Project Title: Assessing the Feasibility of a New Prevention to Reduce Alcohol-related Sexual Revictimization of College Women
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Complete Research Protocol (HRP-503)

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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.*
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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:

  Study 1 (Stage 1a) Focus Groups: No multiple participant groups.

  Study 2 (Stage 1b) Pilot Randomized Clinical Trial:

  Intervention Group: Revictimization Prevention for College Women (RPCW)
  Control Group: Health Education Control (HEC)

Formatting:

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

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- *Update the version date or number **on Page 3.***

PROTOCOL TITLE:

Include the full protocol title.

Response:

Assessing the feasibility of a new prevention to reduce alcohol-related sexual revictimization of college women

PRINCIPAL INVESTIGATOR:

Name
Department
Telephone Number
Email Address

Response: Principal Investigator

Kathleen Parks Marsh, Psychology, 887-3301, kparks@buffalo.edu

VERSION:

Include the version date or number.

Response:

Version 11

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: Funded by NIAAA

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:

Location: Office of Kathleen Parks Marsh

Address: Rm. 350, 1021 Main St., Buffalo, 14203

Department: Psychology

1.0 Objectives

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

Response: The current application proposes to develop a preventive intervention to reduce college women's risk for sexual revictimization (SRV). The intervention will target the high-risk population of women with a history of sexual assault (SA) and recent hazardous drinking (HD).

The primary goals of this application are to decrease women's HD, improve their ability to perceive cues that signal risk for SRV, and strengthen their behavioral skills in situations associated with an increased risk for SRV.

This project has two primary aims which will be addressed in two sequential stages, labeled as Study 1: Focus groups and Study 2: Pilot Randomized Clinical Trial for clarity in the IRB protocol. In Study 1 (i.e., Stage 1a), components of the Revictimization Prevention for College Women (RPCW), a multi-modal intervention that includes on-line education, in-person group skills-based training, and problem solving training and behavioral rehearsal was developed and refined. Study 1 has been completed. Therefore, the current protocol covers Study 2 (i.e., Stage 1b), the pilot randomized clinical trial (RCT). Study 2 will compare the outcomes of women participating in the RPCW intervention (developed in Study 1) to women who receive an active Health Education Control (HEC) condition.

Study 2 addresses Aim 2 of the planned research.

Aim 2: To conduct a Stage 1b pilot randomized clinical trial of the RPCW intervention with women enrolled at the University at Buffalo (UB) who drink alcohol, with follow-up assessments at 3- and 6-months post intervention.

Women (ages 18 – 22 years old) who are enrolled at UB and drink alcohol (N = 96) will be randomly assigned to either the RPCW intervention or to a Health Education Control (HEC) condition. The pilot RCT will be used to establish the feasibility of recruitment, the acceptability and safety of the RPCW intervention, and provide initial efficacy data that will assist in power calculations for a Stage II efficacy trial.

1.2 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.

This protocol covers the second study of the grant, the Randomized Controlled Trial.

Study 2, Randomized Controlled Trial:

Hypothesis 2a: Participants in the RPCW intervention will report fewer days of hazardous drinking and improved perception of SA risk cues on the video risk perception measure (primary outcomes) as compared with participants in the HEC condition.

Hypothesis 2b: Participants in the RPCW intervention will report increased knowledge of safe dating practices and protective behavioral (drinking) strategies (secondary outcomes) compared with participants in the HEC condition.

Hypotheses 2c: Participants in the RPCW intervention will report lower rates of SRV as compared with participants in the HEC condition at 6-month post-intervention follow-up.

2.0 Scientific Endpoints

2.1 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.*

Study 2, Randomized Controlled Trial: Identification of risk cues for sexual assault (SA), increase in effective responding to risk cues for SA, reduction in emotional barriers to responding effectively to reduce risk for sexual revictimization.

Decrease women's HD in order to: 1) reduce the risk that alcohol will impair their ability to perceive risk cues for SA; and 2) increase their ability to remain within safe drinking guidelines (i.e., no more than 3 drinks per day/occasion) to be able to respond assertively and/or react earlier in a potential high-risk SA situation.

3.0 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:

SIGNIFICANCE

College sexual assault (SA) has been labeled a threat against "our families, our communities, and ultimately our entire country" [1]. Women who experience SA have an increased likelihood of serious psychological (e.g.,

depression, anxiety, PTSD; [2, 3]) and physical health (e.g., gastrointestinal, gynecological, cardiopulmonary; [2]) problems. Greater than 20% of women experience an SA while in college. These women consume more alcohol, use fewer drinking protective behavioral strategies PBS), and experience more alcohol-related negative consequences -- including high rates (35-79%) of subsequent SA (i.e., sexual revictimization (SRV); [4-8]) -- compared to those who do not experience an initial SA. The majority of college SAs and SRVs involve incapacitation by alcohol or drugs and first college SAs occur primarily during the first or second year [9, 10]. In our own study, college women were 19.4 times more likely to experience SA or SRV on heavy drinking days (≥ 4 drinks) compared with nondrinking days [11]. Thus, alcohol consumption, particularly, hazardous drinking (HD; ≥ 4 drinks per occasion, ≥ 2 times in 30 days [12]), is a strong proximal predictor of SA for college women (see [13-15] for reviews). Given the strong demand for effective prevention programs that reduce the risk for SRV, it is vital that future SRV preventive interventions include components focused on the relationship between HD and SA, or on strategies for decreasing HD as one way to reduce risk for SRV. To date, no such programs exist. In this application, we propose to develop an innovative prevention intervention program to reduce SRV that combines strategies for decreasing HD and strengthening risk perception of SA cues, two of the strongest risk factors for SRV of college women.

Relationship between Alcohol and Sexual Assault on College Campuses

Between 50-83% of college SA victims report using alcohol prior to or at the time of the assault (e.g., [16-18]), and most do not report the incident to authorities or seek help [19]. Moreover, 72% of college women are too intoxicated to provide consent when they are raped [20]. Our research indicates that on heavy drinking days (≥ 4 drinks, M = 7.46, SD = 3.89), women were 19.4 times more likely to experience SA than on nondrinking days [11], whereas on non-heavy drinking days (< 3 drinks, M = 1.86, SD = 0.78), they were at no greater risk for SA compared to nondrinking days. Collectively, these findings indicate that drinking itself does not place women at increased risk for SA, rather, HD often to the point of incapacitation increases risk for SA. Our data do not distinguish between initial SA and SRV, however, women with a history of SA are more likely to experience SRV if they engage in HD [7].

How does Alcohol Influence Risk for Sexual Assault? Two primary pathways by which alcohol places women at increased risk for SA have been proposed, including reduction of: 1) risk recognition and 2) ability to resist. First, the physiological effects of alcohol reduce a woman's ability to recognize or perceive risk cues for SA. Second, alcohol impairs a woman's ability to utilize protective behavioral strategies (PBS) such as removing herself from risky situations or verbally or physically resisting assailants [21, 22]. Indeed, experimental alcohol studies have found that

women are less likely to notice risk cues, both ambiguous (e.g., isolation, size difference between man and woman, male drinking) and overt (e.g., sexual comments, demands for sex, unwanted sexual advances) under conditions of alcohol intoxication compared to placebo and no alcohol controls [23-25]. They also are less likely to engage in assertive resistance strategies when intoxicated (e.g., saying no, pushing the man away; [21, 26]). These findings have been corroborated in experimental laboratory alcohol studies in which women respond to written SA scenarios under the influence of alcohol [27].

