Study Title: RealConsent: A web-based program to reduce college women's risk of sexual violence by targeting alcohol use, communication and consent, and building supportive networks.

Date of Document: July 31, 2018

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Research Protocol and Statistical Analyses

Title: **Testing the efficacy of a web-based program for college women**
Principal Investigator: **Dr. Laura F. Salazar**
Sponsor: **National Institute of Alcohol Abuse and Alcoholism**

I. Project Summary and Project Goals

Sexual assault of college women is a serious and complex public health problem: one in five college women report being sexually assaulted. The purpose of this study is to conduct a randomized controlled trial study with 750 female college students from three universities to test the efficacy of RealConsent-F, a sexual violence risk reduction program for college women, compared to an attention-placebo comparison condition. The primary outcome will be self-reported sexual violence victimization and the secondary outcomes will be alcohol and dating protective- and risk-related behaviors and resistance strategies. Our expected outcomes are demonstrated feasibility and efficacy of a technologically novel risk reduction program for female college students.

II. Rationale and Background Information

Epidemic of Sexual Violence Against College Women: Recent statistics on sexual violence against women in college have revealed a serious and complex public health problem: 6% of female college students report experiences of rape each year[14] and one in five women report that she was sexually assaulted while in college.[1] Assaults typically occur during freshman or sophomore year[2] and, in most cases (75-80%), women state that they know their attacker, whether as an acquaintance, classmate, friend or (ex)boyfriend.[2] Many women report experiencing an "incapacitated assault" meaning they were sexually abused while they, the victims, were drugged, drunk, passed out, or otherwise incapacitated.[3,4] These data demonstrate the high level of sexual assault occurring among young adult college women. To reduce incidence rates, comprehensive approaches involving evidence-based, easily-disseminated educational products are greatly needed by institutions of higher learning to prevent male perpetration and reduce risk of sexual assault among women; however, evidence-based prevention and risk reduction programming is greatly lacking.[5-7]

In 2014 the Centers for Disease Control and Prevention (CDC) conducted a review of 140 published sexual violence primary prevention interventions and concluded *only three* were

effective in preventing sexual violence perpetration. [Note: RealConsent male version (RealConsent-M) was not included in this review as the publication was "in press" at the time the review was conducted]. Of the three effective programs, none were specific to college students.[5] To reduce sexual violence perpetration, best practices for prevention entail theoretically-driven activities that focus on improving 1) knowledge of consent and understanding the impact of alcohol; 2) addressing hyper-male ideology; 3) reducing hostility toward women; 4) reducing adherence to prescribed gender roles; 5) changing social norms to reduce acceptance of sexual violence; 6) dispelling rape myths; and 7) enhancing communication skills between men and women around sex. RealConsent-M incorporated segments that addressed all seven best practices. Using a randomized controlled trial (RCT), RealConsent-M demonstrated significant reductions in sexual violence perpetration;[13] thus, RealConsent is the first effective prevention program for male college students.

III. Methods

This study plans to conduct a randomized controlled trial with 750 female freshmen between 18-20 years of age from three universities in the state of Georgia (n=250 from each school) to test the efficacy of RealConsent-F compared to an attention-placebo comparison condition. Inclusion criteria for all proposed research activities are: female, aged 18-20 years, full time freshman, and single. Exclusion criteria are: other education levels, married, and/or graduate status. Participants will be randomized to either the intervention or attention-placebo study conditions. To control for Hawthorne effects, women in the RCT will be compared to women in an attention- placebo control condition—a general health promotion web-based program called "Stress Management." Below are descriptions of the intervention, RealConsent and the attention-placebo program.

RealConsent-F

RealConsent includes 18 of 40 well-known behavioral change techniques. The program 1) provides information on the targeted behavior; 2) provides instruction on how to perform the behavior; 3) demonstrates or models the behavior; 4) demonstrates positive outcomes for engaging in the behavior or negative outcomes for failing to change behavior; and 5) provides encouragement and positive feedback as reinforcement.[12,35-38] RealConsent-F uses didactic methods involving presentation of material via video; problem-based learning via quizzes with interactivity; short videos and animation to model the behavior. RealConsent-F is unique in that it includes serial drama episodes (i.e. "Squad") featuring four college women going through their freshman year and experiencing issues related to alcohol use, sexual assault, stalking, and dating violence. This program is grounded in *educational entertainment* to provide educational content within entertainment programming (e.g., Sesame Street or Law and Order).

