

**RESEARCH TRIANGLE INSTITUTE
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS
Request for Approval of Research Protocol**

RTI Project/Proposal No. 09778 Date 7/27/06

To meet the requirements of Federal regulations (45 CFR 46) and RTI Policy and Procedures Memorandum 1030, details of a research project that will involve human subjects must be submitted to the RTI Committee for the Protection of Human Subjects for review and approval before participation by human subjects begin. To request approval for such research, the Project Leader must complete this form, attach the informed consent and relevant supporting materials (e.g., questionnaires or other data collection forms, advance letters, agreements to participate), and deliver the request to one of the IRB Administrators, Evelyn Studer or Diana Sparrow. The Project Leader will be notified if it is necessary to meet with the Committee and will be informed of the results of the Committee's review.

Title: National Prisoner Survey of Sexual Assault (NPS-SA)

Sponsor: Department of Justice

Project Duration:

From 8-1-05 To: 7-31-08
Month/Day/Year Month/Day/Year

Date Approval Requested: 08/07/06
Month/Day/Year

Date Participation of Human Subjects Scheduled to Begin: 1/8/07
Month/Day/Year

Reason for Review: (Check One)

- | | | | |
|--------------------------|-----------|-------------------------------------|---------------------------|
| <input type="checkbox"/> | Proposal | <input type="checkbox"/> | Pretest or Pilot |
| <input type="checkbox"/> | Renewal | <input checked="" type="checkbox"/> | Full Study Implementation |
| <input type="checkbox"/> | Pre-Award | <input type="checkbox"/> | Other (specify): |

Project Leader _____ Date _____
Signature

I. STUDY DESCRIPTION

A. Type of Study: (Check all that apply)

X	Survey
X	Record abstraction
	Participation observation
	Laboratory experiment or measurement
	Device, drug, or procedural trial
	Biological specimen collection
	Environmental measurement or testing
	Other (specify)

B. Study Aims: (200-300 words)

Although prevalence estimates vary, it is generally acknowledged that a portion 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 corrections. As a result, the Bureau of Justice Statistics (BJS) has hired RTI International to conduct a survey to generate valid and reliable facility-level data on the prevalence and nature of sexual assault in correctional facilities and identify facilities in which the rate of sexual assault is non-negligible. Although the stakeholders who conceptualized and supported PREA were extremely diverse, their reported reasons for supporting PREA were consistent: to reduce the prevalence of sexual assault in correctional facilities, to better meet the needs of victims of sexual assault in correctional facilities, and to inform and improve the ability of facilities to identify, investigate, and prosecute incidents of sexual assault in correctional facilities.

We completed the NPSA field test in late Spring 2006. The purpose was to refine the protocol and instrumentation before the national launch of the study. We are looking forward to sharing our experiences in the field test with the IRB and discussing our proposed improvements for the national study.

II. STUDY DESCRIPTION

A. Sample Size(s): _ 150,000 interviews across approximately 450 facilities

B. Special Populations (*Check all that apply*)

<input type="checkbox"/>	None
<input type="checkbox"/>	Minors
<input type="checkbox"/>	Newborns
<input type="checkbox"/>	Pregnant
<input type="checkbox"/>	HIV infected
<input checked="" type="checkbox"/>	Prisoners
<input type="checkbox"/>	Alcohol, drug, or mental health program clients
<input type="checkbox"/>	Incompetent
<input type="checkbox"/>	Other (<i>specify</i>) _____

C. Sample Selection Procedure(s): (100-200 words)

We are drawing samples at two levels. The first is a sample of eligible facilities. The Bureau of Justice Statistics (BJS) will provide RTI with a list of all potential facilities. This list will include Federal, State, and private adult jails and prisons. RTI is currently developing a sampling frame.

The second level sample refers to the inmates randomly selected to be interviewed within each facility. In the week prior to a planned data collection visit, the facility staff will provide RTI with a roster of all inmates currently housed at their facility. Based on this roster, RTI will select a random sample of inmates.

