

Attachment 5

IRB Approval of NSYC-2

Memo

Date: December 29, 2010

To: John Hartge, Project Director

From: Kerry Levin; Chair, Westat IRB



Subject: **Full Approval of NATIONAL PRISON RAPE (NYSC2), Project Number 8733
FWA5551**

On Tuesday, December 14th, 2010 the **NATIONAL PRISON RAPE (NYSC2), Project Number 8733**, was presented to the full Board. Pursuant to 45 CFR pt. 46, the IRB reviews all studies involving research on human subjects. The Bureau of Justice Statistics (BJS) funds this study.

This request was to review and approve the second National Study on youth in Custody (NSYC-2). Westat completed NYSC1 in 2010; approximately 10,000 youth completed surveys in 195 state-owned and privately owned juvenile facilities.

In NYSC2, Westat will implement similar data collection and analysis procedures as was conducted in NYSC1.

During the discussion, the following information was provided to the Board:

- Initially, a brief report of the NYSC1 findings was presented as well as a description of the lessons learned. The selection of findings is reported below:
 - 50% of the interviews conducted used *in loco parentis* (ILP) in place of parent/guardian permission. No reports of complaints or incidents were documented.
 - 12% of parents contacted refused permission for their youth to participate in the study. Refusal conversion was not conducted.
 - 33% of facilities in the study provided insufficient information to contact parents.
 - 99.5% of the youth participants reported comprehending the key elements of consent.
 - 86% of youth participants reported feeling that their information would remain confidential.
 - ~25% of the youth reported finding something upsetting about the survey. This statistic was found regardless of the type of survey completed (i.e., sex, drugs).
- Design changes for the NYSC2 study were discussed and included the following main points:
 - Earlier release of the results of the study to the facilities.
 - Increase the sample size by 15 to 20%.

- Utilize additional procedures such as on-line searches to obtain parent contact information when facilities cannot provide addresses.
 - Add new survey questions (e.g., whether youth knew the rules for reporting sexual contact, who initiated the contact, and if youth thought that the contact was part of a close relationship).
- The Board inquired whether the BJS adopted the Common Rule and they do. The Common Rule is a set of core regulations, adopted by 17 Departments and Agencies in 1991. The regulations, 28 CFR Part 46 for DOJ, set up procedures to establish and operate an Institutional Review Board (IRB) to review human subjects research.
 - A Board member inquired about the study's data destruction date. The project team explained that there will be two types of identifiable data, the identifiable information to track parents to collect informed consent as well as the youth participant survey data. This is a de-identified double blind study with a three ID system set up to prevent any opportunity to re-identify the data. The project team will destroy the data as soon as possible, most likely before the data analysis begins and will not be linkable to any analytic results.
 - The Board inquired as to why the risks and benefits' sections were excluded from the informed consent forms. First, the project team believed that they addressed the issues related to risks by telling youth that they may request the services of a facility or an external counselor. Further, the project team has included mandatory reporting language in this study that is identical to the language used in NYSC1. Second, since there are no direct benefits to youth participants in this study, the project team believed that communicating the concept of potential indirect benefits would be difficult, and that little would be gained from any attempt to describe this to them.

Action Requested: Review protocol, pre-notification letters, informed consent and assent forms, instruments, and accompanying materials.

Action Taken: Per 45 CFR 46, the Westat IRB determined that this research met criteria for classification as minimal risk and assigned it a conditional approval. For: 8; Against: 0; Abstain: 0.

The following is a list of questions and comments that resulted from the discussion between the research team and the Board as well as the research team's responses.

Protocol/Procedures

1. Describe procedures to be used for conducting on-line searches for parents/guardians when a facility cannot supply adequate addresses to mail consent packets. (Page 24)

Project Response: The project summary provides a description of the conditions under which a search would be conducted, including the search engine that will be used, and the procedures that will be followed once any new contact information is obtained. (Pages 14-15 of the revised project summary)

2. State that the outcome of the call to a parent/guardian is to either record verbal consent or refusal regarding the youth's participation in the study. (Page 24)

Project Response: Text was added in the project summary to clarify the fact that some cases will be assigned for prompting calls and others will be assigned for verbal consent calls. Text was also revised to better explain that only recordings of calls resulting in a “consent given” status will be reviewed. (Page 13 of revised Project Summary)

“When interviewers contact parents/guardians to request verbal consent, they will read a scripted version of the consent form designed for telephone delivery (Appendix B). If the intention of the call is to request consent (rather than prompt), as soon as the interviewer determines that the parent/guardian is on the telephone, he/she will ask permission to record the conversation. All recordings of calls that an interviewer codes as “consent received” will be reviewed to confirm that proper procedures were implemented and that the outcome of the call was properly coded. Calls that result in a refusal will not be reviewed. No refusal conversion efforts (i.e., call backs to those who refuse consent) will be attempted.”

3. Describe procedures to ensure interviewer availability throughout the field period (e.g. use of cell phones).

Project Response: All field staff will carry cell phones throughout the data collection.

