# COVER PAGE
# STUDY PROTOCOL

**Title:** The College, Alcohol and Peers Study (CAPS)
**NCT Number:** NCT03890484
**Document Date:** 7/18/2021

The Human Subjects Division (HSD) strives to ensure that people with disabilities have access to all services and content. **If you experience any accessibility-related issues with this form or any aspect of the application process, email hsdinfo@uw.edu for assistance.**

## INSTRUCTIONS

- **This form is only for studies that will be reviewed by the UW IRB**. Before completing this form, check HSD's website to confirm that this should not be reviewed by an external (non-UW) IRB.
- **If you are requesting a determination** about whether the planned activity is human subjects research or qualifies for exempt status, you may skip all questions except those marked with a ( ). For example **1.1** must be answered.
- **Answer all questions**. If a question is not applicable to the research or if you believe you have already answered a question elsewhere in the application, state "NA" (and if applicable, refer to the question where you provided the information). If you do not answer a question, the IRB does not know whether the question was overlooked or whether it is not applicable. This may result in unnecessary "back and forth" for clarification. Use non-technical language as much as possible.
- To check a box, place an "X" in the box. To fill in a text box, make sure your cursor is within the gray text box bar before typing or pasting text.
- For collaborative or multi-site research, describe only the UW activities unless you are requesting that the UW IRB provide the review and oversight for non-UW collaborators or co-investigators as well.
- You may reference other documents (such as a grant application) if they provide the requested information in non-technical language. Be sure to provide the document name, page(s), and specific sections, and upload it to ***Zipline***. Also, describe any changes that may have occurred since the document was written (for example, changes that you've made during or after the grant review process). In some cases, you may need to provide additional details in the answer space as well as referencing a document.

## INDEX



## 1 OVERVIEW

**Study Title:** Peer Groups and Broad Social Motives' Influence on College Student Drinking: A Multimethod Approach Using Alcohol Administration and Daily Diary

**1.1 Home institution**. Identify the institution through which the lead researcher listed on the IRB application will conduct the research. Provide any helpful explanatory information.

*In general, the home institution is the institution (1) that provides the researcher's paycheck and that considers him/her to be a paid employee, or (2) at which the researcher is a matriculated student. Scholars, faculty, fellows, and students who are visiting the UW and who are the lead researcher: identify your home institution and describe the purpose and duration of your UW visit, as well as the UW department/center with which you are affiliated while at the UW.*

*Note that many UW clinical faculty members are paid employees of non-UW institutions.*

*The UW IRB provides IRB review and oversight for only those researchers who meet the criteria described in the **SOP Use of the UW IRB**.*

University of Washington

**1.2 Consultation history**. Has there been any consultation with someone at HSD about this study?

*It is not necessary to obtain advance consultation. However, if advance consultation was obtained, answering this question will help ensure that the IRB is aware of and considers the advice and guidance provided in that consultation.*

☐ **No**

☒ **Yes** → If yes, briefly describe the consultation: approximate date, with whom, and method (e.g., by email, phone call, in-person meeting).

We consulted with Jeff Love via email on 2/28/20 regarding the modifications to screening. He suggested the modification seemed reasonable and considered appropriate safety of participant contact information. He recommended we submit the modification, however, this did not occur because campus closed due to the pandemic a couple weeks later.

We consulted with Maria Savage via email on in March and April 2021 to consult on COVID safety precautions for our study because participants will not be able to wear masks when eating, drinking, or taking breathalyzers. She consulted with the director of HSD and put us in touch with Ellie from EH&S to develop appropriate safety precautions. We consulted with Lindsay Westlake on 7/12/21 via email to confirm we could update our COVID policies consistent with UW's removal of masking and social distancing for vaccinated individuals.

**1.3 Similar and/or related studies**. Are there any related IRB applications that provide context for the proposed activities?

*Examples of studies for which there is likely to be a related IRB application: Using samples or data collected by another study; recruiting subjects from a registry established by a colleague's research activity; conducting Phase 2 of a multi-part project, or conducting a continuation of another study; serving as the data coordinating center for a multi-site study that includes a UW site.*

*Providing this information (if relevant) may significantly improve the efficiency and consistency of the IRB's review.*

☒ **No**

☐ **Yes** → If yes, briefly describe the other studies or applications and how they relate to the proposed activities. If the other applications were reviewed by the UW IRB, please also provide: the UW IRB number, the study title, and the lead researcher's name.

**1.4 Externally-imposed urgency or time deadlines**. Are there any externally-imposed deadlines or urgency that affect the proposed activity?

*HSD recognizes that everyone would like their IRB applications to be reviewed as quickly as possible. To ensure fairness, it is HSD policy to review applications in the order in which they are received. However, HSD will assign a higher priority to research with externally-imposed urgency that is beyond the control of the researcher. Researchers are encouraged to communicate as soon as possible with their HSD staff contact person when there is an urgent situation (in other words, before submitting the IRB application). Examples: a researcher plans to test an experimental vaccine that has just been developed for a newly emerging epidemic; a researcher has an unexpected opportunity to collect data from students when the end of the school year is only four weeks away.*

*HSD may ask for documentation of the externally-imposed urgency. A higher priority should not be requested to compensate for a researcher's failure to prepare an IRB application in a timely manner. Note that IRB review requires a certain minimum amount of time; without sufficient time, the IRB may not be able to review and approve an application by a deadline.*

☒ **No**

☐ **Yes** → If yes, briefly describe the urgency or deadline as well as the reason for it.

**1.5 Objectives** Using lay language, describe the purpose, specific aims, or objectives that will be met by this specific project. If hypotheses are being tested, describe them. You will be asked to describe the specific procedures in a later section.

If this application involves the use of a HUD "humanitarian" device: describe whether the use is for "on-label" clinical patient care, "off-label" clinical patient care, and/or research (collecting safety and/or effectiveness data).

**Aim 1: Examine relations between BSM, peer group and alcohol-related outcomes.** We will assess how individuals with varying levels of BSM differ in response to peer group influences on drinking and risk-taking behavior using an experimental ad-lib drinking design and daily diary assessments on weekends over a four week period. **Hypotheses:** Those with greater BSM will drink more during ad-lib and will have larger increases in risk-taking than those lower in BSM. Those who are drinking with their close friends, as opposed to new peers, will drink more and have greater increases in risk-taking. Further, those higher in BSM will experience greater risk shift in close friends groups compared to new peers groups, than those lower in BSM.
**Aim 2: Predict drinking behavior during natural observation from behavior observed in lab context.** Observations of drinking and risk-taking in the bar lab will be used as time-invariant, person-level predictors of drinking behavior assessed by daily diary. **Hypotheses:** Higher number of drinks consumed and larger increases in risk-taking in the lab are expected to predict greater increase in drinking behavior on days where most drinking companions are close friends, compared to new peers. Larger increases in risk-taking in the lab are expected to predict greater increase in drinking behavior on days with higher BSM.

**1.6 Study design**. Provide a one-sentence description of the general study design and/or type of methodology.

*Your answer will help HSD in assigning applications to reviewers and in managing workload. Examples: a longitudinal observational study; a double-blind, placebo-controlled randomized study; ethnographic interviews; web scraping from a convenience sample of blogs; medical record review; coordinating center for a multi-site study.*

A multimethod design including an ad-lib alcohol administration paradigm and a 4 week daily diary follow up.

**1.7 Intent**. Check all the descriptors that apply to your activity. You must place an "X" in at least one box.

*This question is essential for ensuring that your application is correctly reviewed. Please read each option carefully.*

| Descriptor |
|---|
| ☐ 1. Class project or other activity whose purpose is to provide an educational experience for the researcher (for example, to learn about the process or methods of doing research). |
| ☐ 2. Part of an institution, organization, or program's own internal operational monitoring. |
| ☐ 3. Improve the quality of service provided by a specific institution, organization, or program. |
| ☒ 4. Designed to expand the knowledge base of a scientific discipline or other scholarly field of study, and produce results that:<br>• Are expected to be applicable to a larger population beyond the site of data collection or the specific subjects studied, or<br>• Are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study. |
| ☐ 5. Focus directly on the specific individuals about whom the information or biospecimens are collected through oral history, journalism, biography, or historical scholarship activities, to provide an accurate and evidence-based portrayal of the individuals. |
| ☐ 6. A quality improvement or program improvement activity conducted to improve the implementation (delivery or quality) of an accepted practice, or to collect data about the implementation of the practice for clinical, practical, or administrative purposes. This does not include the evaluation of the efficacy of different accepted practices, or a comparison of their efficacy. |
| ☐ 7. Public health surveillance activities conducted, requested, or authorized by a public health authority for the sole purpose of identifying or investigating potential public health signals or timely awareness and priority setting during a situation that threatens public health. |
| ☐ 8. Preliminary, exploratory, or research development activities (such as pilot and feasibility studies, or reliability/validation testing of a questionnaire) |
| ☐ 9. Expanded access use of a drug or device not yet approved for this purpose |
| ☐ 10. Use of a Humanitarian Use Device |

☐ 11. Other. Explain:

**1.8 Background, experience, and preliminary work**. Answer this question **only** if the proposed activity has one or more of the following characteristics. The purpose of this question is to provide the IRB with information that is relevant to its risk/benefit analysis.

- Involves more than minimal risk (physical or non-physical)
- Is a clinical trial, or
- Involves having the subjects use a drug, biological, botanical, nutritional supplement, or medical device.

*"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

**a.** Background. Provide the rationale and the scientific or scholarly background for the proposed activity, based on existing literature (or clinical knowledge). Describe the gaps in current knowledge that the project is intended to address.

*This should be a plain language description. Do not provide scholarly citations. Limit your answer to less than one page, or refer to an attached document with background information that is no more than three pages long.*

Alcohol misuse by college students is an important public health problem, associated with a range of serious consequences, including an estimated 1,500 deaths annually. Compared to other types of motives, research shows social drinking motives, such as drinking to be social or to celebrate, have the highest association to drinking in college students. In addition, research on *risk shift* shows individuals engage in risky behavior more frequently in peer groups than when alone. However, some studies have found individuals may become more conservative when in peer groups, suggesting some individuals may be more prone to risk shift than others. Those who are more sensitive to social rewards, or higher in Broad Social Motives (BSM), may be more likely to experience risk shift. Discrepancies in research findings regarding risk shift may also result from unfamiliar peer groups present in lab settings as opposed to naturally occurring groups of friends. This suggests research should focus on understanding both individual differences in risk shift as well as the influence of type of peer group, in both controlled and naturalistic settings.

A peer group factor that may impact drinking is familiarity of drinking companions – whether mostly friends or strangers. Different types of peers have different levels of influence on an individual's drinking, such that proximal peer groups (e.g. best friends, close friends) are better predictors of an individual's own drinking than other same-aged peers. One study suggested a mechanism of risk-shift was an increased preference for immediate rewards. It is likely that familiar friends will produce more positive emotional rewards and increase salience of rewarding effects of alcohol more than new peers, thus we hypothesize close friend groups will be associated with more alcohol consumption relative to new peers. However, to our knowledge this is the first study of risk shift using multiple types of peer groups, and the influence of close peers on alcohol use also likely depends on the individual. Because research suggests individuals with social anxiety may drink more when fearing negative evaluation (potentially from new peers) for stress reducing effects of alcohol, we will include social anxiety as a covariate.

Although research has examined social motives for drinking, less research has focused on which students are sensitive to social rewards more broadly, and the relation of this sensitivity to alcohol use. Studies have labeled this construct Broad Social Motives (BSM). Recently, BSM were shown to be associated with increased drinking and consequences. Thus, it is crucial to use multiple methodologies to evaluate how BSM moderate the effect of peer groups on risk-taking and drinking behavior. This study will use alcohol administration, experimental risk-taking assessments, and daily diary methods to evaluate the relation between BSM, risk shift, and college student drinking.

The present study will evaluate BSM in a sample of college students of legal drinking age (N=100) to assess how those with higher BSM engage in drinking and other risk-taking behaviors in different peer groups. This study will employ two sound scientific methods for testing behavior during drinking events (i.e. lab alcohol administration and daily diary) and use novel strategies to compare results of these two methods in the legal drinking student sample. Using an ad-lib drinking paradigm, students' risk-taking will be assessed alone and after entering one of two randomly assigned peer group conditions (close friends or new peers). Participants then will be allowed to freely drink (within safety limits) prior to again assessing risk-taking. These same students will also complete daily electronic diaries on 4 weekends regarding motives to drink or refrain from drinking, as well as size of social group and relationship to companions when they started drinking, amount, consequences, and duration of alcohol use, and if/how their social group changed during the drinking event.

**b.** Experience and preliminary work. Briefly describe experience or preliminary work or data (if any) that you, your team, or your collaborators/co-investigators have that supports the feasibility and/or safety of this study.

*It is not necessary to summarize all discussion that has led to the development of the study protocol. The IRB is interested only in short summaries about experiences or preliminary work that suggest the study is feasible and that risks are reasonable relative to the benefits. Examples: Your team has already conducted a Phase 1 study of an experimental drug which supports the Phase 2 study being proposed in this application; your team has already done a small pilot study showing that the reading skills intervention described in this application is feasible in an after-school program with classroom aides; your team has experience with the type of surgery that is required to implant the study device; the study coordinator is experienced in working with subjects who have significant cognitive impairment.*

**1.9 Supplements**. Check all boxes that apply, to identify relevant Supplements that should be completed and uploaded to ***Zipline***.

*This section is here instead of at the end of the form to reduce the risk of duplicating information in this IRB Protocol form that you will need to provide in these Supplements.*

| Check all That Apply | Type of Research | Supplement Name |
|---|---|---|
| ☐ | **Department of Defense**<br>The research involves Department of Defense funding, facilities, data, or personnel. | SUPPLEMENT Department of Defense |
| ☐ | **Department of Energy**<br>The research involves Department of Energy funding, facilities, data, or personnel. | SUPPLEMENT Department of Energy |
| ☐ | **Drug, biologic, botanical, supplement** | SUPPLEMENT Drugs |

| | | |
|---|---|---|
| | Procedures involve the use of any drug, biologic, botanical or supplement, even if the item is not the focus of the proposed research | |
| ☐ | **Emergency exception to informed consent**<br>Research that requires this special consent waiver for research involving more than minimal risk | SUPPLEMENT Exception from Informed Consent for Emergency Research (EFIC) |
| ☐ | **Genomic data sharing**<br>Genomic data are being collected and will be deposited in an external database (such as the NIH dbGaP database) for sharing with other researchers, and the UW is being asked to provide the required certification or to ensure that the consent forms can be certified | SUPPLEMENT Genomic Data Sharing |
| ☐ | **Medical device**<br>Procedures involve the use of any medical device, even if the device is not the focus of the proposed research, except when the device is FDA-approved and is being used through a clinical facility in the manner for which it is approved | SUPPLEMENT Devices |
| ☐ | **Multi-site or collaborative study**<br>The UW IRB is being asked to review on behalf of one or more non-UW institutions in a multi-site or collaborative study. | SUPPLEMENT Multi-site or Collaborative Research |
| ☐ | **Non-UW Individual Investigators**<br>The UW IRB is being asked to review on behalf of one or more non-UW individuals who are not affiliated with another organization for the purpose of the research. | SUPPLEMENT Non-UW Individual Investigators |
| ☐ | **Other REDCap Installation Attestation for Electronic Consent**<br>The research will use a non-UW installation of REDCap for conducting and/or documenting informed consent. | SUPPLEMENT Other REDCap Installation |
| ☐ | None of the above | |

**1.10 Confirm by checking the box below** that you will comply with the COVID requirements described on HSD's COVID webpage, which are based on the location of the in-person study procedures and the vaccination status of study team members and study participants.

*Review the HSD website for current guidelines about which in-person research activities are allowable.*

☒ **Confirmed**

## 2 PARTICIPANTS

**2.1 Participants**. Describe the general characteristics of the subject populations or groups, including age range, gender, health status, and any other relevant characteristics.

Participants will be 100 students currently enrolled in a 2- or 4-year college/university and who are between the age of 21 and 24 years old. We expect equal gender representation, as well as racial/ethnic demographics representative of the local area (69.5% white, 7.9% black or African American, 13.8% Asian, 0.8% American

Indian and Alaskan Native, 0.4% Native Hawaiian and other Pacific Islander, 5.1% mixed race, 6.6% Hispanic or Latino of any race).

**2.2 Inclusion and exclusion criteria.**

**a. Inclusion criteria.** Describe the specific criteria that will be used to decide who will be included in the research from among interested or potential subjects. Define any technical terms in lay language.

Between 21 and 24 years old, currently enrolled in college, has consumed 3 or more alcoholic drinks in one sitting at least once in the past month and drinking frequency of once a week.

**b. Exclusion criteria.** Describe the specific criteria that will be used to decide who will be excluded from the research from subjects who meet the inclusion criteria listed above. Define any technical terms in lay language.

No past-month alcohol or other substance dependence, mood or anxiety disorder, suicidal ideation or excessive alcohol use reaching a BAC greater than .30%. No history of serious medical conditions, regular use of prescription psychotropic or pain medication, history of negative reactions to alcohol, history of treatment for alcohol use disorder, pregnancy or nursing. Not fully vaccinated against COVID-19.

**2.3 Prisoners**. IRB approval is required in order to include prisoners in research, even when prisoners are not an intended target population.

Is the research likely to have subjects who become prisoners while participating in the study?

*For example, a longitudinal study of youth with drug problems is likely to have subjects who will be prisoners at some point during the study.*

[X] **No**
[ ] **Yes** → If yes, if a subject becomes a prisoner while participating in the study, will any study procedures and/or data collection related to the subject be continued while the subject is a prisoner?

[ ] **No**
[ ] **Yes** → If yes, describe the procedures and/or data collection that will continue with prisoner subjects

**2.4** Will the proposed research recruit or obtain data from individuals that are known to be prisoners?

*For records reviews: if the records do not indicate prisoner status and prisoners are not a target population, select "No". See the **GUIDANCE Prisoners** for the definition of "prisoner", which is not necessarily tied to the type of facility in which a person is residing.*

[X] **No**
[ ] **Yes** → If yes, answer the following questions (i – iv).

i. Describe the type of prisoners, and their location(s):

ii. One concern about prisoner research is whether the effect of participation on prisoners' general living conditions, medical care, quality of food, amenities, and/or opportunity for earnings in prison will be so great that it will make it difficult for prisoners to adequately consider the research risks. How will the chances of this be reduced?

iii. Describe what will be done to make sure that (a) recruitment and subject selection procedures will be fair to all eligible prisoners and (b) prison authorities or other prisoners will not be able to arbitrarily prevent or require particular prisoners from participating.

iv. If the research is funded by one of these federal departments and agencies (Health & Human Services; Energy; Defense; Homeland Security; CIA; Social Security Administration), and/or will involve prisoners in federal facilities or in state/local facilities outside of Washington State: check the box below to provide assurance that study team members will (a) not encourage or facilitate the use of a prisoner's participation in the research to influence parole or pardon decisions, and (b) clearly inform each prisoner in advance (for example, in a consent form) that participation in the research will have no effect on his or her parole or pardon.

☐ **Confirmed**

**2.5** **Protected populations**. IRB approval is required for the use of the subject populations listed here. Check the boxes for any of these populations that will be purposefully included. (In other words, being a part of the population is an inclusion criterion for the study.)

*The WORKSHEETS describe the criteria for approval but do not need to be completed and should not be submitted.*

| Population | Worksheet |
|---|---|
| ☐ Fetuses in utero | WORKSHEET Pregnant Women |
| ☐ Neonates of uncertain viability | WORKSHEET Neonates |
| ☐ Non-viable neonates | WORKSHEET Neonates |
| ☐ Pregnant women | WORKSHEET Pregnant Women |

**a.** If you check any of the boxes above, use this space to provide any information that may be relevant for the IRB to consider.

**2.6** **Native Americans or non-U.S. indigenous populations.** Will Native American or non-U.S. indigenous populations be actively recruited through a tribe, tribe-focused organization, or similar community-based organization?

*Indigenous people are defined in international or national legislation as having a set of specific rights based on their historical ties to a particular territory and their cultural or historical distinctiveness from other populations that are often politically dominant.*

*Examples: a reservation school or health clinic; recruiting during a tribal community gathering*

☒ **No**

☐ **Yes** → If yes, name the tribe, tribal-focused organization, or similar community-based organization. The UW IRB expects that tribal/indigenous approval will be obtained before beginning the research. This may or may not involve approval from a tribal IRB. The study team and any collaborators/investigators are also responsible for identifying any tribal laws that may affect the research.

**2.7 Third party subjects.** Will the research collect private identifiable information about *other individuals* from the study subjects? Common examples include: collecting medical history information or contact information about family members, friends, co-workers.

*"Identifiable" means any direct or indirect identifier that, alone or in combination, would allow you or another member of the research team to readily identify the person. For example, suppose that the research is about immigration history. If subjects are asked questions about their grandparents but are not asked for names or other information that would allow easy identification of the grandparents, then private identifiable information is not being collected about the grandparents and the grandparents are not subjects.*

☒ **No**

☒ **Yes** → If yes, these individuals are considered human subjects in the study. Describe them and what data will be collected about them.

~~Some participants (N=50) will be asked to recruit 2 friends for the alcohol administration procedures (N=100). Participants must get permission from their friends before providing contact~~

**2.8 Number of subjects.** Is it possible to predict or describe the maximum number of subjects (or subject units) needed to complete the study, for each subject group?

*Subject units mean units within a group. For most research studies, a group will consist of individuals. However, the unit of interest in some research is not the individual. Examples:*

- *Dyads such as caregiver-and-Alzheimer's patient, or parent and child*
- *Families*
- *Other units, such as student-parent-teacher*

*Subject group means categories of subjects that are meaningful for the specific study. Some research has only one subject group – for example, all UW students taking Introductory Psychology. Some common ways in which subjects are grouped include:*

- *By intervention – for example, an intervention group and a control group.*
- *By subject population or setting – for example, urban versus rural families*
- *By age – for example, children who are 6, 10, or 14 years old.*

*The IRB reviews the number of subjects in the context of risks and benefits. Unless otherwise specified, if the IRB determines that the research involves no more than minimal risk: there are no restrictions on the total number of subjects that may be enrolled. If the research involves more than minimal risk: The number of enrolled subjects must be limited to the number described in this application. If it is necessary later to increase the number of subjects, submit a Modification. Exceeding the IRB-approved number (over-enrollment) will be considered non-compliance.*

☐ **No** → If no, provide the rationale in the box below. Also, provide any other available information about the scope/size of the research. You do not need to complete the table.

*Example: It may not be possible to predict the number of subjects who will complete an online survey advertised through Craigslist, but you can state that the survey will be posted for two weeks and the number who respond is the number who will be in the study.*

[X] **Yes**

→ If yes, for each subject group, use the table below to provide the estimate of the maximum desired number of individuals (or other subject unit, such as families) who will complete the research.

| Group name/description | Maximum desired number of individuals (or other subject unit, such as families) who will complete the research<br>***Provide numbers for the site(s) reviewed by the UW IRB and for the study-wide total number; example: 20/100*** |
|---|---|
| New peer condition | 50 |
| Close friend condition | 50 |
| Friends of participants in close friend condition | 100 |
| | |
| | |
| | |

## 3 NON-UW RESEARCH SETTING

***Complete this section only if UW investigators and people named in the SUPPLEMENT: Non-UW Individual Investigators will conduct research procedures outside of UW and Harborview***

**3.1 Reason for locations**. Describe the reason(s) for choosing the locations.

*This is especially important when the research will occur in locations or with populations that may be vulnerable to exploitation. One of the three ethical principles the IRB must consider is justice: ensuring that reasonable, non-exploitative, and well-considered procedures are administered fairly, with a fair distribution of costs and potential benefits.*

**3.2 Local context**. Culturally appropriate procedures and an understanding of local context are an important part of protecting subjects. Describe any site-specific cultural issues, customs, beliefs, or values that may affect the research, how it is conducted, or how consent is obtained or documented.

*Examples: It would be culturally inappropriate in some international settings for a woman to be directly contacted by a male researcher; instead, the researcher may need to ask a male family member for permission before the woman can be approached. It may be appropriate to obtain permission from community leaders prior to obtaining consent from individual members of a group. In some distinct cultural groups, signing forms may not be the norm.*

*This federal site maintains an international list of human research standards and requirements:*
*http://www.hhs.gov/ohrp/international/index.html*

**3.3 Location-specific laws**. Describe any local laws that may affect the research (especially the research design and consent procedures). The most common examples are laws about:

- **Specimens** – for example, some countries will not allow biospecimens to be taken out of the country.
- **Age of consent** – laws about when an individual is considered old enough to be able to provide consent vary across states, and across countries.
- **Legally authorized representative** – laws about who can serve as a legally authorized representative (and who has priority when more than one person is available) vary across states and countries.
- **Use of healthcare records** – many states (including Washington State) have laws that are similar to the federal HIPAA law but that have additional requirements.

**3.4 Location-specific administrative or ethical requirements**. Describe local administrative or ethical requirements that affect the research.

*Example: A school district may require researchers to obtain permission from the head district office as well as school principals before approaching teachers or students; a factory in China may allow researchers to interview factory workers but not allow the workers to be paid for their participation.*

**3.5 If the PI is a student: Does the research involve traveling outside of the US?**

☐ **No**

☐ **Yes** → If yes, confirm by checking the box that (1) you will register with the **UW Office of Global Affairs** before traveling; (2) you will notify your advisor when the registration is complete; and (3) you will request a UW Travel Waiver if the research involves travel to the list of countries requiring a UW Travel Waiver.

☐ **Confirmed**

## 4 RECRUITING and SCREENING PARTICIPANTS

**4.1 Recruiting and Screening**. Describe how subjects will be identified, recruited, and screened. Include information about: how, when, where, and in what setting. Identify who (by position or role, not name) will approach and recruit subjects, and who will screen them for eligibility.

*Note: Per UW Medicine policy, the UW Medicine eCare/MyChart system may not be used for research recruitment purposes.*

Participants will be recruited through direct outreach to UW students between 21 and 24 years old via contact information obtained via the UW Registrar's directory list. The Registrar's office will only provide contact info for students who meet the age requirement but will not provide data on age. Additionally, recruitment will occur through community flyers distributed at colleges in the local area, online advertisements, and word of mouth. Recruitment could take place by supervisors, research assistants,

or participants who have completed the protocol (i.e. snowball sampling). Rolling recruitment and screening will take place over the course of the study.

Interested participants can access the screener through an anonymous link, which takes them to the brief screener information statement and a contact information form. Participants will be asked to provide their name, email, phone number, and local address for screening and study procedures. After providing contact info, participants will be randomly assigned a unique PIN and automatically redirected to the brief screening survey. All screening surveys will only be identified by the PIN. If eligible based on initial screening, participants will be redirected to the online AUDADIS Screener for mental health conflicts. Finally, if eligible after the AUDADIS screener, the participants will be redirected to an Availability survey, which will provide them with a referral link for friend recruitment and ask their availability to schedule the Bar Lab appointment. The dedicated scheduler will review survey responses to verify eligibility.

All eligible participants will be provided with a description of the study, our contact information, and a custom referral link to send to their friends. Friends will be informed of the confidentiality of their responses and the participant's responses. Friends may contact us for questions about the study before deciding. Participants are advised to share their referral link with five to seven close friends who are interested and will be required to recruit two eligible friends. Close friends will have to meet the same inclusion and exclusion criteria as target participants and will go through the same procedures. Participants will not be informed of how their friends are selected. Participants who do not recruit two eligible friends will be considered ineligible and notified by email they were not selected to participate, but will not be given a reason why. Once participants recruit two eligible friends, they are eligible and will be randomly assigned to either the Close Friends or New Peers condition.
~~Interested participants will be contacted via email or phone by a dedicated scheduler, which will be either a research assistant or staff member of the lab. Participants meeting the age requirements will be asked to provide their email and phone number for screening purposes. Participants will be sent two separate emails, one will contain a unique PIN for screening and the second will contain a link to a brief online screening survey, which can be completed in the location of the participant's choosing. If eligible based on initial screening, participants will be redirected to the online AUDADIS Screener for mental health conflicts. The dedicated scheduler will review survey responses to verify eligibility.~~

~~Those in the close friend group will be provided with a description of the study and our contact information to discuss with friends. Friends will be informed of the confidentiality of their responses and the participant's responses, and will be informed the only information participants will provide for them is their contact info and familiarity of their relationship. Friends may contact us for questions about the study before deciding. Participants will then provide contact information (email and phone) for five to seven close friends who are interested and rank them in order of closeness of the relationship. Participants must also confirm their friend gave permission to provide the contact info. Friends with the closest relationship to the participant will be contacted first and we will proceed down the list until two friends are found to be eligible. Close friends will have to meet the same inclusion and exclusion criteria as target participants and will go through the same procedures. Participants will not be informed of how their friends are selected.~~

**4.2 Recruitment materials**.

**a.** What materials (if any) will be used to recruit and screen subjects?

*Examples: talking points for phone or in-person conversations; video or audio presentations; websites; social media messages; written materials such as letters, flyers for posting, brochures, or printed advertisements; questionnaires filled out by potential subjects.*

Recruitment materials will include emails sent to students on the registrar's list, small flyers, large flyers for posting, online advertisements posted on various websites and social media outlets (e.g. Craigslist, Facebook, Instagram, Twitter etc.). Additionally, a printable flyer and email will be used for the recruitment of friends of participants in the close friends condition.

**b.** Upload descriptions of each type of material (or the materials themselves) to ***Zipline***. If letters or emails will be sent to any subjects, these should include a statement about how the subject's name and contact information were obtained. No sensitive information about the person (such as a diagnosis of a medical condition) should be included in the letter. The text of these letters and emails must be uploaded to ***Zipline*** (i.e., a description will not suffice).

*HSD encourages researchers to consider uploading descriptions of most recruitment and screening materials instead of the materials themselves. The goal is to provide the researchers with the flexibility to change some information on the materials without submitting a Modification for IRB approval of the changes. Examples:*

- *Provide a list of talking points that will be used for phone or in-person conversations instead of a script.*
- *For the description of a flyer, include the information that it will provide the study phone number and the name of a study contact person (without providing the actual phone number or name). This means that a Modification would not be necessary if/when the study phone number or contact person changes. Also, instead of listing the inclusion/exclusion criteria, the description below might state that the flyer will list one or a few of the major inclusion/exclusion criteria.*
- *For the description of a video or a website, include a description of the possible visual elements and a list of the content (e.g., study phone number; study contact person; top three inclusion/exclusion criteria; payment of $50; study name; UW researcher).*

**4.3 Relationship with participant population**. Do any members of the study team have an existing relationship with the study population(s)?

*Examples: a study team member may have a dual role with the study population (for example, being their clinical care provider, teacher, laboratory directory or tribal leader in addition to recruiting them for his/her research).*

[X] **No**

[ ] **Yes** → If yes, describe the nature of the relationship.

**4.4 Payment to participants**. The IRB must evaluate subject payment for the possibility that it will unduly influence subjects to participate. Refer to GUIDANCE Subject Payment when designing subject payment plans. Provide the following information about your plans for paying research subjects in the text box below or note that the information can be found in the consent form.

- The total amount/value of the payment
- Schedule/timing of the payment [i.e., when will subjects receive the payment(s)]
- Purpose of the payment [e.g., reimbursement, compensation, incentive]
- Whether payment will be "pro-rated" so that participants who are unable to complete the research may still receive some part of the payment

*The IRB expects the consent process or study information provided to the subjects to include all of the above-listed information about payment, including the number and amount of payments, and especially when subjects can expect to receive payment. One of the most frequent complaints received by HSD is from subjects who expected to receive cash or a check on the day that they completed a study and who were angry or disappointed when payment took 6-8 weeks to reach them.*

Participants who complete the brief screener will be entered into a monthly drawing for a $100 Amazon gift card. Participants will be compensated $10 for taking the AUDADIS screener. They will be compensated for their time in the bar at $15/hour with an expected maximum time of 8.5 hours. During daily diary participants will be paid $2 for each survey completed during the four week daily diary period. Additionally, a weekly bonus will be provided to participants who complete at least 80% of surveys. The first week's bonus will be $2, then $4 the second week, $6 the third week, and $8 the 4th week for up to $20 in bonus'. Participants are expected to be paid between $70-$200 but payment will be prorated to the exact amount the participant earned even if outside this range.

Friends will be offered the same compensation by entering the monthly drawing for the $100 gift card after the brief screener. Then additional compensation for study procedures are $10 for the AUDADIS screener and $15/hour during alcohol administration. Friends will not complete daily diary assessments. Friends are expected to be paid between $45-$150 but payment will be prorated to the exact amount the participant earned even if outside this range.~~Participants will be compensated $10 for taking the AUDADIS screener. They will be compensated for their time in the bar at $15/hour with an expected maximum time of 8.5 hours. During daily diary participants will be paid $2 for each survey completed during the four week daily diary period. Additionally, a bonus of $10 will be provided to participants who complete at least 80% of surveys. A participants are expected to be paid between $70-$200.~~

~~Friends will be offered the same compensation of $10 for the AUDADIS screener and $15/hour during alcohol administration. Friends will not complete daily diary assessments. Friends are expected to be paid between $45-$150.~~

**4.5 Non-monetary compensation**. Describe any non-monetary compensation that will be provided. Example: extra credit for students; a toy for a child. If class credit will be offered to students, there must be an alternate way for the students to earn the extra credit without participating in the research.

N/A

**4.6 Will data or specimens be accessed or obtained for recruiting and screening procedures prior to enrollment?**

*Examples: names and contact information; the information gathered from records that were screened; results of screening questionnaires or screening blood tests; Protected Health Information (PHI) from screening medical records to identify possible subjects.*

[ ] **No** → If no, skip the rest of this section; go to question **5.1**.

[X] **Yes** → If yes, describe the data and/or specimens (including PHI) and whether it will be retained as part of the study data.

Name, email ~~and~~ phone number, and local address~~s~~ will be collected prior to screening. The brief screener will consist of self-report measures to assess demographics, past-week depression, anxiety, past-moth alcohol use and other substance use, and health conflicts with alcohol. The AUDADIS Screener will assess for past-month alcohol use disorder, mood or anxiety disorders. Screening data will be retained as part of the study data to investigate potential bias on key variables in the eligible sample.~~Screening data will be retained for eligible participants only. Data for participants who are ineligible based on screening will be permanently deleted after all appropriate communication (e.g. clinical calls) has been completed.~~

**4.7 Consent for recruiting and screening**. Will consent be obtained for any of the recruiting and screening procedures? (Section 8: Consent of Adults asks about consent for the main study procedures).

*"Consent" includes: consent from individuals for their own participation; parental permission; assent from children; consent from a legally authorized representative for adult individuals who are unable to provide consent.*

*Examples:*

- *For a study in which names and contact information will be obtained from a registry: the registry should have consent from the registry participants to release their names and contact information to researchers.*
- *For a study in which possible subjects are identified by screening records: there will be no consent process.*
- *For a study in which individuals respond to an announcement and call into a study phone line: the study team person talking to the individual may obtain non-written consent to ask eligibility questions over the phone.*

[ ] **No** → If no, skip the rest of this section; go to question **5.1**.

[X] **Yes** → If yes, describe the consent process.

Student recruited through the registrar's list will have provided consent for their directory information to be released. All participants regardless of recruitment method will be provided with an information statement about the study and screening process.

**a**. Documentation of consent. Will a written or verifiable electronic signature from the subject on a consent form be used to document consent for the **recruiting and screening procedures**?

[X] **No** → If no, describe the information that will be provided during the consent process and for which procedures.

The information statement will provide a brief description of the purpose of the study, expectations for participation, compensation, and expectations for the online screener.

[ ] **Yes, written** → If yes, and a **written** signature will be used to document consent:

- Upload the consent form to ***Zipline***.

[ ] **Yes, electronic** → If yes, and an **electronic** signature will be used to document consent:

- Upload the consent form to ***Zipline***.
- **If the eSignature process or method for recruiting and screening is different than for the main study procedures**, use the questions about electronic consent in Section 8.3 and 8.4 to differentiate between recruiting/screening and main study electronic consent. **If electronic consent will be used for recruiting/screening but not main study consent**, use 8.3 and 8.4 to describe eConsent and note that it is only for recruiting/screening.

## 5 PROCEDURES

**5.1 Study procedures**. Using lay language, provide a complete description of the study procedures, including the sequence, intervention or manipulation (if any), drug dosing information (if any), blood volumes and frequency of draws (if any), use of records, time required, and setting/location. If it is available: Upload a study flow sheet or table to ***Zipline***.

*For studies comparing standards of care: It is important to accurately identify the research procedures. See UW IRB* ***POLICY Risks of Harm from Standard Care*** *and the draft guidance from the federal Office of Human Research Protections,* ***"Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care";*** *October 20, 2014.*
*Information about pediatric blood volume and frequency of draws that would qualify for expedited review can be found in this* **reference table** *on the Seattle Children's IRB website.*

Participant flow through the protocol is attached in the supporting documents. All measures on each survey are outlined in the next question.

Participants (N=100) will be recruited through direct outreach to UW students over the age of 21 obtained via the UW Registrar's directory list, as well as community flyers distributed at colleges in the local area, online advertisements, and word of mouth. Participants will complete screening measures online. Eligible participants will be asked to recruit five to seven of their close friends. Close friends will have to meet the same inclusion and exclusion criteria as target participants and will go through the same procedures as target participants during alcohol administration. Eligible participants will be stratified on sex, age, and past 30-day peak alcohol use and randomly assigned to one of two conditions: close friends (N=50), where participants will participate with ~~recruit~~ two of their existing friends, or new peers (N=50), where participants will participate~~drink~~ with two undergraduate confederates. ~~To ensure at least two eligible friends, those in the close friend group will be asked to provide email and phone numbers of five to seven close friends. Close friends will have to meet the same inclusion and exclusion criteria as target participants and will go through the same procedures as target participants during alcohol administration.~~ For each pair of participants matched on the three strata (age, sex, alcohol use), confederate drinkers in the new peer group will be matched to the sex of the close friends of the other matched participant's group.

The first session will take place in the bar lab in Guthrie Hall in the UW psychology department. Participants will be asked not to travel to the bar together to ensure they are not exposed to their peer group before entry to the bar, and must get to the lab without operating any vehicle with wheels (e.g. car, bike). Upon arriving to the lab, all participants and peers will review and sign the consent form, and provide a baseline breath alcohol content (BrAC) reading. Female participants and friends will also be asked to take a urine pregnancy test. Participants and friends will complete baseline measures and the Balloon Analogue Risk Task (BART) individually prior to entry to the bar. Participants will be taught the procedures for the daily diary portion of the study (see below). Participants will join their close friends or new peers in the bar and be given 20 minutes to relax while the researcher prepares the materials. After entering groups but prior to receiving alcohol, participants and peers will complete pre-alcohol

measures and the BART. They will then be allowed to order anything from the bar menu for the following hour. Participants and close friends will be allowed to drink freely within limits (BrAC = .12%), for safety. During ad-lib, estimated BAC levels based on age, sex, and weight will be calculated prior to each drink served to ensure the safety of consuming each drink (calculations for BAC can be found in 'CAPS BAC & Ad-Lib Drinking Tracking Form') without interrupting social interaction and making the participant's BAC more salient by taking BrAC readings regularly. Participants or close friends whose BAC may exceed .12% will only be served placebo beverages for the remainder of the hour. Confederate peers (aka research assistants) will only be served placebo beverages and will be instructed to match the drinking behavior of the participant to avoid influencing the drinking of participants. BrAC readings will be taken at the end of ad-lib, every 10 minutes until peak BrAC is reached and readings are descending, and every 30 minutes thereafter. After ad-lib, participants will complete post-alcohol measures and the BART, then provided entertainment until they reach a BAC below .03%. The full protocol will take approximately 2.5 hours. On average, alcohol metabolizes at a rate of .015% per hour, so a participant who reaches .12% will be in the lab on average 8.5 hours. Once sober, participants and friends will be paid for their time in the bar at a rate of $15 per hour, and will be taken home in a taxi or ride share service (e.g. Uber, Lyft). Close friends will not complete the following daily diary protocols.

Daily diary measures will start one week after each participant's alcohol administration appointment and be collected for potential drinking events on Thursday, Friday, and Saturday over the following four consecutive weeks. On each day, participants will be notified of surveys by text message at 4 pm before potential drinking events and the following morning at 11am (Friday, Saturday, and Sunday). Afternoon assessments will measure BSM, motives to drink, motives to refrain from drinking, where they plan to spend their evening, and what type of peers they plan to spend the evening with (e.g. close friends, new peers, family, alone). The morning after each night, participants will retrospectively report amount of drinks and other substances consumed, time spent drinking, and consequences they experienced while drinking or are currently experiencing the morning after drinking. Participants will be prompted to answer the following questions about the composition of their social group when they started drinking: size (i.e. number of people they had direct contact with), number of drinking companions of a given peer type (e.g. close friends, new peers, family), and gender composition of the group (same-sex vs. mixed-sex). Participants will then be asked how many times their social group changed during the event defined as the majority of their drinking companions being of a different peer type than before. For instance, a participant may be at a house party with primarily close friends, but someone invites several people the participant does not know well and they are now drinking with mostly new peers. For each change reported, participants will be asked to describe their social group size, relationships, and gender composition again. On non-drinking evenings, participants will report similar information regarding their social groups and other activities. It will take approximately 5 weeks for each participant to complete the full protocol. After completion of the daily diary phase, participants will be debriefed on the study via phone call and compensated. Participants will be given electronic gift cards for their compensation.

**5.2 Recordings**. Does the research involve creating audio or video recordings?

- [X] **No** → If no, go to question **5.3**.
- [ ] **Yes** → If yes, verify that you have described what will be recorded in 5.1 and answer question **a**.

**a**. Before recording, will consent for being recorded be obtained from subjects and any other individuals who may be recorded?

- [ ] **No** → If no, email hsdinfo@uw.edu before submitting this application in Zipline. In the email, include a brief description of the research and a note that individuals will be recorded without their advance consent.
- [ ] **Yes**

**5.3 MRI scans.** Will any subjects have a Magnetic Resonance Imaging (MRI) scan as part of the study procedures?

*This means scans that are performed solely for research purposes or clinical scans that are modified for research purposes (for example, using a gadolinium-based contrast agent when it is not required for clinical reasons).*

[X] **No** → If no, go to question **5.4**.
[ ] **Yes** → If yes, answer questions **a** through **c**.

**a. Describe the MRI scan(s).** Specifically:

- What is the purpose of the scan(s)? *Examples: obtain research data; safety assessment associated with a research procedure.*
- Which subjects will receive an MRI scan?
- Describe the minimum and maximum number of scans per subject, and over what time period the scans will occur. *For example: all subjects will undergo two MRI scans, six months apart.*

**b. MRI facility**. At which facility(ies) will the MRI scans occur? Check all that apply.

- [ ] UWMC Radiology/Imaging Services (the UWMC clinical facility)
- [ ] DISC Diagnostic Imaging Sciences Center (UWMC research facility)
- [ ] CHN Center for Human Neuroscience MRI Center (Arts & Sciences research facility)
- [ ] BMIC Biomolecular Imaging Center (South Lake Union research facility)
- [ ] Harborview Radiology/Imaging Services (the Harborview clinical facility)
- [ ] SCCA Imaging Services
- [ ] Northwest Diagnostic Imaging
- [ ] Other: identify in the text box below:

**c. Personnel.** For MRI scans that will be conducted at the DISC, CHN or BMIC research facilities: Indicate who will be responsible for operating the MRI scanner by checking all that apply.

- [ ] MRI technician who is formally qualified
- [ ] Researcher who has completed scanner operator training provided by a qualified MRI operator

**5.4 Data variables.** Describe the specific data that will be obtained (including a description of the most sensitive items). Alternatively, a list of the data variables may be uploaded to ***Zipline***.

Brief screening survey: Demographics, Alcohol Use Disorders Identification Test, Depression Anxiety Stress Scale, past 30 day peak alcohol use, COVID-19 vaccination and behaviors, serious medical conditions, regular use of prescription psychotropic or pain medication, history of negative reactions to alcohol, history of treatment for alcohol use disorder, pregnancy or nursing.

AUDADIS screening survey: Alcohol Use Disorder and Associated Disabilities Interview Schedule (includes alcohol and other substance use disorders, mood disorders, anxiety disorders, and suicidal ideation),

Baseline: Broad social motives, drinking motives, alcohol consequences, descriptive and injunctive norms of typical college student, affect, ~~social anxiety,~~ social anxiety, Balloon Analogue Risk Task, Time Line Follow Back 30-day.

Pre-alcohol: Broad social motives, affect, descriptive and injunctive norms of peer group, perception of peer group, Balloon Analogue Risk Task.

Post-alcohol: Broad social motives, affect, perception of peer group, Balloon Analogue Risk Task, number of standard drinks consumed.

**5.5 Data sources.** For all types of data that will be accessed or collected for this research: Identify whether the data are being obtained from the subjects (or subjects' specimens) or whether they are being obtained from some other source (and identify the source).

*If you have already provided this information in Question 5.1, you do not need to repeat the information here.*

All information will be collected from the subjects.

**5.6 Identifiability of data and specimens**. Answer these questions carefully and completely. This will allow HSD to accurately determine the type of review that is required and the relevant compliance requirements. Review the following definitions before answering the questions:

***Access*** *means to view or perceive data, but not to possess or record it. See, in contrast, the definition of "obtain".*
***Identifiable*** *means that the identity of an individual is or may be readily (1) ascertained by the researcher or any other member of the study team from specific data variables or from a combination of data variables, or (2) associated with the information.*
***Direct identifiers*** *are direct links between a subject and data/specimens. Examples include (but are not limited to): name, date of birth, medical record number, email or IP address, pathology or surgery accession number, student number, or a collection of data that is (when taken together) identifiable.*
***Indirect identifiers*** *are information that links between direct identifiers and data/specimens. Examples: a subject code or pseudonym.*
***Key*** *refers to a single place where direct identifiers and indirect identifiers are linked together so that, for example, coded data can be identified as relating to a specific person. Example: a master list that contains the data code and the identifiers linked to the codes.*
***Obtain*** *means to possess or record in any fashion (writing, electronic document, video, email, voice recording, etc.) for research purposes and to retain for any length of time. This is different from* ***accessing****, which means to view or perceive data.*

**a.** Will you or any members of your team have access to any direct or indirect identifiers?

[X] **Yes** → If yes, describe which identifiers and for which data/specimens.

The PIs and dedicated scheduler will have access to identifiers used in the recruitment and screening process including: name, phone number, ~~and~~ email, and local address.

[ ] **No** → If no, select the reason(s) why you (and all members of your team) will not have access to direct or indirect identifiers.

- [ ] There will be no identifiers.
- [ ] Identifiers or the key have been (or will have been) destroyed before access.
- [ ] There is an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to study team members under any circumstances.

*This agreement should be available upon request from the IRB. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.*

☐ There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

☐ There are other legal requirements prohibiting the release of the identifiers or key. Describe them below.

**b.** Will you or any study team members obtain any direct or indirect identifiers?

☒ **Yes** → If yes, describe which identifiers and for which data/specimens.

Name, phone number, ~~and~~ email, and local address will be collected for all participants and participants' nominated friends for the purpose of screening and study proceedures.

☐ **No** → If no, select the reason(s) why you (and all members of your team) will not obtain direct or indirect identifiers.

☐ There will be no identifiers.

☐ Identifiers or the key have been (or will have been) destroyed before access.

☐ There will be an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) under any circumstances.

*This agreement should be available upon request from the IRB. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.*

☐ There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

☐ There are other legal requirements prohibiting the release of the identifiers or key. Describe them below.

**c.** If any identifiers will be obtained, indicate how the identifiers will be stored (and for which data). NOTE: Do not describe the data security plan here – that information is requested in section 9.6.

☐ Identifiers will be stored with the data. Describe the data to which this applies:

☒

Identifiers and study data will be stored separately but a link will be maintained between the identifiers and the study data (for example, through the use of a code). Describe the data to which this applies:

Identifiers will be linked to personal identification numbers (PINs). Only the PIN will be used for data collection so no identifiers are directly linked to data. This applies to all study data.

☐ Identifiers and study data will be stored separately, with no link between the identifiers and the study data. Describe the data to which this applies:

**d. Research collaboration**. Will individuals who provide coded information or specimens for the research also collaborate on other activities for this research? If yes, identify the activities and provide the name of the collaborator's institution/organization.

*Examples include but are not limited to: (1) study, interpretation, or analysis of the data that results from the coded information or specimens; and (2) authorship on presentations or manuscripts related to this work.*

No

**5.7 Protected Health Information (PHI).** Will participants' identifiable PHI be accessed, obtained, used, or disclosed for any reason (for example, to identify or screen potential subjects, to obtain study data or specimens, for study follow-up) that does not involve the creation or obtaining of a Limited Data Set?

*PHI is individually identifiable healthcare record information or clinical specimens from an organization considered a "covered entity" by federal HIPAA regulations, in any form or media, whether electronic, paper, or oral.* ***You must answer yes to this question if the research involves identifiable health care records (e.g., medical, dental, pharmacy, nursing, billing, etc.), identifiable healthcare information from a clinical department repository, or observations or recordings of clinical interactions.***

☒ **No** → If no, skip the rest of this question; go to question **5.8**

☐ **Yes** → If yes, answer all of the questions below.

**a.** Describe the PHI and the reason for using it. *Be specific. For example, will any "free text" fields (such as physician notes) be accessed, obtained, or used?*

**b.** Is any of the PHI located in Washington State?

☐ **No**
☐ **Yes**

**c.** Describe the pathway of how the PHI will be accessed or obtained, starting with the source/location and then describing the system/path/mechanism by which it will be identified, accessed, and copied for the research. *Be specific. For example: directly view records; search through a department's clinical database; submit a request to Leaf.*

**d.** For which PHI will subjects provide HIPAA authorization before the PHI is accessed, obtained and/or used?

Confirm by checking the box that the UW Medicine HIPAA Authorization form maintained on the HSD website will be used to access, obtain, use, or disclose any UW Medicine PHI.

☐ **Confirmed**

e. Will you obtain any HIPAA authorizations electronically (i.e., e-signature)?

☐ **No**

☐ **Yes**

If 'Yes', confirm by checking the box that you have read and understand the 'Special Considerations' section of the **GUIDANCE Electronic Informed Consent** for information regarding the use of electronic signatures and HIPAA authorizations.

☐ **Confirmed**

**f**. For which PHI will HIPAA authorization NOT be obtained from the subjects?

Provide the following assurances by checking the boxes.

☐ The minimum necessary amount of PHI to accomplish the purposes described in this application will be accessed, obtained and/or used.

☐ The PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.

☐ The HIPAA "accounting for disclosures" requirement will be fulfilled, if applicable. See UW Medicine Compliance Policy #104.

☐ There will be reasonable safeguards to protect against identifying, directly or indirectly, any patient in any report of the research.

**5.8 Genomic data sharing**. Will the research obtain or generate genomic data?

☒ **No**

☐ **Yes** → If yes, answer the question below.

**a.** Will genomic data from this research be sent to a national database (for example, NIH's dbGaP database)?

☐ **No**
☐ **Yes** → If yes, complete the **SUPPLEMENT Genomic Data Sharing** and upload it to ***Zipline***.

**5.9 Whole genome sequencing.** For research involving biospecimens: Will the research include whole genome sequencing?

*Whole genome sequencing is sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.*

☒ **No**
☐ **Yes**

**5.10 Possible secondary use or sharing of information, specimens, or subject contact information.** Is it likely that the obtained or collected information, specimens, or subject contact information will be used for any of the following:

- Future research not described in this application (in other words, secondary research)
- Submission to a repository, registry, or database managed by the study team, colleagues, or others for research purposes
- Sharing with others for their own research

**Please consider the broadest possible future plans and whether consent will be obtained now from the subjects for future sharing or research uses** (which it may not be possible to describe in detail at this time). Answer **YES** even if future sharing or uses will use de-identified information or specimens. Answer **NO** if sharing is unlikely or if the only sharing will be through the NIH Genomic Data Sharing described in question 5.8.

*Many federal grants and contracts now require data or specimen sharing as a condition of funding, and many journals require data sharing as a condition of publication. "Sharing" may include (for example): informal arrangements to share banked data/specimens with other investigators; establishing a repository that will formally share with other researchers through written agreements; or sending data/specimens to a third party repository/archive/entity such as the Social Science Open Access Repository (SSOAR), or the UCLA Ethnomusicology Archive.*

☐ **No**
☒ **Yes** → If yes, answer all of the questions below.

**a.** Describe what will be stored for future use, including whether any direct or indirect (e.g., subject codes) identifiers will be stored.

All data with only indirect identifiers (PIN) will be stored. Direct identifiers will be stored with date and location of visit for four weeks after the bar lab visit for the purpose of contact tracing in the event of COVID-19 exposure. Direct identifiers with the link to participant PIN will be stored for the required retention period but not used for future research.
~~No direct identifiers will be stored past the length of the participant's involvement in the study.~~

**b.** Describe what will be shared with other researchers or with a repository/database/registry, including whether direct identifiers will be shared and (for specimens) what data will be released with the specimens.

All data with only indirect identifiers (PIN) will be shared to ClinicalTrails.gov as a requirement of conducting clinical trials according to the NIH definitions of clinical trials.

A visitors log including name, phone number, email, the building location will be shared with UW Environmental Health & Safety and/or public officials if requested for the purpose of contact tracing. No other study data will be stored with this visitors log.

**c.** Who will oversee and/or manage the sharing?

The primary PI of the clinical trial will oversee the sharing of data.

**d.** Describe the possible future uses, including limitations or restrictions (if any) on future uses or users. As stated above, consider the broadest possible uses.

*Examples: data will be used only for cardiovascular research; data will not be used for research on population origins.*

Data will be used only for research on alcohol use.

**e.** Consent. Will consent be obtained now from subjects for the secondary use, banking and/or future sharing?

[ ] **No**

[X] **Yes** → If yes, be sure to include the information about this consent process in the consent form (if there is one) and in the answers to the consent questions in Section 8.

**f.** Withdrawal. Will subjects be able to withdraw their data/specimens from secondary use, banking or sharing?

[X] **No**

[ ] **Yes** → If yes, describe how, and whether there are any limitations on withdrawal.

*Example: data can be withdrawn from the repository but cannot be retrieved after they are released.*

**g.** Agreements for sharing or release. Confirm by checking the box that the sharing or release will comply with UW (and, if applicable, UW Medicine) policies that require a formal agreement with the recipient for release of data or specimens to individuals or entities other than federal databases.

*Data Use Agreements or Gatekeeping forms are used for data; Material Transfer Agreements are used for specimens (or specimens plus data). Do not attach any template agreement forms; the IRB neither reviews nor approves them*

[X] **Confirmed**

**5.11 Communication with subjects during the study**. Describe the types of communication (if any) the research team will have with already-enrolled subjects during the study. Provide a description instead of the actual materials themselves.

*Examples: email, texts, phone, or letter reminders about appointments or about returning study materials such as a questionnaire; requests to confirm contact information.*

A link to screening questionnaires will be included in all online advertisements or sent by email to those on the Registrar's list. Scheduling of the bar lab appointment will be done by email or phone call. Email and text messages will be used for appointment reminders. Daily diary questionnaires will be sent by email or text. ~~Initial contact and confirmation of contact info will occur by phone or email. Screening~~

~~questionnaires will be sent by email. Friends will be contacted by phone call to confirm interest and will be subsequently sent the screener by email. Scheduling of the bar lab appointment will be done by email or phone call. Email and text messages will be used for appointment reminders. Daily diary questionnaires will be sent by email.~~

**5.12 Future contact with subjects**. Is there a plan to retain any contact information for subjects so that they can be contacted in the future?

[X] **No**
[ ] **Yes** → If yes, describe the purpose of the future contact, and whether use of the contact information will be limited to the study team; if not, describe who else could be provided with the contact information. Describe the criteria for approving requests for the information.

*Examples: inform subjects about other studies; ask subjects for additional information or medical record access that is not currently part of the study proposed in this application; obtain another sample.*

**5.13 Alternatives to participation.** Are there any alternative procedures or treatments <u>that might be advantageous</u> to the subjects?

*If there are no alternative procedures or treatments, select "No". Examples of advantageous alternatives: earning extra class credit in some time-equivalent way other than research participation; obtaining supportive care or a standard clinical treatment from a health care provider instead of participating in research with an experimental drug.*

[X] **No**
[ ] **Yes** → If yes, describe the alternatives.

**5.14 Upload to *Zipline*** all data collection forms (if any) that will be directly used by or with the subjects, and any scripts/talking points that will be used to collect the data. Do not include data collection forms that will be used to abstract data from other sources (such as medical or academic records), or video recordings.

- ***Examples**: survey, questionnaires, subject logs or diaries, focus group questions.*
- ***NOTE:** Sometimes the IRB can approve the general content of surveys and other data collection instruments rather than the specific form itself. This prevents the need to submit a modification request for future minor changes that do not add new topics or increase the sensitivity of the questions. To request this general approval, use the text box below to identify the questionnaires/surveys/ etc. for which you are seeking this more general approval. Then briefly describe the scope of the topics that will be covered and the most personal and sensitive questions. The HSD staff person who screens this application will let you know whether this is sufficient or whether you will need to provide more information.*
- ***For materials that cannot be uploaded**: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. You may also provide URLs (website addresses) or written descriptions below. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*
- ***For data that will be gathered in an evolving way**: This refers to data collection/questions that are not pre-determined but rather are shaped during interactions with participants in response to observations and responses made during those interactions. If this applies to the proposed research, provide a description of the process by which the data collection/questions will be established during the interactions with subjects, how the data collection/questions will be documented, the topics likely to be addressed, the most sensitive type of information likely to be gathered, and the limitations (if any) on topics that will be raised or pursued.*

Use this text box (if desired) to provide:

- Short written descriptions of materials that cannot be uploaded, such as URLs
- A description of the process that will be used for data that will be gathered in an evolving way.
- The general content of questionnaires, surveys and similar instructions for which general approval is being sought. (See the **NOTE** bullet point in the instructions above.)

The balloon analogue risk-task is a computer based task that measures risk-taking. Information about this task is available in the following publication:

Lejuez, C. W., Read, J. P., Kahler, C. W., Richards, J. B., Ramsey, S. E., Stuart, G. L., … Brown, R. A. (2002). Evaluation of a behavioral measure of risk taking: The Balloon Analogue Risk Task (BART). *Journal of Experimental Psychology: Applied*, *8*(2), 75–84. https://doi.org/10.1037//1076-898X.8.2.75

**5.15 SARS-CoV-2 testing**. Will the subjects be tested for the SARS-CoV-2 coronavirus?

*If the only testing is to screen the subjects (question 2.8), you do not need to answer this question*

[X] **No**

[ ] **Yes** → If yes:

- Name the testing lab
- Confirm that the lab and its use of this test is CLIA-certified or certified by the Washington State Department of Health
- Describe whether you will return the results to the participants and, if yes, who will do it and how (including any information you would provide to subjects with positive test results).

## 6 CHILDREN (MINORS) and PARENTAL PERMISSION

**6.1 Involvement of minors**. Does the research include minors (children)?

**Minor or child** means someone who has not yet attained the legal age for consent for the research procedures, as described in the applicable laws of the jurisdiction in which the research will be conducted. This may or may not be the same as the definition used by funding agencies such as the National Institutes of Health.

- In Washington State the generic age of consent is 18, meaning that anyone under the age of 18 is considered a child.
- There are some procedures for which the age of consent is much lower in Washington State.
- The generic age of consent may be different in other states, and in other countries.

[X] **No** → If no, go to Section 8.

[ ] **Yes** → If yes, provide the age range of the minor subjects for this study and the legal age for consent in the study population(s). If there is more than one answer, explain.

[ ] **Don't know** →This means is it not possible to know the age of the subjects. For example, this may be true for some research involving social media, the Internet, or a dataset that is obtained from another researcher or from a government agency. Go to Section 8.

**6.2 Parental permission. Parental permission** means actively obtaining the permission of the parents. This is not the same as "passive" or "opt out" permission where it is assumed that parents are allowing their children to participate because they have been provided with information about the research and have not objected or returned a form indicating they don't want their children to participate.

**a.** Will parental permission be obtained for:

☐ All of the research procedures → Go to question **6.2b.**

☐ None of the research procedures → Use the table below to provide justification, and skip question 6.2b.

☐ Some of the research procedures → Use the table below to identify the procedures for which parental permission will not be obtained.

*Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.*

| Children Group[1] | Describe the procedures or data/specimen collection (if any) for which there will be NO parental permission[2] | Reason why parental permission will not be obtained | Will parents be informed about the research?[3] YES | NO |
|---|---|---|---|---|
| | | | ☐ | ☐ |
| | | | ☐ | ☐ |
| | | | ☐ | ☐ |
| | | | ☐ | ☐ |
| | | | ☐ | ☐ |
| | | | ☐ | ☐ |

*Table footnotes*

1. *If the answer is the same for all children groups or all procedures: collapse the answer across the groups and/or procedures.*
2. *If identifiable information or biospecimens will be obtained without parent permission, any waiver granted by the IRB does not override parents' refusal to provide broad consent (for example, through the Northwest Biotrust).*
3. *Will parents be informed about the research beforehand even though active permission is not being obtained?*

**b.** Indicate the plan for obtaining parental permission. One or both boxes must be checked.

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

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

*This is all that is required for minimal risk research.*

If both boxes are checked, explain:

**6.3 Children who are wards.** Will any of the children be wards of the State or any other agency, institution, or entity?

☐ **No**
☐ **Yes** → If yes, an advocate may need to be appointed for each child who is a ward. The advocate must be in addition to any other individual acting on behalf of the child as guardian or in loco parentis. The same individual can serve as advocate for all children who are wards.

Describe who will be the advocate(s). The description must address the following points:

- Background and experience
- Willingness to act in the best interests of the child for the duration of the research
- Independence of the research, research team, and any guardian organization

**6.4 UW Office for Youth Programs Development and Support.** If the project involves interaction (in-person or remotely) with individuals under the age of 18, researchers must comply with **UW Administrative Policy Statement 10.13** and the requirements listed at this website. This includes activities that are deemed to be Not Research or Exempt. It does not apply to third-party led research (i.e., research conducted by a non-UW PI). Information and FAQs for researchers are available.

**This point is advisory only; there is no need to provide a response.**

## 7 ASSENT OF CHILDREN (MINORS)

*Go to Section 8 if your research does not involve children (minors).*

**7.1 Assent of children (minors)**. Though children do not have the legal capacity to "consent" to participate in research, they should be involved in the process if they are able to "assent" by having a study explained to them and/or by reading a simple form about the study, and then giving their verbal choice about whether they want to participate. They may also provide a written assent if they are older. See **WORKSHEET Children** for circumstances in which a child's assent may be unnecessary or inappropriate.

**a.** Will assent be obtained for:

| | |
|---|---|
| ☐ All research procedures and child groups | → Go to question **7.2.** |
| ☐ None of the research procedures and child groups | → Use the table below to provide justification, then skip to question **7.6** |
| ☐ Some of your research procedures and child groups | → Use the table below to identify the procedures for which assent will not be obtained. |

*Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.*

| Children Group[1] | Describe the procedures or data/specimen collection (if any) for which assent will NOT be obtained | Reason why assent will not be obtained |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |

*Table footnotes*

1. *If the answer is the same for all children groups or all procedures, collapse your answer across the groups and/or procedures.*

**7.2 Assent process.** Describe how assent will be obtained, for each child group. If the research involves children of different ages, answer separately for each group. If the children are non-English speakers, include a description of how their comprehension of the information will be evaluated.

**7.3 Dissent or resistance.** Describe how a child's objection or resistance to participation (including non-verbal indications) will be identified during the research, and what the response will be.

**7.4 E-consent.** Will any electronic processes (email, websites, electronic signatures, etc.) be used to present assent information to subjects/and or to obtain documentation (signatures) of assent? If yes, describe how this will be done.

**7.5 Documentation of assent.** Which of the following statements describes whether documentation of assent will be obtained?

| | |
|---|---|
| ☐ None of the research procedures and child groups | → Use the table below to provide justification, then go to question **7.5.b** |
| ☐ All of the research procedures and child groups | → Go to question **7.5.a**, do not complete the table |
| ☐ Some of the research procedures and/or child groups | → Complete the table below and then to go question **7.5.a** |

| Children Group[1] | Describe the procedures or data/specimen collection (if any) for which assent will NOT be documented |
|---|---|
| | |
| | |
| | |

*Table footnotes*

1. *If the answer is the same for all children groups or all procedures, collapse the answer across the groups and/or procedures.*

**a. Describe how assent will be documented**. If the children are functionally illiterate or are not fluent in English, include a description of the documentation process for them.

**b. Upload all assent materials** (talking points, videos, forms, etc.) to ***Zipline***. Assent materials are not required to provide all of the standard elements of adult consent; the information should be appropriate to the age, population, and research procedures. The documents should be in Word, if possible.

**7.6 Children who reach the legal age of consent during participation in longitudinal research.**

Children who were enrolled at a young age and continue for many years: It is best practice to re-obtain assent (or to obtain it for the first time, if it was not obtained at the beginning of their participation).
Children who reach the legal age of consent: Informed consent must be obtained from the now-adult subject for (1) any ongoing interactions or interventions with the subjects, or (2) the continued analysis of specimens or data for which the subject's identify is readily identifiable to the researcher, unless the IRB waives this requirement.

**a.** Describe the plans (if any) to re-obtain assent from children.

**b.** Describe the plans (if any) to obtain consent for children who reach the legal age of consent.

- If adult consent will be obtained from them, describe what will happen regarding now-adult subjects who cannot be contacted.
- If consent will not obtained or will not be possible: explain why.

**7.7 Other regulatory requirements**. (This is for information only; no answer or response is required.) Researchers are responsible for determining whether their research conducted in schools, with student records, or over the Internet comply with permission, consent, and inspection requirements of the following federal regulations:

- PPRA – Protection of Pupil Rights Amendment
- FERPA – Family Education Rights and Privacy Act
- COPPA – Children's Online Privacy Protection Act

## 8 CONSENT OF ADULTS

**Review the following definitions before answering the questions in this section.**

| | |
|---|---|
| **CONSENT** | is the process of informing potential subjects about the research and asking them whether they want to participate. It does not necessarily include the signing of a consent form. |
| **CONSENT DOCUMENTATION** | refers to how a subject's decision to participate in the research is documented. This is typically obtained by having the subject sign a consent form. |
| **CONSENT FORM** | is a document signed by subjects, by which they agree to participate in the research as described in the consent form and in the consent process. |
| **ELEMENTS OF CONSENT** | are specific information that is required to be provided to subjects. |
| **CHARACTERISTICS OF CONSENT** | are the qualities of the consent process as a whole. These are:<br>• Consent must be legally effective.<br>• The process minimizes the possibility of coercion or undue influence.<br>• Subjects or their representatives must be given sufficient opportunity to discuss and consider participation.<br>• The information provided must:<br>  ○ Begin with presentation of key information (for consent materials over 2,000 words)<br>  ○ Be what a reasonable person would want to have<br>  ○ Be organized and presented so as to facilitate understanding<br>  ○ Be provided in sufficient detail<br>  ○ Not ask or appear to ask subjects to waive their rights |
| **PARENTAL PERMISSION** | is the parent's active permission for the child to participate in the research. Parental permission is subject to the same requirements as consent, including written documentation of permission and required elements. |
| **SHORT FORM CONSENT** | is an alternative way of obtaining written documentation of consent that is most commonly used with individuals who are illiterate or whose language is one for which translated consent forms are not available. |
| **WAIVER OF CONSENT** | means there is IRB approval for not obtaining consent or for not including some of the elements of consent in the consent process.<br><br>**NOTE**: If you plan to obtain identifiable information or identifiable biospecimens without consent, any waiver granted by the IRB does not override a subject's refusal to provide broad consent (for example, the Northwest Biotrust). |
| **WAIVER OF DOCUMENTATION OF CONSENT** | means that there is IRB approval for not obtaining written documentation of consent. |

**8.1 Groups** Identify the groups to which the answers in this section apply.

[X] Adult subjects

☐ Parents who are providing permission for their children to participate in research

→ *If you selected **PARENTS**, the word "consent" below should also be interpreted as applying to parental permission and "subjects" should also be interpreted as applying to the parents.*

**8.2 The consent process and characteristics**. This series of questions is about whether consent will be obtained for all procedures except recruiting and screening and, if yes, how.

*The issue of consent for recruiting and screening activities is addressed in question 4.7. You do not need to repeat your answer to question 4.6.*

**a**. Are there any procedures for which consent will not be obtained?

☒ **No**

☐ **Yes** → If yes, use the table below to identify the procedures for which consent will not be obtained. "All" is an acceptable answer for some studies.

*Be sure to consider all research procedures and plans, including future contact, and sharing/banking of data and specimens for future work.*

| Group[1] | Describe the procedures or data/specimen collection (if any) for which there will be NO consent process | Reason why consent will not be obtained | Will subjects be provided with info about the research after they finish? YES | NO |
|---|---|---|---|---|
| | | | ☐ | ☐ |
| | | | ☐ | ☐ |
| | | | ☐ | ☐ |
| | | | ☐ | ☐ |
| | | | ☐ | ☐ |

*Table footnotes*

1. *If the answer is the same for all groups, collapse your answer across the groups and/or procedures.*

**b.** Describe the consent process**,** if consent will be obtained for any or all procedures, for any or all groups. Address groups and procedures separately if the consent processes are different.

*Be sure to include:*

- *The location/setting where consent will be obtained*
- *Who will obtain consent (refer to positions, roles, or titles, not names)*
- *How subjects will be provided sufficient opportunity to discuss the study with the research team and consider participation*

All participants will provide written consent in the bar lab before completing any procedures. Graduate student supervisors and research assistants will be available in person for any questions or concerns about the study. Contact information for the PIs will be provided for any questions supervisors cannot answer.

**c.** Comprehension**.** Describe the methods that will be used to ensure or test the subjects' understanding of the information during the consent process.

Participants will be given adequate time to fully read the consent form at their own pace and verbally asked if they understand the consent form or have any questions.

**d.** Influence**.** Does the research involve any subject groups that might find it difficult to say "no" to participation because of the setting or their relationship with someone on the study team, even if they aren't pressured to participate?

*Examples: Student participants being recruited into their teacher's research; patients being recruited into their healthcare provider's research, study team members who are participants; outpatients recruited from an outpatient surgery waiting room just prior to their surgery.*

[X] **No**

[ ] **Yes** → If yes, describe what will be done to reduce any effect of the setting or relationship on the participation decision.

*Examples: a study coordinator will obtain consent instead of the subjects' physician; the researcher will not know which subjects agreed to participate; subjects will have two days to decide after hearing about the study.*

**e.** Information provided is tailored to needs of subject population. Describe the basis for concluding that the information that will be provided to subjects (via written or oral methods) is what a *reasonable member of the subject population(s)* would want to know. If the research consent materials contain a key information section, also describe the basis for concluding that the information presented in that section is that which is *most likely* to assist the selected subject population with making a decision. See **GUIDANCE Key Information for Consent Materials**.

*For example: Consultation with publications about research subjects' preferences, disease-focused nonprofit groups, patient interest groups, or other researchers/study staff with experience with the specific population. It may also involve directly consulting selected members of the study population.*

Consultation with experts whom have studied college students over the previous 30+ years and consultation with two current senior UW undergraduate students. No other specific populations will be included in this sample.

**f.** Ongoing process. For research that involves multiple or continued interaction with subjects over time, describe the opportunities (if any) that will be given to subjects to ask questions or to change their minds about participating.

Verbally participants may ask questions prior to signing the consent form and during the training for daily diary assessments following alcohol administration procedures. During informed consent, participants will be made aware that they may opt out of the study at any point during the study. All materials sent to participants including screening, scheduling, reminders and daily diary assessments will include contact information for the PIs so that participants may contact them at any time to ask further questions or opt out of the study.

**8.3 Electronic presentation of consent information.** Will any part of the consent-related information be provided electronically for some or all of the subjects?

*This refers to the use of electronic systems and processes instead of (or in addition to) a paper consent form. For example, an emailed consent form, a passive or an interactive website, graphics, audio, video podcasts. See GUIDANCE Electronic Informed Consent for information about electronic consent requirements at UW.*

| | | |
|---|---|---|
| X | **No** | → If no, skip to question 8.4 |
| | **Yes** | → If yes, answer questions **a** through **e** |

**a**. Describe the electronic consent methodology and the information that will be provided.

*All informational materials must be made available to the IRB. Website content should be provided as a Word document. It is considered best practice to give subjects information about multi-page/multi-screen information that will help them assess how long it will take them to complete the process. For example, telling them that it will take about 15 minutes, or that it involves reading six screens or pages.*

**b.** Describe how the information can be navigated (if relevant). *For example, will the subject be able to proceed forward or backward within the system, or to stop and continue at a later time?*

**c**. In a standard paper-based consent process, the subjects generally have the opportunity to go through the consent form with study staff and/or to ask study staff about any question they may have after reading the consent form. Describe what will be done, if anything, to facilitate the subject's comprehension and opportunity to ask questions when consent information is presented electronically. Include a description of any provisions to help ensure privacy and confidentiality during this process.

*Examples: hyperlinks, help text, telephone calls, text messages or other type of electronic messaging, video conference, live chat with remotely located study team members.*

**d**. What will happen if there are individuals who wish to participate but who do not have access to the consent methodology being used, or who do not wish to use it? Are there alternative ways in which they can obtain the information, or will there be some assistance available? If this is a clinical trial, these individuals cannot be excluded from the research unless there is a compelling rationale.

*For example, consider individuals who lack familiarity with electronic systems, have poor eyesight or impaired motor skills, or who do not have easy email or internet access.*

**e**. How will the research team ensure continued accessibility of consent materials and information during the study?

**f**. How will additional information be provided to subjects during the research, including any significant new findings (such as new risk information) If this is not an issue, explain why.

**8.4 Written documentation of consent.** Which of the statements below describe whether documentation of consent will be obtained? NOTE: This question does not apply to screening and recruiting procedures which have already been addressed in question 4.7.

*Documentation of consent that is obtained electronically is not considered written consent unless it is obtained by a method that allows verification of the individual's signature. In other words, saying "yes" by email is rarely considered to be written documentation of consent*

**a.** Is written documentation of consent being obtained for:

| | |
|---|---|
| ☐ None of the research procedures | → Use the table below to provide justification then go to question **8.5.** |
| ☒ All of the research procedures | → Do not complete the table; go to question **8.4.b.** |
| ☐ Some of the research procedures | → Use the table below to identify the procedures for which written documentation of consent will not be obtained from adult subjects. |

| Adult subject group[1] | Describe the procedures or data/specimen collection (if any) for which there will be NO documentation of consent | Will they be provided with a written statement describing the research (optional)? YES | NO |
|---|---|---|---|
| | | ☐ | ☐ |

| | | |
|---|---|---|
| | ☐ | ☐ |
| | ☐ | ☐ |
| | ☐ | ☐ |
| | ☐ | ☐ |

*Table footnotes*

1. *If the answer is the same for all adult groups or all procedures, collapse the answer across the groups and/or procedures.*

**b. Electronic consent signature.** For studies in which documentation of consent will be obtained: will subjects use an electronic method to provide their consent signature?

- *See the GUIDANCE Electronic Informed Consent for information about options (including REDCap e-signature and the DocuSign system) and any associated requirements.*
- *FDA-regulated studies must use a system that complies with the FDA's "Part 11" requirements about electronic systems and records. Note that the UW-IT supported DocuSign e-signature system does not meet this requirement.*
- *Having subjects check a box at the beginning of an emailed or web-based questionnaire is not considered legally effective documentation of consent.*

☒ **No**

☐ **Yes** → If yes, indicate which methodology will be used.

☐ **UW ITHS REDCap**

☐ **Other REDCap installation** → Please name the institutional version you will be using (e.g. Vanderbilt, Univ. of Cincinnati) in the field below and provide a completed **SUPPLEMENT Other REDCap Installation** with your submission.

☐ **UW DocuSign**

☐ **Other** → Please describe in the field below and provide a signed **TEMPLATE Other E-signature Attestation Letter** with your submission.

**b.1** Is this method legally valid in the jurisdiction where the research will occur?
*NOTE: UW ITHS REDCap and UW DocuSign have been vetted for compliance with WA State and federal laws regarding electronic signatures.*

☐ **No**

☐ **Yes** → If yes, what is the source of information about legal validity?

**b.2** Will verification of the subject's identity be obtained if the signature is not personally witnessed by a member of the study team? Note that this is required for FDA-regulated studies.

*See the GUIDANCE Electronic Informed Consent for information and examples*

☐ **No** →If no, provide the rationale for why this is not required or necessary to protect subjects or the integrity of the research. Also, what would be the risks to the actual subject if somebody other than the intended signer provides the consent signature?

☐ **Yes** →If yes, describe how subject identity will be verified, providing a non- technical description that the reviewer will understand.

**b.3** How will the requirement be met to provide a copy of the consent information (consent form) to individuals who provide an e-signature?

*The copy can be paper or electronic and may be provided on an electronic storage device or via email. If the electronic consent information uses hyperlinks or other websites or podcasts to convey information specifically related to the research, the information in these hyperlinks should be included in the copy provided to the subjects and the website must be maintained for the duration of the entire study.*

**8.5 Non-English-speaking or -reading adult subjects**. Will the research enroll adult subjects who do not speak English or who lack fluency or literacy in English?

☒ **No**

☐ **Yes** → If yes, describe the process that will be used to ensure that the oral and written information provided to them during the consent process and throughout the study will be in a language readily understandable to them and (for written materials such as consent forms or questionnaires) at an appropriate reading/comprehension level.

**a.** Interpretation. Describe how interpretation will be provided, and when. Also, describe the qualifications of the interpreter(s) – for example, background, experience, language proficiency in English and in the other language, certification, other credentials, familiarity with the research-related vocabulary in English and the target language.

**b.** Translations. Describe how translations will be obtained for all study materials (not just consent forms). Also, describe the method for ensuring that the translations meet the UW IRB's requirement that translated documents will be linguistically accurate, at an appropriate reading level for the participant population, and culturally sensitive for the locale in which they will be used.

**8.6 Barriers to written documentation of consent**. There are many possible barriers to obtaining written documentation of consent. Consider, for example, individuals who are functionally illiterate; do not read English well; or have sensory or motor impairments that may impede the ability to read and sign a consent form.

**a.** Describe the plans (if any) for obtaining written documentation of consent from potential subjects who may have difficulty with the standard documentation process (that is, reading and signing a consent form). Skip this question if written documentation of consent is not being obtained for any part of the research.

*Examples of solutions: Translated consent forms; use of the Short Form consent process; reading the form to the person before they sign it; excluding individuals who cannot read and understand the consent form.*

Since much of data collection will be conducted by reading and understanding written materials, participants who cannot provide written consent will not be included in the study.

**8.7 Deception**. Will information be deliberately withheld, or will false information be provided, to any of the subjects?

*Note: "Blinding" subjects to their study group/condition/arm is not considered to be deception, but not telling them ahead of time that they will be subject to an intervention or about the purpose of the procedure(s) is deception.*

☐ **No**

☒ **Yes** → If yes, describe what information and why.

*Example: It may be necessary to deceive subjects about the purpose of the study (describe why).*

Participants in the new peer groups will be informed they are drinking with other participants but those new peers will actually be confederate research assistants, who are drinking placebo beverages. Confederates will be used so that groups in the new peer condition can be matched to the close friend groups for gender composition, which is known to influence drinking behavior and is necessary to control for between conditions.

**a.** Will subjects be informed beforehand that they will be unaware of or misled regarding the nature or purposes of the research? (Note: this is not necessarily required.)

☒ **No**

☐ **Yes**

**b.** Will subjects be debriefed later? (Note: this is not necessarily required.)

☐ **No**

☒ **Yes** → If yes, describe how and when this will occur. Upload any debriefing materials, including talking points or a script, to ***Zipline***.

Deception debriefing will take place after participants have completed the alcohol administration protocol and reached a BAC below .03%. Supervisors will verbally explain the deception and a written debriefing sheet will be provided to the participants

**8.8 Cognitively impaired adults, and other adults unable to consent.** Will such individuals be included in the research?

*Examples: individuals with Traumatic Brain Injury (TBI) or dementia; individuals who are unconscious, or who are significantly intoxicated.*

☒ **No** → If no, go to question **8.9**.

☐ **Yes** → If yes, answer the following questions.

**a.** Rationale. Provide the rationale for including this population.

**b.** Capacity for consent / decision making capacity. Describe the process that will be used to determine whether a cognitively impaired individual is capable of consent decision making with respect to the research protocol and setting.

**b.1.** If there will be repeated interactions with the impaired subjects over a time period when cognitive capacity could increase or diminish, also describe how (if at all) decision-making capacity will be re-assessed and (if appropriate) consent obtained during that time.

**c.** Permission (surrogate consent). If the research will include adults who cannot consent for themselves, describe the process for obtaining permission ("surrogate consent") from a legally authorized representative (LAR).

*For research conducted in Washington State, see the **GUIDANCE Legally Authorized Representative** to learn which individuals meet the state definition of "legally authorized representative".*

**d**. Assent. Describe whether assent will be required of all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not (and why not). Describe any process that will be used to obtain and document assent from the subjects.

**e.** Dissent or resistance. Describe how a subject's objection or resistance to participation (including non-verbal) during the research will be identified, and what will occur in response.

**8.9 Research use of human fetal tissue obtained from elective abortion.** Federal and UW Policy specify some requirements for the consent process. If you are conducting this type of research, check the boxes to confirm these requirements will be followed.

- ☐ Informed consent for the donation of fetal tissue for research use will be obtained by someone other than the person who obtained the informed consent for abortion.
- ☐ Informed consent for the donation of fetal tissue for research use will be obtained after the informed consent for abortion.
- ☐ Participation in the research will not affect the method of abortion.
- ☐ No enticements, benefits, or financial incentives will be used at any level of the process to incentivize abortion or the donation of human fetal tissue.
- ☐ The informed consent form for the donation of fetal tissue for use in research will be signed by both the

woman and the person who obtains the informed consent.

**8.10 Consent-related materials**. Upload to ***Zipline*** all consent scripts/talking points, consent forms, debriefing statements, Information Statements, Short Form consent forms, parental permission forms, and any other consent-related materials that will be used. Materials that will be used by a specific site should be uploaded to that site's **Local Site Documents** page.

- *Translations must be submitted and approved before they can be used. However, we strongly encourage you to wait to provide them until the IRB has approved the English versions.*
- *Combination forms: It may be appropriate to combine parental permission with consent, if parents are subjects as well as providing permission for the participation of their children. Similarly, a consent form may be appropriately considered an assent form for older children.*
- *For materials that cannot be uploaded: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. URLs (website addresses) may also be provided, or written descriptions of websites. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*

## 9 PRIVACY AND CONFIDENTIALITY

**9.1 Privacy protections.** Describe the steps that will be taken, if any, to address possible privacy concerns of subjects and potential subjects.

*Privacy refers to the sense of being in control of access that others have to ourselves. This can be an issue with respect to recruiting, consenting, sensitivity of the data being collected, and the method of data collection.*
*Examples:*

- *Many subjects will feel a violation of privacy if they receive a letter asking them to participate in a study because they have ____ medical condition, when their name, contact information, and medical condition were drawn from medical records without their consent. Example: the IRB expects that "cold call" recruitment letters will inform the subject about how their information was obtained.*
- *Recruiting subjects immediately prior to a sensitive or invasive procedure (e.g., in an outpatient surgery waiting room) will feel like an invasion of privacy to some individuals.*
- *Asking subjects about sensitive topics (e.g. details about sexual behavior) may feel like an invasion of privacy to some individuals.*

Participants will be fully informed of the range of items and the most sensitive and personal assessment items in the consent form, and will be informed that they are free not to answer any question they wish not to answer, and can refuse to participate or withdraw from the study at any time without penalty. Additionally, all data will be identified only by a personal identification number (PIN). Separate PINs for screening and participation will be assigned to keep self-reported health data separate from study data. Participants completing the study with friends will be informed the only information provided about each other is the familiarity of their relationship. Assessments completed in the group will be done on a laptop computer, so friends cannot see or hear each other's responses. Participants will be instructed not to share their responses or scores on tasks. Friends will be informed that the participants are nominating several friends and will not know how friends are selected, so they will not be able to discern if a friend was ineligible. Participants will be encouraged to contact the investigators at any time to discuss any concerns they might have

**9.2 Identification of individuals in publications and presentations**. Will potentially identifiable information about subjects be used in publications and presentations, or is it possible that individual identities could be inferred from what is planned to be published or presented?

[X] **No**

☐ **Yes** → If yes, will subject consent be obtained for this use?

☐ **Yes**

☐ **No** → If no, describe the steps that will be taken to protect subjects (or small groups of subjects) from being identifiable.

**9.3** **State mandatory reporting.** Each state has reporting laws that require some types of individuals to report some kinds of abuse, and medical conditions that are under public health surveillance. These include:

- Child abuse
- Abuse, abandonment, neglect, or financial exploitation of a vulnerable adult
- Sexual assault
- Serious physical assault
- Medical conditions subject to mandatory reporting (notification) for public health surveillance

Are you or a member of the research team likely to learn of any of the above events or circumstances while conducting the research **AND** feel obligated to report it to state authorities?

☒ **No**

☐ **Yes** → If yes, the UW IRB expects subjects to be informed of this possibility in the consent form or during the consent process, unless you provide a rationale for not doing so:

**9.4** **Retention of identifiers and data.** Check the box below to indicate assurance that any identifiers (or links between identifiers and data/specimens) and data that are part of the research records will not be destroyed until after the end of the applicable records retention requirements (e.g. Washington State; funding agency or sponsor; Food and Drug Administration). If it is important to say something about destruction of identifiers (or links to identifiers) in the consent form, state something like "the link between your identifier and the research data will be destroyed after the records retention period required by state and/or federal law."

*This question can be left blank for conversion applications (existing paper applications that are being "converted" into a Zipline application.)*

*See the "Research Data" sections of the following website for UW Records management for the Washington State research rectords retention schedules that apply in general to the UW (not involving UW Medicine data):*
***http://f2.washington.edu/fm/recmgt/gs/research?title=R***

*See the "Research Records and Data" information in Section 8 of this document for the retention schedules for UW Medicine Records:* ***https://www.uwmedicine.org/recordsmanagementuwm-records-retention-schedule.pdf***

☒ **Confirm**

**9.5** **Certificates of Confidentiality**. Will a federal Certificate of Confidentiality be obtained for the research data?
*NOTE: Answer "No" if the study is funded by NIH or the CDC, because all NIH-funded and CDC-funded studies automatically have a Certificate.*

☒ **No**

☐ **Yes**

**9.6 Data and specimen security protections**. Identify the data classifications and the security protections that will be provided for all sites where data will be collected, transmitted, or stored, referring to the **GUIDANCE Data and Security Protections** for the minimum requirements for each data classification level. ***It is not possible to answer this question without reading this document. Data security protections should not conflict with records retention requirements.***

**a.** Which level of protections will be applied to the data and specimens? If more than one level will be used, describe which level will apply to which data and which specimens and at which sites.

The data collected during screening could be considered level 3 because we collect self-reported health data for conditions that may conflict with alcohol consumption. All other study data would be considered level 2. However, all data will be stored de-identified. Due to the method of web-based data collection proposed, it is necessary to collect contact information (i.e. email and phone number) and store data as it is being collected on a secure server. Two separate PINs will be used for screening data and for study data. A master contact sheet will provide the only link between identifiers and PINs. This will be stored in a user-specified Shared folder on a secure and password protected server and on a folder on the PI's Microsoft 365 OneDrive for business. This folder will only be shared with study staff, graduate students, and dedicated schedulers working on the study. OneDrive for Business is HIPPA and FERPA compliant. Additionally, after each week of data collection, data for that week will be downloaded as a data file and saved to the secured server. ~~This will be stored in a user-specified Larimer Shared folder on a secure and password protected server.~~ Additionally, after each week of data collection, data for that week will be downloaded as a data file and saved to the secured server. Access to the Shared folder and secured server both ~~Larimer file~~ requires user authentication, with access limited to those with limited group membership and designated by the PI. The server is protected by the UW network and firewalls. Security on the server is at the highest standards and meets all federal HIPAA regulations and Washington State laws. Because the server is for the Department of Psychiatry and Behavioral Sciences, within the School of Medicine, the server is separate (and includes additional protections) from the general UW computing infrastructure. The use of this secure method of housing data is preferable to having data available on only one standalone computer, in that when a dataset is transferred (e.g., to an investigator for data analysis) via flash drives, DVDs, or alternative storage methods there is greater risk of loss, damage, or breach of confidentiality than when a highly secure network is used. Additionally, each computer within the School of Medicine, including all computers within CSHRB, is required to be password-protected. There will be written documentation on who has access to the data and that they have received training in confidentiality and security. To gain access to the data all individuals will sign an agreement on use, storage, and confidentiality of the data.

**b.** Use this space to provide additional information, details, or to describe protections that do not fit into one of the levels. If there are any protections within the level listed in 9.6.a which will *not* be followed, list those here, including identifying the sites where this exception will apply.

## 10 RISK / BENEFIT ASSESSMENT

**10.1 Anticipated risks**. Describe the reasonably foreseeable risks of harm, discomforts, and hazards to the subjects and others of the research procedures. For each harm, discomfort, or hazard:

- Describe the magnitude, probability, duration, and/or reversibility of the harm, discomfort, or hazard, AND
- Describe how the risks will be reduced or managed. Do not describe data security protections here, these are already described in Question 9.6.

- *Consider possible physical, psychological, social, legal, and economic harms, including possible negative effects on financial standing, employability, insurability, educational advancement or reputation. For example, a breach of confidentiality might have these effects.*
- *Examples of "others": embryo, fetus, or nursing child; family members; a specific group.*
- *Ensure applicable risk information from any Investigator Brochures, Drug Package Inserts, and/or Device Manuals is included in your description.*
- *Do not include the risks of non-research procedures that are already being performed.*
- *If the study design specifies that subjects will be assigned to a specific condition or intervention, then the condition or intervention is a research procedure - even if it is a standard of care.*
- *Examples of mitigation strategies: inclusion/exclusion criteria; applying appropriate data security measures to prevent unauthorized access to individually identifiable data; coding data; taking blood samples to monitor something that indicates drug toxicity.*
- *As with all questions on this application, you may refer to uploaded documents.*

Several steps will be taken to protect participants against potential risks posed by participation in this research. First, participants will be fully informed of the range of items and the most sensitive and personal assessment items in the consent form, and will be informed that they are free not to answer any question they wish not to answer, and can refuse to participate or withdraw from the study at any time without penalty. Additionally, all data will be identified only by a personal identification number (PIN). Participants completing the study with friends will be informed the only information provided about each other is the familiarity of their relationship. Assessments completed in the group will be done on a laptop computer, so friends cannot see or hear each other's responses. Participants will be instructed not to share their responses or scores on tasks. Friends will be informed that the participants are nominating several friends and will not know how friends are selected, so they will not be able to discern if a friend was ineligible. Participants will be encouraged to contact the investigators at any time to discuss any concerns they might have.

Additionally, participants will be screened for characteristics that may endanger them if consuming alcohol. This includes past-month alcohol or other substance use disorders, past-month mood or anxiety disorders, suicidal ideation, excessive alcohol use (BAC >.30%) in past 30 days, serious medical conditions, regular use of prescription psychotropic or pain medication, history of negative reactions to alcohol, history of treatment for alcohol or substance use disorders, pregnancy or nursing. Dr. Larimer and Ms. Canning will be responsible for follow-up assessment and referral of individuals expressing suicidal ideation or significant psychological distress. A clinically trained graduate student, supervised by Dr. Larimer, will immediately follow-up by telephone with participants indicating past-month alcohol or other substance use disorder, mood disorder, anxiety disorder, or suicidal ideation to assess their level of risk and refer them for care. Assessment of suicide risk, referral and follow-up of suicidal individuals, facilitation of inpatient placement for acutely suicidal individuals, and reporting requirements involved in threats of imminent harm to self are all part of Dr. Larimer's ordinary clinical duties as an attending clinician at the UW medical center and the inpatient and outpatient psychiatry clinics at UWMC, thus in the extremely unlikely event of a severe adverse psychological reaction, could facilitate inpatient admission. We have previously used these procedures in a variety of studies to ensure participant safety.

Participants are also required to report at least one occasion of consuming 3 or more drinks in one sitting within the last month and a drinking frequency of at least once per week to ensure they are comfortable consuming alcohol and will be consuming alcohol at some point during daily assessments. In the event a participant experiences discomfort due to alcohol consumption, a PI or graduate student with clinical training will be present or on call to provide assessment and referral to resources if necessary. In the event a participant reports feeling discomfort, they will be assessed for level of discomfort and provided food, water and a quiet place to rest. Participants in discomfort will be reminded they may opt out of participating but will be asked to stay in the lab until their BAC reaches below 0.03%. Should the participant feel they need medical attention, emergency services will be contacted. Participant whose BAC reaches above .12% in the lab will be assessed for their level of discomfort. Participants not reporting discomfort will be eligible to continue participation in the study so long as they continue feeling well. Participants who report some level of discomfort will be offered food, water and a quiet place to rest. They will be reminded they may opt out of participation for as long as they do not feel well but will be asked to stay in the lab until they reach a BAC below 0.03%. For participants who report high levels of discomfort and request medical attention, emergency services will be contacted.

During in-person data collection participant will be at an increased risk of exposure to COVID-19. Thus, participants will be screener for COVID-19 vaccinations and required to self-report being fully vaccinated (e.g., 2 weeks after the final dose of whichever vaccine they received). Additionally, lab personnel are required to be in compliance with UW vaccine attestation policy. All shared lab space will be equipped with hand sanitizer and sanitizing wipes to be used before, during, and after the procedures.

All participants will be required to stay in the lab until their BrAC has dropped below 0.03%. After peak intoxication, BrAC readings will be taken every 30 minutes and participants will be provided with entertainment (e.g. Netflix, board games etc.), food and non-alcoholic drinks. Participants will be reminded they are paid for their time including the time it takes to reach a BrAC of 0.03% and will be provided a free ride home using a taxi or ride-share service (e.g. Uber or Lyft) to ensure safe transportation. Prior to their bar lab visit, participants will be informed they must stay in the lab until they reach a 0.03% BrAC and are told they will be in the lab for the full evening (as late as midnight) and should not make plans following their lab visit. A clinically trained graduate student, who has been trained in principles of motivational interviewing, will be present to speak with any resistant participants. Should a participant attempt to leave prior to reaching a BrAC of 0.03%, campus police will be contacted to either a) escort the participant back to the lab if they agree to stay or b) take other necessary action to ensure the participant's safety. Note that this situation is exceedingly rare—participants are paid for their time waiting in the lab, are well aware of this requirement prior to their participation, and are generally happy to remain. Nonetheless, procedures are in place to handle this situation if it should arise.

Timeline Follow Back assessments and alcohol use assessments reported during daily diary reports will estimate BAC using number of standard drinks consumed, time spent drinking, sex, age, and weight. If a participants estimated BAC exceeds .30%, the PI will be notified immediately. Participants who reported a BAC greater than .30% will be contacted by a clinically trained graduate student and informed of the risk of lethality at doses above.30%, and provided with appropriate referrals. Participants who report an excessive BAC greater than .30% in the past 30 days at screening will be ineligible for participation and will additionally receive these resources.

Finally, participants will be debriefed after the completion of the study to address the deception used during alcohol administration procedures. Some participants will be drinking with undergraduate confederates and not peers. The use of confederates to match important group characteristics of the

close friend condition (i.e. group size and sex composition) is necessary to control for potential confounds, which are shown to affect group decision making. Participants will be informed their peers were not consuming alcohol and were trained to match their drinking behavior. They will be informed this was necessary to ensure the study did not interfere with their drinking and we could collect accurate results. Any questions they have regarding this deception will be address and participants will be provided contact information for the UW IRB should the participant feel they were harmed by this deception.

**10.2 Reproductive risks**. Are there any risks of the study procedures to men and women (who are subjects, or partner of subjects) related to pregnancy, fertility, lactation or effects on a fetus or neonate?

*Examples: direct teratogenic effects; possible germline effects; effects on fertility; effects on a woman's ability to continue a pregnancy; effects on future pregnancies.*

[ ] **No** → If no go to question 10.3

[X] **Yes** → If yes, answer the following questions:

**a. Risks**. Describe the magnitude, probability, duration and/or reversibility of the risks.

Drinking alcohol while pregnant or nursing can cause birth defects

**b. Steps to minimize risk**. Describe the specific steps that will be taken to minimize the magnitude, probability, or duration of these risks.

*Examples: inform the subjects about the risks and how to minimize them; require a pregnancy test before and during the study; require subjects to use contraception; advise subjects about banking of sperm and ova.*

*If the use of contraception will be required: describe the allowable methods and the time period when contraception must be used.*

Participants who are pregnant or nursing will be screened out by self-report. All female participant will be required to take a pregnancy test prior to the alcohol administration procedures.

**c. Pregnancy**. Describe what will be done if a subject (or a subject's partner) becomes pregnant

*For example; will subjects be required to immediately notify study staff, so that the study procedures can be discontinue or modified, or for a discussion of risks, and/or referrals or counseling?*

All pregnant individuals will be ineligible for the full protocol. Participants with a positive test will be informed of the results individually by the PI or a trained graduate student, who will recommended following up with their primary care physician and provide them with local health resources. If the pregnant female is in the close friend condition, all individuals will be ineligible and will be informed that there was an error by the research team and we cannot do the run. They will all be paid for the time they are in the lab and provided a ride home. Should anyone become pregnant after alcohol administration procedures, participants would be able to stop drinking without interfering with the study because they choose their own drinking during daily diary reports.

**10.3 MRI risk management.** A rare but serious adverse reaction called nephrogenic systemic fibrosis (NSF) has been observed in individuals with kidney disease who received gadolinium-based contrast agents (GBCAs) for the scans. Also, a few healthy individuals have a severe allergic reaction to GBCAs.

**a. Use of gadolinium**. Will any of the MRI scans involve the use of a gadolinium-based contrast agent (GBCA?)

☐ **No**

☐ **Yes** → If yes, which agents will be used? *Check all that apply.*

| | Brand Name | Generic Name | Chemical Structure |
|---|---|---|---|
| ☐ | Dotarem | Gadoterate meglumine | Macrocylic |
| ☐ | Eovist / Primovist | Gadoxetate disodium | Linear |
| ☐ | Gadavist | Gadobutro | Macrocyclic |
| ☐ | Magnevist | Gadpentetate dimeglumine | Linear |
| ☐ | MultiHance | Gadobenate dimeglumine | Linear |
| ☐ | Omniscan | Gadodiamide | Linear |
| ☐ | OptiMARK | Gadoversetamide | Linear |
| ☐ | ProHance | Gadoteridol | Macrocyclic |
| ☐ | Other, provide name: | | |

1.) The FDA has concluded that gadolinium is retained in the body and brain for a significantly longer time than previously recognized, especially for linear GBCAs. The health-related risks of this longer retention are not yet clearly established. However, the UW IRB expects researchers to provide a compelling justification for using a linear GBCA instead of a macrocyclic GBCA, to manage the risks associated with GBCAs.

Describe why it is important to use a GBCA with the MRI scan(s). Describe the dose that will be used and (if it is more than the standard clinical dose recommended by the manufacturer) why it is necessary to use a higher dose. If a linear GBCA will be used, explain why a macrocyclic GBCA cannot be used.

2.) Information for subjects. Confirm by checking this box that subjects will be provided with the FDA-approved Patient Medication Guide for the GBCA being used in the research or that the same information will be inserted into the consent form.

☐ **Confirmed**

**b.** Who will (1) calculate the dose of GBCA; (2) prepare it for injection; (3) insert and remove the IV catheter; (4) administer the GBCA; and (5) monitor for any adverse effects of the GCBA? Also, what are the qualifications and training of these individual(s)?

**c.** Describe how the renal function of subjects will be assessed prior to MRI scans and how that information will be used to exclude subjects at risk for NSF.

**d.** Describe the protocol for handling a severe allergic reaction to the GBCA or any other medical event/emergency during the MRI scan, including who will be responsible for which actions.

**10.4 Unforeseeable risks**. Are there any research procedures that may have risks that are currently unforeseeable?

*Example: using a drug that hasn't been used before in this subject population.*

[X] **No**
[ ] **Yes** → If yes, identify the procedures.

**10.5 Subjects who will be under regional or general anesthesiology.** Will any research procedures occur while patients are under general or regional anesthesia, or during the 3 hours preceding general or regional anesthesia (supplied for non-research reasons)?

[X] **No**
[ ] **Yes** → If yes, check all the boxes that apply.

- [ ] Administration of any drug for research purposes
- [ ] Inserting an intra-venous (central or peripheral) or intra-arterial line for research purposes
- [ ] Obtaining samples of blood, urine, bone marrow or cerebrospinal fluid for research purposes
- [ ] Obtaining a research sample from tissue or organs that would not otherwise be removed during surgery
- [ ] Administration of a radio-isotope for research purposes**
- [ ] Implantation of an experimental device
- [ ] Other manipulations or procedures performed solely for research purposes (e.g., experimental liver dialysis, experimental brain stimulation)

If any of the boxes are checked:
Provide the name and institutional affiliation of a physician anesthesiologist who is a member of the research team or who will serve as a safety consultant about the interactions between the research procedures and the general or regional anesthesia of the subject-patients. If the procedures will be performed at a UW Medicine facility or affiliate, the anesthesiologist must be a UW faculty member, and the Vice Chair of Clinical Research in the UW Department of Anesthesiology and Pain Medicine must be consulted in advance for feasibility, safety and billing.

*** If the box about radio-isotopes is checked: the study team is responsible for informing in advance all appropriate clinical personnel (e.g., nurses, technicians, anesthesiologists, surgeons) about the administration and use of the radio-isotope, to ensure that any personal safety issues (e.g., pregnancy) can be appropriately addressed. This is a condition of IRB approval.*

**10.6 Data and Safety Monitoring**. A Data and Safety Monitoring Plan (DSMP) is required for clinical trials (as defined by NIH). If required for this research, or if there is a DSMP for the research regardless of whether it is required, upload the DSMP to ***Zipline***. If it is embedded in another document being uploading (for example, a Study Protocol) use the text box below to name the document that has the DSMP. Alternatively, provide a description of the DSMP in the text box below.

A data and safety-monitoring plan is in place for all research conducted at the Larimer Lab. All participants are encouraged to contact the Investigator and the UW IRB to report complaints or adverse events. Instructions for reporting adverse events and complaints, as well as for contacting the Investigators, are included in the consent documents and on all contact emails provided to participants through the course of the study. Screening surveys are designed to assess individuals who may be endangered by drinking alcohol. This includes past-month alcohol or other substance use disorders, past-month mood or anxiety disorders, suicidal ideation, excessive alcohol use (BAC>.30%), serious medical conditions, regular use of prescription psychotropic or pain medication, history of negative reactions to alcohol, history of treatment for alcohol or substance use disorders, pregnancy or nursing. Dr. Larimer and Ms. Canning will be responsible for follow-up assessment and referral of individuals expressing suicidal ideation or significant psychological distress. Ms. Canning or another clinically trained graduate student under Dr. Larimer's supervision will immediately follow-up by telephone with participants indicating past-month alcohol or other substance use disorder, mood disorder, anxiety disorder, or suicidal ideation to assess their level of risk and refer them for care. Assessment of suicide risk, referral and follow-up of suicidal individuals, facilitation of inpatient placement for acutely suicidal individuals, and reporting requirements involved in threats of imminent harm to self are all part of Dr. Larimer's ordinary clinical duties as an attending clinician at the UW medical center and the inpatient and outpatient psychiatry clinics at UWMC, thus in the extremely unlikely event of a severe adverse psychological reaction, Dr. Larimer could facilitate inpatient admission. We have previously used these procedures in a variety of studies to ensure participant safety. The PI or a clinically trained graduate student will be available during all alcohol administration runs to assess potential adverse events and will refer to proper resources when necessary. Further, Timeline Follow Back assessments and alcohol use assessments reported during daily diary reports will estimate BAC using number of standard drinks consumed, time spent drinking, sex, age, and weight. If a participants estimated BAC exceeds .30%, the PI will be notified immediately. Participants who reported a BAC greater than .30% will be contacted by a clinically trained graduate student and informed of the risk of lethality at BACs above .30%, and will be provided with appropriate referral resources. Participants who report .30% or greater BAC at screening will be ineligible for participation and will be followed up by phone to provide referrals. Any significant adverse events will be reported to the HSD within 48 hours, and all adverse events will be reported on the annual status report in compliance with federal regulations.

Also see data storage protections 9.6.

**10.7 Un-blinding.** If this is a double-blinded or single-blinded study in which the participant and/or relevant study team members do not know the group to which the participant is assigned: describe the circumstances under which un-blinding would be necessary, and to whom the un-blinded information would be provided.

**10.8 Withdrawal of participants.** If applicable, describe the anticipated circumstances under which participants will be withdrawn from the research without their consent. Also, describe any procedures for orderly withdrawal of a participant, regardless of the reason, including whether it will involve partial withdrawal from procedures and any intervention but continued data collection or long-term follow-up.

Should a participant become ill during alcohol administration to the point where emergency services are contacted, they will not be able to complete the alcohol administration procedures for safety reasons. Participants who are withdrawn from the alcohol administration procedures will not be eligible for the daily diary four week follow up because of specific aim 2 of this project.

**10.9 Anticipated direct benefits to participants**. If there are any direct research-related benefits that some or all individual participants are likely to experience from taking part in the research, describe them below:

*Do not include benefits to society or others, and do not include subject payment (if any). Examples: medical benefits such as laboratory tests (if subjects receive the results); psychological resources made available to participants; training or education that is provided.*

The direct benefits to participants are few, though increased knowledge of one's own alcohol use behavior could be helpful to some. Further, participants who are excluded due to current alcohol use disorder and/or anxiety or mood disorder will be provided with counseling resources, which could be beneficial to some, especially those who would not seek treatment otherwise, and all participants will be provided with a list of relevant resources at the end of their participation. Benefits to others include increased knowledge of the peer group influences and social motivation on alcohol use among college students, which could inform existing or novel prevention/intervention approaches. These benefits, which include both personal benefits and potentially significant public health benefits, outweigh the fairly minimal risks of participating in the study, especially given the multiple safeguards in place to mitigate risk.

**10.10 Return of individual research results.**

*In this section, provide your plans for the return of individual results. An "individual research result" is any information collected, generated or discovered in the course of a research study that is linked to the identity of a research participant. These may be results from screening procedures, results that are actively sought for purposes of the study, results that are discovered unintentionally, or after analysis of the collected data and/or results has been completed.*

*See the **GUIDANCE Return of Individual Results** for information about results that should and should not be returned, validity of results, the Clinical Laboratory Improvement Amendment (CLIA), consent requirements and communicating results.*

**a**. Is it anticipated that the research will produce any individual research results that are clinically actionable?

*"Clinically actionable" means that there are established therapeutic or preventive interventions or other available actions that have the potential to change the clinical course of the disease/condition, or lead to an improved health outcome.*

*In general, every effort should be made to offer results that are clinically actionable, valid and pose life-threatening or severe health consequences if not treated or addressed quickly. Other clinically actionable results should be offered if this can be accomplished without compromising the research.*

[ ] **No**

[X] **Yes** → If yes, answer the following questions (a.1-a.3).

**a.1.** Describe the clinically actionable results that are anticipated and explain which results, if any, could be urgent (i.e. because they pose life-threatening or severe health consequences if not treated or addressed quickly).

*Examples of urgent results include very high calcium levels, highly elevated liver function test results, positive results for reportable STDs.*

Individuals who meet clinical criteria will be contacted by phone to speak with a clinically trained graduate student or licensed clinical psychologist. If the individual met criteria for past month suicidal ideation, the clinician will do a full suicide risk assessment and create a plan with the individual to ensure their safety. They will also be provided with the national suicide prevention hotline and encouraged to call it at any time. The clinician will inform the participant the study is not right for them, and that they are at increased risk for the disorder(s) they met criteria for, and will explain this test is not diagnostic but simply suggests risk for mental health disorders. Clinicians will recommend they follow up with a mental health professional and will ask them to check their email for a list of local mental health resources, which includes free and insurance-accepting resources from UW and the surrounding community (see 'CAPS mental health resources' in supplementary materials). Clinicians will give the individuals opportunity to ask any questions before closing the call. Should someone not answer the phone, they will receive three phone calls with voicemails over a one week period and if no contact is made, this information and resources will be sent by encrypted email.

All eligible participants will also be provided the list of mental health resources. The following script will be used: "Throughout this study, you were asked many questions about your mental health. We are providing you with a list with many UW and local resources if you would like to continue to speak with someone about some of the topics brought up during this study or learn more about your mental health in general."

The exact scripts used for these conversations will depend on several factors including 1) the presenting clinical problem 2) the level of expressed interest in mental health throughout the study and 3) the responses provided by the participant during the conversation.

**a.2.** Explain which of these results will be offered to subjects.

A synthesis of participants responses to clinically relevant questions may be provided to them during clinical calls, This includes discussing drinking behavior and endorsed mental health symptoms.

**a.3.** Explain which results will <u>not</u> be offered to subjects and provide the rationale for not offering these results.

*Reasons not to offer the results might include:*

- *There are serious questions regarding validity or reliability*
- *Returning the results has the potential to cause bias*
- *There are insufficient resources to communicate the results effectively and appropriately*
- *Knowledge of the result could cause psychosocial harm to subjects*

It will be clarified to the participants these questions are not indicative of a mental illness diagnosis. Additionally, the sum scores on mental health questionnaires and any clinically relevant cut offs will not be provided to participants. Both of these have questionable validity because the data are collected by online self-report and out of context of the participant's life.

**b**. Is there a plan for offering subjects any results that are not clinically actionable?

*Examples: non-actionable genetic results, clinical tests in the normal range, experimental and/or uncertain results.*

[X] **No**

[ ] **Yes** → If yes, explain which results will be offered to subjects and provide the rationale for offering these results.

**c**. Describe the validity and reliability of any results that will be offered to subjects.

*The IRB will consider evidence of validity such as studies demonstrating diagnostic, prognostic, or predictive value, use of confirmatory testing, and quality management systems.*

All mental health symptoms that will be discussed are criteria for the diagnosis of various mental illnesses according to Diagnostic and Statistical Manual - 5. A clinical diagnosis would not be valid, however, the endorsement of symptoms indicate risk of mental illness.

According to the National Institute on Alcohol Abuse and Alcoholism, BAC > .30% has "Significant risk of death in most drinkers due to suppression of vital life functions." See: https://www.niaaa.nih.gov/publications/brochures-and-fact-sheets/understanding-dangers-of-alcohol-overdose#:~:text=As%20BAC%20Increases%E2%80%94So%20Do%20the%20Risks&text=This%20can%20increase%20an%20individual's,)%2C%20and%20death%20can%20occur———

**d**. Describe the process for communicating results to subjects and facilitating understanding of the results. In the description, include who will approach the participant with regard to the offer of results, who will communicate the result (if different), the circumstances, timing, and communication methods that will be used.

A clinically trained graduate student will use a motivational interviewing (MI) technique to discuss results over the phone. MI is an evidence-based method for alcohol use disorder prevention and interventions. Dr. Mary Larimer, an expert in this method will supervise the clinical graduate student.

**e**. Describe any plans to share results with family members (e.g. in the event a subject becomes incapacitated or deceased).

No results will be shared with family members.

**f**. Check the box to indicate that any plans for return of individual research results have been described in the consent document. If there are no plans to provide results to participants, this should be stated in the consent form.

*See the **GUIDANCE Return of Individual Results** for information about consent requirements.*

[X] **Confirmed**

**10.11 Commercial products or patents**. Is it possible that a commercial product or patent could result from this study?

[X] **No**

[ ] **Yes** → If yes, describe whether subjects might receive any remuneration/compensation and, if yes, how the amount will be determined.

## 11 ECONOMIC BURDEN TO PARTICIPANTS

**11.1 Financial responsibility for research-related injuries.** Answer this question only if the lead researcher is not a UW student, staff member, or faculty member whose primary paid appointment is at the UW.

For each institution involved in conducting the research: Describe who will be financially responsible for research-related injuries experienced by subjects, and any limitations. Describe the process (if any) by which participants may obtain treatment/compensation.

**11.2 Costs to subjects**. Describe any research-related costs for which subjects and/or their health insurance may be responsible (examples might include: CT scan required for research eligibility screening; co-pays; surgical costs when a subject is randomized to a specific procedure; cost of a device; travel and parking expenses that will not be reimbursed).

Travel expenses to the lab for alcohol administration procedures, if any are incurred, will not be reimbursed. Participants are encouraged to find a friend or family member to give them a ride.

Despite protections in place, some participants may become ill from consuming alcohol and may need medical attention. In this even, participants will be advised to be taken to UW Medical Center. However, participants who chose to go to an out of network (non-UW facility) provider may incur out of pocket expenses. Medical expenses incurred for out of network providers will be reimbursed up to $10,000 through the Human Subjects Assistants Program.

## 12 RESOURCES

**12.1 Faculty Advisor.** (For researchers who are students, residents, fellows, or post-docs.) Provide the following information about the faculty advisor.

- Advisor's name
- Your relationship with your advisor (for example: graduate advisor; course instructor)
- Your plans for communication/consultation with your advisor about progress, problems, and changes.

**12.2 UW Principal Investigator Qualifications**. Upload a current or recent Curriculum Vitae (CV), Biosketch (as provided to federal funding agencies), or similar document to the Local Site Documents page in Zipline. The purpose of this is to address the PI's qualifications to conduct the proposed research (education, experience, training, certifications, etc.).

*For help with creating a CV, see http://adai.uw.edu/grants/nsf_biosketch_template.pdf and https://education.uwmedicine.org/student-affairs/career-advising/year-4/residency-applications/curriculum-vitae/*

[X] **The CV will be uploaded.**

**12.3 UW Study team qualifications**. Describe the qualifications and/or training for each UW study team member to fulfill their role on the study and perform study procedures. (You may be asked about non-UW study team members during the review; they should not be described here.) You may list these individuals by name, however if you list an individual by name, you will need to modify this application if that individual is replaced. Alternatively, you can describe study roles and the qualifications and training the PI or study leadership will

require for any individual who might fill that role. The IRB will use this information to assess whether risks to subjects are minimized because study activities are being conducted by properly qualified and trained individuals.

**Describe: The role (or name of person), the study activities they will perform, and the qualifications or training that are relevant to performing those study activities.**

**Examples:**

Research Study Coordinator: Obtain consent, administer surveys, blood draw. Will have previous experience coordinating clinical research and be a certified phlebotomist in WA.

Undergraduate Research Assistant: Obtain consent, perform all study procedures. Will have had coursework in research methods, complete an orientation to human subjects protections given by the department, and will receive training from the PI or the graduate student project lead on obtaining consent and debriefing subjects.

Acupuncturist: Perform acupuncture procedures and administer surveys. Must be licensed with WA State DoH and complete training in administering research surveys given by the project director, an experienced survey researcher.

Co-Investigator: Supervise MRI and CT scan procedures and data interpretation, obtain consent. MD, specialty in interventional radiology and body imaging. 5-years clinical research experience.

Principle Investigator: Obtain consent, access participant contact info, supervise clinical calls, oversee study procedures, oversee data protections and sharing. Ph.D. in clinical psychology. Expertise in alcohol use research among college students. 20+ years clinical research experience.

Co-Investigator: Obtain consent, access participant contact info, oversee study procedures. Ph.D. Expertise in alcohol administration research. 20+ years research experience.

Clinical Graduate Student: Access participant contact info, conduct clinical calls. Clinical Psychology graduate student with motivational interviewing training. CITI and HIPAA training.

Supervisor: Obtain consent, access participant contact info, oversee bar lab procedures and emergencies, collect study data, debrief and pay participants. B.A. or B.S. in psychology or relevant field. CITI training.

Dedicated Scheduler: Access participant contact info, oversee screening procedures, contact participants via phone and email, collect data, schedule participants for bar lab run. Undergraduate or post-bac student in psychology or relevant field. CITI training

Undergraduate Research Assistant: Obtain consent, collect study data. Undergraduate or post-bac student in psychology or relevant field. CITI training.

**12.4 Study team training and communication**. Describe how it will be ensured that each study team member is adequately trained and informed about the research procedures and requirements (including any changes) as well as their research-related duties and functions.

☐ **There is no study team.**

## 13 OTHER APPROVALS, PERMISSIONS, and REGULATORY ISSUES

**13.1 Approvals and permissions.** Identify any other approvals or permissions that will be obtained. For example: from a school, external site/organization, funding agency, employee union, UW Medicine clinical unit.

*Do not attach the approvals and permissions unless requested by the IRB.*

N/A

**13.2 Financial Conflict of Interest.** Does any UW member of the team have ownership or other Significant Financial Interest (SFI) with this research as defined by UW policy GIM 10?

- [X] **No**
- [ ] **Yes** → If yes, has the Office of Research made a determination regarding this SFI as it pertains to the proposed research?
  - [ ] **No** → If no, contact the Office of Research (206.616.0804, research@uw.edu) for guidance on how to obtain the determination
  - [ ] **Yes** → If yes, upload the Conflict Management Plan for every UW team member who has a FCOI with respect to the research, to ***Zipline***. If it is not yet available, use the text box to describe whether the Significant Financial Interest has been disclosed already to the UW Office of Research and include the FIDS Disclosure ID if available.