RTI will load the inmate sample into the case management system and download it onto the data collection laptop computer of an on-site manager or lead FI. The roster of sampled participants will only contain publicly available information such as the inmate's name, age, race/ethnicity, gender, arrival date, anticipated release date, and housing assignment. The lead FI will print a hard copy of the sample. FIs will use the hard-copy sample when asking the correctional officer to escort inmates for interviewing. Hard copy samples, which will contain only publicly available information, will be destroyed after response rates are calculated and non-response bias analyses have been conducted.

D. Participant Recruitment Procedures: (50-100 words)

This study requires two phases of recruitment. First, we will recruit facilities. Secondly, sampled inmates within those facilities will be approached for recruitment. Because participation of the facilities is legislatively mandated by PREA, we do not expect to experience very many refusals at the facility level. BJS is drafting a “lead letter” to send to the State Departments of Corrections. The DOC’s will disseminate the information in this lead letter to their facilities. We will forward this letter to the IRB once it has been finalized.

After BJS sends the lead letters and the DOC’s disseminate it to the facilities, RTI logistic coordinators will contact sampled facilities to discuss participation, designate a facility contact, and gather some general facility information. After RTI contacts a facility and solicited participation, a logistics plan will be negotiated and customized, and sent to the facility contact in the weeks prior to the data collection visit.

In addition to a logistics document, RTI will mail facilities a FAQ document, which they will be encouraged to share with all staff and inmates at the facility (Attachment A). We will also have it available on site for staff within facilities who may be assisting with the study (e.g., escorting sampled inmates to interview rooms). Importantly, this document highlights a few key points, including:

- Inmate participation is voluntary and inmates can refuse to participate in the interview, answer any particular questions, or discontinue the interview at anytime.
- Not all inmates will qualify for the study, so some will be in the interview room for only a few minutes while others will be in the room for approximately 30 minutes.
- RTI will randomly assign inmates to receive one of two sets of survey questions: either questions about their experiences with sex and sexual assault, or questions about their use of drugs and alcohol, as well as treatment they may have received, prior to incarceration.
- We have designed procedures for involving inmates who cannot leave their cells in the study.
- We will not ask inmates to provide the names of anyone inside or outside the facility.

RTI staff will accept rooms or areas as adequate if participating inmates can take the CAPI/ACASI survey without anyone being able to overhear anything they or the FI say or see the computer screen. As stated above, we will inform facility staff that some inmates may not qualify to participate in the study and that some inmates may refuse to participate. Therefore, facility staff will not have reason to assume that inmates who are in the room for only a short period of time refused or answered questions a certain way, because they may have simply not qualified. The advantage of facility staff not knowing whether an inmate refused or did not qualify is that staff will not treat inmates who refused to participate any differently.

III. INFORMED CONSENT. *Informed consent must be obtained. A copy of the informed consent must be attached to this protocol.*

A. Type: *Check One*

X	Written not signed
	Written and signed
	Verbal not signed
	Verbal and signed
	Both verbal and written

B. Informed Consent Procedures (200-300 words)

X	Copy of Informed Consent Left with Participant – ***If they so desire. See discussion below.
---	---

X	Copy of Consent with Consent Form Checklist Attached (See Attachment B)
---	---

Once our data collection team arrives at a facility, they will ask facility staff to bring the potential respondents one at a time to the interview room or area, at which point an FI will describe the project.

After the FI describes the study, she will hand the inmate a copy of the consent form and ask him/her to read along as the FI reads the consent. FIs will ask inmates if they have any questions and whether they would like to provide consent and participate in the interview. After the inmate provides verbal consent, the FI will sign her own name or initials on the consent form indicating that consent was obtained. All participants will be provided with a carbon copy of the consent form to take with them (if they so desire and if deemed acceptable by the facility staff), By not requiring inmates to sign their consent forms, we aim to increase confidentiality and increase respondents' comfort level as many inmates do not like to sign papers.

For a variety of reasons, facilities may determine that some inmates will not be able to be escorted to the interview room(s). In these cases, we plan to administer informed consent and a significantly abbreviated PAPI questionnaire to such inmates either in their cells or in adequately private areas that we identify within these inmates' housing units. Our requirements for administering the PAPI version are as follows:

- The FI must be able to:
 - o see the inmate,
 - o hand the consent form to the inmate, and
 - o read the consent form to the inmate.
- There must be no one else within earshot (neither staff nor other inmates) during the informed consent process.

