PROTOCOL TITLE:

Alcohol and Violence Prevention for College Students

PRINCIPAL INVESTIGATOR:

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1.0 Objectives / Specific Aims

Aim 1: Modify Alcohol and Sexual Assault Prevention (ASAP) content to an eHealth format to include personalized content for each risk group (1. cisgender heterosexual men; 2. cisgender heterosexual women; and 3. sexual and gender minorities).

> **Aim 1a**: Assess normative behaviors (n = 750) regarding alcohol use and SA for feedback from Arizona State University (already completed and de-identified data being analyzed) and Georgia State University.
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> **Aim 1b:** Adapt and assess initial acceptability of a workbook version of the intervention content among key stakeholders (college administrators and students from each risk group [n=5 from each group]) from Arizona State University (already completed and de-identified data being analyzed) and Georgia State University.

Aim 2: Open Pilot Trial. Obtain usability of ASAP among 30 students who engage in HED (10 from each risk group) in an open pilot trial at Arizona State University (already completed and de-identified data being analyzed) and Georgia State University.

Aim 3: A pilot to assess effect size and variability for planning a randomized trial in the future. This Aim will only be conducted at Arizona State University. Randomize students who engage in HED to ASAP or control condition to observe preliminary effect sizes and estimate the variability using a 3-month follow-up. Sample size was determined to estimate the variability within a reasonable margin of error. This calculation also accounted the low base rates of SA and 20% attrition. This led to a sample size of 162 students (n=54 from each risk group).

By accomplishing these aims, we will have established the research team, programming, feasibility and preliminary efficacy of the research protocol. If promising, this study will lay the groundwork for an R01 application to test the efficacy of ASAP.

2.0 Background

This study aims to conduct a pilot of a behavioral intervention for heavy episodic drinking (HED) and sexual assault (SA) among college students. Approximately 20% of women experience SA during college with the highest rates of victimization among women and sexual/gender minorities. SA results in significant public health costs with US government sources paying an estimated $1 trillion of the total $3.1 trillion of lifetime costs accrued by SA. The federal guidelines and the Center for Disease Control (CDC) recommend that colleges provide universal SA prevention that incorporates bystander intervention and victimization risk reduction strategies. Although bystander intervention is evidence-based and engages all members of a campus in violence prevention, bystander intervention fails to address the gender- specific factors associated SA victimization and perpetration risk, and fails to address the pervasive role of alcohol in SA. Further, many universities use commercially available mHealth (mobile health) products that currently show no documented efficacy in reducing SA to address this public health concern rather than evidence-based prevention programming. A new approach is needed that can appeal to university administrators nationwide and includes evidence-based bystander and risk reduction content personalized by risk factors, including gender, sexual minority status, and alcohol use. Alcohol is involved in half of SA among college students. SA prevention that does not directly target HED is ineffective for college students who engage in HED. This is problematic because 40% of college students engage in HED, and students who engage in HED are at highest risk of SA victimization and perpetration. It is imperative to develop and test SA interventions aligned with best practices in prevention to provide bystander intervention training, that targets the role of alcohol in SA (and therefore appropriate for students who engage in HED), and provides information relevant to risk and protective factors for SA. Personalized approaches to SA intervention recognize that risk and protective factors for SA vary among

men, women, sexual minorities, and gender minorities; requiring that intervention be personalized in content and approach.

Our research team has developed and tested two gender-specific programs that integrate alcohol and SA intervention for college students. Dr. Gilmore (PI) evaluated the efficacy of a web-based combined alcohol use and SA risk reduction program for college women who engaged in HED. It was most effective over a 3-month follow-up at reducing HED and victimization among women with more severe SA histories and was featured in the NIAAA Director's Report on Institute Activities to the 141st Meeting of the National Advisory Council on Alcohol Abuse and Alcoholism15. This intervention focused on reducing SA victimization dovetails an integrated alcohol and SA intervention developed and tested by the research team (R34 AA020852), designed to reduce perpetration of SA among college men. Preliminary findings suggest that the in-person approach, is feasible, acceptable and promising to reduce SA perpetration and facilitate proactive bystander intervention among college men. These preliminary studies suggest that a mHealth SA prevention approach for women and men that includes bystander intervention and incorporates theory-driven intervention to reduce risk of SA victimization and perpetration is a promising next step. Given that prior work by the research team lacked a focus on the applicability of integrated alcohol and SA prevention programs for gender and sexual minorities, work is also needed to ensure that an integrated alcohol and SA prevention program is appropriate, acceptable, and useful for all members of a campus community. Accordingly, the present research will develop a new multi-pronged, personalized mHealth application targeting alcohol and SA that incorporates the research team's previous work, and infuses standardized bystander intervention content into the approach while also including content on sexual and gender minorities. Our developmental work will ensure that this intervention can be disseminated nationwide with minimal tailoring and cost, thereby addressing the research-practice gap in college SA prevention.

