Cover Page for Protocol, Statistical Plan and ICF

Official Title:	Evaluating the Social Workers Addressing Firearm Risk (SAFR) Intervention: A Pilot Study
NCT number:	
Document Type:	Study protocol with analysis plan
Date of the Document:	1/31/23

Complete Research Protocol (HRP-503)

Table of Contents

Template Instructions

Sections that do not apply:

- *In several sections, the addition of checkboxes for **Not Applicable** have been added to the template as responses.*
    - *If an N/A checkbox is present, select the appropriate justification from the list.*
    - *If an N/A checkbox is not present, or if none of the existing checkboxes apply to your study, you must write in your own justification.*
- *In addition:*
    - *For research where the only study procedures are records/chart review: Sections 6, 21, 22, 24, 25, 26 and 27 do not apply.*
    - *For exempt research: Section 6 may not apply. Section 6.1 will still apply if there is a study intervention.*

Studies with multiple participant groups:

- *If this study involves multiple participant groups (e.g. parents and children), provide information in applicable sections for each participant group. Clearly label responses when they differ. For example:*

Response Example
Intervention Group:
Control Group:

Formatting:

- *Do not remove template instructions or section headings when they do not apply to your study.*

If you are pasting information from other documents using the "Merge Formatting" Paste option will maintain the formatting of the response boxes.

Amendments:

- *When making modifications or revisions to this and other documents, use the **Track Changes** function in Microsoft Word.*
- *Update the version date or number **on Page 3.***

PROTOCOL TITLE:

Include the full protocol title.

Response:

Evaluating the Social Workers Addressing Firearm Risk (SAFR) Intervention: A Pilot Study

PRINCIPAL INVESTIGATOR:

Name
Department
Telephone Number
Email Address

Response:

Patricia Logan-Greene

School of Social Work

716-645-1533

pblogang@buffalo.edu

VERSION NUMBER/DATE:

Include the version number and date of this protocol.

Response:

Version 1 - January 5, 2023

Version 2 – January 6, 2023

Version 3 – January 11, 2023

Version 4 – January 31, 2023

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	1/6/23	Changed sections related to waiver of consent to reflect our actual consent processes.	Yes
2	1/11/23	Added our research assistant, Alexis Glennon, to the template.	No
3	1/31/23	Added Ms. Glennon to section 16.2.	Yes

		Clarified language about the US Bank cash gift cards in sections 12.1 and 27.1 Small clarification regarding the two samples in 12.1. Clarified mechanism for participants to receive continuing education credit in section 24.1	

FUNDING:

Indicate any funding for this proposal. This should match the Funding Sources page in Click IRB.

Response:

We have been awarded funding for this project through the UB Clinical and Translational Science Institute (CSTI).

GRANT APPLICABILITY:

Indicate whether this protocol is funded by a grant (e.g. NIH, foundation grant). For a grant with multiple aims, indicate which aims are covered by this research proposal.

NOTE: This question does not apply to studies funded by a sponsor contract.

Include a copy of the grant proposal with your submission.

Response:

All aims in this study will be funded by the CTSI grant.

RESEARCH REPOSITORY:

Indicate where the research files will be kept, including when the study has been closed. The repository should include, at minimum, copies of IRB correspondence (approval, determination letters) as well as signed consent documents. This documentation should be maintained for 3 years after the study has been closed.

Response:

All files, IRB documentation, digital evidence of informed consent, and downloaded survey responses will be stored electronically on the secured UB Box server. Files will be accessed on the password-protected computer drive of the principal investigator.

Location: Dr. Logan-Greene's office. Baldy Hall

Address:630 Baldy Hall, Buffalo NY, 14260

Department: UB School of Social Work

Study Summary

Study Title	Evaluating the Social Workers Addressing Firearm Risk (SAFR) Intervention: A Pilot Study
Study Design	Aim 1: Repeated surveys (two time points) Aim 2: Randomized controlled trial with pre-, post-, and follow-up tests.
Primary Objective	To evaluate the feasibility, acceptability, and preliminary effectiveness of the Social Workers Addressing Firearm Risk (SAFR) Intervention.
Secondary Objective(s)	Develop measurement tools to be used in the evaluation of the SAFR intervention.
Research Intervention(s)/ Investigational Agent(s)	Social Workers Addressing Firearm Risk (SAFR) Intervention – an online educational intervention to train practicing social workers how to recognize and respond to risks of gun violence among their clients.
IND/IDE #	N/A
Study Population	Practicing social worker adults in New York State
Sample Size	100 for each Aim; 200 total
Study Duration for individual participants	Aim 1: Two short surveys (30 minutes each) one month apart Aim 2: 4-5 months
Study Specific Abbreviations/ Definitions	SAFR: Social Workers Addressing Firearm Risk SSW: School of Social Work

Objectives*

Describe the purpose, specific aims, or objectives of this research.

Response:

Specific Aim 1: To test measurement tools that can be used to assess the efficacy of SAFR on theorized outcomes. Measures that have been used to assess similar

interventions for other professionals, notably medical doctors, will be modified for use with our population. The measures assess clinicians' firearm knowledge, attitudes, beliefs, and behaviors with clients. We will test these measurement tools with 100 practicing social workers recruited through professional networks, social media, and listservs. For all measures, we will address internal reliability, test-retest reliability, and construct validity, utilizing appropriate statistical procedures.

Specific Aim 2: Evaluate the preliminary efficacy of the SAFR intervention using a randomized controlled trial. An additional 100 practicing social workers (excluding participants from Aim 1) will be recruited, with n = 50 allocated to each arm of the study utilizing block randomization. Participants in the control arm will receive invitations to all surveys but not to the SAFR intervention itself. We will utilize the validated measures from Aim 1 to assess changes on study variables. Results will be analyzed using either mixed linear models or generalized estimating equations as appropriate. Analyses will be performed with a focus on estimation of parameters for use in the planning of a subsequent comparative trial designed to fully assess intervention efficacy with a national sample. Supportive analyses that adjust for participant covariates will also be considered. We will also ask participants for feedback on the intervention and will track indicators of feasibility and acceptability (recruitment rates, completion of intervention and measurement tools).

