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Document Title: Assessing the Informed-Assent Procedure for the National Survey of Youth in Custody (NSYC)

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Abstract

The National Survey of Youth in Custody (NSYC) collected data from approximately 11,000 adjudicated youth about sexual contacts that occurred while residing in juvenile facilities. Due to the nature of this research request, an assent protocol was developed and implemented to ensure that youth understood the core elements of the survey. The protocol consisted of an interviewer reading scripted text to a youth and assessing comprehension based on responses to six questions about the nature of participation and study procedures (e.g., voluntary participation, confidentiality). This research describes how often youth understood the consent and examines correlates related to youth and interviewer characteristics.

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Introduction

Background: All research studies must obtain informed consent, request a waiver from adults, or obtain assent from minors.¹ A significant proportion of potential research subjects fail to comprehend the meaning of core elements of the information presented during the consent process (Behrendt et al., 2011; Miller & Emanuel, 2008; Rounsaville et al., 2008). The National Survey of Youth in Custody (NSYC) collected data from approximately 11,000 adjudicated youth about sexual contacts that occurred while residing in juvenile facilities. Because of the nature of this research request—the vulnerability of the study population, the sensitive nature of the survey topic, and the complexity of study procedures used to minimize risks—an assent protocol was developed and implemented to ensure that youth understood the core elements of the survey. The protocol consisted of an interviewer reading scripted text to a youth and assessing the youth’s comprehension based on responses to six questions about the nature of participation and study procedures (e.g., voluntary participation, confidentiality).

This research addresses three questions:

- (1) What percentage of youth understood the informed assent?
- (2) Are youth and interviewer characteristics correlated with youth’s understanding of assent?
- (3) Is understanding the assent related to completing the survey and understanding survey questions?

Method: Descriptive and chi-square analyses were used to assess differences among youth who fully understood the assent procedure, needed questions repeated or paraphrased, or failed to understand. Hierarchical Generalized Linear Models were estimated to control for the effects of interviewers.

Results: The analyses demonstrated the need to provide assistance to individuals who are asked to participate in research—especially to minimize risks for vulnerable youth who are asked to volunteer for studies involving complex procedures. Approximately 28% of youth initially did not understand at least one of the concepts described in the assent materials without assistance (i.e., repetition,

¹This research presents findings from the National Survey of Youth in Custody. The research population consisted mostly of minors. However, some persons ages 18 to 30 were also asked to participate. Recognizing the legal differences between assent and consent, terms are used interchangeably.

paraphrasing). Youth's sex, race, and age were all significantly associated with comprehension. Females were more likely than males to demonstrate comprehension without assistance. Also, the proportion of white youth who responded correctly to the comprehension questions without assistance was higher than proportions of youth from the other race or Hispanic origin groups. Overall comprehension of the assent increased with youth's age. Once assistance was provided, there was no difference in rates of comprehension across sex, race, or age categories.

Findings also indicate a link between comprehension, willingness to participate in research, and the ability to understand survey questions. Those who needed assistance with the assent materials were less likely to complete the survey. If they completed the survey, they were more likely to express difficulty in understanding some survey questions or to provide inconsistent responses within the survey.

Analysis of interviewer characteristics showed that neither the sex nor race of the interviewer was significantly associated with youth's comprehension. However, an interviewer's Hispanic origin significantly predicted comprehension among Hispanic youth.

Implications: This study has implications for the administration of assent protocols that involve complex conditions, especially when youth held in juvenile facilities are the subjects. Findings show that reading assent text may not be sufficient to ensure that youth comprehend the information necessary to make an informed decision, including the voluntary nature of participation and issues associated with data confidentiality. Ensuring voluntary participation is a key aspect of protecting research subjects. Furthermore, youth held in facilities are more likely to have educational deficiencies that may prevent them from fully understanding the research request and their rights without additional steps to ensure comprehension (Sedlak & Bruce, 2010). Incorporating a method of assessing comprehension and providing assistance to potential research subjects is warranted.

Background

The research presented in this report focuses on a procedure that was implemented to assist incarcerated youth to become fully informed as part of the assent and consent process. Established in 1949, federal rules and regulations for obtaining informed consent are based on a set of ethical principles stating that “the voluntary consent of the human subject is absolutely essential” and—

each person involved should have legal capacity to give consent, be able to exercise free power of choice, and have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him/her to make an understanding and enlightened decision. (Nuremberg Military Tribunals, 1949, pp. 181-182)

Along with the Belmont Report (1978) and the Declaration of Helsinki (2002), these principles became the basis for the Code of Federal Regulations, Title 45 Part 46 (45 C.F.R. § 46), issued by the U.S. Department of Health and Human Services (2009), governing federally funded human subjects research. Regulations provide additional protections for children, as this population has been characterized as lacking resources and maturity to make decisions on their own behalf.² Prisoners and jail inmates are also provided additional protections under the regulations because of their increased susceptibility to coercion.³

These regulations require that interviewers inform potential subjects about the nature of the research and obtain their consent before involving them in any study activities. Information that must be conveyed includes—

- a statement that the study involves research and is voluntary
- an explanation of the purpose and procedures
- expected duration of participation
- experimental procedures and disclosure of alternatives to participation (if applicable)
- risks and benefits to the subject or others
- procedures to maintain confidentiality of data

²Subpart D. 45 C.F.R. 46 § 401-409.

³45 C.F.R. 46 § 301-306.

- contact information to get answers about the research and the research participant's rights.

This process becomes more challenging when the subjects are children, who are considered a vulnerable group within the regulations. It becomes even more challenging when conducting research with doubly vulnerable populations, such as youth in juvenile facilities. To foster comprehension among potential research subjects, consent forms should be short, written at a sixth- to eighth-grade reading level, and avoid complicated terminology (Comprehensive Working Group, 1998). Factors associated with the study design may sometimes complicate the application of these suggestions, such as the type and topics of research conducted.

