than days or hours. From the point of view of the prisoner subject, participation in research offers an opportunity to make a contribution to society and to provide an income, much as other jobs in prison do. Nevertheless, the dangers of abuse of prisoners' rights are obvious. For this reason, the proposed rulemaking calls for additional safeguards for the rights of prisoners whose capability to provide informed consent may be affected by the very fact of their incarceration.

Subpart E as described in the present proposed rulemaking offers additional protections for the rights of the mentally ill, the mentally retarded, the emotionally disturbed, and the senile who are confined to institutions, whether by voluntary or involuntary commitment. Such persons, by the very nature of their disabilities, may be severely limited in their capacity to provide informed consent to their participation in research. At the

same time, the nature of their disabilities requires extensive research efforts to the study of the etiology, pathogenesis, and therapy of their conditions. The proposed rulemaking limits the research in which such subjects may be allowed to participate to that which is most likely to be of assistance to them or to persons similarly disabled.

In developing the present proposed rulemaking, the Department has taken into consideration the public's comments relevant to certain parts of the Introduction, Definition, and General Policy Sections of the draft regulations published at 39 FR 18914, November 16, 1973, as well as to the draft regulations themselves. The major comments, and the Department's present proposals, are as follows:

INTRODUCTION, GENERAL POLICY
CONSIDERATIONS

A. Commentators suggested, in several different contexts, that the regulations should (i) apply to all research, regardless of the degree of risk or academic discipline concerned, and (ii) provide for the exclusion of certain types of research, particularly behavioral and social science research as distinguished from biomedical research.

The Department, having considered these comments, notes that the applicability provisions of the basic regulations (45 CFR 46.1) permit the Secretary to determine whether specific programs place subjects at risk. Such determination is to be made only after careful study and publication in the FEDERAL REGISTER, providing an opportunity for comment on the merits of each determination. With respect to research in the social sciences, the Department has already indicated its intention of issuing public rulemaking on this matter (see 39 FR 18914, paragraph A).

B. Comments also included suggestions that regulations should be proposed specifically dealing with activities involving students, laboratory employees, seriously ill or terminal patients, the non-institutionalized mentally disabled, and other special groups.

The Department considers that any abuses relating to these groups are less evident and that they are afforded the protection of the existing regulations published in 39 FR 18914.

C. Several comments suggested the provision of additional guidelines with respect to the distinction between established and accepted methods on the one hand and experimental procedures on the other.

While the Department recognizes the theoretical desirability of such guidelines, and that the practical necessity of making such a distinction is arising with increasing frequency, the feasibility of making this distinction on a generalized basis has yet to be demonstrated. At the moment a regulatory approach to this issue does not appear justified.

D. It was suggested that all meetings of organizational review committees and similar groups established pursuant to

these regulations should be open to the public.

The Department notes that since the purpose of these committees is, for the most part, to advise with respect to the conduct of individual projects and proposals by individual investigators, a blanket provision to this effect would appear to be inconsistent with the need to protect the confidentiality of the proceedings and records of institutional review and evaluation committees.

DEFINITIONS

A. Comments on the definition of "Subject at Risk" suggested changes in language that would (i) limit the concept of risk to that encountered only in addition to that normally experienced, (ii) eliminate demonstration projects as a possible source of risk, since these are nominally limited to application of established and accepted methods, (iii) specifically identify failure to maintain confidentiality as a source of risk, and (iv) provide a mechanism for identifying activities essentially free of risk.

These comments are similar to those made with respect to the same definition as incorporated in an earlier proposed rulemaking (38 FR 27882). In responding to the criticism, the Department has already (i) redefined "Subject at Risk" in 45 CFR 46.3(b) so as to exclude any activity which does not increase the ordinary risks of daily life or the recognized risks inherent in a chosen occupation or field of service, (ii) substituted in 45 CFR 46.1(a) the term "development" for "demonstration," (iii) provided in 45 CFR 46.19(b) specific prohibitions against disclosures of information which refers to or can be identified with a particular subject, and (iv) provided in 45 CFR 46.1(b) authority for determination in advance as to whether a particular Federal program or an investigational method or procedure may place subjects at risk.

B. Comments on the definition of "Clinical Research" suggested inclusion in said definition of the behavioral aspects of research and facets of medical research necessarily concerned with diagnosis and other nontherapeutic aspects of research.

Since the term "clinical research" does not occur in the present rulemaking, the Department reserves its opinion with respect to these suggestions. However, the proposed regulations are applicable to all departmental research, development, and related activities except with respect to Subpart C, where applicability is limited to "biomedical research" (§ 46.303(b)).

C. Comments on "Informed Consent" suggested the addition of language concerning (i) full and complete disclosure, (ii) the likelihood of success or failure of the experiment, (iii) the use of placebos or other control procedures, (iv) provision of information as to the progress of the research, (v) publication of names of all persons, institutions, and review committees involved in approval of consent procedures, (vi) provision of legal counsel and technical advice, and

(vii) assurance that the subject comprehends the disclosure.

The Department, having considered these comments, notes that "Informed Consent" is presently defined in 45 CFR 46.3(c) and not in the present proposed rulemaking. With respect to the specific suggestions the Department notes that: as far as (i) is concerned, the regulations already call for a "fair explanation" of the procedures and a description of risks and benefits reasonably to be expected; (ii) reflects a basic misunderstanding of the experimental process which begins, essentially, with the comparison of two or more methods, procedures, or modalities on the *a priori* hypothesis that there will be no difference; (iii) is implicit in the existing regulations and is better emphasized in interpretive materials; (iv) would not be an element of informed consent unless interim findings affected the risk of benefit involved; and (v) touches on the subject of a possible future proposed rulemaking and the Department reserves its options for the present. The suggestion in (vi) is met in part by the proposals in the present proposed rulemaking to employ consent committees to advise potential subjects. The last suggestion (vii) goes beyond requirements for informed consent as they have generally been articulated by the courts.

D. Comments also included suggestions for the inclusion of additional definitions of (i) Institutions, (ii) Legal Guardian, (iii) Organizational Review Committee, (iv) Institutionalized Mentally Infirm, and (v) Children (with regard to age of consent), Parents, and Father.

The Department, having reviewed these comments, notes that (i) "Organization" is defined for the purpose of these regulations to include "institutions" at 45 CFR 46.3(a); (ii) "Legally authorized representative" is defined for the purpose of these regulations to include legal guardian at 45 CFR 46.3(h); (iii) the definition of "organizational review committee" is implicit in 45 CFR 46.6; (iv) "Institutionalized mentally disabled" has been defined in the present proposed rulemaking at 46.503(d) to meet the suggestion; and (v) definition of "Children," "Parents," and "Father" will be reconsidered prior to the issuance of a future rulemaking covering research on children.

