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Memo

Date: December 6, 2019

To: David Cantor, Principal Investigator
Eric Jodts, Project Director

From: Kerry Levin, IRB Chair *Kerry Levin*

Subject: **Full Approval of National Intimate Partner and Sexual Violence Survey (NISVS) Redesign, Project Number 6650 FWA 0005551**

On Tuesday, October 10, 2019, **NISVS Redesign, Project Number 6650** was presented to the full Board. Pursuant to 45 CFR 46, the IRB reviews all studies involving research on human subjects. This project was last reviewed in September 2019.

This request is to approve the feasibility testing, including all of the procedures for the NISVS redesign (e.g., survey instruments and related materials). The feasibility test will compare alternative procedures to determine a recommended data collection method.

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

- The study includes a graduated consent procedure.
- There is no public use file for this contract, only for CDC's internal use.
- Instructions to remove the survey website from browsing history has not been confirmed at this time.

Action Requested: Review protocols, recruitment materials, consent forms, 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: 7; Against: 0; Abstain: 0). Per [45 CFR 46.117(c)], a waiver of documentation of informed consent is also approved as the research is no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context.

The following is a list of Conditions made by the Board and responses reviewed and approved under expedited authority on December 6:

Project Summary

1. Correct that the feasibility study will not include Spanish translations of the survey instruments (page 4).

PD Response: Historically, NISVS has been conducted in both English and Spanish but we clarified that the feasibility study will only be conducted in English.

2. Under Providing Resources (page 13),
 - a. Revise the first sentence on the page to state that resources are offered to everyone in the study. Specifically:
 - i. For the paper survey, the resources should be a separate insert instead of being listed at the end of the survey (page 292).

PD Response: We currently have the resources in the back of the paper survey and we plan to leave them there. In addition to having the resources in the back of the paper survey, we will print them in the back of the letter. We incorporated the resources with some of the question from the FAQs. Please see Appendix Z. FAQs_For Paper Survey.docx. Please note that since the letter is for respondents to keep, we are leaving information in the household that someone might have participated in a research study related to suicide, domestic violence.

- ii. For the web survey, distinguish between help being offered if respondents need tech support and help provided if the respondent is emotionally upset.

PD Response: We revised the buttons on the web survey based on IRB's feedback. We created a new document named "Appendix X NISVS Web Survey Buttons and FAQs". We changed the help button on the login page to "Login Assistance" button and added an additional button to the extended survey named "Resources". Resources button will display the resources throughout the extended survey. It will be on every page as well as the FAQ button.

- iii. For the CATI survey, confirm that interviewers will begin listing the resources should a respondent want to stop the interview.

PD Response: We added a new sentence to V_INTRO in CATI: *"If at any point, the questions are making you upset and you would like to speak with a trained professional, I can give you a phone number to call."* With this approach, we think that respondents are aware of the resources from the very beginning of the extended survey and can ask for them at any time.

- b. Provide the list of resources when the respondent starts the sensitive sections of the survey.

PD Response: Done.

3. Under Help Desk (page 14), add a sentence that the IRB Office will be informed when help desk voicemails are left by a distressed respondent in the evenings or over the weekend.

PD Response: Done

4. Add an explanation under Section E Confidentiality, Data Security, and Destruction (Page 15-16) that describes more formal data disclosure procedures to minimize any chance of identification of an individual.

PD Response: Done.

5. Revise the third bullet, "...The answers you give will be kept private, and no one will ever be able to figure out the names of people who were in the study." Consider using the explanation found under FAQ's Appendix L (Page 268), "*No information that could personally identify you will be given to CDC or anyone else. Your answers will be combined with responses from others who are in the study when the results are presented.*"

PD Response: Done.

6. Specify how long it takes to complete the survey in the fifth bullet.

PD Response: Updated the survey length reference as 30-40 minutes for CATI.

7. In the sixth bullet, "When we call, we will select ...," add "an adult age 18 or older living at this address."

PD Response: Done.

8. In the last paragraph, add information about Westat such as "If you have any questions about this study, please contact Westat, a social science research firm contracted by CDC, at XXX or email XXX."

PD Response: In the middle of the letter we have "In the next few days, you will receive a call from Westat, a social science firm working for the CDC (www.Westat.com)." Therefore, we didn't repeat it in the last paragraph however we added "please contact Westat at...."

Appendix D: 1a. ABS_Initial Letter_Screener_Non-probabililty (Page 108)

9. Specify that this survey is for men and women aged 18 and older.

PD Response: We added "18 or older" to stay consistent with the "probability" version of the same letter on page 109.

10. Confirm the purpose of the study and ensure that it is consistent throughout all relevant documents.

For example, the purpose is described as:

- a. To learn more about the health and injuries among adults in the U.S [pages 108, 109].
- b. To inform and guide national policies [page 110].
- c. To inform and guide national prevention efforts [pages 114, 115, 131, 293, 294, 295].
- d. About your health and injuries you may have experienced in your lifetime and within the past 12 months [pages 117, 124, 299].

PD Response: We revised the FAQs and the ABS_initial Letter to be consistent with others.

Appendix F: ABS Postcard Nonprobability (Pages 112-113)

11. Submit the updated postcard once CDC selects the photo.

PD Response: Done

Appendix H: NISVIS Mail Screener Roster (Page 117)

Appendix I: NISVIS Mail Screener – YMOF (Page 125)

12. Confirm that the Certificate of Confidentiality language is correct and consistent throughout the submission.

PD Response: Certificate of Confidentiality language is only provided in the FAQs and it's consistent between the screener and extended FAQs.

13. Inform the IRB when it is determined what example will be provided in the screener (Question #3).

PD Response: For item #13: Question 3 in paper screeners (both roster and YMOF) will use the same injury fills as in the web survey. See web survey page 6. Each household will be assigned to an injury from this fill. The injury will be a merge field and merged on the paper screener.

Below is the list of the injuries:

- Cut or wound, dislocation, bruise or sprain
- Bruise, cut or wound, sprain or head injury
- Head injury, sprain, broken bone or cut or wound
- Sprain, bruise, cut or wound or scrape
- Cut or wound, broken bone, sprain or burn
- Cut or wound, bruise, broken bone or sprain
- Cut or wound, sprain, scrape, or broken bone
- Head injury, bruise, cut or wound or sprain
- Bruise, insect bite, sprain, or cut or wound
- Cut or wound, sprain, broken bone or bruise

Appendix K: NISVS Redesign Web Survey (Pages 132- 266)

14. Correct the typo in HC08a, “throught.”

PD Response: Done.

Appendix Q: FAQs (Pages 299-300)

15. Under the second FAQ, delete the second part of the question that asks, “What kind of questions do you ask?”

PD Response: Done.

Appendix R: Web Survey Screens (Pages 301-306)

16. Clarify what “help” means.

PD Response: We changed “Help” with “Login Instructions”.

17. Change the term “survey guide” to “instructions” or “survey instructions”

PD Response: We changed it to “Survey Instructions”.

Appendix S: Distress Protocol for CATI interviewers (Pages 307-318)

18. Respondents who want to stop the interview should not be asked by the interviewer to reschedule another call to complete the interview.

PD Response: Thank you. This was a question from CDC and we will let them know.

19. Respondents should be informed of the name of the hotline the interviewer is connecting them to (page 315).

PD Response: Our current protocol reflects that. This was also a question from CDC and we will let them know.

20. Confirm with the respondent that the interviewer is connecting them to 911 (page 316).

PD Response: Our current protocol includes the following statement *“It sounds like you are being threatened or are in danger right now. We are going to call 911 to contact someone who can help you.”*

21. Once connected, confirm with the respondent that you are giving the 911 operator the respondent’s first name.

PD Response: On page 10 under step 2, we ask respondents if they would like us to give 911 their first name. However, we removed “Do you have any questions before we call 911?” question from step 2. CDC asked if we have to ask whether respondent has a question in a situation where a 911 call is necessary. During our IRB meeting, IRB didn’t raise any concerns about it as well but please let us know if there is a reason why we should keep that question.

Appendix W: NISVS Remove Survey Website (Pages 336-367)

22. Submit the final guide and/or instructions when the directions for removing the survey website from the respondent's browser is finalized.

PD Response: We proposed CDC Westat's survey login and security procedures, explaining the security precautions Westat will undertake to protect respondents' confidentiality. It's technically not possible to provide removing survey website instructions while respondents are still on the web survey. If they close the survey website, then they can't see the instructions to remove the survey website. We can't provide the instructions on a separate site because then it may leave evidence that respondent tried to clear the survey website. CDC was happy with the login and security procedures Westat provided but wanted IRB's input.

Please note the following:

- You are required to submit this study for a continuing review before January 8, 2020.
- IRB approval is required before any new or modified research activities are conducted or when there is a problem involving risks to human subjects.
- Upon learning of an incident, you must contact the IRB Office within 24 hours via telephone (301-610-8828) or email (IRB@westat.com).

cc: Institutional Review Board
Doug Williams