3.0 Intervention to be studied

Intervention Descriptions
Below is a description of each of the intervention components to be integrated into personalized feedback based on gender identity and sexual minority status as described above. While concurrently adapting in person interventions to mHealth interventions (bystander and SA perpetration prevention components as described below) as well as developing sexual and gender minority content, college-specific normative behavior will be collected to integrate into intervention content.

HED feedback component (all risk groups)*:* HED content will be included in the ASAP interventions and has already been developed and used in mHealth delivery modes. Alcohol is directly targeted using algorithm- driven personalized feedback and a social norms approach using web-based BASICS (Brief Alcohol Screening and Intervention for College Students; BASICS) with integrated SA information. A recent meta-analysis assessing the effects of BASICS indicated significant reductions in alcohol use and alcohol-related problems. Web-based BASICS provides the same content in BASICS but online. It provides feedback regarding drinking behavior and consequences. Drinking is compared to perceived and actual gender-specific drinking norms to correct misperceptions regarding normative drinking behavior. Personalized interactive education regarding definitions of a standard drink, gender differences in blood alcohol content, alcohol expectancies and alcohol myopia, and personalized gender-specific information about risks associated with blood alcohol content is provided. Integrated into these alcohol components include examples of SA (i.e., when presenting information about alcohol's cognitive impairment effects the example of decreases in SA risk perception are provided). For transgender students, biologically-based feedback (i.e., blood alcohol content charts) will be provided based on biological sex and normative feedback will be provided based on identified gender.

Adaptation for current study: No adaptation is except for incorporating Arizona State University (ASU)-specific norms and pictures into the mHealth application.

SA risk reduction component (all risk groups)*:* The SA risk reduction content is an already developed web- based intervention, therefore adapting to an mHealth format only includes small changes to the content. This component was originally developed for primarily cisgender heterosexual women. This intervention is rooted in a feminist framework that places the blame on SA perpetrators but provides theoretically-based risk reduction programming (Cognitive Mediational Model and Assess, Acknowledge, and Act). Risk reduction programming targeting these theoretical constructs is relatively new and has yielded significant decreases in SA victimization and has demonstrated efficacy for up to a 2-year follow-up period. The core educational components on SA components include psychoeducation about SA prevalence in the setting (at the specific college), state laws, and college guidelines about what constitutes a SA. In the survey immediately preceding the intervention, participants are presented with a hypothetical SA scenario and they indicate when they would leave the scenario and what resistance strategy they would likely choose. Feedback is given on the strategy choice and other potential strategies are given. Further, barriers to resistance are discussed including social relationships with the perpetrator, use of alcohol, and fear of making the situation worse, and individuals are provided with potential ways to combat the barriers. Information regarding the association between alcohol use and SA is also provided.

Support for this approach: We conducted a RCT evaluating a web-based normative comparison personalized feedback intervention to reduce HED and SA for underage college women who engaged in HED (AA020134; PI: Gilmore) that was developed by Dr. Gilmore (PI). College women (n = 264) were randomly assigned to: 1) alcohol personalized feedback intervention, 2) SA personalized feedback intervention, 3) combined alcohol and SA personalized feedback intervention, 4) assessment only control, 5) minimal assessment control. Retention rates were 78.41% at 3 months. The combined personalized feedback intervention was the only personalized feedback intervention successful at reducing alcohol-involved SA frequency. There was a significant interaction between SA history severity and the combined condition on SA severity, HED, and frequency of incapacitated rape at follow-up such that the combined intervention was more effective at reducing these outcomes for individuals with more severe SA histories at baseline. A secondary outcome analysis revealed that the combined alcohol and SA personalized feedback intervention, compared to the assessment only control conditions, was associated with less drinking to cope with anxiety symptoms at the three-month follow-up for women with higher drinking to cope with anxiety motives. Further, drinking to cope with anxiety symptoms mediated the effects of the combined intervention on heavy episodic drinking outcomes. Taken together, this suggests strong preliminary findings of this intervention component for college women who engage in HED.