E. Several commentators criticized provisions of the draft policy that would have required that activities to be conducted outside the United States satisfy all requirements of the Department's regulations including those based on ethical concepts peculiar to the Judeo-Christian moral heritage or to English common law. It was noted that this would create substantial problems for United States investigators working overseas since these concepts are often inconsistent if not in conflict with normal, ethical, and legal concepts in certain foreign countries. For the same reasons, it was argued that these provisions would create problems for United States citizens assigned, detailed, seconded, or acting as consult-

ants to international organizations or to foreign governmental or private institutions.

Having considered these objections, the Department proposes to retain the basic concept that activities supported by Departmental funds should, in general, be subject to a uniform ethical policy wherever they are conducted, but to permit the Secretary to modify consent procedures if it can be demonstrated to his satisfaction that such procedures, as modified, are acceptable under the legal, social, and ethical standards of the locale in which the activities are to be performed.

FETUSES, ABORTUSES, AND PREGNANT WOMEN

Since comments on the draft provisions in 38 CFR 31738 providing additional protections for fetuses, abortuses, *in vitro* fertilization, and pregnant women were integrated with those on children, it is difficult to identify the communications specifically concerned with these subjects. However, it is estimated that the majority of the more than 400 letters received on research with children, born and unborn, touched on one or more aspects of research with fetuses, abortuses, and pregnant women.

A. A large number of respondents disagreed entirely with the idea of permitting research with the fetus, with the abortus (whether living or dead), or with the pregnant woman if the research might conceivably endanger the fetus.

The Department, having carefully considered these comments and similar proposals reflected in general correspondence and in articles in the public media, notes that their adoption would seriously hamper the development of needed improvements in the health care of the pregnant woman, the fetus, and the newborn. The opposition to research involvement of the fetus and abortus appears to be based in part on the assumption that the needed information can be obtained through research with animal species or with adults. Unfortunately, these assumptions are not valid. While much useful research can be conducted in animals, differences in species are nevertheless so great that any research finding in nonhuman species must ultimately be repeated in man before its general application in human medicine. In addition, the fetus and the newborn are not small adults. They suffer from some diseases not encountered in the adult. They may react differently to the diseases commonly affecting both adult and young, and they may have a different response to the same treatment, both with regard to its effectiveness and to its safety. The Department therefore proposes that (i) the ethical probity of any application or proposal for the support of any activity covered by subpart C be reviewed by an Ethical Advisory Board as described in § 46.304, and (ii) the conduct of any such activity supported by the Department be subject to oversight and monitoring by a consent committee as described in § 46.305.

B. Opinion was divided as to the need for an Ethical Advisory Board. Many respondents called it a welcome addition in the review process. Others felt that it would duplicate the function of the local organizational review committee and that its existence would encourage the organizational review committee to be less critical and would impose an additional roadblock that would delay or prohibit important research while needlessly consuming time, energy, and money, and posing potential danger to a patient waiting for treatment. Complaints were voiced that such decisions should be made locally, not in Washington, and that the investigator should be able to present his case in person. Numerous comments suggested that the Board's function should be limited to advising on policy, guidelines, or procedures, and not be concerned with the review of individual projects. This would avoid duplicating the function of the organizational review committee. Others suggested that the Ethical Advisory Board should serve as an appeal body from the organizational review committee.

There were also numerous comments to the effect that it is unwise and impossible to totally separate ethical and scientific review. Approval based only on ethics would be unethical if the science were bad. Both should be reviewed jointly.

The Department, having reviewed these comments, concludes that Ethical Advisory Board remains, in concept, a useful addition to the review process. It does not duplicate the functions of the local organizational review committee, since the latter is primarily concerned with matters of organizational regulations, local standards of professional practice, applicable law within its jurisdiction, and local community attitudes. The Ethical Advisory Board will be primarily concerned with similar issues at the national level. Applications and proposals should be capable of passing scrutiny at both levels. It is therefore proposed that the Ethical Advisory Board be retained as part of the additional protection mechanism.

Specific comments regarding the establishment of an Ethical Advisory Board touched principally on (i) the possibility that appointment of members at an agency level might lead to "loaded" Boards, while appointment at a higher level, i.e., by a joint Congressional committee or by independent outside bodies, might produce a more objective group, and (ii) disagreement as to the proper balance between scientist and nonscientist members, with a majority of the commentators suggesting that more than one-third of the members should have the scientific expertise necessary to identify risks and their possible consequences. It was specifically suggested that different sizes, compositions, and administrative locations of the Board be tried before selecting a final mechanism. In addition, it was suggested (iii) that a fifteen member Board was too large, (iv) that all members be human geneticists, (v) that at least one member be a psy-

chologist, if behavioral issues were to be considered, (vi) that there be an absolute ban on departmental agency employees, (vii) that all proceedings be confidential, (viii) that all meetings be open to the public, and (ix) that an appeal mechanism be established.

The Department, having considered these views, proposes that while an Ethical Advisory Board to deal with biomedical research involving fetuses, abortuses, pregnant women, and *in vitro* fertilization might logically be established at the National Institutes of Health, (i) the power of appointment should be reserved to the Secretary, (ii) while the membership should include research scientists, physicians, lawyers, clergy or ethicists, and representatives of the general public, the balance between callings should rest with the Secretary as should also (iii) the number of members, so that the membership (iv, v) can be adjusted to the needs of the Board as the workload and the issues before it dictate. The specific suggestion (see vi) that departmental agency employees be excluded is adopted and expanded to include all full-time employees of the Federal Government. The decisions with regard to suggestions (vii) and (viii) will be governed by the provisions of the Federal Advisory Committee Act which generally require that meetings of similar advisory groups be open to the public for the purposes of policy discussion, but closed and confidential for the purpose of review of specific applications and proposals. Since the Board will be advisory to funding agencies, the final action will be that of existing awarding authorities, and appeal mechanisms (ix) will be provided only to the extent available under other existing departmental regulations and policies. These proposals are incorporated into § 46.304.

C. A number of respondents recommended that the policy governing *in vitro* fertilization be strengthened, on the one hand, or liberalized, on the other. The Department has considered these recommendations, and has provisionally chosen not to stipulate at this time protections for the product of *in vitro* fertilization which is not implanted, but rather to leave that series of issues to the Ethical Advisory Board established under § 46.304 (a). The Board will be required to weigh, with respect to specific research proposals, the state of the art, legal issues, community standards, and the availability of guidelines to govern each research situation.

Because biomedical research is not yet near the point of being able to maintain for a substantial period the non-implanted product of *in vitro* fertilization, no clear and present danger arises from not stipulating in these regulations the protections for it. Given the state of the research, we believe that such stipulation would be premature.