To help address these challenges, several studies have either measured the quality of the informed consent process or evaluated various interventions to improve the process. Strategies range from improving the format and length of the consent form, adding quizzes to test participants' understanding of the information presented, and including multimedia interventions (e.g., use of audio, video, or interactive computers) (Flory & Emanuel, 2004; Palmer et al., 2012). It appears that a successful consent process must include some combination of these methods and a well-trained and knowledgeable person to conduct the consent process (Cohn & Larson, 2007).

Numerous studies have assessed the ability of adults and children to understand the text used to gather informed consent. In one review of 29 studies examining children's competence to assent, results demonstrated that participants were more capable of understanding the concepts of voluntary choice, and the right to withdraw at any time during participation, than of understanding the purpose, risks, and benefits of the research (Miller & Emanuel, 2008). Other studies have demonstrated that potential research participants do not read the informed consent form or do not understand or retain the information presented (Behrendt et al., 2011). Finally, the existing literature suggests that the training and knowledge of the person who administers the informed consent process may influence the level of comprehension among adults (Cohn & Larson, 2007).

Comprehension Issues with Informed Assent in the National Survey of Youth in Custody

The National Survey of Youth in Custody (NSYC), sponsored by the U.S. Department of Justice, Bureau of Justice Statistics (BJS), stemmed from the Prison Rape Elimination Act of 2003 (PREA; P.L. 108-79), which called for a “comprehensive statistical review and analysis of the incidence and effects of prison rape,” including assaults experienced by youth in custody.⁴ In 2012, during the second national study (NSYC-2), nearly 11,000 youth from 326 juvenile facilities nationwide were approached for participation. In addition to a target population considered to be vulnerable in two ways (i.e., status as a minor and being incarcerated), unique features of the study posed special challenges to providing youth with the information needed to make an informed decision about participating in NSYC-2. One such challenge was the sensitive nature of the study topics. The main questionnaire asked youth about being sexually assaulted by another youth or staff member while in the facility. Second, the survey protocols had special conditions that limited the scope of confidentiality and mandatory reporting. Researchers made efforts to develop youths’ understanding of these conditions. Third, youth needed to understand that participating in the survey could result in emotional distress and learn what could be done to minimize risk.

Youth living in juvenile facilities are more likely than youth in the general population to demonstrate educational deficiencies, which may impede their ability to comprehend assent information. Findings from the Survey of Youth in Residential Placement (SYRP) showed that at the time they were taken into custody, incarcerated youth (76%) were less likely to be enrolled in school than their nonincarcerated peers (88%) (Sedlak & Bruce, 2010). Twenty-six percent of youth responding to the SYRP reported that they had repeated a grade in the year prior to entering custody—more than twice the lifetime rate of grade retention among youth of the same age in the general population (11%). Nearly half of the youth performed at less than the typical grade level for their age, and 30% of the youth reported that they had been diagnosed with a learning disability.

In addition to educational deficiencies, involvement with the criminal justice system may also influence youths’ understanding of some aspects of the NSYC study design. Rounsaville et al. (2008)

⁴The initial NSYC methodology was developed and pilot tested in 2006. The first national study conducted in 2008-09 involved approximately 11,400 youth from 195 residential facilities nationwide.

reported on a study with young adult substance abusers who were referred to treatment by the criminal justice system. Fewer than half of the sample achieved perfect scores on the comprehension questions embedded into their consent process, and 20% failed to understand their right to refuse to take part in the research.

The complex set of conditions associated with the NSYC-2 assent process posed challenges associated with developing an appropriate protocol. The NSYC-2 survey design exposed youth to two types of risk: retribution by staff or other youth in the facility due to survey responses, and the possibility of becoming emotionally distressed by the survey items (e.g., sexual victimization). Therefore, the protocol took extra precautions to ensure that youth were fully informed of both the risks and procedures in place to protect them, so they could judge the adequacy of the protections. The assent material pointed to the use of audio, computer-assisted interviewing (ACASI) to maximize confidentiality. Studies have shown that the use of self-administered questionnaires (including ACASI) fosters confidentiality and increases the likelihood of respondents disclosing sensitive behaviors (Tourangeau & Smith, 1996; Tourangeau et al., 1997; Kreuter et al., 2008). Using ACASI while conducting the NSYC improved the researchers' ability to maintain the perception of confidentiality and made it physically possible to restrict others from seeing the questions (e.g., the interviewer or another person in the room).

Also maximizing confidentiality, the system randomly assigned questions to youth so that only the youth would know what they had been asked. Youth were told they could be asked about sexual assault or about alcohol and drug use. During the assent process, researchers aimed to communicate clearly to youth that only he or she would know the questions that were asked. This was also done to make it less certain that someone else in the facility would know which questions were administered to any particular youth.

Another aspect of the NSYC study that posed challenges to obtaining informed assent was the need to simultaneously comply with statutory protections to safeguard data confidentiality and the ethical concerns with making reports of child abuse and neglect. As a federal statistical agency, BJS is prohibited from disclosing any information obtained from individuals unless provided by federal law (P.L. 96-157, 42 U.S.C. 3780(g)). This restriction was reaffirmed in the original 2003 PREA legislation, requiring that “the Bureau shall ensure the confidentiality of each survey participant.”

However, this guidance made it impossible for interviewers to report instances of abuse and neglect that were brought to their attention during the interview. In response, Congress amended the act in 2005 to allow BJS and its agents to comply with state requirements for reporting child abuse and neglect.