Adaptation for current study: For cisgender heterosexual women, no adaptation is needed except for incorporating ASU-specific norms and pictures. For cisgender heterosexual men, education regarding SA rates among men and brief general risk perception information (specific information about SA risk perception and risk factors among men as victims is not yet well established). For sexual and gender minorities, specific risks including being targeted for SA victimization and rates of SA among gender and sexual minorities will be included. Acquiring university-specific data on SA is beyond the scope of the current study, therefore, feedback will be based on previous national studies, including those conducted by the research team (Kaysen; consultant). Examples of potential SA situations will include a broad range of victim-perpetrator relationships to best capture the experiences in this risk group. Further, due to the role of minority stress on mental health outcomes after experiencing SA among sexual and gender minority populations, education regarding this association will be included in the content.

SA perpetration prevention component (cisgender heterosexual men): The SA perpetration prevention content is already developed for in person delivery modes and will be included only in the men-specific ASAP intervention. This content will be adapted for a mHealth application from the discussion-based module of the Men's Workshop. This intervention includes feedback regarding one's own fear of false accusations and education regarding actual false accusation rates. Perceived rates of SA perpetration are compared to actual university-specific rates. Misperception of college men's sexual behavior including frequency of sex and number of sexual partners are corrected using personalized normative feedback to relieve men of the social pressure they may feel to have sex. Education regarding sexual consent which includes example scenarios is provided. All of this content is easily translatable to mHealth a delivery mode.

Support for this approach: The SAFE program is grounded in the Men's Workshop, a SA prevention model that, in preliminary work funded by the Centers for Disease Control and Prevention (CDC), showed 50% reductions in SA perpetration among college men over four months. Specifically, four months after the program, 1.5% of men in the treatment group reported sexual aggression compared to 7% of men in the control group ($p < .05$). Next, through NIAAA-funded projects (R34AA020852; PI: Orchowski), (R34 AA020852), Dr. Orchowski integrated a brief motivational interviewing personalized feedback protocol (similar to that described in the HED component above) in conjunction with the Men's Workshop. Initial findings of 25 college men who engage in HED indicated that SAFE is a feasible, acceptable and useful approach. Specifically, participants rated the intervention as high quality (M=3.8, SD = 0.48, Scale 0-4), were satisfied with the program (M=3.7, SD=0.46, Scale 0-4), and indicated that they would participate in the program again (M=3.4, SD=0.58, Scale 0-4). Findings of a randomized pilot trial also revealed promising effects over a 2- and 6-month interim among SAFE participants, in comparison to a dose- and attention matched control.

Adaptation for current study: The in-person manual written by Dr. Orchowski will be adapted to an mHealth delivery format using the following procedures that are built into the study aims: initial adaptation completed by the investigative team, alpha testing (Aim 1) with end users and beta (Aim 2) testing with end users prior to finalization. The content is revised to incorporate feedback from end users at all stages of the adaptation. The investigative team have successfully used this strategy for mHealth applications (EMW-2015- FP-00759; PI: Ruggiero; Co-I: Gilmore; 2016-RF-GX-001; PIs:Kilpatrick/Rheingold; Technology Coordinator: Gilmore). A brief education only version of the content will be developed for women and sexual/gender minorities as well because populations other than cisgender heterosexual men can also be SA perpetrators.

Bystander intervention component (all risk groups): Bystander intervention content is already developed for in person delivery modes and will be included in both the women- and men-specific ASAP interventions. The bystander intervention approach focuses on targeting SA perpetration by eliciting bystanders to intervene in potential SA situations and target social norms for SA. This content will be adapted to a mHealth delivery mode from the discussion-based module of the Men's Workshop. This module includes university- specific feedback regarding perceived and actual social norms of men engaging in insensitive behavior towards women (i.e., using the word "slut" to insult a woman or men joking about having sex with a woman), psychoeducation regarding barriers to intervening with potential SA situations, and practice scenarios using effective intervention strategies, all of which are easily translatable to mHealth delivery modes.

Support for this approach: Bystander intervention as incorporated with the Men's Program has been studied by Dr. Orchowski as described above.

Adaptation for current study: The adaptation strategy will be the same as the perpetration prevention content described above.

Control Group: The control group will be compared to those assigned to the intervention (intervention components described above. The control group will be an assessment only control, meaning that they will only complete the assessment at baseline instead of receiving an intervention.