Mechanisms by Which Prior Sexual Assault Influences Risk for Sexual Revictimization. Similar to the relationship between alcohol and SA, a history of SA reduces women's ability to recognize risk, overcome emotional barriers to resistance and effective management of the situation, and provide effective resistance to SRV. In one study, women with histories of SA who had longer latencies to indicate they would leave hypothetical rape situations had higher rates of SRV at 8-month follow-up [28]. In another study, women who had experienced SRV took longer to respond to a hypothetical rape scenario than women who had experienced only one or no SA [29]. Women with a prior SA display deficits in emotion regulation such as greater levels of emotional nonacceptance, lack of emotional clarity, and problems with impulse control that can reduce their ability to use emotional information to detect and respond to SA risk cues [30-32]. Stoner et al., [33] found that prior SA was associated with women's intentions to use less effective resistance strategies when faced with a simulated interaction with a sexually aggressive male.

Women who have experienced SA or SRV report higher rates of monthly HD compared to women who have not experienced a SA [34]. As previously described, HD decreases risk perception and reduces assertive responding in SA situations. Given that a history of SA has similar effects on risk perception and responding, it is likely that women with a SA history who are engaging in HD will be at high risk for SRV due to reduced ability to perceive risk cues and reduced ability to resist effectively a sexual aggressor. In summary, these studies suggest that impairments in SA risk cue perception, effective resistance and deterrence, and emotion regulation deficits negatively impact risk perception. All of these factors, when combined with HD, can leave women with histories of SA at increased risk for SRV. The proposed preventive intervention seeks to decrease these specific vulnerabilities in order to reduce risk for SRV in HD college women.

Current Status of College Preventive Interventions to Reduce Sexual Revictimization

We are aware of only two programs developed specifically to reduce SRV among college women [35, 36]. The first, a mindfulness-based program, was not effective in reducing SRV [36]. The second, an education-based program included: SA facts, practical SA prevention strategies, risky

dating behaviors, risk-recognition, problem solving, assertiveness, and communication skills [37]. Overall rates of sexual revictimization did not differ between the control and intervention groups; only rates of completed rape were lower for the intervention group. However, the sample was small (N = 66) and rates of completed rape were low across both conditions. In addition, women who were revictimized during follow-up had poorer risk recognition skills than women who were not revictimized, suggesting limited intervention efficacy.

In general, SA education interventions among college students have included SA facts, rape myths, and risk factors. A number of interventions have shown efficacy for changing attitudes and beliefs but these changes are short-lived [37] and, importantly, do not lead to a reduction in incidents of SA. Indeed, a meta-analysis of SA education programs [38] found no effect on behavioral indices of SA (i.e., intentions to commit SA, rates of SA). Some interventions that have included additional components, such as self-defense or behavioral skills training have shown efficacy for reducing incidents of SA but have not been effective in reducing SRV and are limited by small effect sizes, short follow-up periods [39, 40], the use of retrospective comparison groups [41], or a lack of replication. Only one program has been assessed over a 2-year period against an appropriate control condition and was found to significantly reduce rates of completed rape [42]. This multicomponent program provided college women with information, practice assessing risk, and skills for defending against SA. However, this program did not focus on reducing HD or SRV [42, 43].

Current Status of Preventive Interventions to Reduce Alcohol Use on College Campuses

A recent study of college students [44] found that 89% of men and 83% of women reported exceeding the NIAAA recommended daily (4 and 3 drinks, respectively) drinking limits during their first year at college. Thus, college women engage in frequent HD each week. A number of interventions have been developed to reduce HD on college campuses including social norm campaigns, alcohol education, personalized feedback interventions (PFI), and brief motivational interventions (BMI). A meta-analytic review [45] found that BMI and normative PFI for college students led to the greatest reductions in alcohol-related problems compared to other interventions (e.g., alcohol education). Reviews of PFIs for college students indicate that written-feedback-only is as effective as feedback delivered in-person [46], and identified specific components of PFI that have the greatest impact on reducing college student drinking (i.e., decisional balance, practical costs, strategies to limit risks; [47]). Several studies utilizing BMIs have demonstrated success in reducing drinking among college students [45-47]. A study of college women participating in a brief on-line intervention showed significant decreases in alcohol-related problems, increased readiness for change, and reduced

drinking at 1-month follow-up. Similarly, a study of a brief tailored web-based interactive intervention reduced college women's peak and total alcohol consumption as well as alcohol-related negative consequences [48]. Finally, a recent review concluded that brief interventions delivered in different modalities (i.e., face-to-face, computer, telephone) were effective in decreasing alcohol consumption in college women [49]. Thus, BMIs and PFIs have shown efficacy for reducing HD among college students. However, we are not aware of any interventions that effectively address both HD and SA risk reduction elements which both contribute to increased risk for SRV.

In a related line of research, the use of drinking PBS to reduce alcohol use and alcohol-related negative consequences has received increasing attention in the literature [50-52]. A limited number of studies have assessed drinking PBS associated with alcohol-related negative sexual consequences including SA [5, 53, 54]. Studies have found that college women who used more PBS when drinking experienced fewer alcohol-related negative sexual consequences [53] and that college women who experienced prior SA used fewer PBS when drinking [5, 54]. Thus, the inclusion of drinking PBS is an important component in prevention efforts for reducing alcohol-related SRV.

Current Efforts to Reduce Alcohol Consumption and Sexual Assault on College Campuses

Thus far, we are aware of only two studies that have attempted to decrease both alcohol use and SA among college women. In the first study [55], parent-based instruction on alcohol [56] and parent-based instruction on alcohol plus sexual assertiveness provided to incoming freshman women prior to college were compared to a no-intervention control group. Incapacitated rape decreased in the intervention groups due to an indirect effect through increased mother-daughter communication and decreased frequency of heavy drinking. However, overall rates of SA were not reduced compared with control participants. In a second study [57], college women were assigned to one of three treatment conditions (alcohol use reduction, SA risk reduction, or combined) or assigned to one of two control conditions (full or minimal assessment only). There were significant interactions for incapacitated rape and SA severity such that women with a high severity of prior SA reported fewer incapacitated rapes and lower severity SRV at 3-month follow-up in the combined condition compared to women in the full assessment control. This study in combination with the results of studies already reviewed demonstrating the efficacy of SA prevention programs provide initial evidence that decreases in HD and the provision of strategies to reduce risk for SA may be more effective for reducing rates of SA and SRV than interventions that target only HD or SA. Indeed, a recent study comparing a combined alcohol plus alcohol-related risky sexual behavior intervention to several single-intervention control conditions found that only the combined

intervention significantly decreased both drinking and risky sexual behavior [58]. It is important to note that this study did not address SA. Our study differs from previous studies that have focused on HD or primary SA given that our planned preventive intervention targets reduction of SRV by focusing on decreasing HD and increasing SA risk perception and behavior change.

