Angel, Karen C. (CDC/ONDIEH/NCIPC)

From: NCIPC OMB (CDC)
Sent: Wednesday, December 07, 2016 10:27 AM
To: geraldschatz@charter.net
Cc: NCIPC OMB (CDC)
Subject: DHHS-Proposed Data Collection Docket No. CDC–2016– 0113, 81 Fed. Reg. 87037 (Dec. 2, 2016).
Attachments: Forensic Consent Form.pdf; IRB approval.pdf

Dr. Gerald S. Schatz.

Please find responses to your inquiry.

1. How would this project be in the direct interest of and to the direct benefit of the prisoner subjects?

The Centers for Disease Control and Prevention (CDC) has contracted the behavioral research firm American Institutes for Research (AIR) to conduct this study for the purpose of ascertaining which factors or groups of factors may influence violence perpetration that occurs within adult intimate partner relationships. The survey covers many domains that previous research has identified as potentially influential (childhood history of abuse, substance use, attitudes toward women, etc.) The information gathered here is the first step in a long-term CDC project to develop a measure that accurately assesses different types of IPV. Understanding the different contexts in which IPV can occur will allow CDC to develop primary and secondary violence prevention programs that speak to the specific needs of those at risk. Thus, this work will ultimately benefit prison populations because it will inform what services and strategies will be most effect for inmates that may be at risk of committing violence in intimate relationships. This may prevent future contact with justice system as well as reduce personal psychopathologies and adversities. Moreover, we hope that individuals will benefit directly from participation in our study. We will provide participants with contact information for local and regional mental health resources. We will make sure these contacts are legitimate and open to providing help, if needed. Studies found that individuals found participation in research therapeutic, gave them a sense of worth and an opportunity to "do good", while also providing time to talk with someone (Copes et al. 2012, Moser et al. 2004).

2. Was this proposal reviewed for protection of human subjects of behavioral and biomedical research? If so, by what entity and how were the interests of prisoner subjects represented.

The current research project received IRB approval from the contractor's internal IRB. The IRB contained a prison advocate, Bruce Reilly, J.D. who is national figure in criminal justice reform and prisoner rights. We were required to satisfy all of his questions and requirements before receiving IRB approval.

3. How will proposed subjects be assured as to voluntariness of their participation? If informed consent is to be sought, provide a copies of the informed-consent documents and explain how the circumstances will be conducive to voluntariness?

Participants will receive an advanced letter explaining the study. In the advance notice, we will stress that participation is voluntary and that there are no repercussions for not participating. AIR staff will be present at the facilities on selected days and inmates can come, if desired, to schedule appointments for later in the week. Scheduling will be done in a private room. Only essential and minimal facility staff will know the details of this project. Non-essential staff will only be informed that some inmates have an appointment. They will not know the purpose of the appointment or whether an inmate participated in the survey or not. During the appointment, participants may still decline to participate. Additionally, as suggested, we removed the checkbox for "I do not consent" on the consent form. Individuals who do not wish to participate can leave the appointment without signing any paperwork. Previous research suggests that many inmates do not feel pressured to participate by

correctional staff and clearly understand that they have a choice to participate or not (Copes et al., 2012, Moser et al., 2004).

4. How will confidentiality of responses be assured? Who would have access to data identifiable to specific individuals, and what assurance is there that these data will not be taken into account in the individual records of prisoner subjects?

