Appendix H1

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

RTI Project/Proposal No._0215029_ IRB ID # of 12259____Date__12/21/2015_____

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 Administrators, Diana Sparrow or Evelyn Studer. 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 Intimate Partner Violence and Sexual Violence Survey– Cognitive Interviews

Sponsor: National Center for Injury Prevention and Control (NCIPC) of the Center for Disease Control (CDC)

Check Here If Grant ☐

Project Duration:

From___9/28/2015_____ To:_____12/31/16_____
Month/Day/Year Month/Day/Year

Date Approval Requested:____1/07/16_____
Month/Day/Year

Date Participation of Human Subjects Scheduled to Begin:__1/25/16_____
Month/Day/Year

Reason for Review: (Check One)

☐	Proposal	☐	Pretest or Pilot
☐	Renewal	☐	Full Study Implementation
☐	Pre-Award	X	Other (specify) Cognitive Interviews

Project Leaders _____Lisa Carley-Baxter_____

Date 12/21/2015 

Signature

I. STUDY DESCRIPTION

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

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

B. Study Aims: (200-300 words)

II. STUDY DESCRIPTION

The National Center for Injury Prevention and Control (NCIPC) of the Center for Disease Control and Prevention (CDC) promotes the prevention of intimate partner violence, sexual violence and stalking victimization. NCIPC sponsors The National Intimate Partner and Sexual Violence Survey (NISVS) which is the only ongoing national survey dedicated solely to describing and intimate partner violence, sexual violence and stalking victimization as public health issues among adult women and men living in the United States.. NCIPC strives to continuously improve the data collection tool. The purpose of the cognitive interviews is to conduct interviews with both victims of intimate partner violence, sexual violence, and stalking victimization as well as non-victims to gather feedback related to some modifications of existing questions and the addition of some new questions in the NISVS survey. The goal of gathering this feedback is to ensure that the terms and concepts used are universally understood by respondents and that the process of answering the survey questions is not overwhelming from a cognitive, time, or emotional burden perspective. The information collected will be used to refine and improve the NISVS survey to help ensure that the instrument is effective and efficient for measuring these types of victimization.

After developing and cognitively testing the survey instrument, it will be administered in a national RDD survey to approximately 12,500 respondents and 10,862 respondents in a military sub-sample. The data collection methodology for the full implementation will be very similar to what RTI used to conduct the previous rounds of NISVS.

The current RFAFRP requests IRB approval for the cognitive interviewing only. Cognitive testing is critical to ensure that the survey instrument effectively measures intimate partner violence, sexual violence, and stalking among respondents. It is important that the terms used and the concepts covered in the survey are universally understood by respondents, and that the process of answering the survey questions is not overwhelming from a cognitive, time, or emotional burden perspective. As described in detail in this RFAFP, we propose to conduct cognitive testing interviews in-person as the

respondent completes the interview over the phone with a telephone interviewer. The cognitive interviewing lead will be in the room with the respondent and the telephone interviewer will be on the phone.

After cognitive testing is complete, we will come back to the IRB with instrument revisions and a detailed methodology for the full study implementation.

A. Sample Size(s): 30

B. Special Populations (Check all that apply)

X	None
	Minors
	Newborns
	Pregnant
	HIV infected
	Prisoners
	Alcohol, drug, or mental health program clients
	Incompetent
	Employees (specify)_____
	RTI Employees, their family member or friends (specify)_____
	Other (specify)_____

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

The target population for the in-person interviews is victims of intimate partner violence, sexual violence, and stalking and non-victims living within 120 miles of the Research Triangle Park (RTP), North Carolina. The only eligibility criteria are that the respondent be 18 years or older, speak English, and not be RTI employees or family members of RTI employees. We plan to recruit 30 total respondents, 8 non-victims and 22 victims of intimate partner violence, sexual violence, or stalking. Of the total 30 respondents, we plan to recruit 18 females (5 non-victims and 13 victims) and 102males (3 non-victims and 9 victims). Table 1 also describes the types of respondents we hope to recruit.

Table 1.

