Securing Informed Consent from Less Educated Respondents: Results from the National Inmate Survey

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Abstract:
The Prison Rape Elimination Act (PREA) of 2003 (P.L. 108-79) requires the Bureau of Justice Statistics (BJS) to develop new national data collections on the incidence and prevalence of sexual assault within correctional facilities. The Act requires BJS to survey each year not less than 10% of all federal, state, and local correctional facilities and to provide facility-level estimates of sexual assault for each sampled facility. To fully implement PREA, BJS has developed a multiple-measure, multiple-method data collection strategy. One of these data collection activities, the National Inmate Survey (NIS), involves obtaining information directly from adult inmates on their experiences with sexual assault. Approval to conduct the NIS was sought from a number of different Institutional Review Boards (IRBs) including RTI International’s (which serves as the IRB of record), the IRBs for each of the 50 state Departments of Corrections, and IRBs associated with individual jails. As inmates are defined as a protected class by DHHS’s Office of Protection from Research Risks (OPRR) and because the NIS collects data of a very sensitive nature, these IRBs were especially concerned with issues related to inmate coercion, the right to refuse, and ensuring inmates understood exactly what participation entailed. This presentation will discuss the challenges of developing and administering consent materials for an inmate population where literacy and formal education levels are typically lower than in the general U.S. population. We will provide a review of the consent form used in the NIS and an analysis of the questions and comments raised by sampled inmates as they decided whether or not to participate in the study. Our analysis will examine whether there were particular aspects of the NIS consent materials that were especially difficult for the inmate population to understand and discuss the implications of our findings.

Keywords: prisoners, sensitive behaviors, informed consent

Introduction

Although prevalence estimates have varied, it is generally acknowledged that some proportion of the incarcerated population is sexually victimized. Inmates are under the care of Federal, state, or local authorities, and as such should be kept safe from victimization to the extent prevention of such activities is possible. The Prison Rape Elimination Act (PREA) of 2003 (P.L. 108-79) mandates funding for a number of studies on sexual victimization in correctional facilities. The need for these studies is founded in two related problems: (1) some inmates are sexually assaulted and (2) the validity and reliability of existing data on this phenomenon are inadequate.

Prior to the implementation of PREA, there was relatively little research on the sexual assault of inmates, and the validity and reliability of the methods employed and data generated by existing research are largely flawed. The few existing studies have used a variety of definitions, timeframes, and methods yielding unfocused epidemiological data and a wide range of prevalence estimates. For example, Struckman-Johnson and Struckman-Johnson (2000) estimated that 21% of incarcerated males in four Nebraska State prisons experienced pressured or forced sexual contact. Tewksbury (1989) found that none of the inmates in an Ohio prison reported being raped, but almost 5% reported that another inmate tried to use threats or force to make them have sex. Hensley, Tewksbury, and Castle (2003) found that approximately 1% of male inmates in an Oklahoma prison reported being raped, but almost 14% were threatened sexually. Generally, estimates of the prevalence of sexual assault in corrections range from 0 to 40 percent (for a complete summary of the literature see Gaes & Goldberg, 2004).

Although these studies conclude that sexual assault occurs in correctional facilities and provide some insight into the dynamics of such events, there are serious methodological limitations and inconsistencies across these studies that limit the utility and comparability of their findings. Many prison rape studies utilizing personal interviews or self-administered questionnaires suffer from very low response rates (e.g., less than 30%), and few attempt to compare respondents to non-respondents in an effort to address concerns about selection bias or to assess their samples for representativeness. For
example, the Struckman-Johnson & Struckman-Johnson (2000) study that obtained a sexual assault prevalence rate of 21% considered the issue of selection bias, conceding that respondents were different from non-respondents in terms of age, race, instant offense, and sentence length. The inmate response rate for this study was below 29% and the authors did not conduct any statistical tests on these results or attempt to adjust for nonresponse (Struckman-Johnson & Struckman-Johnson, 2000). Additionally, existing studies have used a wide variety of definitions and interview instruments, and there have been no efforts to weight data to adjust for non-response (Gaes & Goldberg, 2004). As a result, there is a need to standardize definitions and concepts; conduct more statistically rigorous sampling; and develop and employ improved data collection and analytic methods to encourage participation and honest responses, assess samples for representativeness, and adjust for selection bias resulting from non-response.