State the hypotheses to be tested, if applicable.

> *NOTE: A hypothesis is a specific, testable prediction about what you expect to happen in your study that corresponds with your above listed objectives.*

Response:

Aim 1: Our measurement tools will be reliable and valid assessments of study constructs.

Aim 2: The SAFR intervention will improve social workers' knowledge of gun violence, attitudes about social workers' need to intervene with all clients, and behaviors regarding discussing guns and gun violence risks with clients compared to pre-test and the control group. We also hypothesize that the SAFR intervention will be feasible and acceptable.

Scientific Endpoints*

3.1 Describe the scientific endpoint(s), the main result or occurrence under study.

NOTE: Scientific endpoints are outcomes defined before the study begins to determine whether the objectives of the study have been met and to draw conclusions from the data. Include primary and secondary endpoints. Some example endpoints are: reduction of symptoms, improvement in quality of life, or survival. Your response should ***not*** *be a date.*

Response:

Aim 1 will be complete when we have measurement tools with satisfactory validity and reliability.

Aim 2 will be complete when the intervention has been completed by experimental group participants, and both control and experimental group participants have completed all measures in the pre-, post-, and follow-up-tests.

Background*

Provide the scientific or scholarly background, rationale, and significance of the research based on the existing literature and how it will contribute to existing knowledge. Describe any gaps in current knowledge. Include relevant preliminary findings or prior research by the investigator.

Response:

Firearm violence remains a major problem in the United States, with annual deaths increasing in recent years. In 2020, 45,222 people died by firearms (Centers for Disease Control and Prevention [CDC], 2022a. The majority of those deaths (54%) were suicides; however, homicides have been on the rise. Mass shootings have also been rising recently, with 2019, 2020, and 2021 each setting new records according to the definition used by the Gun Violence Archive (2022). These deaths are not equally distributed among demographic groups; Black Americans, in particular, have very high rates of firearm deaths. Indeed, homicide is the leading cause of death for Black males ages 15-44 (CDC, 2022b). Beyond these deaths, an even larger number of people are seen in hospitals each year for firearm injuries, which can sometimes result in permanent disabilities in addition to serious mental health consequences (Kaufman et al., 2021). From a public health perspective, these deaths and injuries also affect individuals' families and communities, sometimes with devastating impacts.

While there are a number of policy measures that might address the problem of firearm violence, these solutions are not keeping up with increases in firearm injuries and vary widely across states. Thus, we must seek policy-neutral strategies to reduce firearm violence, including by training workers across multiple professions to discuss firearm safety. Social workers are already interfacing with many individuals who are at-risk of perpetrating or being victimized by firearms, including by suicide, but the scant evidence suggests that training opportunities are minimal both during and after their educational careers (Logan-Greene et al., 2018). In the only published survey of practicing social workers, conducted in one Midwestern state, only 34% of practicing social workers reported regularly assessing for firearm access and only 15.4% regularly counseled about firearm safety (Slovak et al., 2008). In a previous qualitative research project, we established that very few social workers in our region had received training before or after their degrees, and most expressed a desire to learn more (Sperlich et al., 2022). Few social work educational programs offer content in coursework to prepare social workers to address these issues (Feldman et al., 2006; Ruth et al., 2012). To our knowledge, there is no training program

related to firearms readily available to practicing social workers, and certainly none that are accessible through an online format to all social workers in the US.

Include complete citations or references.

Response:

Centers for Disease Control and Prevention (2022a). Web-based Injury Statistics Query and Reporting System (WISQARS) [Online]. National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (producer). Available from http://ww.cdc.gov/ncipc/wisqars

Centers for Disease Control and Prevention (2022b). Health Equity. [Website] Available from https://www.cdc.gov/healthequity/lcod/index.htm

Feldman, B. N., & Freedenthal, S. (2006). Social work education in suicide intervention and prevention: An unmet need?. Suicide and Life-Threatening Behavior, 36(4), 467-480.

Gun Violence Archive (2022). [Website] Available at: https://www.gunviolencearchive.org/

Kaufman, E. J., Wiebe, D. J., Xiong, R. A., Morrison, C. N., Seamon, M. J., & Delgado, M. K. (2021). Epidemiologic trends in fatal and nonfatal firearm injuries in the US, 2009-2017. JAMA Internal Medicine, 181(2), 237-244.

Logan-Greene, P., Sperlich, M., & Finucane, A. (2018). Social work practice and gun safety in the United States: Are we doing enough?. Advances in social work, 18(4), 1165-1186.

Sperlich, M., Logan-Greene, P., & Finucane, A. (2022). “If Not Us, Then Who?”: Frontline Social Workers’ Perspectives on Gun Violence. Journal of Evidence-Based Social Work, 19(1), 77-97.

Ruth, B. J., Gianino, M., Muroff, J., McLaughlin, D., & Feldman, B. N. (2012). You can't recover from suicide: Perspectives on suicide education in MSW programs. Journal of Social Work Education, 48(3), 501-516.

Slovak, K., Brewer, T. W., & Carlson, K. (2008). Client firearm assessment and safety counseling: The role of social workers. Social Work, 53(4), 358-366.

Study Design*

Describe and explain the study design (e.g. case-control, cross-sectional, ethnographic, experimental, interventional, longitudinal, observational).

Response:

Aim 1 is structured to provide essential tests required to establish measurement tools that are suitable to test the effectiveness of the SAFR intervention. Two surveys will be given one month apart, allowing for examination of test-retest validity.

Aim 2 is a randomized controlled trial of participation in the SAFR intervention. Participants complete pre- and posttests and a 3-month follow-up survey.