It is the Department's intent that the definition of the term "fetus" (§ 46.303 (d)) be construed to encompass both the product of *in vivo* conception and the product of *in vitro* fertilization which is subsequently implanted in the donor

of the ovum. Whatever the nature of the conception process, it is intended that upon implantation the protections of subpart C apply to all fetuses. It is only with respect to the protections available to the non-implanted product of *in vitro* fertilization that the regulations are silent.

With respect to the fertilization of human ova *in vitro*, it is expected that the Board will consider the extent to which current technology permits the continued development of such ova, as well as the legal and ethical issues surrounding the initiation and disposition of the products of such research.

With respect to implantation of fertilized human ova, it is expected that the Board will consider such factors as the safety of the technique (with respect to offspring) as demonstrated in animal studies, and clarification of the legal responsibilities of the donor and recipient parent(s) as well as the research personnel.

Since the Department does reserve the option of later specifying such protections by regulation, we invite comment on the question of appropriate regulations in the future.

D. The draft proposals included a suggestion for the establishment of a protection committee which elicited numerous comments that the use of the term "protection committee" implies that the Department recognizes a clear, present need for protection against the investigator, the uncertain relation of this committee to the organizational review committee, and the uniform need for and desirability for such protection.

Having reviewed these comments, the Department proposes an extensive revision in this innovative concept. Initially, it acknowledges that the term "protection committee" is pejorative and proposes the term "consent committee" as more appropriate and consistent with the primary purpose of such bodies. Further, it proposes to eliminate specific requirements for the size and composition of such committees. Instead, applicants and offerors are to propose the establishment of such a committee, specifying its size, composition, and rules of procedure. In addition, where the applicant or offeror believes that the activity involves only negligible risks, it may ask the Secretary to waive or modify the requirement for a consent committee. All proposals for the establishment, modification, or waiver of a consent committee shall be subject to review and approval at the local level by the organizational review committee and at the departmental level by the Ethical Advisory Board. The Ethical Advisory Board may prescribe additional duties for the consent committee. These changes are incorporated in § 46.305. In view of this drastic change in concept of the committee, detailed discussion of the many excellent and often thought-provoking comments concerned with details of the original draft seems inappropriate.

E. Many critical comments were addressed to the definitions used in this subpart, specifically:

1. "Pregnancy." It was suggested that pregnancy should be defined (i) conceptually to begin at the time of fertilization of the ovum, and (ii) operationally by actual test unless the woman has been surgically rendered incapable of pregnancy.

While the Department has no argument with the conceptual definition as proposed above, it sees no way of basing regulations on the concept. Rather, in order to provide an administrable policy, the definition must be based on existing medical technology which permits confirmation of pregnancy. This approach is reflected by § 46.303(c).

2. "Viability of the Fetus". Many recommendations were received concerning the definition of viability of the fetus after premature delivery or abortion. Some respondents urged that presence of fetal heartbeats be definitive (whether or not there is respiration) while others urged that identifiable cortical activity be specified as an alternative sign of viability. The Department has concluded that the issue of viability is a function of technological advance, and therefore must be decided with reference to the medical realities of the present time. We reserve the option of redefining the parameters as conditions warrant.

Only upon the basis of a definition which is both precise and consistent with current medical capability can a regulation realistically be interpreted and enforced. Current technology is such that a fetus, given the benefit of available medical therapy, cannot survive unless the lungs can be inflated so that respiration can take place. Without this capability, even if the heart is beating, the fetus is nonviable. In the future, if technology has advanced to the point of sustaining a fetus with non-inflatable lungs, the definition can and should be modified.

The Department has therefore chosen to specify, in the definition of viability of the fetus (§ 46.303(e)), that heart beat and respiration are, jointly, to be the indicator of viability.

3. "Abortus." Various comments noted that this definition is more restrictive than the usual medical definition of the abortus as a "nonviable fetus," and suggested substitution of the broader definition.

The Department proposes to retain the original definition for the purposes of these regulations. There is general agreement that there are distinct ethical problems involved in decisions concerning research use of the intact fetus, or use of organs or tissues obtained from a fetus that has died *in utero* or from an abortus at autopsy. The definition recurs with minor editorial changes in § 46.303(f).

F. Several comments were critical of the draft regulation's provisions limiting activities involving pregnant women to those not adversely affecting the fetus, except where the primary purpose of the activity was to benefit the fetus. It was suggested that the regulations (i) should contain language permitting exceptions

for research necessary to meet the health needs of the mother, and (ii) should grant the right to participate in research aimed at improvement of methods of abortion, birth control, and genetic intervention.

The Department concurs with the first suggestion, (i), and proposes that the regulations permit research whose primary interest is to benefit the particular fetus or to respond to the health needs of the pregnant woman. It does not fully accept the second suggestion, (ii), and proposes that the regulations permit fetal research concerned with diagnosis and prevention of perinatal disease, and to offset the effects of genetic abnormality or congenital injury, but only when such research is done as part of a procedure properly performed to terminate a pregnancy. These changes are incorporated into § 46.306(a). The Department has tentatively concluded that consideration of risk vs. benefit with respect to fetal research does not seem to be appropriate.

G. Draft regulation provisions required maternal consent and the consent of the father if he were available and capable of participating in the consent process. This provision was strongly criticized on the grounds that it could permit the father of the fetus to deny needed health care to the woman or to the fetus even though he had no marital obligations, and that it might result in undue delay in the delivery of health care. It was also pointed out that the regulation did not touch on the question of the validity of consent by a pregnant minor.

The Department agrees. It is now proposed that paternal consent be sought only if the activity is not responding to the health needs of the pregnant woman and the father is reasonably available. These changes are reflected by § 46.306(b).

H. The Department has provisionally chosen, in § 46.306(a), to permit research to be undertaken from which there will be risk of harm to the fetus if such research is conducted as part of the abortion procedure. This decision, upon which we invite comment, has been made in the expectation that such research may produce new technology which will enable countless premature infants to live who now cannot.

It is not intended that this provision be construed to permit fetal research in anticipation of abortion prior to the commencement of the termination procedure itself.

While it is true that the class of fetuses for whom abortion is contemplated will be placed at greater research risk than all fetuses in general, such risk can arise only after implementation of the double safeguard of parental consent to the contemplated abortion, and second parental consent to the research procedure itself.

I. Comments regarding activities involving the abortus were concerned with the issue of maintaining vital functions and signs. It was argued that maintaining vital functions at the level of the organ, tissue, or cell is essential to studies

and involves no prolongation of the dying of the abortus. At the same time, it was argued that termination of the heart beat should not be prohibited since temporary cardiac arrest has proved essential in the development of surgical techniques necessary to correct congenital heart defects.