If these conditions cannot be met, we will not seek informed consent nor proceed with the PAPA administration. During the pilot, the facilities were not always able to meet these requirements and hence we could not interview some inmates. However, we were able to administer the PAPI eight times. In those eight cases, the inmates completed the 30-item questionnaire easily. The only issue observed was trouble following skip patterns, which resulted in some respondents answering questions unnecessarily. Unfortunately this is a common problem with PAPI forms and not one limited only to survey administered to inmates. We are seeking to make further refinements to the PAPI form to reduce these navigational errors but it is likely that such mistakes will still be made.

We also encountered inmates who were neither able to leave their housing units nor leave their cells without shackles and handcuffed to belly chains. We were able to find private interviewing rooms within these inmates' housing units and the inmates were able to participate in the CAPI/ACASI administration while in handcuffs.

In order to provide a feasible opportunity for an inmate to contact the project team and/or RTI's Office of Research Protection with any questions or concerns, we will provide inmates with a small card that contains the address for contacting both the PI for the project and the Office of Research Protection (Attachment C). The FI will offer the card to the inmate at the conclusion of the interview. When we did this in the field test, one inmate wrote with some suggestions for the study.

C. Individual Participant Burden

	0	.		5	Hours for CAPI/ACASI or Hours for PAPI
	0	.		2	

D. Participant Compensation

X	None
---	------

We are not offering any incentives or compensation to correctional facilities or respondents within correctional facilities for their participation. However, it is possible that some facilities will offer inmates a small incentive such as a generic white t-shirt or a hair cut voucher. These are items and privileges that are commonly earned in a prison setting and therefore will not single out inmates as interview participants. We will make decisions on the provision of IRB approved incentives on a case-by-case basis.

Potential incentives include:

- Generic T-shirt
- Hair cut voucher
- An extra hour of recreational time
- An extra hour before lights out

We will seek IRB approval if a facility wants to provide an incentive which is not on the above list of approved incentives.

E. Number of Recontacts:

X	None
---	------

F. Future Contacts:

	Future contact is planned
X	No future contact is envisioned
	Future contact might or could be considered

***We will not recontact inmates as a result of their participation but it is possible that we will revisit a facility in a future round of data collection.