Study Intervention/Investigational Agent

6.1 Describe the study intervention and/or investigational agent (e.g., drug, device) that is being evaluated.

Response: The Social workers Addressing Firearm Risk (SAFR) intervention was developed after in-depth reviews of current literature on firearm violence prevention and in collaboration with multiple researchers and experts across the country. It is a fully-online intervention that contains four modules that address the following topics: 1) The nature of firearm violence in the United States, including a basic introduction to firearm terminology and an examination of misconceptions about the nature of connection between mental illness and firearm violence; 2) a discussion of policies that are pertinent for mental health providers, such as the mechanism of mental health prohibitions, extreme risk protection orders, and reporting requirements in some states; 3) assessment tools and approaches for individuals at risk of firearm violence across multiple settings; and 4) community approaches to firearm violence prevention, including hospital-based programs. Each module includes interviews with experts, didactic content, handouts, and brief quizzes to check learning (required by New York State for continuing education credit).

Drug/Device Handling: If the research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

If the control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference that SOP in this section.

Response: N/A

If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

Identify the holder of the IND/IDE/Abbreviated IDE.
Explain procedures followed to comply with sponsor requirements for FDA regulated research for the following:

	Applicable to:		
FDA Regulation	**IND Studies**	**IDE studies**	**Abbreviated IDE studies**
21 CFR 11	**X**	**X**	
21 CFR 54	**X**	**X**	
21 CFR 210	**X**		
21 CFR 211	**X**		
21 CFR 312	**X**		
21 CFR 812		**X**	**X**
21 CFR 820		**X**	

Response:

N/A

Local Number of Subjects

Indicate the total number of subjects that will be enrolled or records that will be reviewed locally.

Response:

We plan to enroll 100 participants in each aim for a total of 200.

If applicable, indicate how many subjects you expect to screen to reach your target sample (i.e. your screen failure rate).

Response:

Individuals will complete screening questions online. We are unsure of the number of people who may click on the study's website without being a member of the target population.

Justify the feasibility of recruiting the proposed number of eligible subjects within the anticipated recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?

Response:

According to the NASW-NYS website (the New York State chapter of the National Association of Social Workers, there are 115,000 practicing social workers in the state. We plan to utilize a multi-pronged recruitment strategy using regional listservs, NASW-NYS newsletter ads, and social media to reach as many of these individuals as possible.

We are unsure at this stage of how many individuals may be exposed to advertising mechanisms, but we feel that recruiting 200 over multiple months should be reasonable.

Inclusion and Exclusion Criteria*

*Describe the criteria that define who will be **included** in your final study sample.*

NOTE: This may be done in bullet point fashion.

Response:

- Social work degree (BSW, MSW, DSW, or PhD in Social Work or Social Welfare
- Current employed at least part-time in social work practice.
- Fluent in English
- Aged 18 or older.

*Describe the criteria that define who will be **excluded** from your final study sample.*

NOTE: This may be done in bullet point fashion.

Response:

Anyone who does not meet all four criteria listed above. Anyone who participated in Aim 1 will be excluded from Aim 2.

Indicate specifically whether you will include any of the following special populations in your study using the checkboxes below.

NOTE: Members of special populations may not be targeted for enrollment in your study unless you indicate this in your inclusion criteria.

Response:

☐ Adults unable to consent

☐ Individuals who are not yet adults (infants, children, teenagers)

☒ Pregnant women

☐ Prisoners

Indicate whether you will include non-English speaking individuals in your study.
Provide justification if you will exclude non-English speaking individuals.

*In order to meet one of the primary ethical principles of equitable selection of subjects, non-English speaking individuals may **not** be routinely excluded from research as a matter of convenience.*

In cases where the research is of therapeutic intent or is designed to investigate areas that would necessarily require certain populations who may not speak

English, the researcher is required to make efforts to recruit and include non-English speaking individuals. However, there are studies in which it would be reasonable to limit subjects to those who speak English. Some examples include pilot studies, small unfunded studies with validated instruments not available in other languages, studies with numerous questionnaires, and some non-therapeutic studies which offer no direct benefit.

Response:

The SAFR intervention is currently available only in English. Translation is not possible at this time.

Vulnerable Populations*

If the research involves special populations that are considered vulnerable, ***describe the safeguards included to protect their rights and welfare.***

NOTE: You should refer to the appropriate checklists, referenced below, to ensure you have provided adequate detail regarding safeguards and protections. You do not, however, need to provide these checklists to the IRB.

For research that involves ***pregnant women,*** *safeguards include:*
NOTE CHECKLIST: Pregnant Women (HRP-412)

Response:

Although we are not intentionally recruiting pregnant individuals, some individuals who participate in this study may be pregnant. No aspect of this project presents additional risk above and beyond what the pregnant individual would normally encounter at work.

☐ **N/A**: This research does not involve pregnant women.

For research that involves ***neonates of uncertain viability or non-viable neonates,*** *safeguards include:*
NOTE CHECKLISTS: Non-Viable Neonates (HRP-413), or Neonates of Uncertain Viability (HRP-414)

Response:

☒ **N/A:** This research does not involve non-viable neonates or neonates of uncertain viability.

For research that involves ***prisoners****, safeguards include:*
NOTE CHECKLIST: Prisoners (HRP-415)

Response:

☒ **N/A:** This research does not involve prisoners.

For research that involves ***persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children")****, safeguards include:*
NOTE CHECKLIST: Children (HRP-416)

Response:

☒ **N/A:** This research does not involve persons who have not attained the legal age for consent to treatments or procedures ("children").

*For research that involves **cognitively impaired adults**, safeguards include:*
NOTE CHECKLIST: Cognitively Impaired Adults (HRP-417)

Response:

☒ **N/A:** This research does not involve cognitively impaired adults.

Consider if other specifically targeted populations such as students, employees of a specific firm, or educationally or economically disadvantaged persons are vulnerable. ***Provide information regarding their safeguards and protections, including safeguards to eliminate coercion or undue influence.***

Response:

N/A

Eligibility Screening*

*Describe **screening procedures** for determining subjects' eligibility. Screening refers to determining if prospective participants meet inclusion and exclusion criteria.*

📎 *Include all relevant screening documents with your submission (e.g. screening protocol, script, questionnaire).*

Response:

Individuals will be directed to a link on REDCap to determine eligibility. We have attached the screening questions that will be posted on the website.

"Study Eligibility Determination" attached

☐ **N/A:** There is no screening as part of this protocol.

Recruitment Methods

☐ **N/A:** This is a records review only, and subjects will not be recruited.
NOTE: If you select this option, please make sure that all records review procedures and inclusion/exclusion screening are adequately described in other sections.

Describe when, where, and how potential subjects will be recruited.

NOTE: Recruitment refers to how you are identifying potential participants and introducing them to the study. Include specific methods you will use (e.g. searching charts for specific ICD code numbers, Research Participant Groups, posted advertisements, etc.).

Response:

We are working with Fahlgren Mortine to develop a social media campaign to recruit study participants. In addition to social media, we will utilize regional UB listservs (UB SSW Alumni, Field Education), word of mouth, and advertisements in the National Association of Social Workers NYS newsletter to recruit participants.

There will be two waves of recruitment, one for each Aim of the study, and recruitment methods will be the same. In all cases, individuals will be provided a link to click on that directs them to a landing page (hosted by the SSW) that provides information about the current Aim with instructions on how to enroll.

Describe how you will protect the privacy interests of prospective subjects during the recruitment process.

NOTE: Privacy refers to an individual's right to control access to him or herself.

Response:

Aside from demographic information, the only identifying information we will have for participants is their email addresses – necessary for the repeated contact required in both Aims of the study. These email addresses will never be publicly revealed.

Identify any materials that will be used to recruit subjects.

NOTE: Examples include scripts for telephone calls, in person announcements / presentations, email invitations.

For advertisements, include the final copy of printed advertisements with your submission. When advertisements are taped for broadcast, attach the final audio/video tape. NOTE: You may submit the wording of the advertisement prior to taping to ensure there will be no IRB-required revisions, provided the IRB also reviews and approves the final version.

Response:

We have attached recruitment materials developed in consultation with Fahlgren Mortine and our graphic designer.

Procedures Involved*

*Provide a description of **all research procedures or activities** being performed and when they are performed once a subject is screened and determined to be eligible. Provide as much detail as possible.*

NOTE: This should serve as a blueprint for your study and include enough detail so that another investigator could pick up your protocol and replicate the research. For studies that have multiple or complex visits or procedures, consider the addition of a schedule of events table in in your response.

Response:

Aim 1:

Participants will be recruited as described above. All advertising materials will include a link to a website (hosted by the UB School of Social Work) that describes study aims. If

they click the button to continue, they will be taken to REDCap and screened for eligibility. After passing those criteria, they will be directed to the informed consent form. We will obtain their emails at this stage and send them a copy of the informed consent document.

For those who agree to participate, they will be taken to the initial survey, also hosted by REDCap. We expect this survey will take about 20-30 minutes to complete.

After one month, an invitation to complete a similar survey (minus demographic questions) will be sent to the email address they provided. A follow-up email will be sent to anyone who does complete the second survey within one month.

Participants will be emailed a prepaid US Bank gift card after completing each survey, using the Study Card Program Group under The University at Buffalo Office of Financial Management, in conjunction with U.S. Bank.

At the conclusion of the study, participants in Aim 1 will be given access to the SAFR intervention course at no cost.

Aim 2:

The initial steps of this Aim will be the same as Aim 1 above: same recruitment and screening process (but with a new sample of 100 participants), with the addition of a question to determine whether they participated in Aim 1. The informed consent document will describe this study's procedures. The next link will provide the pre-test assessment, including their email address for later contact. Following block randomization within REDCap, they will find out which arm of the study they were assigned to:

Intervention group: The intervention group will be granted access to the online course, which takes approximately 6 hours to complete. Because the SAFR intervention is online and self-paced, they will be given four weeks to complete the course, with reminders coming once a week to encourage completion.

One month after completing the pre-test, they will be emailed a link to complete the post-test, with a reminder sent out after one week to anyone who has not completed the survey. This assessment will also include questions about the course, including open-ended questions about what worked and didn't work.

Three months after completing the pre-test, they will be emailed a link to complete the follow-up assessment, with a reminder sent out after one week to anyone who has not completed the survey.

Control group: The control group will receive the pre-, post-, and follow-up assessments on the same timeline as the intervention group, although they will not be asked to give feedback on the SAFR intervention. At the conclusion of the study, they will be invited to receive the intervention at no cost.

All participants will receive UB Bank cash gift cards for completing all surveys, as described below.

Describe what data will be collected.

NOTE: For studies with multiple data collection points or long-term follow up, consider the addition of a schedule or table in your response.

Response:

Aim 1:

Survey responses to the first and second survey will be collected using REDCap.

Aim 2:

Survey answers to all three assessments will be collected using REDCap. In addition, the UB SSW Continuing Education Website, which will host the SAFR intervention, retains data on how many people did not complete the course, how well they did on internal quizzes, and their time to completion.

List any instruments or measurement tools used to collect data (e.g. questionnaire, interview guide, validated instrument, data collection form).

Include copies of these documents with your submission.

Response:

The following instruments will be included:

Screening tool (same for both aims of the study)

Aim 1:

Phase 1 First survey

Phase 2 Second survey

Aim 2:

Phase 2 Pretest [same for both intervention and control groups]

Phase 2 Posttest

Phase 2 Additional Questions for Intervention group Posttest [questions will be delivered through UB School of Social Work Continuing Education Course Interface]

Phase 2 Follow-up [same for both intervention and control groups]

Describe any source records that will be used to collect data about subjects (e.g. school records, electronic medical records).

Response:

N/A

*Indicate whether or not **individual** subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings will be shared with subjects or*

others (e.g., the subject's primary care physician) and if so, describe how these will be shared.