Attention-Placebo Condition

Stress Management was developed by ISA Group (www.isagroup.com) and is a multi-media web-based program designed to help manage stress levels. The program is dynamic and interactive with substantial use of video/audio. Each of 4 program modules is ≈30 minutes involving interactive and didactic activities. Thus, it approximates RealConsent-F in format and duration.

Recruitment of N=750 Female College Freshmen

We have agreements with each of the three colleges to test RealConsent-F among female freshmen and they have agreed to provide a list of female students. We will send out email invites from Salazar's email account to a random sample of 500 students per school to ask for their participation in a research project. To control for demand characteristics, we will blind participants to the research question and indicate the purpose is to "test multimedia, web-based interactive programs designed for female college students." If the first round of 500 emails does not produce a 50% response rate, we will send out another batch of 500 email invites to reach our target goal of n=250 at each college. Salazar used this recruitment strategy for testing RealConsent-M.[13] Female freshmen who are interested in the research will be able to access our online eligibility screener through a hyperlink in the body of the email that takes them to our study website. Mr. Long, a computer scientist and programmer, will develop the study website and a web-based application that will help our project director with recruitment and retention efforts. Long developed a website and app for Salazar's current online study of 1,800 male freshmen.

Informed Consent

The website will provide a short description of the study and, if interested, participants can click on a button to assess their eligibility followed by the informed consent process. The informed consent process is a crucial aspect of any study, but especially so when conducting web-based research involving sensitive topics. Special consideration must be made to ensure that participants are aware of their rights as participants in such research.[94] A hyperlink will be displayed following the eligibility screener directing eligible participants to the informed consent form. Those not eligible will receive a message saying they are not eligible. An interactive process will be designed to secure informed consent. As part of registration, we will collect name, preferred email, mailing address, and cell phone number to maximize retention although identifying information will not be linked with survey data. The web app will allow us to collect key data for CONSORT.[95] All participants are eligible to receive up $105 in Amazon e-gift cards for completing RealConsent-F and all surveys, which in our experience of 10 years of conducting online studies is feasible and necessary.[13,96-98]

Baseline Assessment, Randomization, and Completion of RealConsent or Stress Management:

Once a participant is registered, she will get a confirmation email; her response will trigger another email that contains a link to the online baseline survey and a password for accessing. To enhance confidentiality of responses, we will encourage participants to choose a private location, use a secure, encrypted Internet connection, and close their web-browser after they have completed a survey. Once an individual completes the baseline survey, she will be randomized using an automated stratified block randomization program to either RealConsent-F or to Stress Management programs. Stratified block randomization will ensure equal numbers between conditions and that 125 participants from each university are assigned to each condition.

We will communicate to the research participants and encourage them to complete their assigned task (RealConsent-F or Stress Management) within two weeks. Participants can complete the modules at their own pace within the 2-week window and are able to leave a module and finish it later. Email prompts will be sent every 48 hours to remind participants to complete the modules. Participants will be contacted by email and/or text message prior to 6 months post-intervention (Spring 2019) to complete the posttest.

Retention Activities

Based on the experience and expertise of Salazar and her team, we will employ a number of activities to maximize retention. In a preliminary study of N=1,153 college male freshmen assessed three times over 12 months, Salazar and colleagues implemented activities to enhance recruitment: 1) sending touch-point emails in between assessments; 2) enabling participants to update changes in contact information via the web application; 3) providing full incentive amount for those who completed assessments on time as a "bonus;" 4) sending email and text reminders prior to due dates; and 5) emailing, texting and making phone calls up until final date. Our response rates were: 80% at wave 2 (6-months), and 81% at wave 3 (12-months). To ensure we maintain at least 80% retention rate, we will employ these strategies and those used previously by Salazar in other studies involving follow-up assessments of adolescents and adults.

Study Measures

The table below displays the measures that will be used in all study assessments.

Table 1. Measures of Study Variables

Variable	Measure	# Items	α
Primary Outcome:			
Sexual Victimization	Revised Sexual Experiences Survey-SFV (SES)[81]	35	.74
Secondary Outcomes:			
Dating behaviors	The Dating Behavior Survey (DBS)[82,83]	15	.67

	The Dating Self-Protection Against Rape Scale[83,84]	15	.88
Alcohol Protective Behaviors	Protective Behavioral Strategies Survey[26,85]	15	.94
Use of resistance tactics	Use of Resistance Tactics[23]	6	n/a
Mediators:			
Alcohol use	Weekly Drinking and Heavy Episodic Drinking[28,86]	2	n/a
Perceptions of Alcohol-Related Risk	Likelihood of nonconsensual sex due to alcohol[87]	1	n/a
Alcohol Expectancy	Revised Alcohol Expectancy Questionnaire[87,88]	40	.72
Alcohol Use Norms	Drinking norms rating form[26,89]	1	n/a
Bystander Behavior	Bystander Behavior Scale	10	.89
Knowledge of legal definitions of rape	Legal Knowledge Scale[13]	7	.69
Perceptions of informed consent	Informed Consent Index[13]	14	n/a
Empathy for rape victims	Rape Empathy Scale[90]	19	.84
Communication with partner about sex	Communication subscale of SSBQ[91]	7	.80
Sexual Assertiveness	Sexual Communication Survey[82]	10	.90
Self-efficacy to discuss sex	Communication Self-Efficacy[92]	4	.84
Self-efficacy to use assertive responses	Self Efficacy Scale[93]	7	.97
Use of risk reduction strategies	Personal and Social Risk Reduction Strategies Scale	34	n/a

IV. Safety Considerations

There are some potential risks for participating in the RealConsent program. Participants may experience some adverse psychological reactions such as feeling upset or discomfort as they undergo the intervention modules. For example, a potential risk is that a participant may gain a new awareness of an unwanted sexual experience that hitherto she thought of as "her fault for getting drunk", but she now may indicate she was a victim of date rape. Although these instances represent some degree of risk, we have designed the procedures to minimize adverse reactions. Our project director, Dr. Anne Marie Schipani-McLaughlin will conduct a check-in with each participant after completion of each intervention module. Participants can freely elect to terminate participation in the Web-based intervention if so desired. We anticipate that some participants may require counseling and we will be prepared to help these participants with appropriate referrals. Dr. Schipani-McLaughlin has extensive experience in addressing participants' concerns during randomized trials will also undergo training by Dr. Salazar and if needed, the principal investigator will address adverse reactions should they arise. Also, we will include on our study website a (800 715 4225) number that can be accessed 24/7 for immediate crisis counseling in GA (GA Crisis and Access Line): http://www.armstrong.edu/Departments/counseling_center/counseling_georgia_crisis_and_access_line).

Another potential risk for participating is the administered assessments that may cause some participants to experience adverse psychological reaction such as distress, discomfort, or anxiety responding to explicit questions regarding their unwanted sexual experiences. We will state explicitly that participants can refuse to answer any questions, decline to answer any questions, or be allowed to skip any questions of the survey; they can also elect to terminate their participation immediately. The project director will be prepared to provide resources for participants should they request a referral, or as they respond to explicit questions regarding their unwanted sexual experiences.

One last risk entails a loss of confidentiality. A number of steps will be taken to secure sensitive data. These include the required use of personal identification numbers, access codes, and passwords on the study web site and on all web-administered surveys and assessments. Only the PI and the project director will have access to the online survey data through our Qualtrics account. Qualtrics web-survey platform employs a high level of data encryption. We will also secure the web site, which will deliver the RealConsent program. All data and recruitment materials will be stored on the PI's password-protected desktop located in her locked office at GSU.

V. Data Management and Statistical Analysis

Data Management

Data will be stored on servers that are protected by high-end firewall systems, data are encrypted so that information cannot be decoded, and IP addresses will not be collected (every computer that communicates over the Internet is assigned an IP address that uniquely identifies the device). Data files, once downloaded, will be stored on Dr. Salazar's password-protected computer located in her locked office.

Statistical Analysis

The complex empirical methods described below will be conducted by Dr. Hayat, an experienced statistician and colleague of Dr. Salazar's. Data analysis will be performed using the SAS Software System. Descriptive statistics for all measurements will be estimated and reported. Frequency distributions will be created to screen for any errors and will be used to summarize categorical data; measures of central tendency and dispersion will be used to summarize continuous data. All data will be examined for bivariate relationships and results used to build a multivariate statistical model.

We will analyze our study data with an intent-to-treat and per protocol analyses. An intent-to-treat analysis includes all participants who were randomized, regardless of compliance, withdrawal, and anything that happens after randomization. An advantage is that it is an analysis based on original randomization; however, effect estimation may be conservative and misleading with increasing attrition. A per protocol analysis considers only participants who fully complied and completed the study. Per protocol is less conservative and may reflect true treatment differences for those with full compliance. Including an intent-to-treat and per protocol analysis will provide a more complete understanding of treatment effects. Because we will most likely encounter incomplete data due to dropouts and non-response, multiple imputation of missing data will be used to impute missing values based on other available covariates.

Outcomes, including victimization and frequency of risky dating behaviors and alcohol-protective behaviors will be modeled using a general linear mixed model. This is an appropriate statistical model to use with repeated measures data collected over time.[101] A random effect for subject will be included to account for the multiple measurements taken at baseline and 6-month follow-up on each subject. Treatment group and demographics will be included as fixed effects in the model. Mediation models will be tested with a two-tiered approach for mediation testing, with bootstrapping to generate estimates of the indirect effect and 95% confidence intervals.

Sample Size

Primary outcome will be report of victimization; secondary outcomes are protective- and risk- related behaviors. Sample size is based on the number per group needed to detect clinically meaningful treatment effects on victimization. Calculations were based on 80% power, level of significance of .05, and two- tailed statistical tests. Clinically meaningful treatment efficacy was defined for our outcome variable as having between a small and moderate effect size (Cohen's $h \geq .35$). This effect size was considered as a 9% point difference between groups, at a minimum, and could potentially translate to a clinically significant reduction in the number of victimizations on those college campuses that implement RealConsent. Based on previous research with female college students,[22,23,26,28,104-107] assuming incidence of 0.22 without intervention and .13 with intervention, a total of 558 participants are needed (279 in each group). We expect 20% attrition based on previous work. To achieve adequate power, we estimate a needed sample size of at least 670; however, we are increasing sample size to 750 participants (375 in each group) to increase power.

VI. Quality Assurance

Data Safety & Monitoring Plan

In accordance with the NIH recommendations as this is a NIH clinical trial we will have a Data Safety Monitoring Board (DSMB). The proposed study is considered to present minimal risk to participants, given that they will complete surveys and possibly participate in a sexual violence prevention educational program. Members of the DSMB will perform the following activities:

1. Review the research protocol and plans for data and safety monitoring.
2. Review progress of the trial, including analysis of data quality and timeliness; subject recruitment and retention; subject risk versus benefit; and other factors that may affect outcome.
3. Review serious adverse event reports, provide commentary, and provide oversight to ensure that reports are relayed to individual IRBs and to the Office of Human Research Protections (OHRP), as indicated.
4. Review analyses of outcome data and review reports of related studies to

determine whether the current study needs to be changed or terminated.

5. Determine whether the trial should continue as designed, should be changed, or should be terminated based on the data and make recommendations to the NIH and the Institutional Review Board considering conclusion or continuation of the study.
6. Review proposed modifications to the study prior to their implementation.
7. Protect the confidentiality of the trial data and the results of the monitoring.
8. Determine whether and to whom outcome results should be released prior to the reporting of study results.
9. Following DSMB meetings, provide appropriate NIH staff with written information concerning their findings.

The DSMB members will be chosen by Dr. Salazar and will be reviewed and approved by the NIH Project Officer. The members, who will all be voting members, will be chosen based upon their knowledge of clinical trial methodology, their experience with the topical area (i.e., sexual violence risk reduction strategies), and absence of conflicts of interest. They will be appointed for the life of the project. The Chair of the DSMB will be selected from among the DSMB members. The NIH Project Officer will serve as an ex-officio member of the DSMB.

DSMB meetings will be held every 12 months beginning in Year 1 of the study. Serious adverse events will be reported to the Chair as soon as they occur. The Chair of the DSMB will determine whether an in-person meeting or teleconference is needed. Prior to the meetings, a written report containing any study preliminary findings will be sent to DSMB members. Preliminary findings will not be made available to individuals outside of the DSMB. Each meeting will include time to review the progress of the study and to answer questions from members of the DSMB. Members of the DSMB will disclose any potential conflicts of interest, either pre- existing or those that develop during their tenure, to the Principal Investigator and the NIH Project Officer.

In accordance with NIH policy, a data and safety monitoring plan has been developed for the proposed study. Dr. Salazar will provide oversight of all recruitment and study procedures and quality assurance checks will be conducted as planned. All records pertaining to the study and all of the original and electronic files containing collected data will be securely stored. Dr. Salazar and will be solely responsible for dissemination of study findings through presentation and publication formats. Presentations and publications will not disclose the name of the clinics where recruitment occurred. Dr. Salazar will also be solely responsible for handling any requests from other investigators to examine the data collected during Phase II of this Fast- track proposal. Dr. Salazar will present these requests to a Data and Safety Monitoring Board (DSMB) for their consideration.

This research team has extensive experience working with college student populations and extensive experience confronting ethical issues of subjects in behavioral

interventions. We will work with all respective IRBs involved to assure compliance with ethical and HIPPA standards. Additionally, no incentives (i.e., "finder's fees) will be provided to staff for recruiting or referring subjects into the study. Moreover, we are going to make it abundantly clear to subjects that participation in the study will in no way affects their standing at their academic institutions.

Procedures for Monitoring Adverse Events. All study personnel, will be trained regarding how to handle adverse events. Possible adverse events that are unanticipated will be brought to the attention of the PIs, the IRBs, and the NIH project officer. The IRBs who will determine whether it is appropriate to stop the study protocol temporarily or will provide suggestions/modifications to the study procedures as necessary. Possible modifications include adding these possible adverse events to the consent form and re-consenting all study subjects. The PIs will be responsible for monitoring participant safety on a monthly basis at regularly scheduled research meetings. They will keep a written log of all events and ensure that the IRBs are contacted immediately. They will also keep a log of the outcome of IRB decisions regarding adverse events and apprise the research team of any changes that need to occur as a result of IRB decisions.

1. Dr. Salazar will provide oversight of all recruitment and study procedures and quality assurance checks will be conducted by the Project Director Dr. Schipani-McLaughlin as planned. These quality assurance checks will occur once a week during recruitment and assessment time periods to ensure recruitment goals and validity of the data.
2. All records pertaining to the study and all of the original and electronic files containing collected data will be securely stored by Dr. Salazar on her password-protected desktop computer and/or a locked file cabinet located in her locked office on GSU campus. Other than Dr. Salazar, only key study personnel will have access to the data files.
3. Specific procedures to ensure the safety of participants will also occur. The proposed research contains some risk for participants; however, the likelihood of adverse events (AEs) is low. During the efficacy trial, we will contact participants via email and texting to not only check in with them but also to promote compliance. All participants who demonstrate they are in need of assistance will be given a 800 telephone number to obtain immediate crisis counseling and a referral 24/7; thus, young women will have access to help in the event they feel distress or are upset.
4. Dr. Salazar will participate in the monitoring of participants during the course of the research. Should any AEs occur, the project director will be required to immediately contact Dr. Salazar. Dr. Salazar will immediately investigate the event and determine the appropriate manner in which to proceed. A report describing the AE will be submitted to the participating Institutional Review Board and to the project officer from NICHD within 10 days of occurrence. In the event a change in procedures is required, an amendment to IRB will occur

promptly, within 10 days.

5. To monitor that our recruitment and retention projections are being met, Dr. Salazar will hold weekly meetings of the research team to assess recruitment and retention of participants.
6. Drs. Salazar and Hayat will be responsible for dissemination of study findings through presentation and publication formats. The setting for this research will not be named in publications or presentations.
7. Dr. Schipani-McLaughlin, the project director will monitor the data on a weekly basis during assessment periods. She will serve as the project data manager where she will examine the data for accuracy and any inconsistencies. She will rectify any errors and she will maintain a data correction log to record any errors and how they were resolved.
8. Dr. Matt Hayat, a Co-investigator and statistician on the study, will also perform interim analyses to assess the integrity of the data.
9. Finally, Dr. Salazar, will monitor the study using the following criteria:
    a) Review progress of the surveys as they occur, including analysis of data quality and timeliness; subject recruitment, and other factors that may affect outcome.
    b) Review serious adverse event reports, provide commentary, and provide oversight to ensure that reports are relayed to individual IRBs and to the Office of Human Research Protections (OHRP), as indicated.
    c) Review analyses of outcome data of the current study and review reports of related studies to determine whether the current study needs to be changed or terminated.
    d) Review proposed modifications to the study prior to their implementation.
    e) Protect the confidentiality of the accumulated data.
    f) Determine whether and to whom outcome results should be released prior to the reporting of study results.
    g) Provide appropriate NIH staff with written information concerning their findings relevant to the quality of the data.

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