	Female	**Male**	**Total**
Non-Victim	5	3	8
Victim	13[1]	9[2]	22
Total	**18**	**12**	**30**

[1] Of the 13 total female victims, we hope to recruit and conduct interviews with at least four females that have experienced stalking, four that have experienced sexual violence, and four that have experienced physical violence by an intimate partner.

[2] Of the 9 total male victims, we hope to recruit and conduct interviews with at least three males that

have experienced stalking, three that have experienced sexual violence, and three that have experienced physical violence by an intimate partner.

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

The recruitment procedures for the in-person cognitive interviewing are designed to ensure that participants include both female and male survivors of either intimate partner violence, sexual violence, or stalking, in addition to respondents who have not necessarily experienced intimate partner violence, sexual violence, or stalking. We have modeled our cognitive interview recruiting procedures on the successful procedures used in both the NISVS pilot study and 2010 NISVS.

To recruit for the cognitive interviews, RTI staff will reach out to domestic violence shelters or other counseling programs within 120 miles of the Research Triangle Park (RTP), North Carolina. When reaching out to these centers, we will begin by explaining the purpose of the overall NISVS and the cognitive interviewing, and explain that we would like them to inform people who have been victimized about the opportunity to participate in cognitive interviewing. We will ask these staff members to think about survivors with whom they have worked and who they feel are ready to talk about their experiences and be able to provide useful information to inform the development of surveys on this topic.

Once the shelter or program has indicated its willingness to assist with recruitment, we will ask the staff to notify potentially eligible people about the cognitive interviews via word of mouth and flyers, (see ***Appendix A***). The flyers will provide a web address to a short web screener, phone number, and email address for the volunteers interested in participating to contact the project. The shelter or program can distribute or post the flyers if they prefer.

RTI staff will also post a recruitment advertisement on local craigslist.com websites, in local newspapers, and reach out to staff at local non-profits and businesses such as the United Way, YMCAs, and the Durham Rescue Mission (see advertisement content in ***Appendix B***). Flyers will also be offered to organizations for distribution.

Volunteers will be asked to visit the web address provided to complete a brief screening questionnaire to obtain demographic information and determine eligibility (see ***Appendix C***). Volunteers will also be given the option of calling a project staff member to complete the brief screening instead of completing via the web address (see ***Appendix D***). This screener will also provide more information regarding the purpose and content of the interviews to the respondent. Based on responses to this screener and the remaining "types" of respondents needed for cognitive interviewing, a project staff member will follow up with eligible volunteers to confirm the information they provided and schedule a time to conduct the interview.

The web screener will inform participants about the nature of the study and a project staff member will also provide this information via phone calls to eligible volunteers. A screening log based on the web and phone screeners will be kept on the project share and will include only first names. The only other identifying information will be a phone number where they can be reached for an appointment reminder call (if appointment is made far in advance) and to notify them of any last minute changes in appointment time or location. Volunteers do not have to provide a phone number if they do not want to. If volunteers provide a phone number, they will be told that we will call them to remind them of their appointment and will leave a message on their answering machine or voicemail, if necessary. We will inform them that the following script will be used when leaving a message: "Hi, this is [NAME OF

INTERVIEWER] just calling to remind you of our appointment to meet at [TIME] on [DAY][DATE]. If you have any questions, need to reschedule, or need further directions, you can call me/[INTERVIEWER] at [NUMBER]. Thank you!" If volunteers indicate that they do not want us to leave a message we will not do so.

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
	Copy of Consent with Consent Form Checklist Attached

At the beginning of the in-person cognitive interview appointment, the respondent will be handed a hard copy of the informed consent form (see ***Appendix E***) and the interviewer will review the highlights of the informed consent form. If the respondent wants to proceed with the cognitive interview, they will "X" the appropriate lines to participate, allow for recording and, if applicable, allow for observers. If a participant does not want to consent to audio recording or observation, then no recording device will be used and observers will be asked to leave. The interviewer will sign the RTI copy of the consent form and leave a blank hard copy with the respondent. We are not asking respondents to sign the consent form as a measure to protect their confidentiality.