PREA requires the Bureau of Justice Statistics (BJS) to develop new national data collections on the incidence and prevalence of sexual assault within correctional facilities. The Act requires BJS to survey each year not less than 10% of all federal, state, and local correctional facilities and to provide facility-level estimates of sexual assault for each sampled facility. To fully implement PREA, BJS has developed a multiple-measure, multiple-method data collection strategy. One of these data collection activities, the National Inmate Survey (NIS), involves obtaining information directly from adult inmates on their experiences with sexual assault within the correctional facility in which they are housed. The NIS addresses the methodological weaknesses inherent in the previous research. Specifically,

- The sample design of the NIS allows for facility-level as well as national estimates of victimization.
- The study is designed to minimize the burden to participating facilities and sampled inmates to the greatest extent possible thereby improving response rates at both the facility and inmate level.
- The questionnaire includes very specific questions regarding the different behaviors that constitute sexual victimization rather than vague, poorly defined terms such as “raped” or “victimized”. Questions also include clear reference periods such that all inmates report events that occurred during the previous 12 months or since they arrived at the facility (whichever is longer).
- Data are collected via audio-computer assisted self interviewing (ACASI) as this method has been found to result in higher reporting of sensitive topics (Turner, et al., 1998).
- Interviews take place in private locations where the inmate and interviewer cannot be overheard and where the laptop screen cannot be seen by other inmates or facility staff.
- Inmate names are never connected to interview data, further increasing the willingness of inmates to report honestly.

**Protection of Human Subjects**

The U.S. Department of Health and Human Service’s Office for Protection from Research Risks provides regulations for the protection of all human subjects in federally funded research. Commonly referred to as 45CFR, Part 46, these regulations include specific procedures for Institutional Review Boards (IRBs) to follow to determine whether a particular research project is acceptable for human subjects. Typically, though not always, research using a survey instrument to collect data is categorized as being of minimal risk to participants. To be so categorized, the research must ensure that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those that are encountered in ordinary daily life or as a part of routine physical or psychological examinations or testing (U.S. DHHS Code of Federal Regulations, Title 45, Part 46, Subpart A). Subpart C of these same regulations speaks specifically to the requirements that must be met in order to conduct research with prisoners. Only two types of minimal risk research are permitted with prisoners. These include:

- Studies of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided the study presents no more than minimal risk
- Studies of prisons as institutional structures or of prisoners as incarcerated persons (U.S. DHHS Code of Federal Regulations, Title 45, Part 46, Subpart C)

In order to approve research with prisoners, the IRB must determine that:
• Any advantages that accrue to the inmate through participation are not of such magnitude that his or her ability to weigh the risks of the research against the value is impaired
• Risks involved with the research are commensurate with risks that would be accepted by nonprisoner volunteers
• Procedures for selecting subjects are fair and immune from arbitrary intervention by prison authorities or other prisoners. Random selection of prisoners who meet the characteristics needed for the research project is required unless sufficient justification exists for some other selection process.
• All information is presented in language that will be understandable to the prisoners
• Adequate assurance exists that parole boards will not take into account a prisoner’s participation in the research when making decisions about parole. Prisoners must be explicitly informed prior to participation that their decision will have no effect on decisions regarding parole
• Adequate provisions exist to provide any necessary followup care to prisoners once their participation in the study ends.

Two additional types of research may be permitted with prisoners but only after the research is formally vetted with appropriate experts in the field and intent to conduct the research is published in the Federal Register. These research areas include:

• Studies of conditions particularly affecting prisoners as a class. Examples include research on infectious diseases which are more prevalent in prisons than elsewhere
• Studies of practices which have the intent and reasonable probability of improving the health or well-being of the subject. (U.S. DHHS Code of Federal Regulations, Title 45, Part 46, Subpart C)

Ultimately the NIS was approved by RTI’s IRB as a study of the possible causes, effects, and processes of incarceration, and of criminal behavior that presented no more than minimal risk to prisoners. However, there were still challenges to meeting each of six requirements described above, most notably developing procedures for explaining the study protocol and obtaining consent in a way that ensured informed and uncoerced decision-making for each sampled inmate. Research involving inmates is subject to additional scrutiny as the very fact that participants are incarcerated may constrain their ability to make truly voluntary and uncoerced decisions. In addition, the inmate population has less formal education and is more likely to be semi- or illiterate in comparison to the general adult population of the United States. As such, both the text used in the consent materials as well as the process and logistics of obtaining consent are critical to meeting the requirements of the federal regulations. In the remainder of this paper I describe the development of the consent procedures used for the NIS and what we have learned as a result of completing data collection with approximately 150,000 inmates.