4.0 Study Endpoints

Outcome variables include alcohol use, bystander behavior, and sexual assault victimization 3-months after the intervention. Further, self-blame will be assessed directly after receiving the intervention to ensure that the intervention does not have iatrogenic effects (even though previous iterations of this intervention have found no iatrogenic effects).

5.0 Inclusion and Exclusion Criteria/ Study Population

College students aged 18-25 will be recruited from Arizona State University (no participants will be recruited until an inter-institutional agreement is signed by Arizona State University, submitted as an amendment to the MUSC IRB and approved by the MUSC IRB) to complete questionnaires regarding their attitudes and behaviors related to alcohol use, sexual assault victimization, sexual assault perpetration, and bystander intervention. Human subjects are also being recruited to participate in an open pilot and a randomized pilot to determine usability as well as estimate effect size for a larger grant. In Aim 1a, we will recruit 750 college students aged 18-25 (n= 250 women; n=250 men; n=250 sexual/gender minorities) from both Arizona State University (data already collected and have de-identified dataset) and Georgia State University. In this aim, human subjects are needed to assess setting-specific normative attitudes and behavior for alcohol use and sexual assault to incorporate into the intervention content. Aim 1b includes alpha testing of a workbook version of the intervention, which will include interviews with key stakeholders (college administrators and 15 students) to inform programming content at both Arizona State University (data already collected and have de-identified dataset) and Georgia State University. In Aim 2, we will recruit 30 students (10 from each risk group (cisgender heterosexual men, cisgender heterosexual women, and sexual/gender minorities) who engage in heavy episodic drinking in the past month to participate in an open pilot trial to obtain usability feedback to integrate into the intervention content. In Aim 3, which will only be collected from Arizona State University, we will recruit 54 students who engage in heavy episodic drinking in the past month from each risk group (cisgender heterosexual men, cisgender heterosexual women, and sexual/gender minorities) for a total of 162 students aged 18-25 to participate in a randomized pilot trial. Aim 3 focuses on observing effect sizes and estimating the variability using a 3-month follow-up design to design a larger study for an R01 application. In this IRB application at Georgia State University, a total of 967 participants will be recruited (Aim 1a = 750 students from GSU, Aim 1b = 25 [25 students and 10 administrators] from GSU, Aim 2 = 30 students from GSU, Aim 3 = 162 students from ASU).

<u>Inclusion criteria for Aim 1a</u>:

1) 18-25 years old
2) Current college student at Georgia State University
3) Valid Georgia State University email address

<u>Inclusion criteria for Aim 1b (students):</u>

1) 18-25 years old
2) Current college student at Georgia State University
3) Identify as cisgender heterosexual male, cisgender heterosexual female, or sexual/gender minority
4) Valid Georgia State University email address

5) Endorse engaging in heavy episodic drinking at least once in the past month on the screening survey

Inclusion criteria for Aim 1b (administrators):

1) Current administrator role at Georgia State University
2) Individuals must make either final or preliminary decisions regarding alcohol and/or sexual assault programming on the Georgia State University campus

Inclusion criteria for Aim 2:

1) 18-25 years old
2) Current college student at Georgia State University
3) Valid Georgia State University email address
4) Endorse engaging in heavy episodic drinking at least once in the past month on the screening survey

Inclusion criteria for Aim 3:

1) 18-25 years old
2) Current college student at Arizona State University
3) Valid Arizona State University email address
4) Endorse engaging in heavy episodic drinking at least once in the past month on the screening survey

Exclusion criteria for Aims 1, 2, and 3: There are no exclusion criteria aside from not meeting inclusion criteria.

6.0 Number of Subjects

A total of 967 participants will be recruited (Aim 1a = 750 students from GSU, Aim 1b = 25 [25 students and 10 administrators] from GSU, Aim 2 = 30 students from GSU, Aim 3 = 162 students from ASU).

7.0 Setting

The research will be conducted at GSU.

8.0 Recruitment Methods

Aim 1a: A random sample of college students aged 18-25 enrolled at Georgia State University will be selected from the Georgia State University registrar list. Potential participants will be sent a recruitment email (see Recruitment email Aim 1a) to complete a 30-minute online survey. To ensure that there is adequate representation of participants across gender groups, potential participants will complete a brief screening survey prior to taking the baseline survey. Once enrollment across a single group is complete (n=250 women; n=250 men; n=250 sexual/gender minorities), further participation among that group will close, where participation will remain open for individuals of the other groups until enrollment goals are met (n=750).