Neither of these objections appear valid and no significant changes in § 46.307 are proposed. However, in order to emphasize again the distinction between research with the whole fetus or abortus, functioning as an organism with detectable vital signs, and with the dead fetus or abortus, the Department has added § 46.308, concerning activities involving a dead fetus or abortus, and § 46.309, concerning the abortus as an organ or tissue donor. Also § 46.307(d) has been expanded to permit the artificial maintenance of vital functions of an abortus where the purpose is to develop new methods for enabling the abortus to survive to the point of viability.

The Department feels that there is evident distinction between "termination" and "arrest" of the clinical signs as applied to the fetus or premature infant, but that no such distinction is valid or applicable where the abortus is concerned.

PRISONERS

Forty-seven responses spoke to the provisions regarding additional protection for prisoners involved as subjects. Of these, two were from individuals identifying themselves as prisoners, seven were from State correctional institutions or State agencies, and four were from representatives of the pharmaceutical industry.

A. In comments directed at the overall nature of the draft regulations providing additional protection for prisoners, approximately equal numbers of respondents (i) denied that any significant additions were necessary, and (ii) proposed either the exclusion of prisoners from any research or experimentation not intended for the personal benefit of a prisoner, or highly restrictive regulations to accomplish the same purpose.

The Department, having reviewed these comments, has not been persuaded that any change should be made in the initial proposal.

B. A number of comments were concerned with the relationship between the existing organizational review committees and the proposed Protection Committee. It was pointed out by several that, as proposed, the two committees would not only have overlapping functions and authority but could operate independently of each other with conflicting directives and objectives that would not practicably provide additional protection of prisoners used as subjects.

The Department, recognizing the importance of preserving the authority of the organizational review committee as the primary institutional focus for the implementation of the Department of Health, Education, and Welfare regulations, proposes to assign to the organizational review committee the additional duties specified under § 46.404(a).

A committee auxiliary to the organizational review committee, now designated the consent committee, will have the character and responsibilities specified in § 46.406. In keeping with this modified position it should be noted that when the organizational review committee determines that an activity would involve no risk or negligible risk to any prisoner while serving as a subject, the organization may request the Secretary to consider a modification or waiver of the requirement for a consent committee.

C. Comments on the proposed prohibition of research involvement of persons awaiting arraignment, trial, or sentencing expressed doubts that these individuals should be denied the benefits of innovative procedures, particularly those concerned with sociological research.

The Department agrees that the uniform exclusion of any such person from research should not be mandatory and proposes to permit his participation in an activity as a subject when the risk is negligible and the intent of the activity is therapeutic for him or relates to the nature of his confinement. This modification is incorporated into § 46.406.

D. The draft requirement for DHEW accreditation of prison facilities as sites for the performance of research, development, and related activities involving prisoner subjects was severely criticized, principally because of the jurisdictional problems inherent in any attempt to impose a Federal regulatory requirement on an autonomous State facility.

The Department concludes that this draft proposal was ill-advised. However, in order to attain the objective on an activity basis, certain specific prerequisites for the protection of prisoner subjects within facilities have been added to § 46.404(a) to properly relate conditions in a facility to the issue of undue inducements to participation by prisoners as subjects in an activity.

MENTALLY DISABLED

Over 40 of the responses spoke directly to the section of the draft concerned with the "mentally infirm." Many of these objected initially to the use of the word "infirm" as reflecting an antiquated notion of mental illness.

The Department agrees, and proposes to substitute "disabled" for "infirm," though noting that there is no clearly preferable collective term for the groups described.

A. Comments on the purpose of this section expressed satisfaction with the intent to provide additional protection for this group but dissatisfaction with the actual language employed. Specifically, they noted that not institutionalization but rather the limitation of personal rights and freedom imposed by institutionalization is the determining issue. Similarly, it is not only the potential subject's difficulty in comprehending risks that is at issue, but his ability to comprehend generally.

The Department concurs. Proposed changes in language are incorporated in § 46.52.

B. Many of the respondents objected to one or more of the definitions peculiar to this subpart. The criticisms and the Department's proposed changes are as follows:

1. "Mentally infirm." In addition to requesting substitution of another term for "infirm," respondents raised conflicting objections to the definition's coverage. Some felt that it was overly inclusive; others felt it was too narrow. Some felt that epileptics should be specifically included, as well as those who are temporarily or permanently mentally incapacitated as a result of a physical condition such as stroke, brain damage, trauma, etc.

The Department, having carefully reviewed these comments, proposes no basic change in the definition. It concurs with many reviewers in the opinion that the definition is broad enough to include any category of subjects proposed for specific addition. Minor editorial changes have been made in § 46.503(b).

2. "Institutionalized." Commentators noted that (i) the regulations should cover all mentally disabled persons regardless of institutionalization, (ii) not all involuntary commitments are by order of a court, (iii) the draft refers to "residence" and "confinement" in similar contexts, though the terms do not carry the same connotation, and (iv) the definition does not specify halfway houses, lodges, day/night hospitals, nursing homes, and psychiatric wards of hospitals as places where subjects might be institutionalized.

The Department notes that (i) the non-institutionalized mentally disabled are covered by the existing regulations published as 39 FR 18914 and need not be included under these additional protections. Such individuals are not necessarily subject to all limitations on their freedom and rights as described in § 46.502 of this proposed rulemaking. Consideration will be given, however, to dealing with the noninstitutionalized legally incompetent who are mentally disabled in a subsequent notice of proposed rulemaking. With regard to (ii), the implication that court orders are the sole basis for involuntary confinement is incorrect and should be removed. Editorial changes have been made in § 46.503 to emphasize that concern therein is with those " * * * confined * * * in a residential institution * * *" (see iii) and, in order to designate the type of institutions concerned (see iv), it is proposed to separately define "Institutionalized mentally disabled individuals" in § 46.503 to include examples of such institutions. These changes are incorporated in § 46.503(c) and § 46.503(d).

C. While most respondents endorsed the intent of the draft limitations on activities involving the institutionalized mentally disabled, there were several specific criticisms of the terms used. Several persons suggested that any limitation of research to that related to a particular subject's "impairment" be worded so as to include any illness from which the person suffers so that, for ex-

ample, an institutionalized mentally disabled person with cancer could not be denied the benefits of research in cancer therapy.

Further, this limitation could exclude the use of such subjects as controls in research which might benefit those suffering from a mental disability other than the specific one from which a particular subject suffers. Still further, mentally disabled people should be involved as subjects in research on infirmities other than their own because of lack of knowledge of the causes of mental and emotional disorders.