The Logistics of Obtaining Consent

Early in the process of developing procedures for obtaining consent from inmates selected for the NIS it was recognized that privacy was going to be an essential component to voluntary and uncoerced consent and yet a difficult standard for many facilities to meet. Given the very sensitive and highly political nature of the NIS topic the project team was concerned there could be many mechanisms by which an inmate might be subtly or overtly coerced into making a particular decision about participation. For example, coercion to refuse could occur if a victim was selected and his/her perpetrator was to find out and threaten retaliation if the inmate participated in the study. Coercion to refuse could also occur if facility staff attempted to discourage inmates from participating because the administrators disagree with the PREA legislation. In contrast coercion to participate could occur if a facility is trying to make sure a high survey response rate is achieved at the facility and thus introduces consequences to inmates who refuse. Similarly it could occur if an inmate leader of a housing unit might decide that participation is a good idea and coerce all selected inmates in the unit to participate. Efforts to ensure all inmates fully understand what participation entails are likely to require some degree of conversation between the interviewer and the inmate. A private space will increase an inmate’s comfort in raising questions and voicing any concerns prior to making a decision.

Private space is not in great supply in prisons and jails and the variety of demands for such space (for meetings between inmates and their lawyers, staff offices, etc.) make it difficult to obtain for any extended period of time. Nevertheless, the procedures set in place for the NIS require that each inmate meet with an interviewer one-on-one in a private setting to hear about the study, ask any questions he/she might have, and ultimately to make a decision about participation.1 During early

1 The interview itself is conducted in a private setting as well but that is not the topic of this paper so details of how the interview is administered are not included here.
discussions with a sampled facility, project staff describe the required characteristics of the space where the NIS interviews can be conducted. The number of private rooms a facility can provide determines the number of interviewers that will be sent to work at the facility and that in turn plays a significant role in determining how much time it takes to complete data collection at the facility. Throughout the first two years of NIS data collection we have been fortunate that virtually all facilities have been able to identify a sufficient number of private rooms to enable data collection to be completed within a one week period. Identifying such space hasn’t always been easy, however. A number of facilities have had to think creatively to find private space; for example, housing interviewers in the education wing of the facility during weeks when classes are not in session, building wooden dividers that allow large spaces such as a gymnasium to be divided into multiple interviewing “rooms”, and asking facility staff to vacate offices during the week of data collection. Project staff from RTI have made site visits to facilities to assist in identifying suitable space. In the small number of facilities where suitable space could not be identified it was most often when a major renovation was underway at the facility and space of all types was at a premium. In these situations the facility was excused from that year’s data collection as the alternative – interviewing in a semi-private or public location was simply not acceptable.

The other logistical aspect of the consent process involved determining how information about the study would be conveyed to the inmates. Typically a facility provides the interviewing team with at least one staff member who assists with bringing inmates to and from the interviewing rooms. Thus, the first that an inmate hears about his/her selection for the NIS is when an officer calls for or escorts him/her to meet with the interviewer. During the pilot study for the NIS we drafted a brief paragraph of text that these officers could use to explain why the inmate was going to meet with the interviewer. We had no control over whether officers chose to use the text or whether they augmented the text with any additional information. Results from the pilot study indicated that a number of inmates were coded as refusals because they refused to come and meet with the interviewer to even hear about the study. Since we could not be sure what conversation might have taken place between the inmate and the officer and because the officers had not been trained to fully explain the study to the same extent that our interviewers had, we felt such refusals could not really be considered informed decision-making.

Prior to beginning the first year of data collection for the NIS the project team returned to RTI’s IRB with a request for an amendment to our study protocol. Instead of asking the officers to provide the initial introduction to the study we sought approval for an approach whereby officers would simply require each inmate to come to the interviewing room and meet with the interviewer to hear about the study. After speaking with the interviewer each inmate could decide whether to participate in the study. The benefit of this approach was that the project team could more fully ensure that each inmate received an accurate description of the study and had an opportunity to ask any questions of an individual who would know the answers. This procedure more fully meshed with the requirements of informed consent because under the old procedures some inmates were making their decision based on incomplete or even inaccurate information in an environment that might not afford the same privacy as the space where the interviewers were working. RTI’s IRB approved the amendment and the new protocol has been used in the collection of data for both the 2008 and 2009 NIS. While we do still experience situations where an inmate refuses to come to the interviewing room and thus does not have a chance to hear a full description of the study, these cases comprise only a small percentage of the total caseload and typically are due to inmates who are too sick to leave their housing unit.

**Content of the Consent Form**

The other aspect of the consenting process that demanded careful attention during the development of the NIS was the actual content of the consent form. There are specific requirements as to what a consent form must contain. These required elements include:

- That the study involves research
- The purpose of the research and why the subject qualifies (or was selected)
- The duration of the subject's participation
- What procedures will be and which are experimental
- Any foreseeable risks or discomforts to the subject, including both physical and psychological/social/legal risks. (If sensitive questions are being asked, subjects need to be informed about the nature of the questions.)
Any benefits to the subject or to others from the research. (Monetary compensation or gifts are not considered benefits.)

Alternative procedures or courses of treatment that might be advantageous to the subject.

Whether compensation and treatment are available if the subject is injured (applies only for studies posing greater than minimal risk)

The names and telephone numbers (preferably toll-free) for at least two contacts: one contact for study-related questions and a second contact for questions concerning the subject's rights or research related injury

That participation is completely voluntary

That refusal to participate or discontinuing participation will not result in the loss of any benefits to which subject is otherwise entitled

The extent to which the subject's personally identifiable private data will be held in confidence and any exceptions to confidentiality, such as imminent harm or circumstances where mandatory reporting might occur

The compensation offered to subject

If the subject may be re-contacted in the future

Approximate number of subjects in a study

Consequences of subject's decision to withdraw from the study

The need to include so many required elements in the consent form is especially challenging when creating consent materials for individuals with low literacy and/or little formal education. Careful attention must be paid to addressing each element in a way that can be easily understood. Exhibit 1 shows the consent form that was utilized for the 2008 NIS. In developing the content of the NIS consent form the project team consulted with a local adult literacy organization for advice. A first recommendation they made was consistent with our existing protocol, namely that the interviewer read the text aloud while the inmate followed along on their copy. This approach ensured that all content was reviewed as well as addressing the situation of words that are familiar when heard but are not recognized in print (for example, incarceration). Another recommendation was to divide the text into clear topical areas so the inmate would more easily be able to identify the intent of each paragraph. Another suggestion was to use short, more common words whenever possible. So, for example in the first sentence of the form we indicated that the study was being ‘done’ by the Bureau of Justice Statistics as opposed to being ‘conducted’. Unfortunately some of the concepts that must be included are, by their very nature, complex. We know, for example, that the concept of random selection is difficult for many respondents to understand and even an extensive written description seems to make little difference. As a result, we anticipated inmates would have questions about the study goals and procedures even after reviewing the consent and during project training interviewers received extensive training in how to respond to those questions.

In an effort to gain feedback on the consent form, we included an item for the interviewer to complete at the end of each interview. This item asked the interviewer to describe any questions asked or comments made by the inmate during the consent process. These comments were reviewed, codes were created and the comments from inmates housed in prisons (n = 26,311) were coded. After the codes were created two coders independently coded approximately 50 cases and the codes were compared. In cases where the codes assigned did not agree (n = 7), the coders discussed the comment and agreed on how to code the case. Following these discussions an additional 50 cases were independently coded and 100% agreement was attained. At this point the remaining cases were divided between the two coders and coded by only a single coder. A total of 1,829 inmates (7%) made comments and these cases resulted in 1,916 unique comments to be coded (as an inmate might raise more than one question or comment). Table 1 provides the results of this coding exercise, including examples of the types of comments or questions that were included in each code.

The first thing to note from the data in Table 1 is nearly half (43.1%) of the topics raised by the inmate during the informed consent process are not related to the issue of consent. Inmates regularly wanted to discuss other topics with the interviewer. During debriefing meetings with interviewers we were told that many inmates were pleased to have someone to talk with and
Exhibit 1

National Inmate Survey
Consent to Participate in Research

Introduction
The National Inmate Survey is a research study being done by the Bureau of Justice Statistics and RTI International, a not-for-profit research organization in North Carolina. You are one of about [XXX] inmates at this facility who have been randomly selected to participate. Inmates will be interviewed at about 500 facilities across the country. The purpose of this research project is to estimate the number of inmates who are sexually assaulted in prisons and jails each year.

Description of the Study
This interview will take about 30 minutes. To start, the interviewer will ask you some questions about your background, education, and reason for incarceration and enter them into the computer. Next the interviewer will show you how to use the computer and you can complete the rest of the survey on your own in privacy while the interviewer stands on the other side of or outside the room. You will be able to read the questions on the computer screen and listen to them through headphones and then enter your answers directly into the computer by touching the screen. As part of this interview, the computer will randomly decide to ask you questions from one of two questionnaires. In one questionnaire, you will be asked explicit questions about your own experiences with sex and sexual assault in this facility (such as the types of sexual acts and where they occurred). In addition, you may also be asked about your use of drugs and alcohol prior to incarceration. In the other questionnaire you will be asked about your use of drugs and alcohol prior to incarceration and treatment you may have received. Only you will know which set of questions you answered. Not even the interviewer will know unless you discuss the questions with her. You will never be asked to identify anyone by name. To thank you for participating in the study, we will provide you with a snack that you must eat before you leave the interview location.

Possible Risks or Discomforts
Some of the survey questions are personal and it is possible that they may make you feel uncomfortable or upset. There are no right or wrong answers and you can skip any questions you do not want to answer. If you become upset for any reason, you can ask the interviewer to stop the interview. If you want to take a break at any time during the interview, please tell the interviewer. If you find the survey questions to be upsetting for any reason, the interviewer can also provide you with instructions for contacting a mental health counselor employed by this facility.

Benefits
You will not receive any direct benefits for participating in this study. However, the results of this study may help to improve the condition and well-being of inmates in correctional facilities across the nation.

Confidentiality
Your participation in this project is voluntary and you can stop at any time. If you choose not to participate you will not lose any benefits or services that you now receive or might receive in the future. Whether you participate or not will not affect your legal status or any decisions regarding your release from this facility in any way. Your name will never be connected with the information you provide in this interview. We will treat everything you say as private and confidential and we will not share any information you provide with anyone outside or at the facility or anyone who is not working on the project. There is, however, an exception to our promise of
confidentiality. If you tell the interviewer that you intend to seriously harm yourself or a specific person, we may need to inform correctional staff.

Do you have any questions about taking part in this study?

**Further Questions**
You may keep a copy of this form. If you have any questions about the project, you may write to the National Inmate Survey at RTI International, P.O. Box 12194, Research Triangle Park, NC 27709-2194. If you have questions about your rights as a project participant, you can write to RTI’s Office of Research Protection at the same address.

If you would like to help us with our study by participating in the interview, please tell me now and we will begin.

☐ Willing to participate in the interview.

______________________________________________________________

I certify that the nature and purpose, the potential benefits, and possible risks associated with participating in this research have been explained to the participant.

Person Who Obtained Consent: ________________________________

ID Number: ________________

Date: _____/_____/_______

Interviewer: Please indicate whether or not the inmate accepted the snack.

☐ Inmate accepted snack.

☐ Inmate declined snack.
used the opportunity to raise other issues that they hoped the interviewer might be able to help with. Among the comments that were related to informed consent, the most oft cited issue was concerns about confidentiality (13% of the codes) followed by questions about the selection process (10.4% of the codes). These findings are somewhat different from results obtained from some other surveys of sensitive topics conducted by RTI. Albeit not a probability-based sample of all RTI studies, a review of three household-based surveys indicated the most common concern/question raised by respondents is how selection is determined followed by how long the interview will take. It is perhaps not surprising that an inmate population would have slightly different concerns particularly for a survey asking about sensitive behaviors that have occurred during their incarceration. Inmates also tend to have fewer scheduled activities to occupy their time and in fact the interview may be viewed as a pleasant distraction, so it is perhaps not surprising that this concern ranks quite low for NIS respondents. In addition, the NIS is a fairly short interview (approximately 30 minutes) as compared with most of RTI’s household-based surveys which typically last at least an hour.

The results in Table 1 were encouraging to us as the indicated that none of the relevant questions being raised by the inmates were on topics that were not already addressed in our consent form. However, we did use the information to develop further content for our interviewer training. We spent additional time talking with the interviewers about how they could go about addressing questions on these topics and

<table>
<thead>
<tr>
<th>Topic of the Comment/Question</th>
<th>Percent of Inmates</th>
<th>Percent of Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confidentiality Concerns (eg., Who will see my answers? Who will know that I participated?)</td>
<td>13.7</td>
<td>13.0</td>
</tr>
<tr>
<td>Selection Process (eg., Was I selected because of the crime I’m serving time for? I just arrived, why me? Why didn’t you select X?)</td>
<td>10.9</td>
<td>10.4</td>
</tr>
<tr>
<td>Not My Issue (eg., I’ve never been sexually assaulted. I’ve never seen a sexual assault. Sexual assaults don’t happen here.)</td>
<td>6.1</td>
<td>5.8</td>
</tr>
<tr>
<td>Voluntariness (eg., Do I have to participate? What happens if I don’t participate?)</td>
<td>5.6</td>
<td>5.3</td>
</tr>
<tr>
<td>Reason for Study (eg., Who is sponsoring this? Who decided that sexual assault should be studied?)</td>
<td>5.2</td>
<td>5.0</td>
</tr>
<tr>
<td>Outcome of the Study (eg., What will this do for prison policies or for inmates? How will the data be used?)</td>
<td>4.0</td>
<td>3.8</td>
</tr>
<tr>
<td>Impact on the Participant (eg., How will this help me? Will my sentence be reduced? Will I get ‘good time’?)</td>
<td>3.3</td>
<td>3.1</td>
</tr>
<tr>
<td>Who/What is RTI (eg., What is RTI’s relationship to the prison/DOJ? Who does the interviewer work for?)</td>
<td>2.6</td>
<td>2.5</td>
</tr>
<tr>
<td>Length of the Survey (eg., How long will the interview take?)</td>
<td>1.4</td>
<td>1.3</td>
</tr>
<tr>
<td>Unrelated to Consent Process (eg., How did you get this job? Your data will be wrong because people lie. Can you get a message to my family?)</td>
<td>45.2</td>
<td>43.1</td>
</tr>
<tr>
<td>Insufficient Information to Code</td>
<td>6.9</td>
<td>6.6</td>
</tr>
<tr>
<td>TOTAL</td>
<td>100.0</td>
<td>100.0</td>
</tr>
</tbody>
</table>

ensuring they were knowledgeable of the material needed to appropriately address these types of concerns. It is worth noting, however, that the fact that inmates raised questions during the consent process is not an indication of poor interviewer behavior. The interviewer specifically asks the inmate if he/she has any questions and is trained to answer any questions the inmate has before proceeding with the interview. In addition, the interviewer may also address some of these topics as she works to avoid a refusal. Nevertheless we felt additional discussion on responding to these questions could only improve our interviewers’ interactions with the inmates.

One additional method we used to determine whether changes were needed to the consent materials was to talk with the interviewers. With close to 300 interviewers working on the study we were unable to talk with all of them but we did conduct debriefing meetings with a subset of the interviewers and encouraged all interviewers to submit any thoughts they had via email. Based on this input, one small revision was made to the consent form that will be used for the 2010 NIS. Many interviewers noted that they almost always had to explain what the word “explicit” means. The word is used to describe the types of questions that will be asked about sexual assault. Our intent was to make clear that these items would ask about very specific details regarding sexual assault so that respondents wouldn’t be taken aback when they got to those sections. However, the word ‘explicit’ was not familiar to many respondents and as a result the interviewer was put in the somewhat uncomfortable situation of having to describe what the word meant in the context of the NIS. Interviewers also requested that the consent form be written in the first person so that when the interviewer reads it aloud she can say things like, “I will ask...” or “I will show” instead of referring to ‘the interviewer.’ Unfortunately the IRB requires that the form be read exactly as written and making this change would cause the written form to read strangely. Thus, we have not implemented this change.

Conclusions

Protecting the rights of the inmates who participate in the NIS is essential. To that end careful attention was given to the development of the informed consent materials used for the study. The challenge of creating a document that addresses all the elements required by the IRB in a way that is understandable to participants with low literacy levels and less formal education than the average American required great care. The results from our review of inmate comments suggest that our efforts were largely successful. We plan to continue to monitor the comments and questions inmates raise during the informed consent process to determine whether any additional changes may be needed to our materials.

References