Aim 1b: Participants will be recruited through SONA with an advertisement. Participants will be recruited to complete an online survey to determine eligibility (described above; Eligibility Survey), and a total of 5 students from each group (cisgender heterosexual male, cisgender heterosexual female, or sexual/gender minority) will be recruited to provide feedback on the workbook version of the intervention content during in-person one-on-one interviews.

Further, Georgia State University administrators will provide feedback on the workbook version of the content. Administrators will be recruited if they make either final or preliminary decisions regarding alcohol and/or sexual assault programming on the Arizona State University campus (e.g., Dean of Student Affairs, Title IX Coordinators).

Aim 2: Participants will be recruited from SONA using an advertisement on SONA. Participants will be recruited to complete an online survey to determine eligibility (described above; Eligibility survey), and a total of 10 students from each group (cisgender heterosexual male, cisgender heterosexual female, or sexual/gender minority) will be recruited to participate in an open pilot trial of the intervention (Recruitment Email Aim 2).

Aim 3: Participants will be recruited from flyers on campus, ads online, and from relevant campus organizations (no participants will be recruited until an inter-institutional agreement is signed by Arizona State University, submitted as an amendment to the GSU IRB and approved by the GSU IRB). Potential participants will email the study (e.g., ASAP@gsu.edu) from an Arizona State University email address. Participants will be recruited to complete an online survey to determine eligibility (described above; Eligibility Survey), and a total of eligible 54 students from each group (cisgender heterosexual male, cisgender heterosexual female, or sexual/gender minority), for a total of 162 students will be recruited to participate in an open pilot trial of the intervention (Recruitment Email Aim 3).

9.0 Consent Process

Aim 1a: We are requesting a waiver of consent to conduct Aim 1a. All potential participants will be assigned a unique Personal Identification Number (PIN) that will be sent in the invitation email, and login information for completing the survey. Upon logging into the study website, potential participants will be presented with more information about the study (Aim 1a Information Statement). Upon reading about the study, they can decide if they want to continue or exit the survey. If they decide to continue, participants will be automatically re-directed to participate in the study. They will also be emailed the information statement for their records. If they decide to exit, we will ask if they'd like to be contacted for this study in the future or if they are not interested in the study. If they are not interested in the study, we will remove them from the reminder list.

Aim 1b: For Aim 1b, we are completing interviews in person. The interviewer, which will be an IRB-approved study staff member, will conduct the interview in a private office space. Study staff will obtain consent from the potential participant prior to beginning the study procedures. If a participant is not interested in participating after reviewing the consent document, they will not be enrolled in the study. Participants will have time to review the document, ask questions, and decide if they would like to give informed consent or not participate in the study.

Aim 2: A waiver of consent was applied for to conduct Aim 2. All interested eligible participants will be assigned a unique Personal Identification Number (PIN) that will be sent in an email to their Georgia State University email account which will include login information for completing the study. Upon logging into the study website, potential participants will be presented with more information about the study (Aim 2 Information Statement). Upon reading about the study, they can decide if they want to continue or exit the survey.

Aim 3: A waiver of consent was applied for to conduct Aim 3. All interested and eligible participants will be assigned a unique Personal Identification Number (PIN) that will be sent in an email to their Arizona

State University email account which will include login information for completing the study. Upon logging into the study website, potential participants will be presented with more information about the study (Aim 3 Information Statement). Upon reading about the study, they can decide if they want to continue or exit the survey.

10.0 Study Design / Methods

Aim 1a: Upon agreeing to participate in the study, participants will be automatically re-directed to complete a 30-minute online survey to assess campus norms to include in the intervention in subsequent study aims (see Aim 1a survey). Participants will have one month to complete the survey and will be sent reminder emails. Participants will be emailed a $15 e-gift card for completing the study to their Arizona State University email account. Upon completing the survey, they will be given local resources regarding alcohol use, sexual assault, and mental health resources (see Resources). All participants will be given this information, regardless of their risk. Participants will be given the option of contacting the study staff if they are distressed by the study procedures. Members of the research team are licensed clinical psychologists and are well-equipped to follow-up with individuals in need. As been the case with our previous studies, we will establish a schedule in which members of the research team will be on call 24 hours a day, seven days a week to address urgent matters. If a participant is distressed and wishes to talk with a member of the research team, the clinical psychologist team member will be available at all times during the study period.