The assent process informed youth that all answers recorded on the laptop would remain confidential and that no one would be able to track individual's to their responses. However, they were also told that any statement made to the interviewer that suggested harm to the youth or others would be reported to local authorities (e.g., a child protective services or law enforcement agency). Although this condition satisfied statutory obligations, communicating this information to youth clearly and simply was challenging. Generally, youth in facilities are fully aware of mandatory reporting obligations. Researchers made efforts to explain the different conditions of confidentiality associated with incidents alleged through responses to survey questions and those alleged verbally to the interviewer.

Although the NSYC questionnaire was administered using ACASI, the assent was administered directly by the interviewers using a pen-and-paper method, as suggested by Cohn and Larson (2007). Due to the interviewer-administered assent process, the researchers had concern about the possible influence that individual interviewers could have on comprehension. For example, Davis et al. (2010) describe findings related to interviewer effects of race, sex, and level of interviewing experience. These findings sometimes have limited applicability to other studies due to differences in survey design (e.g., subject matter, mode of administration). Therefore, the assent text had to clearly communicate the role of the interviewer and the self-administered aspect of survey participation.

Research Questions

To ensure that the respondent understood the various conditions associated with the study, the assent protocol implemented an interactive process whereby interviewers asked questions about key elements needed to make an informed decision (Flory & Emanuel, 2004; Rounsaville et al., 2008).

The remainder of this report addresses three basic research questions related to the implementation of this procedure:

- First, how many youth had problems with understanding the NSYC assent process? As noted above, there have been a number of studies that have found that a significant proportion of child respondents may not fully understand all the conditions of an informed assent. The NSYC poses a unique situation by interviewing incarcerated youth about a sensitive topic. This leads to several unusual requirements for the assent and consent. The analysis below provides data on the extent to which youth had problems with the assent.
- Second, are there correlates related to not understanding the assent process fully? The analysis correlates the extent to which youth understood the assent with demographic and educational characteristics of the youth and interviewers.
- Third, was the ability to understand the assent process correlated with a willingness to complete the survey and any difficulties the youth may have had with the survey questions?

Methods

Text box 1 shows the items used to assess youth’s comprehension during the assent process. The assent form is provided in appendix A.⁵ The interviewers were instructed to read the text and each question verbatim. If the youth did not answer the question correctly, the interviewer repeated the relevant scripted text and question. If the youth still failed to answer the question correctly, the interviewer paraphrased the scripted text to explain the concept in a different way. Youth who failed to correctly respond to one or more questions by the end of this process were politely asked not to complete the survey. In both the pilot test and the full-scale NSYC-1 data collections, fewer than 1% of the youth who took part in the assent process failed to answer one or more questions correctly once the interviewer provided assistance (repetition and paraphrasing).⁶ Limited documentation of the nature of youth comprehension was captured during the pilot test and NSYC-1 collections. The interviewers were asked only to record youth’s decision on whether to participate in the survey once they gave correct responses to the imbedded comprehension questions. The pilot interviewers did not document youth’s need for assistance or the form of assistance provided.

For NSYC-2, interviewers recorded whether youth answered each question correctly during the initial reading of the assent text, responded correctly after repetition of the text, responded correctly after paraphrasing, or failed to answer correctly after provision of both forms of assistance. Youth responses were coded using the following options: “understood on the first attempt,” “needed repetition to understand,” “needed paraphrasing to understand,” or “failed to understand.”

⁵A consent form from a parent or guardian was required before any minor was asked to participate. Youth who had reached the age of majority, as defined by their state of residence, were allowed to self-consent.

⁶In the pilot test, 1 in 684 youth failed to respond correctly to one or more assent questions. In the NSYC-1, 56 in 10,697 youth failed the assent process.

Results

During the course of the NSYC-2 data collection, 10,678 eligible youth were approached to participate in the survey. Of these, 49 youth had missing data on all assent items because of their refusal to participate prior to the administration of the assent protocol. For the remaining 10,629 youth, the protocol consisted of an interviewer reading scripted text to a youth and assessing comprehension based on youth's responses to six questions (**text box 1**).

Text box 1. Comprehension questions asked during the assent and consent process

1. Do you think I will be asking you the questions, or do you think the questions will be asked by the computer?
2. Do you think I will decide which questions to ask you, or do you think the computer will decide?
3. Do you believe that anyone, even me, will know which questions you are asked or what you answer?
4. Now, if someone asked you whether you had to do the interview or whether it was voluntary, what would you say?
5. If you tell me that you or anyone else has been abused or harmed, will I have to report it to a government agency?
6. If you answer on the computer that you or anyone else has been abused or harmed, will I have to report it to a government agency?

To get an overall summary of how many needed assistance, youth were categorized into mutually exclusive groups based on the highest level of assistance provided. Forty-nine youth had missing data on one or more key grouping elements and were excluded from the analyses, leaving a total of 10,580 cases.⁷

Overall, approximately 71% of youth understood all elements in the NSYC assent without any form of assistance (**table 1**). About 30% of youth did not initially understand at least one element.

Twenty-one percent needed repetition of the text related to at least one element, approximately 7% needed to have the text about one or more elements paraphrased, and fewer than 1% failed to demonstrate understanding of at least one element after all assistance had been provided.

⁷The 49 youth with missing data on one or more key grouping elements were different from the 49 youth who refused to participate prior to the administration of the assent protocol.

Table 1. Overall assent comprehension status

Understood		Repeated		Paraphrased		Failed*		Total	
Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
7,557	71%	2,206	21%	774	7%	43	0%	10,580	100%

Note: Excludes 49 youth who do not meet one in four comprehension definitions.

*Approximately 0.41% of the sample failed to comprehend at least one assent item.