Response:

N/A

*Indicate whether or not **study** results will be shared with subjects or others, and if so, describe how these will be shared.*

Response:

N/A

Study Timelines*

Describe the anticipated duration needed to enroll all study subjects.

Response:

Timeline for study activities (2023):

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Survey 1 for Aim 1		X	X									
Survey 2 for Aim 1			X	X								
Analyze data on measures; implement needed changes.				X	X							
Recruit for Aim 2; pre-test and course begins						X	X	X				
Post-test for both arms.							X	X	X			
Follow-up survey.									X	X	X	
Analyze data.											X	X

Describe the duration of an individual subject's participation in the study. Include length of study visits, and overall study follow-up time.

Response:

Aim 1:

One survey that takes approximately 30 minutes to complete.

A similar follow-up survey one month later.

Aim 2: Intervention group:

Three surveys spread across three months.

Pre-test should take about 20-30 minutes

SAFR intervention takes about 6 hours

Post-test one month later takes about 20-30 minutes

Follow-up two months later takes about 15-20 minutes.

Aim 2: Control group:

Three surveys spread across three months.

Pre-test should take about 20-30 minutes

Post-test one month later takes about 15-20 minutes

Follow-up two months later takes about 15-20 minutes.

Describe the estimated duration for the investigators to complete this study (i.e. all data is collected and all analyses have been completed).

Response:

One year (see timeline above).

Setting

Describe all facilities/sites where you will be conducting research procedures. Include a description of the security and privacy of the facilities (e.g. locked facility, limited access, privacy barriers). Facility, department, and type of room are relevant. Do not abbreviate facility names.

NOTE: Examples of acceptable response may be: "A classroom setting in the Department of Psychology equipped with a computer with relevant survey administration software," "The angiogram suite at Buffalo General Medical Center, a fully accredited tertiary care institution within New York State with badge access," or, "Community Center meeting hall."

Response:

All activities will be conducted online.

For research conducted outside of UB and its affiliates, describe:

- *Site-specific regulations or customs affecting the research*
- *Local scientific and ethical review structure*

NOTE: This question is referring to UB affiliated research taking place outside UB, i.e. research conducted in the community, school-based research, international research, etc. It is not referring to multi-site research. UB affiliated institutions include Kaleida Health, ECMC, and Roswell Park Cancer Institute.

Response:

☒ **N/A:** This study is not conducted outside of UB or its affiliates.

Community-Based Participatory Research

Describe involvement of the community in the design and conduct of the research.

NOTE: Community-Based Participatory Research (CBPR) is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.

Response:

☒ **N/A:** This study does not utilize CBPR.

Describe the composition and involvement of a community advisory board.

Response:

☒ **N/A:** This study does not have a community advisory board.

Resources and Qualifications

*Describe the qualifications (e.g., education, training, experience, expertise, or certifications) of the Principal Investigator **and** staff to perform the research. When applicable describe their knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research.*

NOTE: If you specify a person by name, a change to that person will require prior approval by the IRB. If you specify a person by role (e.g., coordinator, research assistant, co-investigator, or pharmacist), a change to that person will not usually require prior approval by the IRB, provided that the person meets the qualifications described to fulfill their roles.

Response:

Patricia Logan-Greene is an Associate Professor at the UB School of Social Work. She has extensive experience researching trauma, violence, and other adversities. She and Co-I Dr. Sperlich have been collaborating for years on social workers' guidelines and responses to gun violence research, which enabled them to develop this intervention. She and Dr. Sperlich have co-authored multiple articles on the problem of gun violence, including interviews with practicing social workers on the topic. She also maintains other research projects, including an NIH-funded study of the effects of neglect and poverty on adolescent development.

Mickey Sperlich is an Assistant Professor at the UB School of Social Work. She has extensive experience as a trauma and posttraumatic stress disorder researcher and has

developed and tested two prior curricular-based interventions particular to the perinatal epoch. She also has expertise in both quantitative and qualitative research methodology. Owing to the significant influence firearm violence has on maternal mortality, Sperlich has focused on firearm research for the field of social work for the past several years, collaborating with Dr. Logan-Greene to develop knowledge specific to the social work response to firearm violence.

Gregory Wilding is Chair and Tenured Full Professor in the Department of Biostatistics at the State University of New York at Buffalo (SUNYAB), housed within the School of Public Health and Health Professions, and has been a member of the faculty in the Department since its inception in 2002. He is a statistician with expertise in clinical trial design, permutation tests, resampling techniques, goodness-of-fit tests, and distributional characterizations, among other techniques and has extensive experience in the design of pilot randomized clinical trials. Furthermore, he directs the Biostatistics, Epidemiology, and Research Design Core of the UB Clinical and Translational Science Institute where he oversees the statistical efforts as it pertains to associated interdisciplinary clinical and non-clinical research projects.

Alexis Glennon (Research Assistant) is a current Doctorate in Social Work (DSW) student at the UB School of Social Work. She also holds an active LCSW in NY (*No. 083536*). She has participated in multiple research projects, including investigating the intersections of technology and mental health, specifically on marginalized populations including LGBTQ youth. Ms. Glennon will be responsible for participant tracking, data management, and responding to any emerging issues during the course of the study.

Describe other resources available to conduct the research.

Describe the time and effort that the Principal Investigator and research staff will devote to conducting and completing the research.

NOTE: Examples include the percentage of Full Time Equivalents (FTE), hours per week. The question will elicit whether there are appropriate resources to conduct the research.

Response:

Drs. Logan-Greene and Sperlich will devote 10% of their time to this study throughout the study.

Dr. Wilding will devote 2% of this time to this study.

Ms. Glennon will devote 10 hours per week, of 50% FTE for a student, to this study.

Describe the availability of medical or psychological resources that subjects might need as a result of anticipated consequences of the human research, if applicable.

NOTE: One example includes: on-call availability of a counselor or psychologist for a study that screens subjects for depression.

Response:

We do not anticipate that participants will experience distress as a result of participating in this study. However, they will be given information about 988 crisis services accessible from anywhere in New York during the consent process.

Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

Response:

Other Approvals

Describe any approvals that will be obtained prior to commencing the research (e.g., school, external site, funding agency, laboratory, radiation safety, or biosafety).

Response:

☒ **N/A:** This study does not require any other approvals.

Provisions to Protect the Privacy Interests of Subjects

Describe how you will protect subjects' privacy interests during the course of this research.

NOTE: Privacy refers to an individual's right to control access to him or herself. Privacy applies to the person. Confidentiality refers to how data collected about individuals for the research will be protected by the researcher from release. Confidentiality applies to the data.

Examples of appropriate responses include: "participant only meets with a study coordinator in a classroom setting where no one can overhear", or "the participant is reminded that they are free to refuse to answer any questions that they do not feel comfortable answering."

Response:

Participants will have no direct contact with the research team or anyone else in the study.

Indicate how the research team is permitted to access any sources of information about the subjects.

*NOTE: Examples of appropriate responses include: school permission for review of records, consent of the subject, HIPAA waiver. This question **does apply** to records reviews.*

Response:

We will not have access to any data beyond what the participants supply through survey tools.

Data Management and Analysis*

Describe the data analysis plan, including any statistical procedures. This section applies to both quantitative and qualitative analysis.

Response:

Aim 1:

Items in all scales will be analyzed for variance and proper range. Scales will be examined for internal reliability, test-re-test reliability, content validity, and factoral reliability as appropriate. Any items or scales that demonstrate problematic results will be revised as needed before use in Aim 2.

Aim 2:

Scores on all scales will be compared over time (pre-, post-, and follow-up tests) and across groups (intervention/control groups) using either mixed linear models or generalized estimating equations as appropriate. Analyses will be performed with a focus on estimation of parameters for use in the planning of a subsequent comparative trial designed to fully assess intervention efficacy with a national sample. Supportive analyses that adjust for participant covariates will also be considered.

SPSS and SAS will be used for all analyses.

If applicable, provide a power analysis.

NOTE: This may not apply to certain types of studies, including chart/records reviews, survey studies, or observational studies. This question is asked to elicit whether the investigator has an adequate sample size to achieve the study objectives and justify a conclusion.

Response:

Not applicable at this time as the effect sizes from this intervention are unknown.

Describe any procedures that will be used for quality control of collected data.

Response:

We will check for proper importation from REDCap into downloaded datasets. We will also check that respondent answers are appropriately recorded per scale expectations.

Confidentiality*

A. Confidentiality of Study Data

*Describe the local procedures for maintenance of confidentiality of **study data and any records that will be reviewed for data collection**.*

*A. Where and how will all data and records be stored? Include information about: password protection, encryption, physical controls, authorization of access, and separation of identifiers and data, as applicable. Include physical (e.g. paper) **and** electronic files.*

Response:

All data will be stored electronically on UB REDCap and UB cloud folders that are only accessible to research team members. These will only be accessible via password protected computers in team members' offices.

A. How long will the data be stored?

Response:

Identifying materials (records of emails) will be destroyed as soon as the study is complete. Deidentified data will be kept until seven years past when all analyses are complete.

A. Who will have access to the data?

Response:

Only authorized members of the research team will have to the data.

A. Who is responsible for receipt or transmission of the data?

Response:

Only authorized members of the research team.

A. How will the data be transported?

Response:

N/A

B. Confidentiality of Study Specimens

*Describe the local procedures for maintenance of confidentiality of **study specimens**.*

☒ **N/A:** No specimens will be collected or analyzed in this research.
(Skip to Section 21.0)

B. Where and how will all specimens be stored? Include information about: physical controls, authorization of access, and labeling of specimens, as applicable.

Response:

B. How long will the specimens be stored?

Response:

B. Who will have access to the specimens?

Response:

B. Who is responsible for receipt or transmission of the specimens?

Response:

B. How will the specimens be transported?

Response:

Provisions to Monitor the Data to Ensure the Safety of Subjects*

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

NOTE: Minimal risk studies may be required to monitor subject safety if the research procedures include procedures that present unique risks to subjects that require monitoring. Some examples include: exercising to exertion, or instruments that elicit suicidality or substance abuse behavior. In such cases, N/A is not an acceptable response.

Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

Response:

There are no anticipated physical or psychological risks to this research that could be mitigated by a monitoring procedure.

Describe what data are reviewed, including safety data, untoward events, and efficacy data.

Response:

N/A

Describe any safety endpoints.

Response:

N/A

Describe how the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).

Response:

N/A

Describe the frequency of safety data collection.

Response:

N/A

Describe who will review the safety data.

Response:

N/A

Describe the frequency or periodicity of review of cumulative safety data.

Response:

N/A

Describe the statistical tests for analyzing the safety data to determine whether harm is occurring.

Response:

N/A

Describe any conditions that trigger an immediate suspension of the research.

Response:

N/A

Withdrawal of Subjects*

☐ **N/A:** This study is not enrolling subjects. This section does not apply.

*Describe **anticipated** circumstances under which subjects may be withdrawn from the research without their consent.*

Response:

We do not anticipate withdrawing participants from the study without their consent.

Describe any procedures for orderly termination.

NOTE: Examples may include return of study drug, exit interview with clinician. Include whether additional follow up is recommended for safety reasons for physical or emotional health.

Response:

Participants may choose to withdraw from the study at any time. We do not anticipate a need to follow up with them for safety reasons.

Describe procedures that will be followed when subjects withdraw from the research, including retention of already collected data, and partial withdrawal from procedures with continued data collection, as applicable.

Response:

Unless requested, we will retain participant study data even if they withdraw before completing the study.

Risks to Subjects*

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to their participation in the research. Consider physical, psychological, social, legal, and economic risks. Include a description of the probability, magnitude, duration, and reversibility of the risks.

NOTE: Breach of confidentiality is always a risk for identifiable subject data.

Response:

Aim 1:

There are no foreseeable risks to participants beyond what they normally encounter in their workdays.

Aim 2:

The foreseeable risks are minimal. Participants may experience mild distress as a result of intervention materials that discuss firearm violence, however there is no graphic content. Control group members may experience some distress that their enrollment in the intervention is delayed.

Describe procedures performed to lessen the probability or magnitude of risks, including procedures being performed to monitor subjects for safety.

Response:

The SAFR intervention has been developed by two social work professors who are experts on trauma and trauma-informed care. The course will also be previewed by individuals in the UB SSW continuing education department. Thus, we feel that the chances of distress are very low.

However, we will examine feedback on the course as it arrives to ensure that individuals are finding the intervention acceptable.

*If applicable, indicate **which procedures** may have risks to the subjects that are currently unforeseeable.*

Response:

N/A

If applicable, indicate which research procedures may have risks to an embryo or fetus should the subject be or become pregnant.

Response:

N/A

If applicable, describe risks to others who are not subjects.

Response:

N/A

Potential Benefits to Subjects*

Describe the potential benefits that individual subjects may experience by taking part in the research. Include the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit.

*NOTE: Compensation **cannot** be stated as a benefit.*

Response:

Participants who complete the SAFR intervention will receive training on how to recognize and respond to risks of gun violence in their clients. Those eligible will also receive continuing education credits. The UB SSW Continuing Education Department is accredited by the State of New York to provide such trainings which practicing social workers need to maintain their licensure. After completing the course, participants will have access to an Electronic Certificate of Completion verifying their credits..

Compensation for Research-Related Injury

☒ **N/A:** The research procedures for this study do not present risk of research related injury (e.g. survey studies, records review studies). This section does not apply.

***If the research procedures carry a risk of research related injury,** describe the available compensation to subjects in the event that such injury should occur.*

Response:

Provide a copy of contract language, if any, relevant to compensation for research related injury.

*NOTE: If the contract is not yet approved at the time of this submission, submit the current version here. If the contract is later approved with **different language regarding research related injury**, you must modify your response here and submit an amendment to the IRB for review and approval.*

Response:

Economic Burden to Subjects

Describe any costs that subjects may be responsible for because of participation in the research.

NOTE: Some examples include transportation or parking.

Response:

There are no anticipated economic burdens to participants. All study components are online and can be accessed at the time and place of their choosing.

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

Compensation for Participation

27.1 Describe the amount and timing of any compensation to subjects, including monetary, course credit, or gift card compensation.

Response: The following table presents the compensation schedule. In addition to the US Bank cash gift card incentives, eligible participants will receive six hours continuing education credit through the UB School of Social Work Continuing Education Office..

	Specific Aim 1	**Specific Aim 2**
First survey/Pre-test	$30	$30
Re-test survey/Post-test	$40	$40
Follow-up test	N/A	$50
Total	$70	$120
For 100 participants	**$7,000**	**$12,000**

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

☐ **N/A:** There is no compensation for participation. This section does not apply.

Consent Process

Indicate whether you will be obtaining consent.

NOTE: This does not refer to consent documentation, but rather whether you will be obtaining permission from subjects to participate in a research study.
Consent documentation is addressed in Section 29.0.

☒ ***Yes*** *(If yes, Provide responses to each question in this Section)*
☐ ***No*** *(If no, Skip to Section 29.0)*

Describe where the consent process will take place. Include steps to maximize subjects' privacy.

Response:

Consent will occur online.

Describe how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study.

NOTE: It is always a requirement that a prospective subject is given sufficient time to have their questions answered and consider their participation. See "SOP: Informed Consent Process for Research (HRP-090)" Sections 5.5 and 5.6.

Response:

Participants can proceed with the study if they choose with no time pressure. We will also provide team members' contact information if they have questions before enrolling.

Describe any process to ensure ongoing consent, defined as a subject's willingness to continue participation for the duration of the research study.

Response:

Participants will be reminded with each re-contact that participation is voluntary.

Indicate whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." Pay particular attention to Sections 5.4-5.9. If not, or if there are any exceptions or additional details to what is covered in the SOP, describe:

The role of the individuals listed in the application who are involved in the consent process

The time that will be devoted to the consent discussion

Steps that will be taken to minimize the possibility of coercion or undue influence

Steps that will be taken to ensure the subjects' understanding

Response:

☒ We have reviewed and will be following "SOP: Informed Consent Process for Research (HRP-090)."

Non-English Speaking Subjects

☒ **N/A:** This study will not enroll Non-English speaking subjects.
(Skip to Section 28.8)

Indicate which language(s) other than English are likely to be spoken/understood by your prospective study population or their legally authorized representatives.

NOTE: The response to this Section should correspond with your response to Section 8.4 of this protocol.

Response:

If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language, how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study, and any process to ensure ongoing consent. Indicate the language that will be used by those obtaining consent.

NOTE: Guidance is provided on "SOP: Informed Consent Process for Research (HRP-090)."

Response:

N/A

Cognitively Impaired Adults

☒ **N/A**: This study will not enroll cognitively impaired adults.
(Skip to Section 28.9)

Describe the process to determine whether an individual is capable of consent.

Response:

Adults Unable to Consent

☒ **N/A**: This study will not enroll adults unable to consent.
(*Skip to Section 28.13)*

When a person is not capable of consent due to cognitive impairment, a legally authorized representative should be used to provide consent (Sections 28.9 and 28.10) ***and, where possible, assent of the individual should also be solicited*** *(Sections 28.11 and 28.12).*

Describe how you will identify a Legally Authorized Representative (LAR). Indicate that you have reviewed the "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" for research in New York State.

NOTE: Examples of acceptable response includes: verifying the electronic medical record to determine if an LAR is recorded.

Response:

☐ We have reviewed and will be following "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."