Aim 1b: Upon consenting to participate in the study, participants will complete the pre-interview survey (30-minute survey) using a study computer in a private room. Participants will then complete a 30-minute interview regarding the review content (Aim 1b interview script). Upon completing the interview, student participants will receive research credit, while Administrators/Staff will not receive compensation. Upon completing the interview, they will be given local resources regarding alcohol use, sexual assault, and mental health resources (see Resources). All participants will be given this information, regardless of their risk. Participants will be given the option of contacting the study staff if they are distressed by the study procedures. Members of the research team are licensed clinical psychologists and are well-equipped to follow-up with individuals in need. As been the case with our previous studies, we will establish a schedule in which members of the research team will be on call 24 hours a day, seven days a week to address urgent matters. If a participant is distressed and wishes to talk with a member of the research team, the clinical psychologist team member will be available at all times during the study period.

Aim 2: Upon agreeing to participate in the study, participants will be automatically directed to complete a 30-minute online survey regarding their demographics, alcohol use, sexual assault experiences, and bystander experiences and attitudes (Aim 2 Pre-Intervention Survey). Upon completing the survey, they will be automatically directed to receive the personalized feedback intervention (described above). This intervention will take approximately 15 minutes to complete (Aim 2 Post-Intervention Survey). Immediately following the intervention, they will complete a 15-minute post-intervention survey regarding their feedback and immediate potential outcomes. Participants will receive research credit on SONA for completing the study. Upon completing the post-intervention survey, they will be given local resources regarding alcohol use, sexual assault, and mental health resources (see Resources). All participants will be given this information, regardless of their risk. Participants will be given the option of contacting the study staff if they are distressed by the study procedures. Members of the research team are licensed clinical psychologists and are well-equipped to follow-up with individuals in need. As been the case with our previous studies, we will establish a schedule in which members of the research team will be on call 24 hours a day, seven days a week to address urgent matters. If a participant is distressed and wishes to talk with a member of the research team, the clinical psychologist team member will be available at all times during the study period.

Aim 3: Upon agreeing to participate in the study, participants will be automatically re-directed to complete a 30-minute online survey regarding their demographics, alcohol use, sexual assault experiences, and bystander experiences and attitudes (Aim 3 Baseline Survey). Upon completing the survey, they will be randomly assigned to either receive the personalized feedback intervention (described above) or to an assessment only control condition. If they were assigned to receive the personalized feedback intervention, they will be automatically directed to receive the personalized feedback intervention (described above). This intervention will take approximately 15 minutes to complete. Immediately following the intervention, they will complete a 15-minute post-intervention survey regarding their feedback and immediate potential outcomes (post-intervention survey). A total of 162 eligible participants will be paid $25 for completing the baseline portion of the study. Upon completing the post-intervention survey, they will be given local resources regarding alcohol use, sexual assault, and mental health resources (see Resources). All participants will be given this information, regardless of their risk. Participants will be given the option of contacting the study staff if they are distressed by the study procedures. Members of the research team are licensed clinical psychologists and are well-equipped to follow-up with individuals in need. As been the case with our previous studies, we will establish a schedule in which members of the research team will be on call 24 hours a day, seven days a week to address urgent matters. If a participant is distressed and wishes to talk with a member of the research team, the clinical psychologist team member will be available at all times during the study period. The procedure will be the same for Arizona State University student and administrator participants except student participants will be compensated for their time and administrators will be volunteering their time.

Participants will be contacted 3 months after completing the initial survey in an email (Aim 3 Follow-Up Email) with their PIN. The follow-up survey will be exactly the same as the baseline survey, except time periods will include the "past 3 months" for questions. Participants will have one month to complete the survey and will be sent reminder emails if they have not completed the survey. Upon completing the survey, they will be emailed an e-gift card for $35 for completing the survey. Upon completing the survey, they will be given local resources regarding alcohol use, sexual assault, and mental health resources (see Resources). All participants will be given this information, regardless of their risk. Participants will be given the option of contacting the study staff if they are distressed by the study procedures. Members of the research team are licensed clinical psychologists and are well-equipped to follow-up with individuals in need. As been the case with our previous studies, we will establish a schedule in which members of the research team will be on call 24 hours a day, seven days a week to address urgent matters. If a participant is distressed and wishes to talk with a member of the research team, the clinical psychologist team member will be available at all times during the study period. The procedure will be the same for Arizona State University student and administrator participants except student participants will be compensated for their time and administrators will be volunteering their time.