4. Under the third paragraph on page 12, replace the word “experienced” with “reported experiencing.”

Project Response: Done

5. Provide more details about the information included in the interviewer’s human subjects protections trainings prior to performing the following procedures:

- Obtaining documented informed consent from parents/guardians for their youth to participate by facility staff. (Page 23)
- Obtaining verbal parent permission by telephone interviewers. (Page 24)
- Obtaining verbal youth assent by field interviewers. (Page 25)
- Conducting the youth survey by field interviewers. (Page 26)

Project Response:

Obtaining documented informed consent from parents/guardians for their youth to participate by facility staff. (Page 15 of revised Project Summary)

The interviewer’s human subjects protections training will cover the following topics:

All facility staff engaged in contacting parents/guardians regarding consent will receive training on human subjects protections. As was done in NSYC-1, Westat senior project staff will conduct a training session by telephone with facility staff. Training of Westat staff will follow standard protocols used by the Telephone Research Center for interviewers working from their homes. Sessions will address the following topics:

- Parents/guardians need to be fully informed before making a decision. Information provided must include what the study is about, who is sponsoring the study, and how it will be administered.

- Staff should be sensitive to how parents/guardians react to the request for consent and understand that no attempts will be made to convert a refusal.
- Parents/guardians have a right to talk to the youth prior to consenting and youth will have the right to refuse to participate.
- There will be no effect on services or treatment of youth if parents/guardians (or youth) refuse.
- Study staff will comply with state mandatory reporting requirements if the youth makes a verbal statement to the survey administrator regarding any abuse or harm to him/her or another child

Obtaining verbal parent permission. (Pages 15-16 of revised Project Summary)

Westat interviewers will also receive training on the procedures for recording calls aimed at collecting verbal consent. This will include discussion of the fact that all consent calls will be recorded (if the parent/guardian agrees), and the procedures for asking the parent/guardian for consent to record the call and what to do if the parent/guardian refuses to be recorded. Training will also address the fact that all consent recordings will be reviewed by project staff to ensure that the consent procedures were followed and that the documented consent decision reflects the parent/guardian's wishes as stated in the recording.

Obtaining verbal youth assent. (Pages 16-17 of revised Project Summary)

NSYC-2 will follow the same procedures to contact and obtain assent from youth as were used in NSYC-1. Monitors will receive training on issues related to human subjects protections and will become familiar with the procedures used to inform youth of their rights and assess their comprehension of the study purpose, procedures, their risks, and rights as participants. Training will address the following topics:

- Confidentiality of youth data, including their obligations under the Westat Confidentiality Pledge and the BJS Privacy Agreement, the prohibition on asking youth their name or other identifying information, and the restrictions on discussing the study experiences with anyone other than their supervisors.
- Compliance with state mandatory reporting requirements, including the requirement to follow predetermined facility-specific procedures when a youth makes a verbal statement suggesting abuse or harm of a resident.
- Verification of youth eligibility, including restrictions and procedures related to overriding the date of birth recorded in the survey management system such that consent status might be changed.
- Procedures used to assess youth comprehension of the key elements of assent and acceptable responses to questions the youth might have about the elements reflected in the assent materials.

Conducting the youth survey. (Page 22 of revised Project Summary)

Monitors will receive training on how to protect the youths' privacy and observe the youth for emotional upset during the interview session. For example, the monitors will be instructed on how to assist the youth if they have questions about specific survey items. This will help prevent a monitor from learning the youth's survey responses as revealed by the routing through the questionnaire (i.e., skip pattern). In addition, monitors will be trained to remain continually alert to the youth's affect as it may be conveyed in comments, utterances, or body language. These observations may help identify youth in distress and lead the monitor to ask if the youth would like to speak to a counselor.

Informed Consent Process

6. Make the following requests for waivers or modifications of informed consent:

1. Accepting a waiver of documentation of informed consent from parents/guardians.
2. Accepting verbal assent from youth participants.
3. Omitting a statement on “Benefits” from the informed consent and assent process.
4. Accepting only one parent’s permission for youth participation in the study.

Project Response: Text was added to reflect requests for waivers and modifications to consent regulations.

1. As with NSYC-1, a waiver of documentation of informed consent from parents/guardians is requested as many states do not permit Westat to have possession of youth names and the names must appear on the consent forms. In addition, since Westat (and some facilities) sometimes collect verbal consent by telephone, documentation is not always possible.
2. To protect the confidentiality of the youth, field staff is not permitted to collect the names of youth.
3. Since there are no direct benefits to youth participants in this study and communicating the concept of potential indirect benefits would be difficult, the project team believes that little would be gained from any attempt to describe this to them. Therefore, a waiver to omit this element is requested.
4. The primary reason for requesting consent from one parent is again related to the likely inability to locate both parent/guardians. NSYC-1 demonstrated that locating one parent/guardian was very difficult and often impossible. The prospect of contacting both would have serious implications for the project team’s ability to conduct the study.

7. In the Parent Permission Form, replace the phrase “legal certificate” with another phrase that more accurately describes the confidentiality agreement that the project team signs to be on this study. (Page 43)

Project Response: “All of the researchers working on this study have signed a legal certificate document saying that they will protect your child’s privacy and not to tell anyone anything that he/she has said. Anyone who intentionally breaks this promise would lose their job and might face criminal charges.” (Pages B4 and B7 of the revised informed consent materials)

Action Taken: Per 45 CFR 46, this project meets criteria for classification as minimal risk and is assigned a full approval.

As the Project Director you are responsible for the following:

- You are required to submit this study for a continuing review on or before December 14, 2011.
- In the interim, you are responsible for notifying the IRB Office as soon as possible if there are any injuries to the subjects, problems, or changes to the study design that relate to human subjects.

cc: Institutional Review Board
Mark Freedman