C. Individual Participant Burden

	1-2	. 0	**Hours**

D. Participant Compensation

	None

$		4	0	. 0	0

Participants who complete cognitive interview will receive $40 cash.

E. Number of Recontacts:

X	None
	Recontacts

F. Future Contacts:

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

IV. DATA COLLECTION PROCEDURES

A. Type: (Check all that apply)

	Survey
	NA
	Mail
	Anonymous
	Personal Interview
X	Self-administered Questionnaire (web-based)
	Telephone Interview
X	Other (specify)
	____cognitive interview_____

	Biological Specimen
	NA
	Invasive
	Noninvasive

	Device, Drug, or Procedure Trial
	NA
	Invasive
	Noninvasive

	Record Abstraction
	NA
	File review
	At agency or facility
	Computer
	Request records from agency or facility
	Other (specify)
	_____

	Laboratory Experiment or Measurement
	NA
	Psychological
	Physical invasive
	Physical noninvasive
	Focus group
	Other (specify)
	_____

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

To protect interviewer safety in the unlikely event that anyone become upset during the cognitive interviews, we will make an effort to conduct most cognitive interviews and all interviews with men in

the cognitive interview lab at the RTI RTP office.. This way, if the interviewer needs to seek help, assistance will be readily available. In the unlikely event that a female volunteer cannot travel to the RTP office (for example, if they live further than 30 miles away) we will try to make arrangements to conduct the interview at a location local to them (such as a domestic abuse shelter) only if we can conduct the interview in a location that will afford privacy to the volunteer so that no one will be able to overhear the interviewer.

Two female RTI project staff will be involved in each interview. One person will administer the questionnaire over the telephone from a separate room, in order to simulate the CATI interview as closely as possible. The other person will be sitting in the room with the participant and will administer the probes and follow-up questions to the participant. Participants will be providing both answers to the survey questions as well as feedback and comments about the survey questions.

After obtaining informed consent, the interviewer will begin by further explaining the purpose of the interview; that we are interested in the participant's understanding of the questions, not necessarily their responses to them.

The cognitive interviews will be guided by the interview protocol (see ***Appendix F***) and will cover the entire survey instrument (see ***Appendix G)***. Interviews will last approximately 1 to 2 hours. With the respondent's consent, the interviews will be audio-recorded. For respondents who do not consent to audio-recording, the interviewer will take notes within an electronic excel spreadsheet and/or hard copy; however, no identifying information will be documented in the notes. During the interviews, participants will be asked a series of open-ended probes at key points in the interview, which will be designed to capture understanding of the interview and verbal feedback from the participants. Probes will be both scripted and spontaneous depending upon the direction of the interview and level of understanding from the participant.

At the conclusion of the interview, participants will receive $40 cash in appreciation for their time. They will be asked to sign the incentive receipt with an "X" (see ***Appendix H)*** and given a blank copy of it to keep. The interviewer will initial the incentive receipt in lieu of the respondent's signature for confidentiality purposes.

V. POTENTIAL RISKS

A. Type: (Check one or more)

	None
	Minimal physical
X	Minimal psychological/social/legal
	Substantial physical
	Substantial psychological/social/legal

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

There are no direct physical risks to participating in the cognitive interview.

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

Participation in the cognitive interviews may be mildly distressing for some individuals who have experienced physical violence by and intimate partner, sexual violence, or stalking given the sensitive nature of the topics covered in the survey. RTI staff have extensive experience interviewing subjects about sensitive topics, including intimate partner violence and sexual violence, and will be sensitive to the impact that some of the survey questions could have on survivors. Participants will also be aware of the nature of the interview after completing the eligibility screener via web or phone and prior to agreeing to participate in the interview. All participants in the cognitive interviews will be individuals who reached out to us after learning about the study. Though the likelihood of an adverse reaction from respondents is low, we will have a list of national and local resources such as the National Domestic Violence Hotline and The Rape, Abuse, and Incest National Network to hand out to participants should they want it. Examples of the resource sheets are presented in ***Appendix I***.