12.0 Data Management

The research material obtained from human participants in this protocol will include:

1. De-identified survey questionnaire to obtain normative attitudes and behavior related to alcohol use and sexual assault;
2. De-identified survey and open ended questions assessing the usability of the interventions within an open pilot trial;
3. De-identified survey and open ended questions assessing the usability of the interventions within a randomized pilot trial and follow-up alcohol use and sexual assault-related constructs 3 months after receipt of intervention (if assigned to ASAP condition) or completion of baseline survey (if in control condition).

Recruitment Sources/Sites Where Data Will Be Collected and How These Data Will Be Obtained, Managed, and Protected:

All quantitative data will be collected via mHealth application or online (via DatStat Illume) – on a secure server hosted at Brown University (the site of study Co-Investigator, Dr. Lindsay Orchowski). Surveys will be identified only by a unique numeric ID, that will be different from the participant ID. A separate list will link participant name to participant ID (i.e., the database), and a separate file will link the survey ID to the participant ID that will only be available to the PI and GSU study staff. Thus, identifying information will not be stored with participant data or on the Brown University server. Records containing potentially-identifying information (i.e., consent forms and master list linking participant ID to survey ID, database of participant names and contact information) will be kept separate from research data. All information will be treated as confidential material and will be available only to research staff. All paper records will be kept in locked file cabinets. No participant will be identified in any report of the project. Computer data files will be password protected. Computer data files will be available only to authorized personnel and no names or obvious identifying information will be stored in data files. Data transmissions to and from the data server are encrypted by SSL (Secure Socket Layer) and 40, 56, or 128-bit Public Key Encryption technology. A VeriSign security certificate has been obtained to verify SSL encryption. Data will be downloaded to password-protected computers belonging to research staff or investigators. Databases on the server are password protected and can be accessed only by project staff that has completed requirements and training in Human Subjects Protections. The Illume DatSTAT survey is also administered via a "https:" site, which provides enhanced security over a "http:" site. Participants IP addresses will not be collected in cases where online screening surveys are completed outside of the laboratory space.

13.0 Provisions to Monitor the Data to Ensure the Safety of Subjects (if applicable)

A data and safety monitoring plan approved by the sponsor (NIAAA) will be submitted as an amendment.

14.0 Withdrawal of Subjects (if applicable)

Participants are allowed to withdraw from the study at any time. They will be asked to either email or call the study to inform us that they are no longer interested in participating in the study and we will either remove their data from the study or no longer contact them to participate in the study based on their request.

15.0 Risks to Subjects

This study has minimal risk to subjects.

Potential risks include possible embarrassment or discomfort related to sensitivity of the information disclosed on the questionnaires. Research has found that the assessment of details of a traumatic event (e.g. sexual assault) has in general left participants feeling like they have gained something positive from the experience (Dyregov et al., 2000; Griffin et al., 2003; Johnson & Benight, 2003; Walker et al., 1997). This research has shown that although a small number of participants do report some distress after assessment, they express willingness to participate again in the future. In addition, research at the University of Washington examining sexual assault risk perception and resistance (1R01AA12219; PI: Norris; "Alcohol and Acquaintance Sexual Assault Risk Perception"), participants were contacted approximately 3 weeks after participation to inquire

about negative effects of participation. No participant reported any negative effects, nor did any request follow-up contact with project staff or outside referral. Rather, several participants expressed appreciation that the topic was being studied, and two participants refused payment because they "just wanted to help other women." Thus, we feel that participation in the proposed research will not cause extreme psychological distress. Relevant safeguards for protection against potential risks are detailed below in the next question.

Breach of confidentiality is also a risk, however, we are taking precautions to ensure that this risk is minimal. Similarly, if a participant is threatening to hurt her/himself or someone else, confidentiality may have to be broken to make a report to the necessary authorities. Given that suicidality is a risk of sexual assault victimization, while not a direct risk of the study, it is an important issue to assess and monitor closely with participants. Procedures for assessing and addressing suicide attempts are addressed in the following protection against risks section.

With regard to potential alternative treatments, all college students will receive some form of sexual assault prevention programming at college as a standard care. Therefore, those who participate in the study will only receive additional services on top of standard care and in no way will participating in the current study take away their standard of care. When the study is advertised to potential participants, it will be made very clear that students have the right to choose not to participate in the study and to be provided with appropriate referrals if they so prefer, including resources at the college regarding alcohol and sexual assault.