IV. DATA COLLECTION PROCEDURES

A. Type: (Check all that apply)

<p>Survey</p> <table border="1" style="width: 100%;"> <tr><td style="width: 50px; height: 30px;"></td><td>NA</td></tr> <tr><td style="width: 50px; height: 30px;"></td><td>Mail</td></tr> <tr><td style="width: 50px; height: 30px;"></td><td>Anonymous</td></tr> <tr><td style="text-align: center;">X</td><td>Personal Interview</td></tr> <tr><td style="width: 50px; height: 30px;"></td><td>Telephone Interview</td></tr> <tr><td style="width: 50px; height: 30px;"></td><td>Other (<i>specify</i>):</td></tr> </table>		NA		Mail		Anonymous	X	Personal Interview		Telephone Interview		Other (<i>specify</i>):	<p>Biological Specimen</p> <table border="1" style="width: 100%;"> <tr><td style="width: 50px; height: 30px; text-align: center;">X</td><td>NA</td></tr> <tr><td style="width: 50px; height: 30px;"></td><td>Invasive</td></tr> <tr><td style="width: 50px; height: 30px;"></td><td>Noninvasive</td></tr> </table> <p>Device, Drug, or Procedure Trial</p> <table border="1" style="width: 100%;"> <tr><td style="width: 50px; height: 30px; text-align: center;">X</td><td>NA</td></tr> <tr><td style="width: 50px; height: 30px;"></td><td>Invasive</td></tr> <tr><td style="width: 50px; height: 30px;"></td><td>Noninvasive</td></tr> </table>	X	NA		Invasive		Noninvasive	X	NA		Invasive		Noninvasive
	NA																								
	Mail																								
	Anonymous																								
X	Personal Interview																								
	Telephone Interview																								
	Other (<i>specify</i>):																								
X	NA																								
	Invasive																								
	Noninvasive																								
X	NA																								
	Invasive																								
	Noninvasive																								
<p>Record Abstraction</p> <table border="1" style="width: 100%;"> <tr><td style="width: 50px; height: 30px;"></td><td>NA</td></tr> <tr><td style="width: 50px; height: 30px;"></td><td>File review</td></tr> <tr><td style="width: 50px; height: 30px;"></td><td>At agency or facility</td></tr> <tr><td style="width: 50px; height: 30px;"></td><td>Computer</td></tr> <tr><td style="text-align: center;">X</td><td>Request records from agency or facility</td></tr> <tr><td style="width: 50px; height: 30px;"></td><td>Other (<i>specify</i>):</td></tr> </table>		NA		File review		At agency or facility		Computer	X	Request records from agency or facility		Other (<i>specify</i>):	<p>Laboratory Experiment or Measurement</p> <table border="1" style="width: 100%;"> <tr><td style="width: 50px; height: 30px; text-align: center;">X</td><td>NA</td></tr> <tr><td style="width: 50px; height: 30px;"></td><td>Psychological</td></tr> <tr><td style="width: 50px; height: 30px;"></td><td>Physical invasive</td></tr> <tr><td style="width: 50px; height: 30px;"></td><td>Physical noninvasive</td></tr> <tr><td style="width: 50px; height: 30px;"></td><td>Focus group</td></tr> <tr><td style="width: 50px; height: 30px;"></td><td>Other (<i>specify</i>):</td></tr> </table>	X	NA		Psychological		Physical invasive		Physical noninvasive		Focus group		Other (<i>specify</i>):
	NA																								
	File review																								
	At agency or facility																								
	Computer																								
X	Request records from agency or facility																								
	Other (<i>specify</i>):																								
X	NA																								
	Psychological																								
	Physical invasive																								
	Physical noninvasive																								
	Focus group																								
	Other (<i>specify</i>):																								

B. Description of Procedures: (200-300 words)

We will preload potential Field ID Numbers into the data collection laptops. These IDs will not be directly linked with the corresponding interview data. The Field ID's will provide a means for the analysis team to explore response bias by providing basic demographic information on who participated and who refused. We are using a

bifurcated identification system to provide maximum confidentiality for the interview data without sacrificing the ability to analyze response bias.

In the field, we will assign each potential participant a "Field ID Number." This will be a unique identifier which will be assigned to each sampled inmate and entered into the laptop by the Field FI at the start of the of the participant's interview. There will be a computer program on the laptop (running behind the scenes) that will convert the Field ID Number into a "Study ID Number," another unique identifier. This program will use a mathematical algorithm to create the Study ID Number. The participant's survey data will be linked solely to the Study ID Number. The Field ID Number will not exist anywhere in the survey data file. The data analysis team back at RTI will have access to the computer program that creates the Study ID Numbers. They will be able to link the Field ID Number with the Study ID Number, which will be necessary only when there is a discrepancy between data reported by FIs on the number of interviews they completed or who they interviewed, and the actual survey data we receive. However, with the type of conversion program we are using, even RTI data analysis staff can only convert one direction. For example, they can learn a Study ID from a Field ID, but they cannot learn a Field ID from entering a Study ID.

FIs will ask correctional officer escorts to retrieve inmates listed on the hard-copy sample list printed out by a lead FI. Once an inmate is escorted to the interview location, an FI will verify the inmate's identity to ensure that the integrity of the sample is maintained. To initiate the interview, FIs will read the informed consent statement to the sample member. We will not ask respondents to sign a paper consent form. If consent is not obtained, FIs will finalize the case with the appropriate disposition code in the computer as well as on the hard-copy sample list which will be in the possession of the FI at all times, thereby enabling the computation of an accurate response rate and the conduct of a nonresponse bias analysis. In situations where a sampled inmate is unavailable when called, FIs will make subsequent attempts to interview the inmate during the week at the facility. RTI will assign final disposition codes to all non-interview cases, including inmates who were released prior to data collection.