Many respondents felt that there was inadequate recognition of the need for research with the mentally disabled on basic psychological processes (e.g., learning, perception, and cognitive functions) which are fundamental to the study of the treatment, etiology, pathogenesis, prevention, and treatment of such disabilities.

The Department agrees that the language of the draft limiting research to the disease entities affecting individual subjects is probably not in the interests of the institutionalized mentally disabled as a class. The Department does not agree that it would be appropriate to permit this class of subjects to be involved in research unrelated to the causes, nature, or circumstances of their institutionalization. While there are possible disadvantages to the institutionalized mentally disabled inherent in this restriction, the possible risks of using the mentally disabled in such research outweigh its advantages. The proposed changes are incorporated in § 46.504(a). Editorial changes are reflected in § 46.504(b) and § 46.504(c).

D. Criticisms of the draft's suggestion of the establishment of a protection committee in connection with each activity conducted in an institution for the mentally retarded were similar to those aimed at the protection committee to be established in connection with research on the pregnant woman and on the fetus. The Department proposes to change the title of the committee to "consent committee" and to change the regulations governing size, composition, and operating rules to conform to those previously described for § 46.305. Such changes are incorporated in § 46.506.

E. With respect to § 46.603(b), the Department reserves the right to amend this section if legislation now being developed by the Executive Branch on the safe guarding of individually linked data used for statistical and research purposes is enacted.

Written comments concerning the proposed regulation are invited from interested persons. Inquiries may be addressed and data, views, and arguments relating to the proposed regulations may be presented in writing, in triplicate, to the Chief, Institutional Relations Branch, Division of Research Grants, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20014. All comments received will be available for inspection at the National Institutes of

Health, Room 303, Westwood Building, 5333 Westbard Avenue, Bethesda, Maryland, weekdays (Federal holidays excepted) between the hours of 9:00 a.m. and 4:30 p.m. All relevant material received on or before November 21, 1974 will be considered.

Notice is also given that it is proposed to make any amendments that are adopted effective upon publication in the FEDERAL REGISTER.

Dated: August 15, 1974.

CASPAR W. WEINBERGER,
Secretary.

It is therefore proposed to amend Part 46 of Subtitle A of Title 45 of the Code of Federal Regulations by:

1. Revising §§ 46.19 through 46.23 and renumbering them as §§ 46.603 through 46.606, reading as set forth in Subpart F below.
2. Designating §§ 46.1 through 46.18 as Subpart A, renumbering these §§ 46.101 through 46.118, and modifying all references thereto accordingly.
3. Reserving Subpart B.
4. Adding the following new Subparts C through F.

Subpart C—Additional Protections Pertaining to Biomedical Research, Development, and Related Activities Involving Fetuses, Abortuses, Pregnant Women, and In Vitro Fertilization

- Sec.
- 46.301 Applicability.
 - 46.302 Purpose.
 - 46.303 Definitions.
 - 46.304 Ethical Advisory Board.
 - 46.305 Establishment of a consent committee.
 - 46.306 Activities involving fetuses *in utero* or pregnant women.
 - 46.307 Activities involving abortuses.
 - 46.308 Activities involving a dead fetus or abortus.
 - 46.309 Activities involving the abortus as an organ or tissue donor.
 - 46.310 Activities to be performed outside the United States.

Subpart D—Additional Protections Pertaining to Activities Involving Prisoners as Subjects

- 46.401 Applicability.
- 46.402 Purpose.
- 46.403 Definitions.
- 46.404 Additional duties of the organizational review committee where prisoners are involved.
- 46.405 Establishment of a consent committee.
- 46.406 Special restrictions.
- 46.407 Activities to be performed outside the United States.

Subpart E—Additional Protections Pertaining to Activities Involving the Institutionalized Mentally Disabled as Subjects

- 46.501 Applicability.
- 46.502 Purpose.
- 46.503 Definitions.
- 46.504 Activities involving the institutionalized mentally disabled.
- 46.505 Additional duties of the organizational review committee where the institutionalized mentally disabled are involved.
- 46.506 Establishment of a consent committee.
- 46.507 Activities to be performed outside the United States.

Subpart F—General Provisions

- 46.601 Applicability.

- Sec.
- 46.602 Multiple consent committee requirements.
- 46.603 Organization's record; confidentiality.
- 46.604 Reports.
- 46.605 Early termination of awards; evaluation of subsequent applications.
- 46.606 Conditions.
- 46.607 Activities conducted by Department employees.

AUTHORITY: 5 U.S.C. 301.

Subpart C—Additional Protections Pertaining to Biomedical Research, Development, and Related Activities Involving Fetuses, Abortuses, Pregnant Women, and In Vitro Fertilization

§ 46.301 Applicability.

(a) The regulations in this subpart are applicable to all Department of Health, Education, and Welfare grants and contracts supporting biomedical research, development, and related activities involving: (1) the fetus *in utero*, (2) the abortus, as that term is defined in § 46.303, (3) pregnant women, and (4) *in vitro* fertilization. In addition, these regulations are applicable to all such activities involving women who could become pregnant, except where the applicant or offeror shows to the satisfaction of the Secretary that adequate steps will be taken in the conduct of the activity to avoid involvement of women who are pregnant.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will in any way render inapplicable pertinent State or local laws bearing upon activities covered by this subpart.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.302 Purpose.

It is the purpose of this subpart to provide additional safeguards in reviewing activities to which this subpart is applicable to assure that they conform to appropriate ethical standards and relate to important societal needs.

§ 46.303 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health, Education, and Welfare or any other officer or employee of the Department of Health, Education, and Welfare to whom authority has been delegated.

(b) "Biomedical research, development, and related activities" means research, development, or related activities involving biological study (including but not limited to medical or surgical procedures, withdrawal or removal of body tissue or fluid, administration of chemical substances or input of energy, deviation from normal diet or hygiene, and manipulation or observation of bodily processes).

(c) "Pregnancy" encompasses the period of time from confirmation of implantation until delivery.

(d) "Fetus" means the product of conception from the time of implantation to the time of delivery.

(e) "Viability of the fetus" means the

ability of the fetus, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat and respiration. If the fetus has this ability, it is viable and therefore a premature infant.

(f) "Abortus" means a fetus when it is expelled whole, prior to viability, whether spontaneously or as a result of medical or surgical intervention. The term does not apply to the placenta; fetal material which is macerated at the time of expulsion; or cells, tissue, or organs excised from a dead fetus.

(g) "*In vitro* fertilization" means any fertilization of human ova which occurs outside the body of a female, either through admixture of donor sperm and ova or by any other means.

§ 46.304 Ethical Advisory Board.

(a) All applications or proposals for the support of activities covered by this subpart shall be reviewed by an Ethical Advisory Board, established by the Secretary within the National Institutes of Health, which shall advise the funding agency concerning the acceptability of such activities from an ethical standpoint.

(b) Members of the Board shall be so selected that the Board will be competent to deal with medical, legal, social, and ethical issues and shall include, for example, research scientists, physicians, lawyers, and clergy and/or ethicists, as well as representatives of the general public. No Board member may be a regular, full-time employee of the Federal Government.

§ 46.305 Establishment of a consent committee.

(a) Except as provided in paragraph (c) of this section, no activity covered by this subpart may be supported unless the applicant or offeror has provided an assurance acceptable to the Secretary that it will establish a consent committee (as provided for in the application or offer and approved by the Secretary) for each such activity, to oversee the actual process by which individual consents required by this subpart are secured, to monitor the progress of the activity and intervene as necessary, and to carry out such other duties as the Secretary (with the advice of the Ethical Advisory Board) may prescribe. The duties of the consent committee may include:

(1) Participation in the actual selection process and securing of consents to assure that all elements of a legally effective informed consent, as outlined in § 46.3, are satisfied. Depending on what may be prescribed in the application or offer approved by the Secretary, this might require approval by the committee of individual participation in the activity or it might simply call for verification (e.g., through sampling) that procedures prescribed in the approved application or offer are being followed.

(2) Monitoring the progress of the activity. Depending on what may be prescribed in the application or offer approved by the Secretary, this might

include: visits to the activity site, identification of one or more committee members who would be available for consultation with those involved in the consent procedure (i.e., participants) at the participant's request, continuing evaluation to determine if any unanticipated risks have arisen and that any such risks are communicated to the participants, periodic contact with the participants to ascertain whether they remain willing to continue in the activity, providing for the withdrawal of any participants who wish to do so, and authority to terminate participation of one or more participants with or without their consent where conditions warrant.

(b) The size and composition of the consent committee must be approved by the Secretary, taking into account such factors as: (1) the scope and nature of the activity; (2) the particular subject groups involved; (3) whether the membership has been so selected as to be competent to deal with the medical, legal, social, and ethical issues involved in the activity; (4) whether the committee includes sufficient members who are unaffiliated with the applicant or offeror apart from membership on the committee; and (5) whether the committee includes sufficient members who are not engaged in research, development, or related activities involving human subjects. The committee shall establish rules of procedure for carrying out its functions and shall conduct its business at convened meetings, with one of the members designated as chairperson.

(c) Where a particular activity, involving fetuses *in utero* or pregnant women, presents negligible risk to the fetus, an applicant or offeror may request the Secretary to modify or waive the requirement in paragraph (a) of this section. If the Secretary finds that the risk is indeed negligible and other adequate controls are provided, he may (with the advice of the Ethical Advisory Board) grant the request in whole or in part.

(d) The requirements of this section and § 46.304 do not obviate the need for review and approval of the application or offer by the organizational review committee, to the extent required under Subpart A of this part.

§ 46.306 Activities involving fetuses in utero or pregnant women.

(a) No activity to which this subpart is applicable, involving fetuses *in utero* or pregnant women, may be undertaken unless: (1) the purpose of the activity is to benefit the particular fetus or to respond to the health needs of the mother, or (2) the activity conducted as part of (but not prior to the commencement of) a procedure to terminate the pregnancy and is for the purpose of evaluating or improving methods of prenatal diagnosis, methods of prevention of premature birth, or methods of intervention to offset the effects of genetic abnormality or congenital injury.

(b) Activities covered by this subpart which are permissible under paragraph (a) of this section may be conducted

only if the mother and father are legally competent and have given their consent, except that the father's consent need not be secured if: (1) the purpose of the activity is to respond to the health needs of the mother or (2) his identity or whereabouts cannot reasonably be ascertained.

(c) Activities covered by this subpart which are permissible under paragraph (a) (2) of this section may not be undertaken unless individuals engaged in the research will have no part in: (1) any decisions as to the timing, method, or procedures used to terminate the pregnancy, and (2) determining the viability of the fetus at the termination of the pregnancy.

§ 46.307 Activities involving abortuses.

No activity to which this subpart is applicable, involving an abortus, may be undertaken unless:

(a) Appropriate studies on animals have been completed;

(b) The mother and father are legally competent and have given their consent, except that the father's consent need not be secured if his identity or whereabouts cannot reasonably be ascertained;

(c) Individuals engaged in the research will have no part in: (1) any decisions as to the timing, method, or procedures used to terminate the pregnancy, and (2) determining the viability of the fetus at the termination of the pregnancy;

(d) Vital functions of an abortus will not be artificially maintained except where the purpose of the activity is to develop new methods for enabling the abortus to survive to the point of viability; and

(e) Experimental procedures which would terminate the heart beat or respiration of the abortus will not be employed.

§ 46.308 Activities involving a dead fetus or abortus.

Activities involving a dead fetus or abortus shall be conducted in accordance with any applicable State or local laws governing autopsy.

§ 46.309 Activities involving the abortus as an organ or tissue donor.

Activities involving the abortus as an organ or tissue donor shall be conducted in accordance with any applicable State or local laws governing transplantation or anatomical gifts.

§ 46.310 Activities to be performed outside the United States.

Activities to which this subpart is applicable, to be conducted outside the United States, are subject to the requirements of this subpart, except that the consent procedures specified herein may be modified if it is shown to the satisfaction of the Secretary that such procedures, as modified, are acceptable under the laws and regulations of the country in which the activities are to be performed and that they comply with the requirements of Subpart A of this part.

Subpart D—Additional Protections Pertaining to Activities Involving Prisoners as Subjects

§ 46.401 Applicability.

(a) The regulations in this subpart are applicable to all Department of Health, Education, and Welfare grants and contracts supporting research, development, and related activities involving prisoners as subjects.

(b) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.402 Purpose.

It is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable, inasmuch as, because of their incarceration, they may be under constraints which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate in such activities.

§ 46.403 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health, Education, and Welfare or any other officer or employee of the Department of Health, Education, and Welfare to whom authority has been delegated.

(b) "Prisoner" means any individual involuntarily confined in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute and also individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution.

§ 46.404 Additional duties of the organizational review committee where prisoners are involved.

(a) In addition to the responsibilities prescribed for such committees under Subpart A of this part, the applicant's or offeror's organizational review committee shall, with respect to activities covered by this subpart, carry out the following additional duties:

(1) Determine that there will be no undue inducements to participation by prisoners as subjects in the activity, taking into account such factors as whether the earnings, living conditions, medical care, quality of food, and amenities offered to participants in the activity would be better than those generally available to the prisoners;

(2) Determine that (i) all aspects of the activity would be appropriate for performance on nonprisoners, or (ii) the activity involves negligible risk to the subjects and is for the purpose of studying the effects of incarceration on such subjects;

(3) Determine that the application or proposal contains adequate procedures for selection of subjects, securing consents, monitoring continued subject participation, and assuring withdrawal with-

out prejudice, in accordance with § 46.405 of this subpart;

(4) Determine that rates of remuneration are consistent with the anticipated duration of the activity, but not in excess of that paid for other employment generally available to inmates of the facility in question, and that withdrawal from the project for medical reasons will not result in loss of anticipated remuneration; and

(5) Carry out such other responsibilities as may be assigned by the Secretary.

(b) Applicants or offerors seeking support for activities covered by this subpart must provide for the designation of an organizational review committee, subject to approval by the Secretary, where no such committee has been established under Subpart A of this part.

(c) No award may be issued until the applicant or offeror has certified to the Secretary that the organizational review committee has made the determinations required under paragraph (a) of this section.

§ 46.405 Establishment of a consent committee.

(a) Except as provided in paragraph (c) of this section, no activity covered by this subpart may be supported unless the applicant or offeror has provided an assurance acceptable to the Secretary that it will establish a consent committee (as provided for in the application or offer and approved by the organizational review committee and the Secretary) for each such activity, to oversee the actual process by which individual subjects are selected and their consents secured, to monitor the progress of the activity (including visits to the activity site on a regular basis) and the continued willingness of the subjects to participate, to intervene on behalf of one or more subjects if conditions warrant, and to carry out such other duties as the Secretary may prescribe. The duties of the consent committee may include:

(1) Participation in the actual process by which individual subjects are selected and their consents secured to assure that all elements of a legally effective informed consent, as outlined in section 46.3 of this part, are satisfied. Depending on what may be prescribed in the application or offer approved by the Secretary, this might require approval by the committee of each individual's participation as a subject in the activity or it might simply call for verification (e.g., through sampling) that procedures prescribed in the approved application or offer are being followed.

(2) Monitoring the progress of the activity and the continued willingness of subjects to participate. Depending on what may be prescribed in the application or offer approved by the Secretary, this might include: visits to the activity site, identification of one or more committee members who would be available for consultation with subjects at the subjects' request, continuing evaluation to determine if any unanticipated risks have arisen and that any such risks are communicated to the subjects, periodic contact with the subjects to ascertain

whether they remain willing to continue in the study, providing for the withdrawal of any subjects who wish to do so, and authority to terminate participation of one or more subjects with or without their consent where conditions warrant.

(b) The size and composition of the consent committee must be approved by the Secretary, taking into account such factors as: (1) the scope and nature of the activity; (2) the particular subject groups involved; (3) whether the membership has been so selected as to be competent to deal with the medical, legal, social, and ethical issues involved in the activity; (4) whether the committee includes a prisoner or a representative of an organization having as a primary concern protection of prisoners' interests; (5) whether the committee includes sufficient members who are unaffiliated with the applicant or offeror apart from membership on the committee; and (6) whether the committee includes sufficient members who are not engaged in research, development, or related activities involving human subjects. The committee shall establish rules of procedure for carrying out its functions and shall conduct its business at convened meetings, with one of its members designated as chairperson.

(c) Where a particular activity involves negligible risk to the subjects, an applicant or offeror may request the Secretary to modify or waive the requirement in paragraph (a) of this section. If the Secretary finds that the risk is indeed negligible and other adequate controls are provided, he may grant the request in whole or in part.

§ 46.406 Special restrictions.

Persons detained in a correctional facility pending arraignment, trial, or sentencing or in a hospital facility for pre-arraignment, pre-trial, or pre-sentence diagnostic observation are excluded from participation in activities covered by this subpart, unless (a) the organizational review committee finds that the particular activity involves only negligible risk to the subjects and (b) the activity is therapeutic in intent or relates to the nature of their confinement.

§ 46.407 Activities to be performed outside the United States.

Activities to which this subpart is applicable, to be conducted outside the United States, are subject to the requirements of this subpart, except that the consent procedures specified herein may be modified if it is shown to the satisfaction of the Secretary that such procedures, as modified, are acceptable under the laws and regulations of the country in which the activities are to be performed and that they comply with the requirements of Subpart A of this part.

Subpart E—Additional Protections Pertaining to Activities Involving the Institutionalized Mentally Disabled as Subjects

§ 46.501 Applicability.

(a) The regulations in this subpart are applicable to all Department of

Health, Education, and Welfare grants and contracts supporting research, development, and related activities involving the institutionalized mentally disabled as subjects.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will necessarily result in a legally effective consent under applicable State or local law to a subject's participation in such an activity; nor in particular does it obviate the need for court approval of such participation where court approval is required under applicable State or local law in order to obtain a legally effective consent.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.502 Purpose.

It is the purpose of this subpart to provide additional safeguards for the protection of the institutionalized mentally disabled involved in activities to which this subpart is applicable, inasmuch as: (a) they are confined in an institutional setting where their freedom and rights are potentially subject to limitation; (b) they may be unable to comprehend sufficient information to give an informed consent, as that term is defined in § 46.103; and (c) they may be legally incompetent to consent to their participation in such activities.

§ 46.503 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health, Education, and Welfare or any other officer or employee of the Department of Health, Education, and Welfare to whom authority has been delegated.

(b) "Mentally disabled" includes those institutionalized individuals who are mentally ill, mentally retarded, emotionally disturbed, or senile, regardless of their legal status or basis of institutionalization.

(c) "Institutionalized" means confined, whether by voluntary admission or involuntary commitment, in a residential institution for the care or treatment of the mentally disabled.

(d) "Institutionalized mentally disabled individuals" includes but is not limited to patients in public or private mental hospitals, psychiatric patients in general hospitals, inpatients of community mental health centers, and mentally disabled individuals who reside in halfway houses or nursing homes.

§ 46.504 Activities involving the institutionalized mentally disabled.

Institutionalized mentally disabled individuals may not be included in an activity covered by this subpart unless:

(a) The proposed activity is related to the etiology, pathogenesis, prevention, diagnosis, or treatment of mental disability or the management, training, or rehabilitation of the mentally disabled and seeks information which cannot be obtained from subjects who are not institutionalized mentally disabled;

(b) The individual's legally effective informed consent to participation in the

activity or, where the individual is legally incompetent, the informed consent of a representative with legal authority so to consent on behalf of the individual has been obtained; and

(c) The individual's assent to such participation has also been secured, when in the judgment of the consent committee he or she has sufficient mental capacity to understand what is proposed and to express an opinion as to his or her participation.

§ 46.505 Additional duties of the organizational review committee where the institutionalized mentally disabled are involved.

(a) In addition to the responsibilities prescribed for such committees under Subpart A of this part, the applicant's or offeror's organizational review committee shall, with respect to activities covered by this subpart, carry out the following additional duties:

(1) Determine that all aspects of the activity meet the requirements of § 46.50 (a) of this subpart;

(2) Determine that there will be no undue inducements to participation by individuals as subjects in the activity, taking into account such factors as whether the earnings, living conditions, medical care, quality of food, and amenities offered to participants in the activity would be better than those generally available to the mentally disabled at the institutions;

(3) Determine that the application or proposal contains adequate procedures for selection of subjects, securing consents, protecting confidentiality, and monitoring continued subject participation, in accordance with § 46.506 of this subpart; and

(4) Carry out such other responsibilities as may be assigned by the Secretary.

(b) Applicants or offerors seeking support for activities covered by this subpart must provide for the designation of an organizational review committee, subject to approval by the Secretary, where no such committee has been established under Subpart A of this part.

(c) No award may be issued until the applicant or offeror has certified to the Secretary that the organizational review committee has made the determinations required under paragraph (a) of this section.

§ 46.506 Establishment of a consent committee.

(a) Except as provided in paragraph (c) of this section, no activity covered by this subpart may be supported unless the applicant or offeror has provided a separate assurance acceptable to the Secretary that it will establish a consent committee (as provided for in the application or offer and approved by the organizational review committee and the secretary) for each such activity, to oversee the actual process by which individual subjects are selected and consents required by this subpart are secured, to monitor the progress of the activity (including visits to the activity site on a regular basis) and the continued willing-

ness of the subjects to participate, to intervene on behalf of one or more subjects if conditions warrant, and to carry out such other duties as the Secretary may prescribe. The duties of the consent committee may include:

(1) Participation in the actual process by which individual subjects are selected and their consents secured to assure that all elements of a legally effective informed consent, as outlined in § 46.3, are satisfied. Depending on what may be prescribed in the application or offer approved by the Secretary, this might require approval by the committee of each individual's participation as a subject in the activity or it might simply call for verification (e.g., through sampling) that procedures prescribed in the approved application or offer are being followed.

(2) Monitoring the progress of the activity and the continued willingness of subjects to participate. Depending on what may be prescribed in the application or offer approved by the Secretary, this might include: visits to the activity site, identification of one or more committee members who would be available for consultation with subjects at the subjects' request, continuing evaluation to determine if any unanticipated risks have arisen and that any such risks are communicated to the subjects, periodic contact with the subjects to ascertain whether they remain willing to continue in the study, providing for the withdrawal of any subjects who wish to do so, and authority to terminate participation of one or more subjects with or without their consent where conditions warrant.

(b) The size and composition of the consent committee must be approved by the Secretary, taking into account such factors as: (1) the scope and nature of the activity; (2) the particular subject groups involved; (3) whether the membership has been so selected as to be competent to deal with the medical, legal, social, and ethical issues involved in the activity; (4) whether the committee includes sufficient members who are unaffiliated with the applicant or offeror apart from membership on the committee; and (5) whether the committee includes sufficient members who are not engaged in research, development, or related activities involving human subjects. The committee shall establish rules of procedure for carrying out its functions and shall conduct its business at convened meetings, with one of its members designated as chairperson.

(c) Where a particular activity involves negligible risk to the subjects, an applicant or offeror may request the Secretary to modify or waive the requirement in paragraph (a) of this section. If the Secretary finds that the risk is indeed negligible and other adequate controls are provided, he may grant the request in whole or in part.

§ 46.507 Activities to be performed outside the United States.

Activities to which this subpart is applicable, to be conducted outside the

United States, are subject to the requirements of this subpart, except that the consent procedures specified herein may be modified if it is shown to the satisfaction of the Secretary that such procedures, as modified, are acceptable under the laws and regulations of the country in which the activities are to be performed and that they comply with the requirements of Subpart A of this part.

Subpart F—General Provisions

§ 46.601 Applicability.

Sections 46.602 through 46.606 are applicable to all grant or contract supported activities covered by this part.

§ 46.602 Multiple consent committee requirements.

Where an application or proposal would involve human subjects covered by more than one consent committee requirement imposed under this part, upon approval by the Secretary, these multiple requirements may be satisfied through use of a single consent committee appropriately constituted to take account of the nature of the subject group.

§ 46.603 Organization's records; confidentiality.

(a) Copies of all documents presented or required for initial and continuing review by the organization's review committee or consent committee, such as committee minutes, records or subjects' consent, transmittals on actions, instructions, and conditions resulting from committee deliberations addressed to the activity director, are to be retained by the organization, subject to the terms and conditions of grant and contract awards.

(b) Except as otherwise provided by law, information in the records or possession of an organization acquired in connection with an activity covered by this part, which information refers to or can be identified with a particular subject, may not be disclosed except:

(1) With the consent of the subject or his legally authorized representative; or

(2) As may be necessary for the Secretary to carry out his responsibilities under this part in the exercise of oversight for the protection of such subject or class of subjects.

§ 46.604 Reports.

Each organization with an approved assurance shall provide the Secretary with such reports and other information as the Secretary may from time to time prescribe.

§ 46.605 Early termination of awards; evaluation of subsequent applications.

(a) If, in the judgment of the Secretary, an organization has failed materially to comply with the terms of this policy with respect to a particular Department of Health, Education, and Welfare grant or contract, he may require that said grant or contract be terminated or suspended in the manner prescribed in applicable grant or procurement regulations.

(b) In evaluating proposals or applications for support of activities covered by this part, the Secretary may take into account, in addition to all other eligibility requirements and program criteria, such factors as: (1) whether the offeror or applicant has been subject to a termination or suspension under paragraph (a) of this section, (2) whether the offeror or applicant or the person who would direct the scientific and technical aspects of an activity has in the judgment of the Secretary failed materially to discharge his, her, or its responsibility for the protection of the rights and welfare of subjects and (3) whether, where

past deficiencies have existed in discharging such responsibility, adequate steps have in the judgment of the Secretary been taken to eliminate these deficiencies.

§ 46.606 Conditions.

The Secretary may with respect to any grant or contract or any class of grants or contracts impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary for the protection of human subjects.

§ 46.607 Activities conducted by Department employees.

The regulations of this part (except for this subpart) are applicable as well to all research, development, and related activities conducted by employees of the Department of Health, Education and Welfare, except that: (a) subpart C is applicable only to biomedical research, development, and related activities and (b) each agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint.

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