Protection Against Risk: To protect against violations of confidentiality: (a) a federal certificate of confidentiality is included in all NIH studies, which renders the data immune from subpoena (due to the sensitivity of some of the data that we are collecting - e.g., self-reports of alcohol use and sexual assault - and the potential legal jeopardy faced by some of the participants); while aware of the ambiguities about the reach of the certificates, we are convinced that they are the best protection available for confidentiality of research data; (b) all staff will sign confidentiality agreements, and our training sessions will emphasize the critical importance of confidentiality; and (c) computers containing the data will be password-protected as a security precaution to eliminate unauthorized access.

To minimize distress or discomfort associated with participation in the study (from either assessment or the intervention): (a) participants will be informed that they can discontinue participation at any time; and (b) if other problems arise, a licensed psychologist will be available to address the distress. Upon completing the survey, they will be given local resources regarding alcohol use, sexual assault, and mental health resources (see Resources). All participants will be given this information, regardless of their risk. Participants will be given the option of contacting the study staff if they are distressed by the study procedures. Members of the research team are licensed clinical psychologists and are well-equipped to follow-up with individuals in need. As been the case with our previous studies, we will establish a schedule in which members of the research team will be on call 24 hours a day, seven days a week to address urgent matters. If a participant is distressed and wishes to talk with a member of the research team, the clinical psychologist team member will be available at all times during the study period.

A detailed safety plan - detailing what to do and whom to speak with if ideation should occur - will be included in standard referral information provided to all participants, including specifics on how to access 24-hour care for suicidality via dialing 9-1-1 and/or going to the closest emergency department when a PI is not available. Thus, a 24-hour safety plan is in place, including access to medical care 24 hours per day. Further, any participant in which it is deemed that medication is warranted will be referred to a psychiatrist for such services and monitoring. Suicidal risk factors - including suicidal ideation, intent, plan, and means - will continue to be assessed on an ongoing basis throughout the students' participation

in the study for those who are participating in the open and randomized pilot trial.

To address electronic data security, Dr. Gilmore will work closely with the programmers at Brown University, to support electronic data security. Questionnaire data will be collected via DatStat Illume survey software, which is maintained by programmers at Brown Unviersity – the site of Co-Investiagor Dr. Lindsay Orchowski. These programmers have extensive experience safeguarding the security and integrity of sensitive materials, including protected health information and sensitive financial information. Data transmissions to and from the data server are encrypted by SSL (Secure Socket Layer) and 40, 56, or 128-bit Public Key Encryption technology. A VeriSign security certificate has been obtained to verify SSL encryption. Data will be downloaded to password-protected computers belonging to research staff or investigators. Databases on the server are password protected and can be accessed only by project staff that has completed requirements and training in Human Subjects Protections. The Illume DatSTAT survey is also administered via a "https:" site, which provides enhanced security over a "http:" site. Participants IP addresses will not be collected in cases where online screening surveys are completed outside of the laboratory space. Respondent confidentiality will be masked in all data files by the use of project identification numbers rather than personal information. All other electronic records, including digital recordings of interview feedback, are de-identified in collection and will be maintained in password-protected locations on the secure server. The only document linking participants with identification numbers will be retained in an encrypted file on the secure server with access limited to the investigative team. Data presented at professional meetings or published in journals or books will not allow identification of individual participants. These procedures are expected to minimize any potential adverse effects from participating in this study.

16.0 Potential Benefits to Subjects or Others

The risks to college students participating in this project are minimal and do not exceed risks associated with participating in mandatory sexual assault prevention programming while in college. Potential benefits to participants who receive the prevention program are substantial, including decreased likelihood of alcohol misuse and sexual assault, thereby decreasing the risk of subsequent development of substance use disorders and sexual (re-)victimization/(re-)perpetration, though these cannot be guaranteed. In addition, the successful demonstration of an intervention for alcohol use and sexual assault would be of significant benefit to society. Further, this technology could be adapted to other populations and university settings if effective.

Importance of the knowledge to be gained: Sexual assault is widespread on college campuses and individuals who engage in heavy episodic drinking are more likely to experience sexual assault victimization, to perpetrate sexual assault, and to not intervene when witnessing a potential sexually assaultive situation. mHealth interventions are promising and have the potential to reach a large targeted group of college students who use alcohol. The proposed research is a first step of establishing the research team, programming, feasibility, and preliminary efficacy of the research protocol. If promising, this study will lay the groundwork for a large-scale R01 application to test the efficacy of tailored gender-specific ASAP in a randomized controlled trial. The minimal risks to participants are reasonable given the importance of the knowledge to be gained.

17.0 Sharing of Results with Subjects

Results will not be shared with participants.