***For research conducted outside of New York State**, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response:

*Describe the process for **assent of the adults**:*

*Indicate whether assent will be obtained from all, some, or none of the subjects. **If some, indicate which adults will be required to assent and which will not.***

Response:

If assent will not be obtained from some or all subjects, provide an explanation of why not.

Response:

*Describe whether **assent of the adult** subjects will be documented and the process to document assent.*

NOTE: The IRB allows the person obtaining assent to document assent on the consent document using the "Template Consent Document (HRP-502)" Signature Block for Assent of Adults who are Legally Unable to Consent.

Response:

Subjects who are not yet Adults (Infants, Children, and Teenagers)

☒ **N/A**: This study will not enroll subjects who are not yet adults.
(Skip to Section 29.0)

*Describe the criteria that will be used to determine **whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research** under the applicable law of the jurisdiction in which the research will be conducted **(e.g., individuals under the age of 18 years)**. For research conducted in NYS, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children."*

NOTE: Examples of acceptable responses include: verification via electronic medical record, driver's license or state-issued ID, screening questionnaire.

Response:

***For research conducted outside of New York State**, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response:

Describe whether parental permission will be obtained from:

Response:

☐ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

☐ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

☐ Parent permission will not be obtained. A waiver of parent permission is being requested.

NOTE: The requirement for parent permission is a protocol-specific determination made by the IRB based on the risk level of the research. For guidance, review the "CHECKLIST: Children (HRP-416)."

*Describe whether permission will be obtained from individuals **other than parents**, and if so, who will be allowed to provide permission. Describe your procedure for determining an individual's authority to consent to the child's general medical care.*

Response:

*Indicate whether assent will be obtained from all, some, or none of the **children**. If assent will be obtained from some children, indicate which children will be required to assent.*

Response:

When assent of children is obtained, describe how it will be documented.

Response:

Waiver or Alteration of Consent Process

Consent will not be obtained, required information will not be disclosed, or the research involves deception.

☒ **N/A:** A waiver or alteration of consent is not being requested.

If the research involves a waiver or alteration of the consent process, please review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure that you have provided sufficient information for the IRB to make the determination that a waiver or alteration can be granted.

NOTE: For records review studies, the first set of criteria on the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" applies.

Response:

If the research involves a waiver of the consent process for planned emergency research, please review the "CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)" to ensure you have provided sufficient information for the IRB to make these determinations. Provide any additional information necessary here:

Response:

N/A

Process to Document Consent

☐ **N/A:** A Waiver of Consent is being requested.
(Skip to Section 31.0)

Indicate whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not or if there are any exceptions, describe whether and how consent of the subject will be obtained including whether or not it will be documented in writing.

NOTE: If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent. This is sometimes referred to as 'verbal consent.' Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information.

📎 *If you will document consent in writing, attach a consent document with your submission. You may use "TEMPLATE CONSENT DOCUMENT (HRP-502)". If you will obtain consent, but not document consent in writing, attach the script of the information to be provided orally or in writing (i.e. consent script or Information Sheet).*

Response:

Because participants will be completing all study activities online, we are obtaining consent electronically. However, we will be providing participants with an informed consent information document to read and download if they so choose.

1. The informed consent document will be electronically displayed, including all required elements of consent disclosure in Section 7: ELEMENTS OF CONSENT DISCLOSURE in the WORKSHEET: Criteria for Approval (HRP-314).

2. The research presents no more than Minimal Risk of harm to subjects. 3. The research involves no procedures for which written consent is normally required outside of the research context.

We have attached two different informed consent documents for Aim 1 and Aim 2.

☒ We will be following "SOP: Written Documentation of Consent" (HRP-091).

Multi-Site Research (Multisite/Multicenter Only)*

☒ **N/A:** This study is not an investigator-initiated multi-site study. This section does not apply.

Indicate the total number of subjects that will be enrolled or records that will be reviewed across all sites.

Response:

*If this is a multi-site study **where you are the lead investigator**, describe the processes to ensure communication among sites, such as the following.*

All sites have the most current version of the IRB documents, including the protocol, consent document, and HIPAA authorization.

All required approvals have been obtained at each site (including approval by the site's IRB of record).

All modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.

All engaged participating sites will safeguard data as required by local information security policies.

All local site investigators conduct the study appropriately in accordance with applicable federal regulations and local laws.

All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.

Response:

Describe the method for communicating to engaged participating sites.

Problems (inclusive of reportable events)

Interim results

Study closure

Response:

*If this is a multicenter study **where you are a participating site/investigator**, describe the local procedures for maintenance of confidentiality.*

Where and how data or specimens will be stored locally?

How long the data or specimens will be stored locally?

Who will have access to the data or specimens locally?

Who is responsible for receipt or transmission of the data or specimens locally?

How data and specimens will be transported locally?

Response:

If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods. Local recruitment methods are described elsewhere in the protocol.

Describe when, where, and how potential subjects will be recruited.

Describe the methods that will be used to identify potential subjects.

Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping

because of inappropriate wording, provided the IRB reviews the final audio/video tape.)

Response:

Banking Data or Specimens for Future Use*

☒ **N/A:** This study is not banking data or specimens for future use or research outside the scope of the present protocol. This section does not apply.

*If data or specimens will be banked (stored) for **future use, that is, use or research outside of the scope of the present protocol**, describe where the data/specimens will be stored, how long they will be stored, how the data/specimens will be accessed, and who will have access to the data/specimens.*

NOTE: Your response here must be consistent with your response at the "What happens if I say yes, I want to be in this research?" Section of the Template Consent Document (HRP-502).

NOTE: If the UBIRB has approved this study to bank data and/or specimens for potential future use outside the scope of this research study, any future use or disclosure of the data that is not described within the approved study must be submitted for review to the UBIRB.

Response:

List the data to be stored or associated with each specimen.

Response:

Describe the procedures to release banked data or specimens for future uses, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

Response: