BOISE STATE UNIVERSITY

Study Protocol for Human Subjects Research and Statistical Analysis Plan

Efficacy of a Web-Based Alcohol Intervention for High School Students

January 27, 2021

BOISE STATE UNIVERSITY

DIVISION OF RESEARCH & ECONOMIC DEVELOPMENT
Office of Research Compliance | Institutional Review Board
(phone) 208.426.5401 | (fax) 208.426.2055
humansubjects@boisestate.edu | MS 1138

EXPEDITED/FULL BOARD PROTOCOL APPLICATION

INSTRUCTIONS

- The application must be typed. **Handwritten applications will not be accepted.**
- Spellcheck will not work on this application. Proofread before submitting.
- **SUBMIT COMPLETED APPLICATION AND ALL SUPPORTING APPENDICES TO: HUMANSUBJECTS@BOISESTATE.EDU**
- The second page must be signed by all applicable investigators and must be submitted to the Office of Research Compliance via:
  - Email—humansubjects@boisestate.edu (as a scanned PDF);
  - Campus Mail—Mail Stop 1138;
  - Mail—*Office of Research Compliance, 1910 University Drive, Riverfront Hall 311, Boise, ID 83725-1138; or*
  - Fax—208.426.2055

SECTION A: General Information

1. Project Title: **Efficacy of a Web-Based Alcohol Intervention for High School Students (Capital and Boise High)**

2. Anticipated Start Date: **7/1/2017** Anticipated End Date: **6/30/2019**

3. **PRINCIPAL INVESTIGATOR (PI)** (Refer to the IRB PI Eligibility requirements. IRB staff will confirm your eligibility. Graduate thesis or dissertation students MUST list an eligible PI as their co-investigator)

Name: **Diana Doumas**

Title: ☒ Full Professor ☐ Associate Professor ☐ Assistant Professor

If you fall into any of the titles in the grey box below, you must have an eligible PI listed as your Co-Investigator.

☐ Adjunct Faculty	☐ Visiting Faculty
☐ Instructor/Lecturer	☐ Staff
☐ Graduate Student—Thesis	☐ Graduate Student—Dissertation

Department: **Counselor Education** Phone: **6-2646**

E-mail: **dianadoumas@boisestate.edu**

Roles and responsibilities in this study:

As the Principal Investigator, I will be overseeing the entire project including the participant recruitment, collection of data, supervision of the research team, analyzing data, reporting data at conferences, and writing manuscripts for publication.

CITI Training Completed: ☒ Social & Behavioral Researchers ☐ Biomedical Researchers

4. **CO-INVESTIGATOR** (IRB staff will confirm your title with the directory.)

Name: **Susan Esp**

☐ Full Professor	☒ Associate Professor	☐ Assistant Professor
☐ Adjunct Faculty	☐ Instructor	☐ Staff
☐ Graduate Student	☐ Undergraduate Student	
☐ Other:		

Department: **Social Work** Phone: **6-3970**

E-mail: **susanesp@boisestate.edu**

Roles and responsibilities in this study:

As co-investigator, Dr. Esp will assist in overseeing participant recruitment, data collection, and implementation of the intervention program. Dr. Esp will also assist in analyzing data, reporting data at conferences, and writing manuscripts for publication.

CITI Training Completed: ☒ Social & Behavioral Researchers ☐ Biomedical Researchers

5. Do you have additional research personnel (Co-Investigators, key personnel, student research assistants, etc.)?
   - ☐ **NO**
   - ☒ **YES**

   To list additional investigators and/or key personnel, complete and attach an ADDITIONAL PERSONNEL form.

6. Is this research supported in whole or in part by a grant or contract?
   - ☐ **NO**
   - ☒ **YES:**

   Sponsor Name: **National Institute on Alcohol Abuse and Alcoholism**
   PI on Grant: **Diana Doumas**
   Grant Title/Contract: **Efficacy of a Web-Based Alcohol Intervention for High School Students**
   Project Period: From: **7/1/2017** To: **6/30/2019**
   ☐ Grant Project Summary Attached
   OSP Proposal Number (if known): **this grant is pending - it has received a score in funding range - IRB required for JIT information for Advisor Council meeting in May 2017**

7. Has this protocol previously been considered by Boise State University's IRB?
   - ☒ **NO**
   - ☐ **YES:** IRB Number: _____ Date Approved: _____

SECTION B: Financial Conflict of Interest Disclosure

Conflicts of interest must be disclosed in accordance with the Boise State Conflict of Interest and Commitment Policy #1110.

1. Do any investigators (PI, Co-Investigator) or research team members (key personnel) have any relationship or equity interest with any institutions or sponsors related to this research that might present or appear to present a conflict of interest with regard to the outcome of the research?
   - ☒ **NO POTENTIAL CONFLICTS EXIST**
   - ☐ **YES:**

   2. Name of the person(s) with the potential COI: _____
      ☐ This potential conflict has been disclosed to the Boise State Conflict of Interest Office via the electronic disclosure form: https://web.boisestate.edu/conflictofinterest/app.html.
      ☐ This conflict has not been disclosed to the Boise State COI Office.

Note: If a significant conflict of interest exists, you must also attach the Boise State COI Committee approved management plan. If you have questions about conflicts of interest, contact the Boise State Conflict of Interest Officer at (208) 426-1252.

SECTION C: Signatures

Principal Investigator Assurance and Acknowledgement

I certify that the information provided in this application is complete and accurate. As the principal investigator, I have ultimate responsibility for the conduct of this study, the ethical performance of the project, the protection of the rights and welfare of human participants, and strict adherence to any stipulations designated by the IRB. I accept and will conform to all federal, state, and institutional provisions concerning the protection of human participants in research. I will ensure all personnel involved in the research will be appropriately trained for all procedures used in this project.

I agree to conduct the research involving human participants as presented in this protocol application as approved by the Boise State Institutional Review Board (IRB), and am qualified to perform the procedures described herein. I will submit any proposed changes/modifications for review and approval before they are implemented. I agree to notify the IRB and Office of Research Compliance of any adverse events that may occur during the study. I also assure that I will follow through with the storage and destruction of data as outlined in the protocol. I understand that Boise State owns the research data. If I choose to transfer to another institution, I will need departmental approval to take the data with me.

If I am a graduate student investigator on this research application, I further agree to meet with my faculty adviser on a regular basis to discuss the progress of the study. I agree to meet with my faculty adviser to solve protocol issues as they arise.

I understand that data collection (including recruitment) is not permitted until final approval is granted by the IRB.

Diana Doumas		**3-8-17**
Principal Investigator (PRINT)	**Signature**	**Date**

Co-Investigator/Faculty Advisor Assurance and Acknowledgement

I certify I have read this protocol application and that the information is complete and accurate. I ensure that the principal investigator is qualified to perform the procedures described. I understand that I will be included in all email correspondence related to the protocol application including questions from the IRB committee and approval notifications.

I further agree to meet with the principal investigator on a regular basis to monitor the progress of the study. I agree to be available and to personally supervise the student investigator in solving problems as they arise. I will arrange for an alternate Co-Investigator to assume responsibility if I become unavailable, as when on sabbatical leave or vacation, and will notify the IRB of this change. I assure that the PI will follow through with the storage and destruction of data as outlined in the protocol.

Susan Esp		**3-8-17**
Co- Investigator (PRINT)	**Signature**	**Date**

SECTION D: Review Category

Indicate the applicable review category for your research:

☐ **FULL BOARD Review:**

Any research or training project involving the use of human participants which does not fall into an exempt or expedited review category must be submitted for full board IRB review. Research involving more than minimal risk requires full board review.

☒ **EXPEDITED Review** (Indicate category(ies) below):

☐	**1.**	**Clinical studies of drugs and medical devices only when condition (a) or (b) is met.**
	☐ **a.**	research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review).
	☐ **b.**	research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
☐	**2.**	**Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:**
	☐ **a.**	from healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
	☐ **b.**	from other adults and children[1] considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
☐	**3.**	**Prospective collection of biological specimens for research purposes by noninvasive means.**
		Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
☐	**4.**	**Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)**
		Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing where appropriate given the age, weight, and health of the individual.
☐	**5.**	**Research involving materials (data, documents, records, or specimens) that have been collected, or will**

	be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human participants. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
☐	**6. Collection of data from voice, video, digital, or image recordings made for research purposes.**
☒	**7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.** (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human participants. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
☐	**8. Continuing review of research previously approved by the convened IRB as follows:**
	☐ **a.** where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up participants; or
	☐ **b.** where no participants have been enrolled and no additional risks have been identified; or
	☐ **c.** where the remaining research activities are limited to data analysis.
☐	**9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.**

SECTION E: Purpose

1. Provide a summary of the purpose of your project. Include information about the background and rationale for the study and goal(s) of the proposed study. Use language understood by a person unfamiliar with this area of research. Specific jargon should be avoided or explicitly explained.

Underage drinking and the negative associated consequences represent a significant problem in the United States. Drinking in adolescence significantly increases the risk for developing alcohol dependence and heavy drinking in high school is associated with multiple negative interpersonal, academic, legal, and neurocognitive consequences. A significant body of literature supports the use of brief interventions based on social norming theory and motivational enhancement models to reduce heavy drinking and the associated consequences among college students. Recent reviews of the literature also indicate brief interventions are effective when delivered in a web-based format. In spite of the compelling need to provide alcohol interventions to high school students, application of evidence-based interventions is limited. Further research examining the efficacy of brief interventions delivered to seniors through the high school curriculum is warranted. The proposed project will address this gap by examining the efficacy of a web-based intervention for this high school age group.

The goal of this study is to reduce underage drinking. This study builds upon research conducted over the past five years in the school district. We evaluated the efficacy of a web-based intervetnion, eCHECKUP TO GO (San Digo State University Research Foundation, n.d), shown to be effective with college students (Doumas, Kane, 2011; Doumas, Workman, Smith, 2011; Doumas, Workman, Navarro, 2011; Doumas, Haustveit, 2010; Doumas, Anderson, 2009). Results of this evaluation with 9th grade students were promising, but results were not sustained over time. Because high school seniors' drinking patterns are more similar to those of college students than 9th grade students, this approach may be more useful with high school seniors. We evaluated this hypothesis with pilot data collected in the Boise School District in 2015-2016. Results suggest that the eCHECKUP TO GO was effective in reducing risk factors associated with alcohol use (Doumas, Esp, Trull, & Shearer, 2017) and alcohol use (Doumas, Esp, Flay, & Bond, in press) at a short-term follow-up.

The proposed study extends the literature by examining the eCHECKUP TO GO wiht high school seniors over a longer follow-up period, as well as examining mediators and moderators of interveniton effects. All 12th grade students at the two participating school sites will be given the opportunity to participate in the study. All participants will complete an assessment packet containing questionnaires including demographic

informaiton, the quantity and frequency of their drinking, beliefs about both the quantity and frequency of their peers' drinking, alcohol beliefs and expectancies, problems associated with drinking, personality characteristics, and future goals (see attachment 1). Classrooms within the high school schools will be randomly assigned to the following groups: eCHECKUP TO GO and control group.

What is your research question? State your hypothesis.

The project is designed to evaluate the following hypothesis: Participants in the eCHECKUP TO GO intervention condition will report a reduction in their quantity of alcohol consumption and alcohol-related consequences relative to those in the control group. We are also interested in mechanisms of change (e.g. changes in estimates of peer drinking and/or drinking expectancies) and if this program is more effective for some students than others (e.g. gender, baseline drinking status, social-emotional maturity, college-bound status).

What will you do with the results of your study (e.g. contributing to generalizable knowledge, publishing, sharing at conference, etc.)? If this project is only for internal evaluation or to complete a class assignment, IRB may not be required. Please contact the ORC for additional information.

Results of this study will be presented at conferences via oral or poster presentations and through publication in peer-reviewed journals. In addition a project summary report will be sent to the partipating schools and/or school district.

SECTION F: Participant Population

1. Provide a description of the participant population you intend to recruit and collect data from. Describe the characteristics of the participant population such as gender, age ranges, ethnic background and health status, as applicable to the research.

Participants (12th grade students; N = 1000) will be recruited from Capital High School and Boise High School in the Boise School District. All 12th grade students will be given the opportunity to participate in the study.

We anticipate the demographics to be as follows:
47% male; 53% female
Ages 16-18
91% Caucasian, .03% African American, . 05% Asisan American, .002% Native American, . 06 % Hispanic and . 01% other

We anticipate the student participants will be healthy.

2. Will your research involve vulnerable populations, such as children or adolescents under the age of 18, pregnant women, prisoners or cognitively, economically, or educationally impaired participants?

☐ NO ☒ YES (indicate population): _____

If yes, describe additional safeguards planned to protect the rights and welfare of this population(s):

Student participants recruited to this research study will be approximately 1000 high school seniors (ages 16-18) from Capital High School and Boise High School in the Boise School District. Classrooms within the schools will be randomized to intervention or assessment-only control conditions. Participants will be recruited from classes. A letter will be sent by the schools to parents and their students prior to the study explaining the research. Parents will be asked to return consent forms using a self-addressed stamped postcard. Students will be invited to participate in the research study during class. Those students who decline participation will participate in an alternate academic activity under the supervision of the teacher. Consent procedures will be the same for minors and 18 year old students as the Boise School District requires parental consent for 18 year old students.

The surveys will ask student participants about their own alcohol use/non-use and any negative consequences, attitudes and beliefs about alcohol use, reasons for using alcohol use, norms for alcohol use, personality characteristics, future plans, and demographic information. Similar procedures have been used in previous research with 9th grade students and high school seniors without adverse incident. Psychological risks posed by the research are primarily related to the content of the assessment measures. Items include thoughts and feelings that may be private and personal behavior such as alcohol use. These questions may make participants uncomfortable, or be perceived as an intrusion on their privacy. Although it is important to consider there potential risks, and it is important to point out the potential for these risks, we have not observed any indications of these risks materializing in all of our previous research using procedures similar to those we will use in the proposed study.

All data and other information in this study will be maintained confidentially, but data will not be anonymous due to the longitudinal nature of participation. In order to protect against risks posed by the potential loss of confidentiality, we will take the following steps: 1) participants will be assured that they are free to refrain from answering any questions they do not wish to answer; 2) all data will be identified only by a unique personal identifier (PIN), which will be randomly generated for study purposes; 3) a master list of names and code numbers will be stored in locked file cabinets under the supervision of the PI and will be available only to research staff on this project. Data will be retained on computers with restricted and password protected access, without links to the master code list. All data based on this research will be reported in aggregate form.

3. Will you be recruiting students from a class that you teach? (See IRB guidelines for using your own students.)
☒ NO ☐ YES
If yes, explain why this population is necessary to the study, and how you will ensure participants do not feel coerced to participate. Coercion is a significant concern.

4. Will you be recruiting employees who report to you?
☒ NO ☐ YES
If yes, explain why this population is necessary to the study, and how you will ensure participants do not feel coerced to participate. Coercion is a significant concern.

5. Indicate any exclusion criteria for participants.
There are no exclusion criteria for recruitment other than not meeting inclusion criteria other than not being a senior at one of the two school sites.

6. How many participants do you anticipate are needed for this research?
We anticipate a 45% response rate (students with parental acitve consent, student assent, and who are present the day of data collection) - this will yeild 450 student participants in this study which will provide a large enough sample to adequately power this study.

SECTION G: Recruitment and Informed Consent

1. Attach copies of all applicable **recruitment** materials:
☐ Recruitment Scripts (what will be said to participants during recruitment)
☐ Recruitment Emails
☒ Cover Letters
☐ Flyers
☐ Advertisements
☐ Other:

2. Who will recruit potential participants?
We have recruited Capital High School and Boise High School in the Boise School District by contacting the principal. Participants will be recruited through the high schools from 12th grade classes. Student participants' names will be obtained from the registrar's list of seniors, which have the names, street addresses, and current phone numbers for all students. This information can be obtained directly from the registrar's computer database. Recruitment letters to parents will be sent directly from the school.

3. Describe how, when, and where individuals will be first contacted about their interest in participating in the study (e.g., face-to-face, email, flyers, advertisements, phone call, etc.).
A pre-notification letter will be sent by the school to parents early in the academic year. A second letter will be sent explaining the study, include the consent form and a project-addressed stamped envelope for return of the consent form. A reminder letter and consent form with project-addressed stamped envelope will be sent to parents who do not return the initial consent form. All letters will be sent to parents' permanent addresses, provided to us via the registrar's office. Additionally, letters with consent form with a project-addressed stamped envelope will be sent home with students.

Students with parental consent will be invited to participate in the research study during class. Students will be given an assent form which will address the voluntary nature of participation, participants' rights, the risks of participation, the availability of referral options outside the study for help with alcohol use prevention or treatment, data retention and storage information, protections for and limits to confidentiality, a description of the interventions, and procedures for reporting complaints and/or adverse events to the investigators and to the University Human Subjects Review Committee. Participants will be given a copy of the consent document. Students who elect not to participate will be given an alternative academic activity to complete under the supervision of the teacher during the assessment and intervention class periods.

4. Are you are directly emailing or mailing participants?

☐ **NO**

☒ **YES**

If yes, how are you obtaining emails and/or mailing addresses?

Participants' parents will be mailed, although recruitment letters to parents will be sent directly from the school, not from Boise State. Student participants' names will be obtained from the registrar's list of seniors, which have the names, street addresses, and current phone numbers for all students. This information can be obtained directly from the registrar's computer database.

RECRUITING BOISE STATE STUDENTS

Recruiting Boise State students may require additional internal and departmental permissions, in addition to IRB approval. It is the PIs responsibility to obtain these permissions before moving forward with recruitment. The Boise State Office of the Vice President for Student Affairs (VPSA) provides guidelines for sending mass emails to students. It is the PI's responsibility to be familiar with these guidelines and any additional departmental, college or unit processes.

5. Are you recruiting Boise State students?

☒ **NO, skip to #6**

☐ **YES:**

Indicate which students or employees you are targeting:

_____

☐ Approval(s) obtained and attached, if applicable.

*6. Attach copies of all applicable informed **consent** materials:*

☐ Informed Consent Form
☐ Cover Letter
☐ Web-based Cover Letter
☒ Assent Form
☒ Parent/Guardian Informed Consent Form
☐ Verbal Consent Script
☐ Debriefing Statement

7. Are you requesting an alteration or waiver to any informed consent requirements, including documentation of informed consent (signed consent)?

☒ NO ☐ YES

If YES, complete the section below. If NO, skip to question 4.

INDICATE THE TYPE OF WAIVER YOU ARE REQUESTING:

☐ I am requesting to waive the required documentation of informed consent (i.e. waive obtaining the signature for anonymous internet-based survey, telephone survey, mailed survey, etc.). ➔**COMPLETE SECTION A**

☐ I am requesting to waive or alter the required elements of the informed consent process.➔**COMPLETE SECTION B**

SECTION A

Check the box next to the condition that best fits your research study and justify how your research study meets that condition. If waiving the signature, you must still submit a verbal script or cover letter for participants that addresses the eight required elements of consent as stated in 45 CFR 46.116 (a)(1-8).

☐ **CONDITION 1**

The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern.
Justify why your study meets this condition:

☐ **CONDITION 2**
The research presents no more than minimal risk to the participant and involves no procedures for which written consent is normally required outside the research context (i.e. no questions are being asked that could result in potential embarrassment, personally or professionally.)
Justify why your study meets this condition:

SECTION B

☐ I am requesting to **waive the informed consent process.**

☐ I am requesting **alteration** of the informed consent process.
Describe which elements of consent will be altered and/or omitted:

You must justify your request to waive or alter the informed consent process in accordance with each of the following four criteria established under 45 CFR 46.116 (d) (1-4). Provide supporting information for **ALL FOUR** criterion:

1. The research involves no more than minimal risk to the participants.
   Justify:
2. The waiver or alteration will not adversely affect the rights and welfare of the participants.
   Justify:
3. The research could not practicably be carried out without the waiver or alteration.
   Justify:
4. Whenever appropriate, the participants will be provided with additional pertinent information after participation. *(If a debriefing statement is used, submit a copy with this application.)*
   Explain:

8. Describe the consent **process**. Do not answer, "see attached consent form," as this does not describe the **process** of obtaining informed consent. **Describe how, when and where the informed consent process will take place and who will obtain informed consent.**

A pre-notification letter will be sent by the school to parents early in the academic year. A second letter will be sent explaining the study, include the consent form and a project-addressed stamped envelope for return of the consent form. A reminder letter and consent form with project-addressed stamped envelope will be sent to parents who do not return the initial consent form. All letters will be sent to parents' permanent addresses, provided to us via the registrar's office. Additionally, letters with consent form with a project-addressed stamped envelope will be sent home with students.

9. If the participants are not able to give legal consent (e.g., minors), explain how assent will be secured.

Students will be invited to participate in the research study during class. Students will be given an assent form which will address the voluntary nature of participation, participants' rights, the risks of participation, the availability of referral options outside the study for help with alcohol use prevention or treatment, data retention and storage information, protections for and limits to confidentiality, a description of the interventions, and procedures for reporting complaints and/or adverse events to the investigators and to the University Human Subjects Review Committee. This will be presented by Dr. Susan Esp. It will be clearly stated to the participants that participation is voluntary. Students who elect not to participate will be given an alternative activity to complete during the assessment and intervention class periods.

10. Into what languages will the consent be translated? *(NOTE: Translated consent documents must be reviewed and approved by the IRB prior to use.)*

None

11. If your research involves collecting a **combination** of demographic data (e.g., a combination of gender, age, race, and ethnicity) that may make a participant identifiable, you must inform the participants the following: *"For this research project, the researchers are requesting demographic information. Due to the make-up of Idaho's population, the combined answers to these questions may make an individual person identifiable. The researchers will make every effort to protect your confidentiality. However, if you are uncomfortable answering any of these questions, you may leave them blank."*

    If applicable, indicate where and how participants will be informed of this.
    This information will be included in the informed consent and assent.

SECTION H: Data Collection

1. Attach copies of all data collection tools and methods to be used. Check all that apply.

☒ Questionnaire/Survey *(attach questions)*	☐ Videotaping
☐ Observation	☐ Photographing
☐ Interviews *(attach questions and scripts)*	☐ Audiotaping
☐ Focus Groups *(attach questions and scripts)*	☐ Using direct quotes
☐ Reviewing Medical/Education Records	☐ Deception
☐ Other:	

2. Indicate all biomedical procedures that apply to your research:

☐ Physical Activity	☐ Body Mass Index
☐ Venipuncture	☐ X-rays
☐ Magnetic resonance imaging (MRI)	☐ Anthropomorphic evaluations
☐ Electrocardiograms (EKGs)	☐ Intravenous catheter insertion

    ☐ Collection of blood samples by finger stick, heel stick, ear stick or venipuncture
    ☐ Other:

3. If applicable, describe the procedures being performed already for diagnostic or treatment purpose.
    N/A

4. What are you going to ask participants to do? Provide a step-by-step description of each procedure, including the frequency and duration of each procedure. **This question is mandatory and may not be skipped. Applications missing this section will not be accepted.**
    All student participants will be asked to complete an online survey during class time. This will take no longer than 20 minutes. Participants in the classrooms randomly assigned to the intervention group will be asked to complete an online intervention program which will occur during class time. The program involves a comprehensive assessment of the participant's drinking and drinking-related behaviors, followed by systematic personalized feedback to the participant about their alcohol use feedback in relation to their peer group. The program will take about 30 minutes to complete. Participants will then be asked to complete a brief exit survey regarding the intervention. Participants will be asked to complete the surey at 6 weeks and 6 months in the computer lab at their school. This survey will completed online during class periods and will take no longer than 20 minutes to complete. Participants will also complete a very brief survey to assess help seeking. This will occur at the 6 week and 6 month follow-up assessments.

5. Where will the data collection and data analysis procedures take place? (i.e., explain where you are distributing surveys, conducting interviews, etc.)
    Onsite at Capital High School and Boise High School in the computer lab via electronic methods.

6. Does your study include plans to conduct research at an external site? (i.e., off Boise State campus. For example, an elementary school, hospital, prison, etc.)
    ☒ YES ☐ NO
    If YES, indicate the external site(s) and you must attach an acknowledgement (letter or email) indicating you have permission to use their facility and personnel.
    Capital High School, Boise, ID and Boise High School, Boise, ID

    If YES, does your study include plans to conduct research at external sites that are engaged in the research? If so, will that site's IRB approve this research or will it rely upon the BSU IRB?

The external site is not engaged in the research other than in facilitating the process and sending parental informed consent letters. Additionally, a school counselor may help facilitate data collection in the computer lab with the research team. We do, however, have approval from the Boise School District Research Board to conduct the study.

7. Will monetary or other compensations be offered to the participants (e.g., gift certificates, raffle, cash payment or class extra credit?)
☒YES ☐NO

If YES, identify the amount of compensation and method of payment. Explain how participants would earn compensation if their participation is anonymous. If students are offered extra credit, you must provide other options to fulfill the research component if they do not wish to participate.

Classroom incentives will be given to classrooms with at least a 60% response rate. These will include a $100 gift certificate to the teacher for classroom supplies and a pizza party for the class.

SECTION I: PARTICIPANT PRIVACY

Privacy *refers to persons during data collection. It is the control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others (e.g., surveys are completed in the privacy of their own home; interviews will be done in a location of their choosing where it is unlikely they will be overheard).*

1. Describe the provisions to protect the privacy of the participants **during the data collection procedures**.

Participants will complete all questionnaires and the intervention on a computer situated so no other person can see the computer screen. The participants will be given a code number to use during each assessement. The research staff will have a master list that links the code number to the participant. Once the 6 month follow-up data is collected the master list will be destroyed.

SECTION J: CONFIDENTIALITY OF DATA

CONFIDENTIALITY*: Confidentiality refers to how DATA is handled after collection. It is the treatment of information already revealed and states that there is an expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission (e.g., data is secured on a password-protected computer or locked file cabinet, data is de-identified or coded, only the researchers have access to the data).*

1. Provide details as to how you plan to protect the data while on site and during travel (e.g. from data collection site back to the office). When traveling (especially overseas) or just with portable devices, data security is vital, especially if the device or data is lost or stolen. Address the storage and security of electronic data as well as any physical data, such as paper consent forms or surveys, during travel.

All data will be collected via online surveys - it will not be transported as it is electronic.

2. Describe how you will maintain confidentiality of the data after it has been collected, including measures to protect the identity of the participants and their responses (coding procedures, encryption, etc.).

Confidentiality of data will be maintained through the use of a code number. All data collected through electronic means will be delivered directly to the research database upon completion of the survey. The master list of volunteer names and their corresponding code numbers will be confidential and will only be accessible by the principal investigator at BSU. After completion of the post-intervention surveys, the master list will be destroyed.

3. Where will you store the data? A copy of the data must be kept within the campus departmental area, not stored at home. OIT offers virtual servers and storage for BSU researchers, click for more details. Describe procedures for both electronic and hard copy data.

Survey data are collected online and will be kept on a password protected computer in a locked office. The data will be stored on a password protected computer in a locked office at Boise State and will be kept for a minimum of three years.

4. Who will have access to the data?

Only members of the research team will have access to the data through permission from the PI.

5. In what format will the data be stored (e.g., paper or electronic copy)?

The data will be stored in electronic format.

SECTION K: Risks and Benefits

1. What are the risks and inconveniences to the participants? Describe all known anticipated psychological, physical, sociological, financial, economic risk to participants:

   Examples include, but are not limited to:

   ☐ Loss of confidentiality
   ☐ Identifiable links to individual participants
   ☐ Feeling guilty for lying in study requiring deception
   ☒ Emotional stress or discomfort *(describe below)*

   No physical, psychological, legal or economic risks or consequences to the participants are anticipated. Any potential psychological risks posed by the research are primarily related to the sensitivity of some of the measures. Items include thoughts, feelings, and personal difficulties that may be private and personal behavior such as alcohol and other drug use. These questions may make participants uncomfortable, or be perceived as an intrusion on their privacy. Participants are also asked to report on potentially illegal behaviors, such as drinking under the legal drinking age or driving after drinking. However, there is no risk of coercion of individuals, as individuals are free to delete the invitation email should they choose to do so and may discontinue involvement in the study at any time.

   ☐ Physical injury or discomfort *(describe below)*

   ☐ Other:

2. How will you minimize these risks and their impact to the participants?

The primary procedure for guarding against this risk is to fully inform them of their right to refuse to participate in any portion of the study or to discontinue the study altogether. Dr. Susan Esp is a Licensed Clincial Professional Counselor and will be with the students during all assessments and the online intervention will also be prepared to respond in an appropriate and caring manner to any querries by a participant. Participants will also be provided information about follow-up counseling services.

3. Describe how you are able to identify and handle the risks above. Provide a brief description of all relevant training, experience, education, and credentials.

The intervention will be administered by Dr. Susan Esp who is a Licensed Clinical Professional Counselor and is fully trained and licensed to work with students experiencing distress and provide appropriate resources for participants. In addition, this project is similar to several projects conducted by this PI and Dr. Susan Esp with no adverese events. The PI and Co-I have extensive experience working with this population.

In addition, program staff are licensed mental health professionals and are trained to manage any crisis that might occur. Dr. Doumas is a licensed psychologist with over 10 years experience in clinical work. Dr. Esp is a Licensed Clinical Professional Counselor with 15 years experience in clinical work.

4. Describe your plan for an emergency situation. Even if you feel this situation is unlikely, please have a plan in case of emergency (e.g., the researcher will carry a cell phone, etc.).

If a participant were so distressed as to represent a harm to themselves, the participant would be walked to school counselor's office where arrangements would be made to have the police escort the participant to an appropriate facility for an evaluation. Dr. Susan Esp is a Licensed Clinical Professional Counselor - she will be administering the survey and intervention and is trained to evaluate and manage crisis situations. The PI will be available by cellular phone to supervise and manage any crisis that might occur.

5. What are the potential direct benefits to the research participants? (This may not be applicable to your research.)

Participants in the study who are using alcohol may decrease their drinking. Interventions such as those used in this study have been shown in the literature to decrease high-risk drinking and alcohol initiation. Thus, participating in this study has the potential to positively impact students, including those who are at high-risk for alcohol-related consequences.

6. What are the potential broader benefits of the study?

n addition to benefits for participants, the development and implementation of intervention programs for high school students has the potential for reducing the serious public health problem of underage drinking and the negative associated consequences. Given the relatively high rates of heavy drinking in high school, the relationship between high school drinking and drinking in college students and non-college attending young

adults, and the relationship between underage drinking and the development of alcohol use disorders, dissemination of efficacious intervention programs has the potential for significant societal benefits. Given the potential benefit to both individual participants and society, the risks of participation are outweighed.

SECTION L: Unanticipated Problems/Adverse Events

Unanticipated Problem: includes any information that is unexpected, related or possibly related to the research, or indicates that participants or other individuals may be placed at greater risk of harm than initially anticipated by the IRB.

Adverse Event: Any untoward or unfavorable medical occurrence in a human participant, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

If an unanticipated problem or adverse event should occur, you must immediately complete and submit the IRB Incident Report Form to HumanSubjects@boisestate.edu, and contact the Office of Research Compliance at 208.426.5401.

Statistical Analysis Plan

To identify reductions in alcohol use and negative alcohol-related consequences among high school seniors over the duration of the study, we will evaluate each outcome using analysis of variance in a linear or generalized linear mixed model framework, with random effects of repeated observations on students, students nested in classes, periods or teachers, and within school. We will address the appropriateness of the model for non-normal outcomes and apply the appropriate distribution as necessary, and we will assess models for the necessity of all random effects using AIC_C. The fixed effects will include treatment (intervention, control), time (baseline, 6-weeks, and 6-months), and their interaction.