Previously Victimized Women as a High-Risk College Population

Our recent analysis of the relationship between SA and alcohol consumption from the last year of high school through college (N = 989 college women) found that compared to women who did not experience a SA, women who experienced a past year severe SA (attempted/completed rape) had a three-fold increase in the likelihood of severe SA in the current year (i.e., SRV; OR = 3.22, CIs = 2.30, 4.51, $p < .001$) [59]. Furthermore, 30% of women experienced a SA at some point during the four years at college and 57% of these women experienced 1 or more SRVs during this same period [60]. This rate of SRV is likely to be an underestimate, as it does not account for women who were victimized as adolescents (prior to entering college), and then experienced a SRV after entering college. Thus, SRV is a substantial problem on college campuses that is not being addressed by current preventive intervention efforts. Several studies, including our own [10], indicate that a history of victimization and heavier alcohol consumption are associated with increased risk for SRV [17, 28, 61, 62].

A Framework for Reducing Alcohol-Related Sexual Revictimization of College Women

The Information, Motivation, Behavioral Skills (IMB) Model [63], a Health Behavior Change model, provides a framework to guide the development of our planned preventive intervention to decrease college women's HD and risks for SRV. The IMB model has been used successfully to develop an AIDS risk reduction prevention program for college students and for men who have sex with men [63, 64]. In our application of the IMB model, individuals are provided with SA and HD risk-reduction information and motivation which together increase SA and HD risk-reduction behavioral skills to promote SA and HD preventive behavior. Thus, risk-reduction information and motivation are used to promote the use of risk-reduction (i.e., protective) behavioral skills leading to preventive behavior. For purposes of our proposed intervention, desired preventive behaviors would be increased SRV protective behaviors (dating PBS; e.g., increased SA risk recognition, assertive responding to unwanted male sexual attention) and safer drinking practices (drinking PBS; e.g., increased drink refusal).

Proposed Preventive Intervention to Reduce Alcohol-Related Sexual Revictimization

The proposed preventive intervention in Study 2, the pilot randomized clinical trial of this treatment development study is designed to increase previously victimized college women's ability to identify risk cues for SA (i.e., increase risk perception), respond effectively to those cues (i.e., appropriate behavioral response), and reduce emotional barriers to responding effectively in order to reduce the risk of SRV. Furthermore, it is designed to decrease women's HD in order to: 1) reduce the risk that alcohol will impair their ability to perceive risk cues; and 2) increase their ability to remain within safe drinking guidelines (i.e., no more than 3 drinks per day/occasion) to be able to respond assertively and/or react earlier in a potential high-risk SA situation. As part of the preventive intervention, women will be provided with information about cues that indicate threat for SA, drinking PBS (e.g., interchanging alcoholic drinks with water, setting a drink limit) and dating PBS (e.g., informing a trusted other where you are going and when returning). Women will be motivated to use the behavioral skills through observation of these skills and the resulting positive outcomes (e.g., increased assertiveness, decreased SA risk, increased self-efficacy and ability to leave an uncomfortable situation) modeled in the interactive in-person and online training materials. Women also will learn to use the drinking and dating behavioral skills through the interactive training videos as well as group discussions and opportunities to practice these skills through role plays. These behavioral skills will include ways to reduce HD (i.e., drink refusal), as well as ways to reduce risk for SA (i.e., assertively responding to unwanted sexual attention, or uncomfortable or sexually risky interactions).

Advancing Sexual Assault Prevention Efforts for Previously Victimized College Women

The proposed research focuses on developing a successful preventive intervention to decrease SRV of college women. Interventions demonstrating efficacy for reducing SA rates among college women have not shown efficacy for reducing SRV. In our study of 998 college women, we found that among 300 women who experienced SA during their college years, 57% (N = 171) experienced SRV before graduating, of which half involved severe assault (i.e., coercive sexual intercourse, or attempted or completed rape; [60]). Given the significant negative sequelae resulting from SA (e.g., PTSD, depression, sexual problems), a preventive intervention focused on reducing the additive effects of multiple SAs (i.e., SRV) is essential. In our sample, women who experienced SA or SRV reported drinking significantly more prior to entering college and throughout the college years than women who did not experience a SA during college [60]. The proposed intervention differs from prior interventions given its dual focus on: (1) increasing risk-reduction behavioral skills for SRV and decreasing emotional barriers to enacting these skills through the use of group sessions with training videos; and (2) on-line materials to decrease HD and increase drinking and

dating PBS. The proposed intervention will teach women to recognize both clear and ambiguous risk cues for SRV and provide practical strategies for removing themselves from situations in which they perceive these cues (i.e., assertive verbal and physical responses to unwanted sexual attention, exit strategies). It is clear that college women can experience significant emotional barriers to engaging in these strategies (e.g., embarrassment, not wanting to hurt the male's feelings, fear of rejection or personal injury; [21]), therefore, we also will include information on these emotional barriers within the dating PBS on-line module and initiate a discussion to assist women in overcoming these emotional barriers during the second group session. Women's emotional reactions to rehearsing these behavioral skills will be discussed, as well as skills for regulating their emotions when faced with SRV risk cues. This is an important addition to the intervention as empirical evidence indicates that emotion dysregulation mediates the relationship between prior SA and SRV by decreasing women's ability to perceive risk cues [31, 65]. We also will provide women with information on the increased risks for SRV associated with HD and strategies for decreasing their drinking in social situations (e.g., drink refusal, drinking PBS). By teaching women to limit their alcohol consumption, they are more likely to recognize cues that signal risk for SRV and respond effectively. To be clear, SRV is never a woman's fault or responsibility, regardless of her level of intoxication or the circumstances in which the assault occurs; therefore, women are not to be blamed for being victimized when under the influence of alcohol. However, HD does increase risk for SRV, and a prevention program that aims to reduce HD and increase risk recognition and effective resistance responding has the potential to make a significant and direct impact on reducing the incidence of college women's SRV.

2.1 Include complete citations or references.

Response:

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4.0 Study Design

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

Response:

Study 2: Behavioral interventional study design.

5.0 Local Number of Subjects

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

Response:

Study 2: N=96

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

Response:

Study 2: We anticipate screening up to 2800 women to recruit n=96 during the randomized controlled trial.

5.3 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:

Study 2: We have access to 2800 students during the spring semester of 2022 for recruitment to meet the goal of recruiting N = 96 participants. Thus, we need 3.4% of women to screen eligible and enter the study. .

6.0 Inclusion and Exclusion Criteria

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

NOTE: This may be done in bullet point fashion.

Response:

Study 2:

Eligibility Criteria. Inclusion criteria are: (1) 18-22 years of age, (2) female currently enrolled at the University at Buffalo in an undergraduate program, (3)

able to comprehend the study protocol, consent form and provide written consent, (4) have had a prior SA experienced since the age of 14 years (i.e., adolescent or young adult), and (5) have engaged in hazardous drinking in the past month (i.e., ≥ 4 drinks one or more times in the past 30 days.

We are recruiting women 18-22 years of age who are currently enrolled at the University at Buffalo. Given that HD has been associated with SA, we are incorporating reduction of HD into our intervention; therefore, we include women with a history of drinking or HD.