VI. PROTECTION OF SUBJECTS:

A. Guarantees:

	Anonymity (no link between individual and data is possible)
	Confidentiality (RTI guarantee only)
X	Confidentiality (RTI & other guarantee) (specify)

B. Types of Procedures Provided to Reduce or Alleviate Risks

	Maintenance or environmental cleanup or correction
	Psychological counseling
	Medical treatment
X	Other (specify)

Resource list – Offer to skip questions or end interview as necessary.

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

All participants will be informed about the nature of the survey questions prior to making the decision to participate in the study, and the consent form will indicate that respondents can skip any questions they want, or discontinue their participation at any time. Participants will also be allowed to deny consent for audio recording should they choose.

Throughout the interview, the interviewers will employ a graduated response to detect and respond to respondent distress. Should a participant begin to show visible signs of emotional distress (such as crying), the interviewers will offer to skip to the next question or ask if they would like to take a break. If the participant continues to show signs of distress, the interviewer will offer to end the interview,

providing the participant their incentive regardless of how much of the protocol was completed. RTI has conducted similar cognitive interviews (e.g., for the National Intimate Partner and Sexual Violence Survey) and had no occurrences of emotional distress.

All respondents to the in-person cognitive interviews who have been victimized or who seem to be distressed will be provided a list of national hotline/helpline telephone numbers and a list (customized , as necessary, for each of the 3 sites) of local resources at the end of the interview (see ***Appendix I***).

D. Description of Security Measures: (50-100 words)
Cognitive interviews will be digitally-recorded for participants who consent; for those who do not consent to audio-recording, hard copy notes will be taken by the interviewer within an electronic excel spreadsheet or via hard copy and will be void of any PII (including the participant first name or other names the participant may divulge). Hard copy notes will be kept in a locked filing cabinet. The digital files from the interviews will be saved on the project share drive and only accessible by relevant RTI project staff. Both the audio files and hard copy notes will be destroyed at the end of the project.

VII. BENEFITS

A. Information Provided to Study Participants

X	No direct benefit
	Medical or physical data (e.g., serum levels)
	Social data (e.g., eligibility for service)
	Psychological data (e.g., test scores)
	Environmental data (e.g., toxicity levels)
	Other (please specify)

_____

Brief description:_____

_____

B. Services Provided to Study Participants:

X	No direct services provided
	Medical or rehabilitation treatment
	Social/economic service
	Psychological counseling
	Environmental cleanup or correction
	Other (please specify)

_____

Brief description:_____

C. Other Benefits: (please describe)

VIII. RISK/BENEFIT RATIO

A. Type:

	No risk/no individual benefit
X	Minimal risk/no individual benefit
	Minimal risk/minimal individual benefit
	Minimal risk/substantial individual benefit
	Substantial risk/substantial individual benefit
	Substantial risk/substantial research/society benefit

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

When interviewing respondents about sensitive topics, like intimate partner and sexual violence, it is possible that the respondent will find the process or the interaction upsetting, especially if the respondent has experienced violence. RTI staff have been doing work of this kind for many years and have extensive experience conducting cognitive interviewing with victims of violence. It has been our experience that self-identified victims who volunteer to participate in cognitive interviewing are fully capable of understanding the risks involved and do not have difficulty participating. In fact, some respondents have told us that they are doing it because they want to help make sure the survey is as good as it can be so it works well in the field and so other victims will be comfortable responding. They see participating as a way to help other victims. We have also had respondents tell us that they find the process cathartic.

Cognitive interviewing is an important methodological component of survey research, especially when the goal is to measure a problem as complex as intimate partner and sexual violence. We believe that the benefits of cognitively testing the NISVS instrument thus far outweigh the potential risks of cognitive testing.

IX. SPECIAL ISSUES

A. Type of Issue or Risk:

X	None
	Collaborative research

	RTI is prime contractor
	RTI is subcontractor
	Other (please specify)_____

	Need to release information on risk
	Follow-on studies
	Other (please specify)_____

_____

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

X. NEEDS FOR FUTURE REVIEW

	Pre-Award	Date	_____
	Pretest/Pilot	Date	_____
X	Full Study Implementation	Date	___January 2016_____
X	Renewal	Date	____November 2015 (was received on 11/26/2015)_____
	Other (please specify)	Date	_____