Researchers observed significant variation of comprehension by demographic characteristics (**table 2**). A higher proportion of females (76%) understood the assent concepts than males (71%) ($\chi^2 = 9.4, p = .02$). A significantly higher proportion of males than females needed repetition (21% compared to 18%) and paraphrasing (7% compared to 6%). There was no difference in the rate of failure to understand based on youth sex. Whites (77%) were more likely than blacks (68%), Hispanics (69%), and youth from other racial groups (68%) to display understanding without assistance ($\chi^2 = 117.9, p < .0001$). Conversely, as a group, blacks, Hispanics, and youth from other racial groups were more likely than whites to need repetition (23% compared to 18%) and, separately, they were more likely to need paraphrasing (9%, 7%, and 9% compared to 5%). Although the overall failure rate was low, a higher proportion of black youth (1%) failed to comprehend one or more elements than whites (fewer than 1%).

Table 2. Overall assent comprehension status results, by youth demographics

Youth demographic	Number	Percent	Understood		Repeated		Paraphrased		Failed		Chi-square significance test	
			Number	Percent	Number	Percent	Number	Percent	Number	Percent	Value	Probability
Sex												
Male	9,626	91%	6,803	71%	2,026	21%	714	7%	39	0%	9.4	0.02
Female	1,003	9	754	76	180	18	60	6	4	0		
Race												
White	3,988	38%	3,063	77%	694	18%	216	5%	3	0%	117.9	<.0001
Black	4,362	41	2,939	68	991	23	381	9	29	1		
Hispanic	1,668	16	1,145	69	385	23	120	7	8	0		
Other ^a	590	6	397	68	132	23	55	9	2	0		
Age												
14 or younger	565	5%	340	60%	155	27%	69	12%	1	0%	62.4	<.0001
15	1,147	11	781	68	266	23	92	8	5	0		
16	2,287	22	1,625	71	461	20	176	8	15	1		
17	2,821	27	2,033	72	582	21	189	7	7	0		
18 or older	3,809	36	2,778	73	742	20	248	7	15	0		
Highest education level attained^b												
None–grade 8	1,261	13%	812	65%	308	25%	137	11%			87.3	<.0001
Grade 9	2,383	24	1,670	70	535	23	170	7				
Grade 10	2,275	23	1,664	73	450	20	156	7		~		
Grade 11	1,716	18	1,259	73	336	19	119	7				
Grade 12 or higher	2,184	22	1,687	77	398	18	99	5				
Below expected grade level^{b,c}												
No	7,445	76%	5,441	73%	1,514	20%	484	6%			12.9	0.00
Yes	2,374	24	1,651	70	513	22	197	8		~		

Note: Excludes 49 youth who refused before administration of the assent.

~Not applicable.

^aIncludes American Indians and Alaska Natives; Asians, Native Hawaiians, and Other Pacific Islanders; and persons of two or more races. Excludes 21 youth who did not identify race.

^bDefined as two more grades below the expected grade level for current age.

^cExcludes missing responses and youth who failed the assent process, refused, or otherwise did not participate.

Age was significantly associated with assent comprehension ($\chi^2 = 62.4, p < .0001$). Younger youth more often needed assistance than older youth. Youth 14 or younger demonstrated the highest likelihood of needing both repetition (27%) and paraphrasing (12%). Conversely, youth 18 or older demonstrated the lowest need for assistance. Similar linear patterns were observed across education levels ($\chi^2 = 87.3, p < .0001$). Because education level is strongly correlated with age, a dichotomous measure of “below expected grade level” was developed by considering the youth’s age relative to expected grade level. Those youth two or more grades below the normative grade level based on age were coded as “Yes,” and youth at or near expected grade level relative to age were coded as “No.” Cross-tabular analyses showed that those performing at or near expected grade level were slightly more likely than youth below expected grade level to understand all assent elements after the initial reading of the text ($\chi^2 = 12.9, p < .01$).

Youth had more difficulty understanding some concepts related to assent. Four of the six concepts were understood by at least 94% of the youth without any assistance (**table 3**). These concepts pertained to the mode of survey administration (i.e., computer- or interviewer-administered), random assignment to questionnaire, privacy of survey process, and confidentiality of verbal statements (Q1-Q4). Questions 5 (86%) and 6 (88%) about the voluntary nature of participation and confidentiality of computer responses were understood by smaller proportions of youth. Likewise, these elements had the highest rates of repetition (11% for Q5 and 8% for Q6) and paraphrasing (3% for Q5 and 4% for Q6). However, after the initial reading and repetition as needed, youth comprehension of the voluntary nature of participation and the confidentiality of computer responses was similar to the levels of understanding seen with the other assent elements (approximately 96% compared to 98%).

There is a strong relationship between youth’s comprehension of the assent and agreeing to participate on the survey (**table 4**). Youth who completed the survey (72%) were more likely to participate than those who did not understand all elements (49% who partially completed and 65% who refused, $\chi^2 = 71.0, p < .0001$).

Table 3. Assent comprehension status, by item

Assent concept	Assent text	Understood		Repeated			Paraphrased			Failed		
		Number	Percent	Number	Percent	Total*	Number	Percent	Total*	Number	Percent	Total*
Respect for persons												
Q1: Survey procedure	<i>Do you think I will be asking you the questions, or do you think the questions will be asked by the computer?</i>	10,252	96.5%	304	2.9%	99.3%	64	0.6%	99.9%	9	0.1%	100%
Q2: Random assignment to question	<i>Do you think I will decide which questions to ask you, or do you think the computer will decide?</i>	10,384	97.8	200	1.9	99.6	28	0.3	99.9	10	0.1	100
Beneficence												
Q3: Privacy of survey process	<i>Do you believe that anyone, even me, will know which questions you are asked or what you answer?</i>	10,005	94.3%	464	4.4%	98.6%	127	1.2%	99.8%	18	0.2%	100%
Q4: Confidentiality of verbal statements	<i>If you tell me that you or anyone else has been abused or harmed, will I have to report it to a government agency?</i>	10,257	97.0	265	2.5	99.5	44	0.4	99.9	8	0.1	100

Q5: Confidentiality of computer responses	<i>If you answer on the computer that you or anyone else has been abused or harmed, will I have to report it to a government agency?</i>	9,130	86.4	1,116	10.6	97.0	304	2.9	99.8	17	0.2	100
Justice												
Q6: Voluntary nature	<i>Now, if someone asked you whether you had to do the interview or whether it was voluntary, what would you say?</i>	9,328	88.1%	859	8.1%	96.3%	388	3.7%	99.9%	9	0.1%	100%

*Cumulative percent.

Table 4. Assent comprehension status and likelihood of survey completion, by status of survey comprehension

Status of survey completion	Total Number	Assent comprehension status			Chi-square significance test	
		Understood Percent	Repeated Percent	Paraphrased Percent	Value	Probability
Completed	9,922	72%	21%	7%	71.0	<.0001
Partially completed	161	49	31	20		
Refused	453	65	24	11		

Note: Excludes youth who failed the assent and one missing response.

Youth comprehension of the assent was also related to the extent an inactivity flag was triggered during the interview. An inactivity flag was triggered if the youth spent more than 30 seconds on three or more interview screens within a section of the questionnaire. If the activity flag was tripped, the youth was instructed to raise his or her hand and call over the interviewer. The interviewer checked in with the youth to see if there were any questions or other issues with filling out the survey. Table 5 provides the relationship between this flag and whether the youth experienced any comprehension problems with the assent. The percentage of youth having problems does not differ by whether an activity flag was tripped during the interview.

As noted above, the assent involved an extended interaction between the interviewer and youth. There were more female (82%) than male (18%) interviewers, and there were more white (79%) and non-Hispanic (86%) interviewers than black (21%) or Hispanic (14%) interviewers. Conversely, the youth population was predominantly male (91%) and nonwhite (62%). Researchers considered whether youth comprehension differed when the sex or race of the interviewer and youth matched. For example, certain sex and racial differences may contribute to the respondent “form[ing] opinions about the interviewer,” which may influence their participation or understanding of the survey items (Davis et al., 2010, p. 3).

Table 5. Assent comprehension status, by inactivity flags

Assent comprehension status	Number	Inactivity flags		Chi-square significance test	
		None	Any	Value	Probability
Understood	7,113	73%	72%	6.3	0.04
Repeated	2,035	21	21		
Paraphrased	682	6	7		

Note: Excludes youth who failed the assent or refused, and missing responses.

A binary assent variable was created by placing all youth who needed any assistance (those needing repetition or paraphrasing, and those that failed to comprehend) into the “needed assistance” category, and all youth with full comprehension after the initial reading of the assent text were grouped as “understood.” Results of chi-square tests showed that the proportion of youth needing assistance was slightly lower among those paired with male interviewers (25%) than those paired with female interviewers (29%) ($\chi^2 = 16.4, p < .0001$). Similar patterns were also observed by interviewers of Hispanic origin. Youth needing assistance were less often paired with non-Hispanic interviewers (30%) than with Hispanic interviewers (34%) ($\chi^2 = 21.2, p < .0001$). These results suggested a possible interviewer effect in youth assent comprehension.

To fully explore whether there were interviewer effects related to administration of the consent, a hierarchical generalized linear model (HGLM) was estimated. The use of an HGLM allows for partitioning the variation in to what extent youth need assistance that is associated with youth or interviewer characteristics. It also enables testing interactions between the two levels (Tabachnick & Fidell, 2007).

Appendix B provides the details of the HGLM model estimates. Overall, this analysis found that there are significant differences between interviewers with respect to the extent youth initially understood the assent. In a few cases, interviewer characteristics seemed to interact with respondent characteristics. For example, there was an indication that Hispanic youth who were interviewed by Hispanic interviewers were somewhat less likely to exhibit problems with the consent. However, even after controlling for interviewer characteristics, youth characteristics remained significant. In particular, black, Hispanic, and youth age 14 or younger still exhibited more problems with understanding the consent than their demographic counterparts. In the bivariate analysis, sex was

not significant, and females were somewhat less likely to have comprehension problems. When controlled for interviewer characteristics, this was no longer significant.

Two measures were created to address the relationship between needing assistance during the assent and survey comprehension. First, researchers measured problems getting through the survey by using the survey’s paradata. Periods of prolonged inactivity (30 or more seconds) after a survey question was displayed on the screen were flagged (inactivity flag). After three consecutive inactivity flags in the same section of the questionnaire, a message appeared on screen instructing the youth to ask the interviewer for assistance. This process allowed the interviewer to monitor for signs of distress or other problematic behavior and take action as needed. Youth records were collapsed into two groups: “no flags” and “one or more flags.” These groups were then analyzed for assent comprehension.

The second measure was a direct question about the survey. Youth were asked a series of debriefing questions about their overall experiences with the survey. One of these questions explored difficulties in understanding the survey items, asking if they “strongly agree,” “agree,” “disagree,” or “strongly disagree” with the statement, “Some of the questions were hard to understand.” Responses to this question were collapsed into a dichotomous variable (“agree” or “disagree”) and compared with assent comprehension.

Table 6. Assent comprehension status, by difficulty in understanding survey items

Questions were difficult to understand	Total Number	Assent comprehension status			Chi-square significance test	
		Understood Percent	Repeated Percent	Paraphrased Percent	Value	Probability
Agree	1,819	63%	26%	11%	105.9	<.0001
Disagree	7,893	75	19	6		

Note: Excludes youth who failed the assent or refused, and missing responses.

The overall number of inactivity of flags triggered during the interview was significantly related ($\chi^2 = 6.3, p < .04$) to the level of comprehension of assent elements, and differences were small (table 6). However, youth needing assistance on the assent correlated with their self-report of the difficulty of questions. Those who found the questions difficult to understand needed more repetition (26%

compared to 19%) and paraphrasing (11% compared to 6%) than youth who did not find the survey questions difficult to understand.

Table 7. Interviewer demographic characteristics, by binary assent status

Interviewer characteristic	Total sample		Binary assent status				Chi-square significance test	
			Understood		Needed assistance*		Value	Probability
	Number	Percent	Number	Percent	Number	Percent		
Sex								
Male	1,915	18%	1,442	75%	473	25%	16.4	<.0001
Female	8,594	82	6,074	71	2,520	29		
Race								
White	8,297	79%	5,961	72%	2,336	28%		
Black	2,212	21	1,555	70	657	30		
Hispanic origin								
Non-Hispanic	9,067	86%	6,558	72%	2,509	28%	21.2	<.0001
Hispanic	1,442	14	958	66	484	34		

*Includes youth who needed repetition or paraphrasing, or failed to comprehend at least one item.

Discussion

Since 1991, when the U.S. Department of Health and Human Services issued the Code of Federal Regulations Title 45 Volume 46 (45 C.F.R. 46), informed consent of prospective research participants has been required for all federally funded research studies. Many studies have found that participants often do not comprehend the information that they receive during the consent process—confirmed in this report for the incarcerated youth asked to participate in the National Survey of Youth in Custody (NSYC), a study involving highly sensitive topics with several complex design features. Approximately 30% of the youth did not initially understand one of the crucial elements of assent. However, with assistance from the interviewer, nearly all youth expressed an understanding of the key elements of participation.

Studies should not rely entirely on the text to convey information to prospective participants in studies involving incarcerated youth. NSYC procedures were tested through cognitive interviews conducted during the development of the study design, and the informed-assent text was written at a seventh-grade reading level to help ensure comprehension. These efforts appeared moderately successful. Seventy-one percent of the youth were able to correctly answer questions assessing their comprehension of the study procedures and based solely on the information presented on the assent form and read aloud by the interviewer. Repeating the text was sufficient to help an additional 21% of the youth understand, and paraphrasing the text provided enough assistance for nearly all remaining youth. Fewer than 1% of the youth approached for the study did not answer the comprehension questions after going through this process.

Not limited to repetition, special efforts may be necessary to assist subgroups within the youth population. Males, nonwhites, younger youth (ages 14 or younger), and those with educational deficiencies demonstrated more difficulty comprehending the NSYC assent materials than was observed in other youth in the survey. Repetition of the text appeared to overcome the differences based on youth's sex. However, paraphrasing was necessary to help place nonwhites, younger youth, and those with educational deficiencies on par with their peers in terms of comprehension.

Unique characteristics of the NSYC population may influence understanding of the study procedures, as these youth are minors and residents of correctional facilities. Youth had the most

challenges in comprehending issues associated with the voluntary nature of NSYC participation and data confidentiality. Based on the initial reading of the assent text, 12% did not appear to recognize their right to refuse to take part in the study, and 14% failed to understand that answers recorded on the laptop computer would remain confidential. Fewer than 6% of youth demonstrated a lack of understanding with regard to any of the other design elements after the initial reading of the text.

Assessment of study protocol comprehension and assistance to prospective participants may also affect the quality of data. A positive relationship was found between failure to comprehend the NSYC assent material without assistance (i.e., repetition or paraphrasing) and survey nonresponse. If the assent protocol did not allow for assistance, uncertainty, or confusion about the study design, this may have led some youth to refuse to participate. Potential refusals from subgroups of the youth population in custody may have introduced bias into the study findings.

Although these findings suggest the need for interviewers to assess comprehension and provide assistance to research subjects, the development and use of a more stringent assessment technique would be advantageous. The NSYC asked subjects six questions to assess comprehension. Each question offered dichotomous answer choices of “Yes” or “No.” Therefore, the first answer provided by youth in response to each question indicates comprehension, or at least attention. However, when answering a question incorrectly the first time, youth may learn that the correct answer is the one not provided initially and simply change the answer to continue, regardless of understanding. The findings presented in this paper may inflate the utility of repetition and paraphrasing as ways to improve comprehension.

In addition, features unique to the NSYC potentially limit applicability of the findings to other populations and conditions, such as the specialized population of incarcerated youth. Although findings point to the need to offer this population more support, they do not speak directly to the potential merits of using an assessment and assistance protocol among the general population or other special populations, such as older adults or persons with cognitive impairments. The results also do not necessarily suggest the most appropriate procedures to use with other groups of youth (e.g., school populations).

Conclusions

Researchers must inform their study subjects of the ethical and legal issues involved in informed assent and consent so they may make informed decisions on whether to participate in a study. As reported by various interviewers cited in this report, researchers face challenges when conducting studies with vulnerable populations and, in particular, minors and incarcerated persons. The incorporation of comprehension assessments into the informed consent protocol helps to ensure that interviewers have fulfilled their obligations to prospective participants.

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Appendix A. National Survey of Youth in Custody Youth Assent

We are doing a special study for the U.S. Department of Justice to find out more about what it's like for young people living in places like this. The study is called the National Survey of Youth in Custody.

The government will use the study to see if changes need to be made at places like this. We will combine the answers that people from this place give into a report on this facility. No names will appear in the report, and it won't say anything about who said what.

We're asking people in every state in the country to be part of this study, and we would like you to be part of the study. If you agree to be part of the study, you'll answer some questions using this computer.

- Answering the questions takes about 30 minutes.
- You will be asked questions about what it is like living at the facility, including questions about the staff, other youth who live in the facility, and some of the health services you might have used.
- You might be asked questions about alcohol and drug use before you came here, or you might be asked about sexual experiences, including those that may have happened in this facility.
- The computer will randomly decide which questions you are asked; it has nothing to do with why you are at this place or what you might have told someone.
- Answering is easy. You'll see the questions on the screen and hear the questions in the headphones. You touch the computer screen to answer the questions.
- Nobody, not even me, will know which questions you get or what you answer.
- You don't have to do this study. It's entirely up to you. No matter what you decide, your case will not be affected in any way. You can start the interview and then decide to quit at any time. Just tell me that you want to stop, and I'll tell you what to do. If you want to skip a question, that's okay too.

- **Everyone working on this project is required by law to protect your privacy.** Your answers will always be kept private. I will not ask your name, and you will not be asked to put your name in the computer. No one on the project or on staff here will ever know your answers.
- **There is one important exception to this privacy rule.** If you tell me that you or anyone else has been abused or harmed, I will report it to the government agency that investigates these reports.
- **So again, if you answer on the computer, even if it is about being abused or harmed, no one will know your answer, not even me. But, if you tell me directly that you or anyone else has been abused or harmed, I will report it to the government agency that investigates these reports.**
- If thinking about the questions upsets you or makes you sad, I can arrange for you to talk with a counselor who works here. If you don't want to talk to a counselor who works here, I can arrange for you to talk with a counselor who does not work here or someone from the ChildHelp National Hotline (1-800-4-A-Child or 1-800-422-4453). Just let me know.

If you have any questions, you can ask me anytime while I'm here. After I leave—

- If you have any questions about your rights as a study participant, you can call XXXXXX (1-800-XXX-XXXX, ext. XXXX). She works for the same company that I work for.
- If you have questions about how the study works, call the National Survey of Youth in Custody Information Line (1-XXX-XXX-XXXX).

So that's it. I hope that you'll be willing to take part in this important study. No matter what experiences you have had, your answers will help us understand what it's like for young people in places like this.

Appendix B. Hierarchical Generalized Linear Model Estimates

A two-level random-effect hierarchical generalized linear modeling (HGLM; Raudenbush & Bryk, 2002) was estimated to test for the effects of interviewers on youth’s comprehension of the consent. The outcome predicted in the model was whether the respondent needed assistance during the assent process. The HGLM model with a binary outcome (needed or did not need assistance) is expressed as—

$$\text{Level 1: } \eta_{ij} = \text{logit}[\pi_{ij}(\underline{x})] = \ln\left[\frac{\pi_{ij}(\underline{x})}{1 - \pi_{ij}(\underline{x})}\right] = \beta_{0j} + \beta_{1j}X_{1ij} + \beta_{2j}X_{2ij} + \dots + \beta_{Qj}X_{Qij}$$

$$\text{Level 2: } \beta_{qj} = \gamma_{q0} + \sum_{s=1}^{S_q} \gamma_{qs}W_{sj} + u_{qj}$$

where η_{ij} represents the logit of whether assistance was needed or not, X_{Qij} stands for the Q^{th} youth-level predictor, and W_{sj} stands for the W^{th} interviewer-level predictors. γ_{q0} and γ_{qs} represent the fixed effects of the intercept and slopes. u_{qj} indicates the random effects and can be either fixed or random.⁸

Three models were tested consecutively. The null model without any predictors was first run to explore whether there was significant variation in youth’s comprehension across interviewers. The null model is expressed as—

Separate models	Level-1: $\eta_{ij} = \beta_{0j}$
for each level	Level-2: $\beta_{0j} = \gamma_{00} + \mu_{0j}$

Combined model	$\eta_{ij} = \gamma_{00} + \mu_{0j}$
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The parameter μ_{0j} represents the effects of interviewers. Significant variation in this parameter is indicative of significant differences between interviewers.

⁸To acquire better accuracy, an adaptive quadrature estimation method (with 5 quadrature points) was used as the estimation method instead of the penalized quasi-likelihood method or the Laplace method (O’Connell et al., 2010). Any missing cases were list-wise deleted.

Table B-1 provides the estimates from this model. The fixed effect estimate $\hat{\gamma}_{00} = -1.16$ was significant ($p < .001$), demonstrating that a youth had an expected log odds of -1.16 of being in the “needed assistance” group or a 1 to 3 ratio (OR = 0.31). This is consistent with the overall average shown in **text table 1**, that about 30% of the youth expressed some confusion. Significant variation associated with μ_{0j} ($p < .001$) signals that there was significant variation across interviewers.

Table B-1. HGLM model predicting “needed assistance with assent” without youth- or interviewer-level predictors

Fixed effects	Coefficient	Odds ratio	p value
For level-1 intercept β_{0j} , level-2 intercept γ_{00}	-1.16	0.31	<.001
Random effects	Variance		p value
Variance in intercept μ_0	1.0		<.001

This model does not account for the nonrandom assignment of interviewers to particular respondents. Interviewers were assigned to a facility based on their availability and residential location. This is not random, and interviewers may have been systematically paired with respondents who were less likely to comprehend the survey. To control for this possibility, a conditional model was estimated that added in youth-level characteristics as predictors. These included sex, race, Hispanic origin, and age (**table B-2**). For this model, all the level-1 slopes were allowed to vary, although no predictors were included for the slopes besides the intercept.

Table B-2. HGLM model predicting “needed assistance with assent” with youth-level predictors

For level-1 intercept β_{0j} , level-2 intercept γ_{00}	-0.85	0.43	<.001
For level-1 sex of youth β_{1j} (reference = male), level-2 intercept γ_{10}	-0.32	0.72	.003
For level-1 black youth β_{2j} , level-2 intercept γ_{20}	0.53	1.70	<.001
For level-1 Hispanic youth β_{3j} , level-2 intercept γ_{30}	0.43	1.54	<.001
For level-1 other race youth β_{4j} , level-2 intercept γ_{40}	0.40	1.49	<.001
For level-1 age 15 β_{5j} , level-2 intercept γ_{50}	-0.41	0.66	<.001
For level-1 age 16 β_{6j} , level-2 intercept γ_{60}	-0.58	0.56	<.001
For level-1 age 17 β_{7j} , level-2 intercept γ_{70}	-0.58	0.56	<.001
For level-1 age 18 β_{8j} , level-2 intercept γ_{80}	-0.76	0.47	<.001
Variance in intercept μ_0	0.84		<0.001
Youth sex slope, u_1	0.12		0.08
Black youth slope, u_2	0.05		0.013
Hispanic youth slope, u_3	0.09		0.121
Other race youth slope, u_4	0.12		0.362
Age 15 slope, u_5	0.04		>0.500
Age 16 slope, u_6	0.03		>0.500
Age 17 slope, u_7	0.04		>0.500
Age 18 slope, u_8	0.02		>0.500

The results indicate that all the respondent characteristics were significant ($p < .05$). More specifically—

- Females were less likely than males to need assistance.
- Black, Hispanic, and youth from other racial groups were more likely than white youth to need assistance.
- Youth age 14 or younger were more likely to need assistance than youth older than 14.

These findings confirm the previously presented descriptive and bivariate results. Also, even after controlling for youth-level characteristics, significant variation existed across interviewers (variation in μ_0 was statistically significant, $p < .001$).

A third model was estimated that investigated how the interaction between the interviewer's demographic characteristics (i.e., sex, race, Hispanic origin) and the youth's demographic characteristics may have affected youth comprehension. This model introduces demographic characteristics of the interviewer into the interviewer-level portion of the model. **Table B-3** shows the combined model, which includes respondent- and interviewer-level predictors.

Table B-3. HGLM model predicting “needed assistance with assent” with youth- and interviewer-level predictors

For level-1 intercept β_{0j} , level-2 intercept γ_{00}	-1.58	0.21	0.031
Level-2 sex of interviewer γ_{01}	0.46	1.59	0.186
Level-2 race of interviewer γ_{02}	-0.14	0.87	0.754
Level-2 Hispanic origin of interviewer γ_{03}	0.19	1.20	0.654
For level-1 sex of youth β_{1j} , level-2 intercept γ_{10}	-0.93	0.39	0.314
Level-2 sex of interviewer γ_{11}	0.39	1.48	0.377
Level-2 race of interviewer γ_{12}	-0.11	0.90	0.661
Level-2 Hispanic origin of interviewer γ_{13}	0.21	1.24	0.585
For level-1 black youth β_{2j} , level-2 intercept γ_{20}	0.84	2.32	0.023
Level-2 sex of interviewer γ_{21}	-0.15	0.86	0.378
Level-2 race of interviewer γ_{22}	-0.02	0.98	0.896
Level-2 Hispanic origin of interviewer γ_{23}	-0.15	0.86	0.415
For level-1 Hispanic youth β_{3j} , level-2 intercept γ_{30}	1.22	3.38	0.026
Level-2 sex of interviewer γ_{31}	-0.13	0.88	0.599
Level-2 race of interviewer γ_{32}	-0.41	0.66	0.083
Level-2 Hispanic origin of interviewer γ_{33}	-0.45	0.64	0.009
For level-1 other race youth β_{4j} , level-2 intercept γ_{40}	0.35	1.42	0.564
Level-2 sex of interviewer γ_{41}	0.27	1.31	0.326
Level-2 race of interviewer γ_{42}	-0.47	0.63	0.122
Level-2 Hispanic origin of interviewer γ_{43}	0.41	1.51	0.050
For level-1 age 15 β_{5j} , level-2 intercept γ_{50}	-0.37	0.69	0.002
For level-1 age 16 β_{6j} , level-2 intercept γ_{60}	-0.53	0.59	<0.001
For level-1 age 17 β_{7j} , level-2 intercept γ_{70}	-0.57	0.56	<0.001
For level-1 age 18 β_{8j} , level-2 intercept γ_{80}	-0.70	0.50	<0.001

Table B-3. HGLM model predicting “needed assistance with assent” with youth- and interviewer-level predictors (continued)

Random effects	Variance	<i>p</i> value
Variance in intercept μ_0	0.92	<.001
Sex of youth slope, u_1	0.32	.093
Black youth slope, u_2	0.22	.006
Hispanic youth slope, u_3	0.27	.269
Other race youth slope, u_4	0.34	.435

Model 3 results found one significant interaction. If both the interviewer and youth were of Hispanic origin, then the youth was less likely to need assistance (see γ_{33} ; OR = .64, $p < .01$). Approximately 18% of all Hispanic youth in the National Survey of Youth in Custody were administered the assent by a Hispanic interviewer. The other Hispanic youth received the assent by a non-Hispanic interviewer. Consequently, this estimate is based on a relatively small number of interviews.

For the remainder of the model, the effects of youth characteristics remained significant. Youth who were black, Hispanic, and age 14 or younger were more likely needed assistance. Youth sex and other racial groups became nonsignificant when added to the multivariate level-1 model. The random effects table indicated unexplained variation across interviewers in general, and differences in the relationship between the interviewer and black youth.