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

NOTE: This may be done in bullet point fashion.

Response:

Study 2:

Exclusion criteria are: (1) Major mental illness as indicated by: (a) severe level of depressive symptoms as assessed by the BDI-II (a score greater than 30) or a self-reported diagnosis of: (b) Schizophrenia, (c) Bipolar Disorder; (2) unable to commit to attending 2 in-person group sessions, approximately one week apart (3) no access to a computer to complete the on-line intervention modules, and (4) currently being in another research study designed to reduce drinking/alcohol consumption and/or sexual victimization.

The score BDI-II score for inclusion is being increased from 25 to 30 given recent literature indicating that since the beginning of COVID depressive symptoms have increased in the population as a whole and among college students in particular. The intervention is designed to provide women with increase behavioral skills for decreasing drinking and reducing social risk, therefore, this should benefit women who are just below the cut off score for severe-depression (i.e, 30) as well as women who are in the upper moderate range of depression (i.e., 25-30). Given that depression is a risk factor for SA and SRV, we had originally set this criterion lower to minimize the effect of depression on our outcome of SRV. Given the increased rates of depression in the population, this seems to be a criterion that is too low. Hence our reason for increasing the cut-off score for participation.

6.3 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

6.4 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:

No, all participants will be recruited from the University at Buffalo where all students speak English.

7.0 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.

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

Response:

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

7.2 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.

7.3 For research that involves ***prisoners****, safeguards include:*

NOTE CHECKLIST: Prisoners (HRP-415)

Response:

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

*7.4 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").

*7.5 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.

*7.6 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: College students will be included. Screening and participation are voluntary. There is no penalty for declining either screening or participation. No information regarding individual participation is provided to the university. Remuneration is modest to prevent coercion or undue influence.

8.0 Eligibility Screening

*8.1 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:

Study 2: The project director or a member of the study team will screen potential participants who contact the project by phone or through the Qualtrics contact survey to determine eligibility. All potential participants will be sent a link to the Qualtrics contact survey in the initial invitation email. The link to the Qualtrics contact survey is provided with the links to the online intervention units. The screening survey is attached along with the other survey measures.

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

9.0 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.

9.1 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:

Study 2:

We will be obtaining e-mail addresses of female students enrolled at UB during the spring or fall semesters of 2022-2023, who agree to have their information published in the student directory (~ 85% of students) from UB. An email describing the project, including a link to an online contact form (Qualtrics) will be sent to all of these students. The form will collect basic contact information and availability to complete the eligibility screener on the phone with a staff member. Copies of the email and link to the online Qualtrics form are attached. In addition, we will supplement recruitment by hanging flyers with a brief description of the project and project contact information, as well as a QR code that links to the online Qualtrics contact form, in select academic buildings and common areas on the UB North Campus. A copy of the flyer is attached.

9.2 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:

Study 2:

Participants will have the right to decline to be screened or to participate. Screening will be conducted on research study computers and all other assessments will be completed over the web or on additional, individual study laptops to insure participant privacy.

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:

Study 2:

A random sample of approximately 1400 women will be sent invitation e-mails to participate in the study each week during active participant recruitment. These

invitations will introduce the project to the women indicating we would like their help in evaluating a new program designed to educate college women about safe dating and drinking practices, as well as increase awareness of signs of unwanted sexual experiences. The invitation will explain that the study involves two group sessions and two on-line learning modules. The email also will have a link to an online form. The form will collect basic contact information and availability to complete the eligibility screener on the phone with a staff member. Copies of the email and form are attached.

10.0 Procedures Involved

*10.1 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:

Study 2:
During the Stage 1b Randomized Controlled Trial of the active intervention, the first group session will focus on viewing each of 4 cue recognition training videos and the Interventionist will lead a discussion intended to highlight the risk cues in each of the videos. After the session, links and passwords will be sent via email to each participant for the online safe dating and safe drinking learning modules and participants will be asked to complete them prior to the second group session, which will take place about one week after the first session. This second group session will elicit feedback on the dating and drinking learning modules (e.g., length, ease of use, engagement, interest). The training videos will be viewed again individually and participants will engage in behavioral skills rehearsal of appropriate responses in paired role plays with feedback from the PI and Interventionist. During the behavioral rehearsal segment, the PI or Interventionist will engage the group in a discussion of emotional barriers to engaging in appropriate dating and drinking safety behaviors (e.g., “I feel bad for the guy”, “He might get really mad, “I might miss out on being with a great guy”) and strategies for overcoming these barriers. Adaptive emotion regulation strategies will include cognitive reappraisal, distress tolerance, mindfulness of current emotions, acceptance, and problem solving. Immediately following this session, the post-intervention measures, including feedback on the intervention content and process, will be completed. Following the in-person RPCW sessions, a debriefing will occur to ensure that women have an opportunity to discuss any emotional discomfort or distress with the interventionist. Women will receive $30 for completion of the post-intervention measures.

Health education control (HEC). The two in-person sessions and two online units of the HEC condition will impart health information that is relevant and engaging for college women but does not directly address heavy drinking or SA risk. *Thus, the proposed HEC condition is a time and attention control intended to control for nonspecific intervention factors related to health* behavior change. This 4-session active control condition will begin with information regarding the importance of good health and its association to academic, relationship and vocational success. This will be followed by a discussion of health concerns from group members. Following the first group session, links and passwords will be emailed to

participants for the two online learning modules: (1) good nutrition simplified and (2) developing an exercise plan. These two modules are similar in format to the drinking and dating safety modules provided in the RPCW. The second group session will, importantly, elicit feedback regarding the relevance of the content and ensure the learning modules are being presented in an engaging format. In addition, at this session, we will present information on strategies for good sleep derived from a popular, empirically-validated cognitive-behavioral program to manage insomnia [88] and elicit similar feedback on this material. To ensure that HEC participants receive SA risk reduction and HD reduction information, they will have the opportunity to receive the RPCW intervention following the 6-month follow-up assessment, if they choose to do so.

At the beginning of the first in-person session and at the end of the second in-person session, for both the RPCW active intervention and the HEC condition, three standardized instruments will be administered to participants. **Participants will be seated a minimum of 6 feet apart in the group session room and administered these instruments on an individual laptop with earphones to allow them privacy.** These include the Video Vignette Risk Perception Measure (VVRPM) which assesses women's standardized ability to assess sexual assault risk cues. The Adult Faces test from the Diagnostic Analysis of Nonverbal Accuracy 2 (DANVA2) which is used to measure an individual's general ability to sensitivity to perceive nonverbal cues, and the sDERS a measure used to assess state emotion regulation (assessed using a web-based platform as are the other survey measures for the study). All data will be uploaded off of these laptops and saved to the project UB Box at the end of each in-person session.

Outlines for the in-person RPCW and HEC sessions are attached and links to the on-line learning units for both the RPCW and HEC are included for review.

10.2 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:

Study 2:

Participants will participate in the intervention over about one week. They will attend two in-person group intervention sessions about one week apart, and complete two on-line units during the intervening week. They will be asked to complete follow-up on-line assessment surveys at 3 months and 6 months post intervention.

The follow-up surveys will be administered online and are included for review.