When setting up the touch-screen computer, FIs will require a private setting where the screen can only be seen by the individual sitting in front of it. Prior to beginning the ACASI portion of the interview, the FI will give brief instructions on the use of the computer including the proper way to tap the screen, how to change answers, back up, and hear a question read again. In addition, the FI will observe the respondent's completion of a short ACASI tutorial, making sure that the respondent can see the screen, hear the questions through the headphones, and enter their responses. Once a respondent is ready to begin the interview, the FI will move to another part of the room (or step outside the interview room if they can observe through a window) so they can be available to answer any questions while still maintaining respondent confidentiality.

It is important to note here that a random 10% of respondents will not be asked about their experiences with sex and sexual assault. Instead, these respondents will receive various questions about their use of drugs and alcohol, as well as treatment they may have received, prior to incarceration. Neither correctional staff nor inmates will know who actually receives the sex and sexual assault items. They also will not know with certainty who refused to participate in the study, since inmates and staff know that some inmates will not qualify to participate while some inmates might refuse to participate. Additionally, if an inmate refuses to answer three questions in a row within the

sex/sexual assault module, they will automatically be taken to the next module and not asked any more questions about sex/sexual assault.

We will offer both the computerized and PAPI interview English and Spanish. It is possible that in future years we may expand our language offerings based on our experiences in year one of data collection.

Included in the ACASI instrument are some questions that will permit Latent Class Modeling (LCM), which will help determine the extent to which the data provided by inmates are invalid. LCM will allow us to generate estimates of the rate of false negatives (i.e., inmates claiming they were *not* victimized when in fact they were) and false positives (i.e., inmates claiming they *were* victimized when in fact they were not).

After the inmate completes his/her portion of the interview, he/she will be instructed to tell the FI that he/she is through. The FI will take back the computer and answer a few debriefing questions. At the screen where the inmate is told to turn over the computer to the FI, there is no way to back up in the interview. This prevents the FI from viewing the inmate's responses to the ACASI questions. Upon completion of the interview, the FI will retrieve the computer and check the case management system to verify that the interview was finalized.

It is important that we conduct this study the most valid manner possible. One component of validity relates to the representativeness of the sample from which data are collected. As the universe for this study is all incarcerated individuals in the United States, it is therefore important that all (or at least the large majority of) inmates we sample are afforded an opportunity to participate in the study. It is estimated that a total of about five to 10 percent of inmates in participating correctional facilities will not be able to leave their cells and use the ACASI instrument because the correctional facility will not be comfortable escorting these inmates from their cells to the interview room(s). It may be that these inmates are more likely to be victims of sexual assault, so giving them an opportunity to participate in the study is critical if the validity of the sample and therefore the study are to be maintained.

To accommodate the inmates who the facility *is* willing to let us survey but only in their cells or in areas of the facility other than where we are conducting our interview (e.g., disciplinary segregation housing unit), we will offer a 30-item paper and pencil (PAPI) version of the survey instrument.(Attachment D). In order to maintain the integrity of the sample and the data, FIs must be able to see the respondent and hand the informed consent form (which will be administered the same way it is for ACASI administration) and PAPI survey to the respondents as well as receive the completed PAPI form from the respondents (i.e., correctional staff cannot be involved with the transaction in any way). Facility staff may supervise the transaction, but from a distance that will preclude them from hearing or seeing what transpires. Additionally, inmates completing the PAPI version will be provided with envelopes and instructed to put the completed survey into the envelope and place a tamper proof seal across the envelope flap prior to handing it over to the FI. Envelopes will be FedExed directly to RTI at the end of each day. The PAPI forms will not have any identifying information and envelopes themselves will only have a facility identifier on the outside. We are using the facility identifier so we will be able to combine the resulting data with those produced via CAPI/ACASI at that facility.

In addition to the CAPI/ACASI interview, we will request records from the facilities to enable us to complete a nonresponse bias study to determine whether inmates who agree to participate in the study are truly representative of the larger population of the facility. To conduct this analysis we will request the following data items: age, race, gender, ethnicity, date of admission, primary offense, total maximum sentence (or anticipated release date), and height and weight (when available). RTI will request this information for all inmates selected to ensure that an inmate's participation status (refusal, ineligible, interviewed, etc.) remains unknown to facility staff. The facility will provide the data directly to staff at RTI, where it can be used in conjunction with the result codes from the field, after data collection at the facility is over, to compare respondents and nonrespondents. These basic demographic and criminal history data will never reside with the survey data provided by respondents – they will simply be analyzed to produce aggregate findings as to whether inmates who participated in the study are different from inmates who did not participate on these demographic and criminal history measures.

V. POTENTIAL RISKS

A. Type: *(Check one or more)*

<input type="checkbox"/>	None
<input checked="" type="checkbox"/>	Minimal physical
<input checked="" type="checkbox"/>	Minimal psychological/social/legal
<input type="checkbox"/>	Substantial physical
<input type="checkbox"/>	Substantial psychological/social/legal

B. Description of Physical Risks: (200-300 words)

None

C. Description of Psychological/Social/Legal Risks: (100-200 words)

Our experiences in the field test bolstered our belief that participating in this study will expose inmates to no more than minimal risk. Inmates and staff were comfortable and cooperative and we experienced no adverse events. Correctional officers routinely move inmates within facilities. Inmates also regularly meet with a wide variety of staff, volunteers, lawyers, and visitors. Thus, the act of being brought to the interview room in and of itself should not constitute anything out of the ordinary or create any particular risk.

We took measures in the field test to minimize risk and we are adding to those measures for the full study. For example, we reduced risk in the field test by stating in the FAQs and consent form that some inmates would randomly receive questions about sexual assault and others would receive questions about alcohol and drugs. We also mentioned in the FAQs and consent forms that we were not asking the inmate to name anyone in the interview. We believe that the change to the protocol we made during the field test (with the IRB's review and approval), to allow inmates to be brought to the

interview rooms/areas rather than letting them refuse to be escorted (i.e., require them to make a decision in front of their peers) increased the freedom of the inmates to make their decision of whether to participate free from the pressure of their peers and with a greater sense of privacy. As a reminder, the justifications presented to the IRB for this change included:

- Correctional officers are not equipped to sufficiently or accurately describe the study or the human subject protections.
- Inmates are almost never given the option of whether to accompany an officer, so allowing inmates to refuse to be escorted put officers and inmates in an awkward situation and potentially put inmates at future risk for it might have given them a false sense of power and led to disagreements in the future when they did not want to follow an officer's instruction that was not optional.
- The integrity of the study is somewhat dependent on us knowing that an inmate had the opportunity to refuse, as well as an opportunity, to participate in the study, rather than having to trust officers.
- When inmates are given a choice of whether to go with the officer or not, they do not have sufficient privacy or autonomy to make that decision. When among their peers, inmates are likely influenced positively or negatively, which affects their ability to make an informed decision for themselves.

Some items in the interview are of a sensitive nature and may be uncomfortable or distressing for the respondent. These items include questions regarding being the victim of sexual assault or abuse. However, given our experience conducting sensitive research with inmates in correctional facilities and the field test we conducted, we consider the likelihood of severe distress to be small and we have procedures in place to appropriately handle both mildly and severely distressed respondents.

In addition to the potential distress by respondents, another risk of the study is a breach of confidentiality. Although FIs will establish a private setting before administering the interview and no identifying information will link to the survey data, there is always a slight risk that the respondents' answers might be discovered or subsequently divulged in some manner unanticipated by the project staff. Such a disclosure could affect inmates' relationships with other inmates and corrections staff, and perhaps their jobs and housing situations. However, we have put in place many precautions to ensure that the information collected in the interview remains completely confidential.

Another possibility is that a respondent will voluntarily disclose information to the FI that would be sensitive in nature and ask the FI to do something with that information. For example, an inmate might tell an FI he has been sexually victimized and that he would like the FI to help him in some way (e.g., by reporting the victimization). In these instances, FIs will provide information to the inmate on how to go about filing an official grievance either at the facility or to whatever state reporting mechanisms exist. We will identify possible grievance reporting mechanisms at each facility, and equip FIs with this information so they can provide it to inmates in need and explain to inmates that reporting such things is not part of their job.

VI. PROTECTION OF SUBJECTS:

A. Guarantees:

<input type="checkbox"/>	Anonymity (no link between individual and data is possible)
<input checked="" type="checkbox"/>	Confidentiality (RTI guarantee only)
<input type="checkbox"/>	Confidentiality (RTI & other guarantee) (<i>specify</i>)

B. Types of Procedures Provided to Reduce or Alleviate Risks

<input type="checkbox"/>	Maintenance or environmental cleanup or correction
<input type="checkbox"/>	Psychological counseling
<input type="checkbox"/>	Medical treatment
<input checked="" type="checkbox"/>	Other (<i>specify</i>)

***See below.

C. Description of Procedures to Reduce or Alleviate Risks: (100-200 words)

After our experiences in the pilot, we have refined the minimum conditions under which we will conduct data collection at a facility. Once we begin communicating directly with facilities, we will ensure that each facility:

- Has at least one counselor, psychologist, or psychiatrist who is either at the facility or on call and can be summoned to the facility within 24 hours
- Can provide us with the name of the person (or at least the name of the department if there are multiple individuals who can provide this service, as is the case in some large facilities) who can provide services to distressed respondents and procedures for how an inmate can go about accessing these services.

If a facility cannot meet these criteria, we will bring the situation to the IRB to see if what the facility can offer in terms of capabilities in this area is sufficient. If it is not sufficient, we will establish a consulting agreement or subcontract with a local mental health service provider to come into the facility and provide necessary services during and several weeks after data collection.

If a respondent becomes distressed, the FI will first attempt to respond to the situation by giving the inmate time to collect him or herself, offering to skip questions that may be upsetting, or terminating the interview altogether. For the few inmates for which this is not adequate, the FI will suggest to the respondent that he or she see the designated facility person and follow the protocol for accessing available services (which the FI will provide). If the inmate remains upset or if the FI feels she or the inmate is in danger, then the FI will alert the escorting correctional officer, which will help ensure the safety of the inmate, the FI, and facility staff. As a reminder, in an effort to decrease the potential for respondent distress, if inmates refuse to answer three questions in a row within the

sex/sexual assault module, they will automatically be skipped to the next module. Attachment E contains the Distressed Respondent Protocol for the study. Field staff will report severe adverse events to the PI within 24 hours. The PI in turn will report all such events to Wendy Visscher within 48 hours of receipt.

D. Description of Security Measures: (50-100 words)

In order to prevent a breach of confidentiality, we have taken the following steps:

- Neither names nor Field ID Numbers will be stored with interview data.
- The computer will generate unique Study ID numbers that will only be able to link to the Field ID Numbers using a highly complex translation key created specifically for this project and made known only to three or four project computer programmers at RTI. This translation key will not be available to the sampling staff who will have access to the sample containing identifying information.
- Hard copy samples will be destroyed when data collection at that facility is finished.
- All laptops will be password protected and all data and documentation files related to data collection will be encrypted with PGP software.
- FIs will not be able to view ACASI data after the inmate has completed that section of the interview.
- FIs will not be able to access a closed interview case.
- All data will be encrypted and transmitted off of the laptops daily
- All PAPI surveys will be sealed in tamper-proof envelopes by the respondent before being handed to the FI.
- The PAPI surveys will be sent via fed-ex to RTI daily
- Inmate samples will be kept for use in the response bias analysis. However, neither the Field ID Numbers nor the inmate names will be able to be linked to the Study ID Numbers that will reside with the survey data without the translation key discussed above.
- Before any data or findings are released to the public or individual correctional facilities, the project management will share plans for release and dissemination with the IRB to help ensure that participant confidentiality will be maintained throughout the dissemination process in compliance with the relevant federal regulations.

Hard-copy materials and laptop computers will remain in the possession of the FIs at all times, and the laptops will be password-protected. All data and documentation files on the laptops related to subject recruitment and data collection will be encrypted with PGP software. Therefore, even if someone steals or confiscates a laptop and hacks past the password-protection, they will not be able to get into the encrypted files. Data that are transmitted to RTI will be encrypted so if someone somehow intercepts a transmission, the file they obtain will not be accessible.

VII. BENEFITS

A. Information Provided to Study Participants

<input checked="" type="checkbox"/>	No direct benefit
<input type="checkbox"/>	Medical or physical data (e.g., serum levels)
<input type="checkbox"/>	Social data (e.g., eligibility for service)
<input type="checkbox"/>	Psychological data (e.g., test scores)
<input type="checkbox"/>	Environmental data (e.g., toxicity levels)
<input type="checkbox"/>	Other (<i>please specify</i>)

B. Services Provided to Study Participants:

<input checked="" type="checkbox"/>	No direct services provided
<input type="checkbox"/>	Medical or rehabilitation treatment
<input type="checkbox"/>	Social/economic service
<input type="checkbox"/>	Psychological counseling
<input type="checkbox"/>	Environmental cleanup or correction
<input type="checkbox"/>	Other (<i>please specify</i>)

C. Other Benefits: (*please describe*)

None

VIII. RISK/BENEFIT RATIO

A. Type:

<input type="checkbox"/>	No risk/no individual benefit
<input checked="" type="checkbox"/>	Minimal risk/minimal individual benefit
<input type="checkbox"/>	Minimal risk/substantial individual benefit
<input type="checkbox"/>	Substantial risk/substantial individual benefit
<input type="checkbox"/>	Substantial risk/substantial research/society benefit

B. Weighing of Risk/Benefit: (200-300 words)

There are risks to inmates who participate in this study. However, the project team has taken considerable measures to minimize the risks to a minimal level. It is our belief that the remaining risks are outweighed by the tremendous benefits that might result from this data collection proceeding as planned. Currently, no valid and reliable data on the prevalence and nature of sexual assault in corrections exist. Not until such data are generated will we understand the magnitude of the problem or how to best go about preventing future assaults and protecting those inmates who are at accelerated risk of being victimized. Members of Congress have mandated that this research be conducted because they understand that the potential consequences of not learning more about sexual assault in correctional facilities are profound.

The first step in understanding how sexual assault might be affecting incarcerated populations and how to go about preventing it in the future is to collect valid and reliable data on the prevalence and nature of sexual assault in America's correctional facilities. The proposed study is a field test of the methodology that BJS, Congress, and we believe will produce these much-needed data.

Although the potential risks associated with being asked to participate or actually participating in the NPS-SA cannot be erased completely, they can be seriously mitigated, and we believe our procedures accomplish this goal.

X. SPECIAL ISSUES

A. Type of Issue or Risk:

<input checked="" type="checkbox"/>	None
<input type="checkbox"/>	Collaborative research

<input checked="" type="checkbox"/>	RTI is prime contractor
<input type="checkbox"/>	RTI is subcontractor
<input type="checkbox"/>	Other (<i>please specify</i>) _____

<input type="checkbox"/>	Need to release information on risk
<input type="checkbox"/>	Follow-on studies
<input type="checkbox"/>	Other (<i>please specify</i>) _

B. Discussion of Special Issues and Approach to Minimize Risks: (200-300 words)

Due to the nature of this study, we have taken a number of steps to minimize risks:

- A random 10% of the respondents will be given an alternative version of the questionnaire. The purpose of the questionnaire masking is so that neither correctional officers nor other inmates know which version of the questionnaire a given respondent actually received. Therefore, no one will know whether the respondent received the sexual victimization questions or another set of questions.
- Any respondent who gives three refusals in a row in the sex/sexual assault section will be automatically skipped out of this module to avoid the risk of upsetting the respondent.
- Inmates and staff will be informed that not all inmates will qualify for the study and that some inmates might refuse to participate in the study. Therefore, neither staff nor other inmates will know if an inmate who does not remain in the interview room for ~30 minutes refused to participate or did not qualify to participate for some reason.
- Data to be used for the non-response bias study will be collected for the entire sample so that facility staff cannot be certain who did and who did not participate.
- FIs will be required to sign a Statement of Confidentiality (Attachment F).

X. NEEDS FOR FUTURE REVIEW

<input type="checkbox"/>	Pre-Award	Date	_____
<input type="checkbox"/>	Pretest/Pilot	Date	_____
<input type="checkbox"/>	Full Study Implementation	Date	_____
<input checked="" type="checkbox"/>	Renewal	Date	_____ 8/07 _____
<input type="checkbox"/>	Other (<i>please specify</i>)	Date	_____