   This project will be receiving a Certificate of Confidentiality, which will protect the privacy of respondents by protecting research staff from being forced to release respondents' identifying information in any civil, criminal, administrative, legislative, or other proceeding. The participants will be informed of this as well. Surveys will be conducted individually in a private, quiet room. In order to not disclose to the staff who does and does not participate in the survey, all eligible offenders will spend time equivalent to the amount of time it takes to complete the survey in the survey room, no matter if they are sampled to take the survey or not. If this is not possible, we will employ another method to ensure that facility staff do not know who is taking the survey. This protects participants from feeling coerced into consenting into the survey because they fear punishment from facility staff if they do not. We will have a memorandum of understanding (MOU) in place to address roles and responsibilities of facility staff, especially in regard to confidentiality. AIR will maintain confidentiality by using a secure file transfer protocol site to transfer identifiable information between the facilities and AIR. All identifiable information and survey data will be kept on FISMA compliant servers with restricted access only to necessary researchers. All paper consent forms will be stored in locked file containers. The survey data collected through DatStat's Illume survey software will be stored on DatStat databases and servers. AIR staff will be in possession of the iPads and monitor their use at all times. All iPads will be password protected and stored in locked storage containers when not in use. Data will be uploaded to DatStat servers daily, or as soon as possible, and taken off of the iPad. DatStat's servers, databases, and web presences are HIPAA compliant and employ multiple forms of security features. Their security protocols are designed to protect the data as well as the confidentiality of research participants. After data collection, data will then be transferred to a FISMA compliant server for storage.

Thank you for your comments and questions.

IRB/OMB Unit
Centers for Disease Control and Prevention Chamblee Campus
National Center for Injury Prevention and Control
4770 Buford Highway, MS F63
Atlanta, GA 30341-3717
email: ncipcomb@cdc.gov

Understanding Relationship Dynamics and Conflict Survey

Consent Form-Incarcerated Population

Thank you for coming today. Please read (or ask me to read) the information below about our survey. Be sure to ask if you have any questions. If you are willing to take part in the survey, please sign your name at the bottom and give the form back to us.

What is this survey about? What will you ask me to do?
This survey is about problems and violence that sometimes happen in relationships between partners, such as boyfriends and girlfriends or husbands and wives. We will ask you to answer questions about yourself and your relationships.

You are one of about 700 people taking this survey. Everything we learn will help us think about ways to understand violence in relationships.

This survey will take about 75 minutes. You are welcome to help yourself to one of the snacks we have here.

Who is giving the survey?
The American Institutes for Research (AIR) is giving this survey. AIR is a research organization based in Washington, DC. The survey is funded by the Centers for Disease Control and Prevention (CDC), a government agency.

Do I have to take the survey?
No. It is your choice whether to do the survey or not. If you decide to start the survey, you can stop taking it at any time. You do not have to answer any questions that you don't want to. There are no penalties or punishments if you choose not to take the survey. There are no penalties or punishments if you chose to take the survey and change your mind later.

What are the risks if I take the survey?
You may feel uncomfortable answering some of the questions on the survey. Remember, you can, at any time, skip questions that you are uncomfortable answering or stop taking the survey.

Some questions ask about your thoughts, experiences, or illegal activities, including violence towards other people. We know that if other people found out about your answers, it can be embarrassing or cause problems with your job and in your relationships. Please know that anything you share will be kept private and never linked to your name.

There is one exception. If you share information about child abuse or abuse of an elderly or disabled person that is currently happening, we must report this to the proper

authorities. We will not ask you to tell us about this and we suggest that you do **not** share this information during the survey.

What are the benefits if I take the survey?
Please know that taking this survey will not affect your case. It will neither help nor hurt your case in any way.

The benefits to taking the survey are that you will help add to what is known about violence in relationships. This could help form better programs that address relationship violence.

How will you protect my privacy?
We know how important it is to keep your information private. We will take all steps to keep your information confidential. No one besides the AIR researcher in the room will know if you decide to take the survey or not. All inmates will sit in this room for 75 minutes even if they do not take your survey. This way no one, not even the facility staff, will know who took the survey.

Your answers will have a code number given to you by AIR. We will not link your name or Facility ID number with anything you say. Additionally, results from this survey will only be reported for groups of participants. We will never report results about specific people.

This project has a Certificate of Confidentiality from the CDC. This means that we cannot and will not share any information about you in any legal situation. Any documents that could identify you will be kept in a securely locked place.

What if I want more information?
Please ask us today if you have any questions.

If you have additional questions or concerns about this survey, please contact the director of the survey at AIR, Melissa Scardaville, Ph.D. at (404) 260-1046.

If you have concerns or questions about your rights as a participant, contact AIR's Institutional Review Board (which is responsible for the protection of people taking this survey) toll free at 1-800-634-0797 or c/o IRB, 1000 Thomas Jefferson Street, NW, Washington, DC 20007.

Signature of Subject or Legally Authorized Representative
I have read (or someone has read to me) the above information. I have been given the chance to ask questions, and my questions have been answered to my satisfaction. I have been given a copy of this form.

Please check the appropriate box below to indicate if you agree to participate in this research:

Incarcerated Population Consent Form

___ I agree to take the survey
___ I would like to talk with someone from the research team before making my decision.

Your signature:_____ Date:_____

Print your name:_____ Appointment time:_____

From: padii@air.org [mailto:padii@air.org]
Sent: Tuesday, November 08, 2016 12:47 PM
To:
Cc:
Subject: IRB submission approved for project IPV METRIC (project number 01410.104/B&P number 85684)

Dear Applicant,

The IRB has completed its review of your PADII submission for the project (project number 01410.104/B&P number 85684) and has granted approval. Please keep in mind these directives made by the IRB Reviewer:

On the basis of this review, the IRB has determined that the project, as described in the materials submitted, is research and does involve human research participants. The research is approved because the selection of participants is equitable and the risks to the participants are minimized and are reasonable in relation to the knowledge that may reasonably be expected to result. Because this research project involves (in part) participants who are prisoners, the IRB has made findings for each of the relevant requirements under Subpart C. These are as follows: 1. Category of permissible research The IRB finds that this research fits into category (iii) the study of on conditions particularly affecting prisoners as a class. As is required under 45 CFR §46.306(a)(2), we find that the study presents no more than minimal risk, and no more than minor inconvenience to the subjects. Approval requires the study may proceed only after the Secretary of Health and Human Services and her designee has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research. 2. Advantages to the prisoner do not impair the ability to weigh risks There are no direct advantages to the incarcerated persons for taking the survey. These include no changes in living conditions, medical care, quality of food, amenities, or opportunity for earnings. There are small monetary incentives and access to snacks during the survey administration session. 3. Risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers We find that this is minimal risk research, which for prisoners means that the probability and magnitude of physical or psychological harm involved in participating in the interview is no greater than what is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. 4. Procedures for the selection of participants are fair The incarcerated participants will be purposively selected from the incarcerated populations at participating facilities. 5. Understandable language Only English-speaking participants will be included in the interviews 6. Parole boards will not take research participation into account The consent form specifies the following: "Please know that taking this survey will not affect your case. It will neither help nor hurt your case in any way." 7. Need for follow-up or care of participants addressed We find that there is no reasonable expectation that follow-up or care will be required following participation in the survey. Given these findings, and the approval of AIR's prisoner advocate who also has carefully reviewed this project, the IRB makes this determination of approval. Data collection may proceed.

If you have questions about this determination, please check with the primary reviewer for this submission, KENDZIORA, KIMBERLY T.. The next IRB review for this project is set for

10/08/2017. Please submit an IRB Progress/Final Report before that time.

Thank you,

PADII Support,
padiisupport@air.org

Any material changes made to the study or the study procedures require the submission of an updated IRB package.

Any unanticipated problems or adverse events must be promptly reported to the IRB Administrator or IRB Chair

Angel, Karen C. (CDC/ONDIEH/NCIPC)

From: NCIPC OMB (CDC)
Sent: Thursday, February 09, 2017 3:17 PM
To: Gerald Schatz
Cc: NCIPC OMB (CDC)
Subject: DHHS-Proposed Data Collection Docket No. CDC–2016– 0113, 81 Fed. Reg. 87037 (Dec. 2, 2016).

Dr. Gerald S. Schatz.

Thank you for your comments and questions. Please find responses to your second inquiry.

As an ethicist concerned with protection of human subjects of behavioral and biomedical research and as a lawyer concerned with regulatory compliance by researchers and sponsor agencies, I felt duty-bound to look into this proposed research on vulnerable subjects.
The above-caption notice was issued pursuant to the Paperwork Reduction Act, which inter alia requires compliance with relevant law.
Despite an apparent good-faith attempt to comply with human subjects protection law, the project is not yet in compliance. Problems include:

The consent form is misleading in important respects and reflects inadequate IRB review. The consent form overpromises confidentiality. The consent form mentions a Certificate of Confidentiality as affording complete protection against disclosure except where harm to another is threatened. But Department of Health and Human Services Certificates of Confidentiality do not protect against voluntary disclosure by a researcher or handler of the research data. Moreover, whether they can withstand state court subpoena has not been subjected to Constitutional test.

Response

- The American Institute for Research's IRB has provided a careful review in compliance with our Federalwide assurance.
- However, in order to be responsive to the spirit of the comments, we have removed the language pertaining to the certificate of confidentiality in response the commenter's point so to reduce the risk of "overpromising" confidentiality. In addition, we have added significant description about the specific steps that will be taken to protect their privacy and removing any language that would guarantee confidentiality.

That data will be locked or coded says nothing about identifiability or who has access under what conditions

Response

- AIR's IRB places a strong value on concision in consent forms. IN particular with this population it is imperative that we ensure the consent forms are at a reading and detail level that will not interfere comprehension. Lengthy consent forms can make it less likely that a participant will be willing or able to read and comprehend such detail. We do not generally include in consent forms information about who has access to study records, since in almost every case access is strictly limited to the study team. For this project, access is limited to the study team.

The consent form minimizes the likelihood that responses will be self incriminating and subject to disclosure. Yet much of the whole survey delves into behavior that might be incriminating.

Response

- The consent form states, "This survey is about problems and violence that sometimes happen in relationships between partners, such as boyfriends and girlfriends or husbands and wives. We will ask you to answer questions about yourself and your relationships."
  The consent form further specifies: "Some questions ask about your thoughts, experiences, or illegal activities, including violence towards other people. We know that if other people found out about your answers, it can be embarrassing or cause problems with your job and in your relationships.

  Please know that anything you share will be kept private and never linked to your name. There is one exception. If you share information about child abuse or abuse of an elderly or disabled person that is currently happening, we must report this to the proper authorities. We will not ask you to tell us about this and we suggest that you do **not** share this information during the survey."
  Therefore, the IRB regards this issue as adequately covered.

I am a District of Columbia lawyer, not an Indiana lawyer, but my reading of Indiana's corrections information disclosure statute tells me that confidentiality can be overridden for compelling reasons in the public interest (not further defined in statute). Indiana's statute apparently thus presumes prior knowledge of what might be disclosed. In this regard, the IRB record of decision does not reflect inquiry into whether there is credible assurance that the interview room will not be wired for possible eavesdropping.

Response

- We do not consider these remote issues to be relevant for inclusion on a consent form.

The consent form's provision for further information or complaint is an illusory promise, inasmuch as these forms of communication are expensive, often unaffordable for prisoners, and if they do take place the calls, e-mail, and paper mail are routinely monitored by prison authorities.
This project has not undergone Secretarial-level review procedures still required, as the IRB pointed out:
"Approval requires the study may proceed only after the Secretary of Health and Human Services and her designee has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research"
A Paperwork Reduction Act notice does not satisfy this requirement.

Response

- This project was carefully reviewed by a prisoner advocate and has been approved by OHRP. This approval occurred after the OMB documents were submitted.

Unless these and any other problems that may be found in further review are remedied, this project should not proceed.

Again, thank you for your comments and questions.

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