10.3 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:

Study 2 data collection instruments include: Screening instrument, baseline survey, post-intervention survey with client satisfaction questionnaire, and 3 and 6 month follow up surveys to assess outcomes (i.e., any potential sexual victimization experiences, hazardous drinking/changes in drinking). At the beginning of the first in-person session and at the end of the second in-person session three standardized instruments will be administered via individual laptops. These include the Video Vignette Risk Perception Measure (VVRPM) which assesses women's standardized ability to assess sexual assault risk cues. The Adult Faces test from the Diagnostic Analysis of Nonverbal Accuracy 2 (DANVA2) which is used to measure an individual's general ability to sensitivity to perceive nonverbal cues, and the sDERS a measure used to assess state emotion regulation. A copy of all surveys and measures are attached.

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

Response: None

*10.5 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

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

Response:

Study results will be shared with the scientific community through scientific meetings and publications in peer reviewed journals. If requested, findings will be provided to participants at the end of the study in the aggregate.

11.0 Study Timelines

11.1 Describe the anticipated duration needed to enroll all study subjects.

Response:

Study 2:

Participants will be enrolled during the spring or fall 2022-2023 semesters at UB and then followed for 6 months.

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

Response:

Study 2: The length of each group session will be no longer than 1.5 hours, those are the only in-person sessions required of participants. The two on-line learning modules require approximately 30 minutes to complete. Participants will be asked

to complete a follow-up assessment at 3-months and 6-months post-intervention, each approximately 15-20 minutes in length.

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

Response:

Study 2: 9 months – 1.5 years

12.0 Setting

12.1 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:

Study 2: Screening will be conducted by study team members located in the Psychology Department at Park Hall on the UB North Campus, Amherst, NY or at the Clinical & Research Institute on Addictions (CRIA) building, located at 1021 Main St, Buffalo, NY located on the UB Medical Campus. Intervention sessions will be held on the University at Buffalo's North Campus (Amherst), in a large room equipped with individual tablet computers for participants to insure privacy. On-line participation will be on participants' own computers in their own private setting.

12.2 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.

13.0 Community-Based Participatory Research

13.1 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.

13.2 Describe the composition and involvement of a community advisory board.

Response:

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

14.0 Resources and Qualifications

*14.1 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:

The Principal Investigator is an NIH-funded investigator with 20+ years of experience conducting research in this area.

Describe other resources available to conduct the research.

14.2 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:

Study 2:

PI Parks Marsh will devote 25% effort, 10 hours per week to the project. Co-I Barrick will devote 2% effort, 1.9 hours per week to the project, Co-I David DiLillo will devote 3% effort, 1.2 hours per week to the project. Co-I Noelle St. Vil will devote 10% effort, 4 hours per week to the project. The Project Coordinator will devote 50% effort, 18.75 hours per week to the project, and the

graduate and undergraduate Research Technicians will each devote 9-15 hours per week to the project.

14.3 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: Co-IBarrick is a licensed clinical psychologistand will be available should participants express distress or a need to discuss negative thoughts or feelings that emerge during the study.

14.4 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:

All investigators and staff will be thoroughly trained in the protocols for the study. As well as procedures for screening participants, identifying distress, and contacting PI Parks Marsh with problems. Once developed, the intervention will be manualized and all investigators and staff will be trained in the manualized intervention and control.

15.0 Other Approvals

15.1 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:

We have obtained agreement from the University at Buffalo to recruit students.

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

16.0 Provisions to Protect the Privacy Interests of Subjects

16.1 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:

Study 2: Participants will answer questions privately on a tablet with headphones individually over the telephone with a research staff member, or on a device of their own choosing in a location of their own choosing. Participants are free to refuse to answer any questions that they do not feel comfortable answering. During group sessions, no individual will be called upon to disclose personal information. Participants are told that they can participate a lot, some or not at all in the group sessions. Thus, there will never be any pressure for individuals to disclose personal information.

16.2 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:

Consent of the subject.

17.0 Data Management and Analysis

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

Study 2:

Data Analyses

For the RCT, data will be analyzed according to the intention-to-treat principle [122]. All participants who complete the baseline assessment will be followed (i.e., post-intervention, 3-month and 6-month post-intervention) regardless of treatment participation. Given our experience and past record of retaining participants in longitudinal studies and the relatively brief period of follow-up (6-mos), dropout due to attrition is expected to be low. We anticipate no more than 5% of data will be missing through attrition or wave nonresponse (i.e., not completing all measures at a given time period). To adjust for any missing assessments, we will use multiple imputation procedures [123, 124].

We have three specific hypotheses for the RCT, our analyses are organized below for each hypothesis.

Hypothesis a: Participants in the RPCW intervention will report fewer days of hazardous drinking and improved perception of SRV risk cues on the video risk perception measure (primary outcomes) as compared with participants in the HEC condition.

Differences in relevant outcome variables (e.g., number of heavy drinking days, perception of SRV risk cues) will be tested using a 2 (Condition: RPCW vs. HEC) x 4 (Time: baseline, post-treatment, and 3- and 6-month post-treatment) repeated-measures analysis of variance (RM-ANOVA). The primary effects of interest are the intervention condition main effect and the intervention x time interaction. If a significant condition by time interaction is found, it means that (a) change over time in heavy drinking days differs across intervention conditions and (b) the effect of intervention condition on the outcome is different across time. Therefore, a significant intervention condition by time interaction will be explored by computing the conditional effect of time for each intervention condition and (b) the conditional effect of treatment condition at each of the four time points.

Hypothesis b: Participants in the RPCW intervention will report increased knowledge of safe dating practices and protective behavioral (drinking) strategies (secondary outcomes) compared with participants in the HEC condition.

Differences in relevant outcome variables (e.g., safe dating practices, protective behavioral drinking strategies) will be tested using the same 2 (Condition) x 4 (Time) repeated-measures analysis of variance (RM-ANOVA) described above for hypothesis a.

Hypothesis c: Participants in the RPCW intervention will report lower rates of SRV as compared with participants in the HEC condition at 6-month post-intervention follow-up.

Given that SRV has a low base rate of occurrence, we consider this hypothesis exploratory and will conduct a preliminary comparison of the incidence of SRV at 3-months and 6-months post-treatment across the RPCW and HEC conditions using a chi-square test.

Effect sizes will be calculated with all analyses in preparation for a Stage II efficacy trial of the intervention.

17.2 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:

Study 2:

The sample size of 96 women (48 women per intervention condition) was selected to provide 80% power to detect at least medium effect sizes in RM-ANOVA. For Hypotheses a and b, power calculations were conducted for a 2 (treatment condition) x 4 (time) RM-ANOVA. We calculated power using the following assumptions (1) a sample size of 48 women in each intervention condition (RPCW, HEC), (2) 4 time points for assessment (baseline, post-intervention, and 3- and 6-months post-intervention), (3) a range of correlation values among repeated assessments (r = .3 to .9), (4) no violation of the sphericity assumption, (5) $\alpha = .05$, two-tailed, and (6) power = 80% . Based on these assumptions, there is 80% power to detect an intervention condition main effect with medium effect sizes (f = .20 to .28) and both a time main effect and an intervention condition x time interaction with small to medium effect sizes (f = .05 to .21). For Hypothesis c, statistical power was estimated for a $\chi 2$ test (1 df) of the number of women who were and were not revictimized post treatment by intervention condition (RPCW, HEC). Assuming (1) a total sample of 96 women, (2) $\alpha = .05$, and (3) 80% power, the chi-square analysis can detect a medium effect (w = .29) at 3- and 6-month post-intervention.

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

Response:

Study 2:

RPCW/HEC Adherence Scale Development. The proposed study will develop and pilot test RPCW and HEC adherence measures. Adherence refers to the degree to which the interventionist follows the treatment manual guidelines [89, 90]. The RPCW and HEC adherence measures development will be based on our prior experience developing adherence

measures for cognitive-behavioral interventions and HEC conditions [68, 91]. Scale items and written instructions for scoring will be developed during Stage 1a. During Stage 1b, inter-rater reliability of individual items will be calculated by having two raters (PI Parks and Co-I St. Vil) evaluate the same sessions. Intra-class correlation coefficients (ICCs; [92]) of .70 or better indicate strong agreement and will be considered acceptable for the retention of an item.

Intervention Integrity. Intervention integrity refers to the degree to which the intervention is delivered as intended and will be assessed using several state-of-the art methods [93, 94]. First, both interventions will be manualized. Second, an instructor checklist will be completed following each session to indicate which intervention components were delivered to participants. These are intended to help the Interventionist monitor her own performance and to enhance the supervision process. Third, the clinical supervisors (Drs. Parks, Barrick, and St. Vil) will conduct weekly supervision with the instructor focused on intervention adherence, competent delivery of the interventions and corrective feedback. Fourth, to facilitate consistency of treatment quality and delivery, all group sessions will be audio-recorded and 25% of the RPCW and HEC intervention sessions will be reviewed and rated for adherence by Drs. Parks, Barrick, and St.Vil utilizing the RPCW/HEC adherence measures. Problems with adherence and/or competence will require booster training sessions. Controlled trials with more intensive monitoring have yielded stronger outcome data [95].

18.0 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**.*

*18.1 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:

Study 2:

Electronic informed consent documents will be stored on the secure Qualtrics servers. All electronic data files will not include identifying information. All participants will be given an alpha-numeric code that will identify their data. The file that links their identity with this code will be password protected and kept on a separate server from all password protected data files.

A. How long will the data be stored?

Response:

The identifying data will be stored for five years after the study has been completed.

18.2 A. Who will have access to the data?

Response:

The PI, Co-Is, and Research Staff (Project manager and Research Technicians), and Computer personnel as needed.

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

Response:

PI Parks Marsh or project coordinator. Appropriate Computer Department personnel, who will only have access to de-identified data.

18.4 A. How will the data be transported?

Response:

Study 2: All data collected through the tablets for questionnaires, online education programs, and online follow-up surveys will be encrypted and transmitted to data files stored on UB Box.

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 19.0)*

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

Response:

18.6 B. How long will the specimens be stored?

Response:

18.7 B. Who will have access to the specimens?

Response:

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

Response:

18.9 B. How will the specimens be transported?

Response:

19.0 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.

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

Response:

Study 2:

PI Parks will closely monitor all aspects of the research and will be informed of any adverse or potentially adverse events that occur in the course of the intervention groups and research contact with participants. All serious adverse events during the intervention and follow-up period will be reported (in writing) to the University at Buffalo Institutional Review Board, and the NIH Program Official within 48 hours, and the Chair of the Psychology Department at the University of Buffalo also will be notified of all adverse events.

The three potential risks to participants include breach of confidentiality, distress or discomfort with the intervention material, and indication of intent to harm oneself or another. Several steps will be taken to ensure the confidentiality of the data. All electronic informed consent acknowledgement will be kept in a computer file separate from all survey data stored on the Qualtrics secure servers or the project UB Box. The audiotaped data files will be used for reliability checks for treatment fidelity purposes only and will be destroyed at the end of the study. PI Parks will closely monitor all research intervention sessions. All data collected through laptop computers also will be stored on UB box only accessible to authorized project staff. For the purpose of scientific publication, only group means will be reported, and individual participants will not be identified. To ensure participant anonymity, a separate list with the participants' names and contact information will be stored in a different location than their data (Secure data file on UB Box), and only

the research staff will have access. The second potential risk, participant discomfort as a result of intervention material or questionnaire assessments will be monitored carefully through feedback questionnaires, observations during in-person sessions, debriefing following in-person sessions, and through follow-up phone calls at the participant's request. Should a participant express discomfort during or following any of the intervention components, the source of this discomfort will be discussed in a clinically-sensitive manner. PI Parks will be notified and will place a call to the participant. In addition, all participants will be told that they can refuse to answer any questions they do not feel comfortable answering and can withdraw from the study at any time. The third risk involves having the participant report information to research staff that suggests she is a danger to herself or others. We discuss how this information will be handled below.

a. Incidents during in-person intervention assessments. Should a participant become very agitated or report information that suggests she may be a danger to herself or others, the project staff will immediately inform PI Parks, who has worked with this population of women for 20 years and has experience conducting suicidality/ homicidality assessments. In addition, Co-I Barrick (Counseling Psychologist) will be available for consultation by phone if the PI is not available. If the PI or Co-I determines that the participant may pose an imminent threat, they will immediately call 911 or the Buffalo General Hospital Psychiatric Emergency Room to obtain a psychiatric evaluation. Should the psychiatric evaluation result in an inpatient admission, the participant's study participation will be terminated. If a referral to the Psychiatric Emergency Room is not warranted, Dr. Parks and the other Co-I will discuss steps that should be taken to ensure the safety and well-being of the participant.

b. Ensuring validity of the data. Validity of the data will be ensured in several ways. First, measures for use in the study were selected carefully with regard to their established psychometric properties with women who have experienced sexual victimization and trauma. Data files will be checked on a scheduled basis for any irregularities.

c. Appointment of a data and safety monitoring board (DSMB). Although this is not a Stage III clinical trial and, as such, does not require a DSMB, we have chosen to convene one as an extra measure of oversight given the serious and sensitive nature of sexual revictimization (SRV) experiences among young women. The DSMB will be convened during the Spring of 2022 and will meet twice through the end of the project to discuss any adverse and serious adverse events, and strategies for ensuring the safety and well-being of the study participants. All members of the DSMB will receive reports of adverse and serious adverse events that occur on the project. The DSMB will meet as soon as feasible following a serious adverse event.

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

Response:

Study 2:

Negative reactions of participants to the intervention material will be monitored and reported. Incidents of sexual victimization – frequency and severity will be carefully monitored and used to assess the efficacy of the intervention as will changes in drinking patterns.

Describe any safety endpoints.

Response:

Study 2: Outcomes at the follow-up points of 3 and 6 months will be monitored carefully to determine what affect the intervention appears to be having on hazardous drinking and risks for sexual victimization.

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

Response:

Study 2: At all group sessions, through all contact with participants during screening, e-mails, follow-up calls and data monitoring.

19.4 Describe the frequency of safety data collection.

Response:

Study 2: Safety data will be collected throughout the study.

19.5 Describe who will review the safety data.

Response:

The PI, Dr. Parks Marsh will review the safety data.

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

Response:

Study 2: Data will be reviewed for the randomized controlled trial (RCT) on an ongoing basis to determine whether the anticipated changes in the outcomes (reduced hazardous drinking and low or no occurrence of sexual victimization) are observed.

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

Response:

Study 2: No specific tests given the small number of participants. A preponderance of negative events seen through descriptive analyses of follow up data – for example, high rates of sexual victimization at 3-month and 6-month follow-up or increased hazardous drinking at follow-ups.

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

Response:

Study 2: Multiple serious adverse events.

20.0 Withdrawal of Subjects

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

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

Response:

Study 2: If participants are being noncompliant with the intervention, report homicidal thoughts or feelings, or report suicidal thoughts or feelings or if information comes to light during the study period that the participant was not actually eligible for the study.

20.2 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:

Study 2: An exit interview with Dr. Parks will be conducted and if the participant is found to be a danger to herself or others appropriate measures will be taken to insure her safety (i.e., calling 911, obtaining a psychiatric evaluation).

20.3 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:

Study 2: We will retain data that has already been collected but no further data will be collected. Participants will not be withdrawn from the study once they are enrolled and randomized to the study. Their data will be retained for analyses under the intent to treat principle.

21.0 Risks to Subjects

21.1 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:

Study 2:

The risks involved as a result of participation in this study are no greater than minimal and consistent with previous research in this area. There are three main risks for participants in this study:

(1) Breach of confidentiality such that an individual's data is disclosed to an individual who is not a research staff member. This is a minimal, and unlikely risk of all human subjects research. A number of safeguards are in place to prevent this risk. Group members will be told before each group that they should never discuss the content of the group sessions in a way that could potentially identify another group member. Should this happen, the magnitude would be embarrassment to the participant given the personal nature of the information being collected. The breach would likely be contained, however reversibility is unlikely.

(2) Some individuals may become embarrassed or distressed when asked about their past or current experiences with sexual assault, hazardous drinking, or other health-related behaviors. In addition, given participants' histories of prior sexual assault, some may experience discomfort or distress when viewing some of the training materials (e.g., training videos, online multi-media) or responding to questionnaires during screening and follow-up assessments.

The probability of this risk is minimal, with a minimal magnitude and a likely short duration and reversibility with intervention at the time of occurrence through procedures in place to mitigate distress through calming techniques, discussions with Dr. Barrick, a counseling psychologist and Dr. Noelle St. Vil a trained social worker, and referral to outside sources with expertise in victimization.

(3) Although unlikely, it is possible that a participant might report information to a staff member that suggests she poses a danger to herself or others. As a result of this disclosure, the individual's confidentiality may be compromised.

The probability of this risk is low, with a high magnitude of harm/concern. It is difficult to estimate the duration. Immediate actions would be taken to insure the participant's safety and the safety of other individuals.

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

Response:

Study 2:

The risk to participants in this study is no greater than minimal with a possibility of mild distress as a result of disclosing information about a recent SA or as a result of viewing intervention materials (e.g., videos or on-line multi-media) or answering questionnaires during screening or follow-up assessments that may trigger traumatic memories of a sexual assault (SA). To mitigate these minimal risks, several steps will be taken.

First, both conditions of the pilot RCT (RPCW and HEC) will be fully manualized. All group sessions will be audio recorded (with participants' permission), and these digital recordings will be reviewed by Drs. Parks, St. Vil, and Barrick to ensure treatment fidelity. All interventions will be administered by Masters Students who will have undergone extensive training conducted by Drs. Parks, Barrick, and St. Vil, who have experience with the intervention materials and techniques. Finally, the PI, Dr. Parks will closely monitor all aspects of the research and will be informed of any adverse or potentially adverse events that occur during the course of the intervention and research contacts with participants. All adverse events will be reported (in writing) to the University at Buffalo Institutional Review Board and the Chair of the Psychology Department at the University at Buffalo.

The first potential risk involves a potential breach of confidentiality. Several steps will be taken to ensure the confidentiality of the data. The Project Coordinator and the PI will closely monitor all research interviews and both the intervention sessions. Group members will be told that that they should never discuss the content of the group sessions in a way that potentially identifies specific group members. Data collected for research purposes will be stored on the Project's UB Box. For the purpose of scientific publication, only group means will be reported, and individual participants will never be identified. To ensure participant confidentiality, a separate file with the participants' names will be stored in a different location on UB Box from the data and only the research staff will have access to this file.

The second potential risk involves a participant experiencing discomfort, or embarrassment when viewing or discussing the RPCW intervention materials (e.g., videos, educational, or on-line), answering questions about or discussing their past experiences with SA, or for the HEC condition, discussing their current or past health-related behaviors. In addition, given that all participants have a history of sexual victimization, they may experience discomfort or distress with some of the questionnaire items (screening, follow-up assessment items). The most likely questions to elicit distress during the research (screening, post-intervention and follow-up questionnaires) are those pertaining to prior SA. During our previous studies using similar materials, the video vignettes and questionnaires caused discomfort or mild distress among 8% of participants. In addition, less than 3% of women wanted to speak with a clinician as a result of this distress, when offered by a project staff member. However, despite the low frequency of these occurrences several procedures will be followed to ensure that participants are less likely to experience this distress, and that they are carefully monitored for any signs of discomfort or distress resulting from the intervention materials and assessments. These procedures include the following:

- At the beginning of the screening and during informed consent, women will be thoroughly informed of the types of questions being asked, that some might be distressing, and that they are free to refuse to answer any questions.

- All women will be provided with a list of woman-focused resources at the University at Buffalo and in the immediate area (e.g., substance abuse, violence, health care) that will be provided to them, along with their informed consent, following participation.

- At the beginning as well as the end of the screen survey, intervention, and follow-up, women will be told that if they are concerned or upset by their participation in any way that they are encouraged to call or email the project. They will be provided with the project number as well as the project email address. At the end of screening and at the end of the first in-person group session, all women will be emailed and/or handed a hard copy of a list of woman-focused resources (e.g., substance abuse, violence, health care). They also will be provided with the telephone number for Crisis Services, and told to call there if they need immediate help or someone to talk to if their call to the project line is not immediately answered and they are in distress.

- All participants, regardless of intervention condition, will receive resource materials and will be assessed for current PTSD symptoms using the PCL (see Measures). Women who score in the above average (i.e., clinical) range of symptoms will be referred to the University at Buffalo's Psychological Services Center.

- We estimate that more than 40% of women who are screened and report experiencing a prior SA and agree to participate in the study will have current PTSD symptoms. Thus, we will have contact with them shortly after they complete the screen survey, during the intervention, and throughout follow-up. We will monitor these women for their reactions to all study materials through direct questioning about their reactions to the questionnaires and training materials (i.e., during in-session discussions, debriefing following sessions, and feedback questionnaires at the end of each in-person and on-line session). This will allow us to provide additional support and referral if needed.

- Brief feedback questionnaires will be included following each treatment module (in-person and on-line). In these questionnaires, a direct question will be included that asks the participant whether she wishes to be contacted by one of the PI (Dr. Parks) the following day to discuss any of the material or concerns she is having with any of the material or topics related to the program. In this way, she will be able to indicate unobtrusively that she would like further contact. Should a participant indicate that she would like additional contact, a call will be placed to her the following day and additional information, discussion, or a referral will be provided as needed. In this way we will be able to get an estimate of

the rate at which women are experiencing distress and if needed, adjust our procedures.

- Should a participant indicate that she is very distressed during the research or intervention, she will be given the option of a quiet location to regain her composure and the option to meet with PI Parks, who will discuss the source of this distress in a sensitive manner and encourage the participant to seek counseling, if appropriate. All participants will be told that they can refuse to answer any questions they do not feel comfortable answering and can withdraw from the study at any time.

- Following the second in-person intervention session, women will be told that they are welcome to call the project at any time following the intervention should they have concerns or experience distress regarding their participation. They also will be given the opportunity to ask questions and to schedule a private meeting with one of the PIs to discuss anything that has caused them concern or discomfort if they choose to, prior to leaving the session.

- During follow-up assessments, as with the feedback questionnaires, women will be asked if they would like one of the PIs to contact them. If they respond affirmatively, contact will be made within 24 hours. We are hesitant to contact all women who report a sexual revictimization without them asking to be contacted given that a large percentage of women who experience sexual assault do not acknowledge their experience as a sexual assault (e.g., Koss, Gidycz, & Wisniewski, 1987). To do so might actually produce more trauma for a participant.

As noted above, in our previous study, less than 10% of women have indicated experiencing any distress or discomfort as a result of viewing the videotapes developed by PI Parks or answering questions about SA. In addition, none of these women indicated that the distress would have prevented them from participating in the research (Parks et al., 2016).

The third risk involves having the participant spontaneously report information to research staff that suggests she is a danger to herself or others. All group intervention sessions and research assessments will take place at the University at Buffalo's North Campus (Amherst). Given the group nature of the interventions, we believe that this is more likely to occur during the individual research assessments. Should a participant spontaneously report information that suggests that she may be a danger to herself or others, the RT conducting the research assessment will immediately inform the PD or the PI or Dr. Barrick (a licensed Psychologist). The participant will be interviewed to determine the extent of her distress and/or the risk to herself or others. If necessary, Dr. Barrick (Co-I) will conduct an emergency mental health assessment. If it is determined that the participant may pose an imminent threat, Dr. Parks, St. Vil or Barrick will either call 911 or the Psychiatric Emergency Room of Buffalo General Hospital to obtain a psychological evaluation. If the participant refuses to cooperate, the

assistance of the Buffalo Police Department will be sought. If the ERT determines that no immediate action is required, one of the PIs will encourage the participant to discuss the relevant issues with her general practitioner or the campus health clinic physician as to the best course of action. We have used this process successfully in several of our prior studies. Participants have been cooperative and no participant has reported any negative after effects as a result of these procedures.

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

Response:

None

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

Response:

None

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

Response:

None

22.0 Potential Benefits to Subjects

22.1 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:

Study 2: By participating in this project, participants may potentially benefit from the RPCW intervention and HEC conditions with respect to their levels of hazardous drinking, awareness of risks for sexual revictimization, and knowledge of safe dating and drinking practices and/or associated health behaviors. However, there is no guarantee of improved health and safety outcomes.

23.0 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.

*23.1 **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: N/A

23.2 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:

24.0 Economic Burden to Subjects

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

NOTE: Some examples include transportation or parking.

Response:

Study 2: There is no cost to participants.

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

25.0 Compensation for Participation

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

Response:

Study 2: Participants will be remunerated $30 for the baseline surveyat the first group intervention session, $30 for the post intervention survey, $40 for the 3 month follow-up survey, and $50 for the 6 month follow-up survey.

☐ **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.

26.0 Consent Process

26.1 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 27.0.

☒ ***Yes*** *(If yes, Provide responses to each question in this Section)*
☐ ***No*** *(If no, Skip to Section 27.0)*

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

Response:

Study 2: Consent will occur prior to completing the initial baseline survey before the first group intervention session. Group sessions will be small, limited to 8 women. Every effort will be made to include women who do not know each other in each group session. In addition, if a woman has a concern or question about consent she will be given the opportunity to meet with the PI or Project coordinator by telephone to answer questions and provide individual consent.

26.3 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:

Study 2: Each woman will be emailed a link to the online consent form and provided with time to read the consent document, the project coordinator or one of the study team members will then provide a summary of the main points of the document and provide time for all questions to be answered. Once the participant has had time to ask any questions, she will be asked to initial and sign the online consent document exit the document. This will send a message to the study email indicating that the consent document has been signed and saved in the Qualtrics secure data server.

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

Response:

Study 2: Prior to each study activity, participants will be verbally asked to indicate their willingness to continue to participate in the study.

26.5 Indicate whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." 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 26.8)

26.6 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 6.4 of this protocol.

Response:

26.7 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. 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:

Cognitively Impaired Adults

☒ **N/A**: This study will not enroll cognitively impaired adults.
(Skip to Section 26.9)

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

Response:

Participants will be required to respond to several queries about information provided in the consent document in order to determine understanding.

Adults Unable to Consent

☒ **N/A**: This study will not enroll adults unable to consent.
(*Skip to Section 26.13)*

When a person is not capable of consent due to cognitive impairment, a legally authorized representative should be used to provide consent (Sections 26.9 and 26.10) ***and, where possible, assent of the individual should also be solicited*** *(Sections 26.11 and 26.12).*

26.9 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)."

26.10 ***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:

26.11 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:

26.12 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 27.0)*

26.13 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:

Study 2:

Screening questionnaire, and driver's license or state-issued ID at first in-person session.

***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:

26.14 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)."

*26.15Describe 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:

*26.16 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:

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

Response:

27.0 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.

27.1 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:

27.2 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:

28.0 Process to Document Consent

☐ **N/A:** A Waiver of Consent is being requested.
(Skip to Section 29.0)

28.1 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:

Study 2: Verbal consent for screening is attached and will occur prior to administration of the screening survey..

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

29.0 Multi-Site Research (Multisite/Multicenter Only)

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

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

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

Response:

29.2 Describe the method for communicating to engaged participating sites:

- *Problems*
- *Interim results*
- *Study closure*

Response:

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

Response:

29.4 If this is a multicenter study for which UB will serve as the IRB of record, and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods.

Response:

30.0 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.

*30.1 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).

Response:

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

Response:

30.3 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:

31.0 Drugs or Devices

☒ **N/A:** This study does not involve drugs or devices. This section does not apply.

31.1 If the research involves drugs or devices, list and describe all drugs and devices used in the research, the purpose of their use, and their regulatory approval status.

Response:

31.2 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.

Response:

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:

31.3 Identify the holder of the IND/IDE/Abbreviated IDE.

Response:

31.4 Explain procedures followed to comply with FDA sponsor requirements 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:

32.0 Humanitarian Use Devices

☒ **N/A:** This study does not involve humanitarian use devices. This does not apply.

32.1 For Humanitarian Use Device (HUD) uses provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.

Response:

32.2 For HUD uses provide a description of how the patient will be informed of the potential risks and benefits of the HUD and any procedures associated with its use.

Response: