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 your 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 your 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.
- The word "you" refers to the researcher and all members of the research team, unless otherwise specified.
- For collaborative research, describe only the information that is relevant to you unless you are requesting that the UW IRB provide the review and oversight for your collaborators 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: Coping Skills for Alcohol Use

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. Have you consulted with anyone at HSD about this study?

It is not necessary to obtain advance consultation. If you have: answering this question will help ensure that the IRB is aware of and considers the advice and guidance you were provided.

[x] **No**
[ ] **Yes** → If yes, briefly describe the consultation: approximate date, with whom, and method (e.g., by email, phone call, in-person meeting).

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.

[x] **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 your 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**

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

We have received a Just In Time request from NIH for this research. We would like to submit this documentation to NIH as soon as possible.

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 your 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).

This study aims to develop an interactive, brief, web-based intervention for young adults who report drinking to cope and report negative alcohol-related consequences during the transition to young adulthood. To do this, we will develop measurement tools to assess weekly coping skill acquisition, knowledge, and use, and incorporate these tools in the development of an interactive web-based intervention with text-message reminders for young adults who drink to cope. **Phase 1** includes formative research on the development of the drinking to cope intervention (through focus groups and rapid prototyping sessions) and developing tools to assess knowledge and use of coping skills. **Phase 2** will be a 3-month pilot test with weekly assessments to assess feasibility, acceptability, use and barriers to use of coping skills, and alcohol outcomes.
We currently have IRB approval for phase 1 activities (focus groups, rapid prototyping sessions to further refine the intervention and obtain user feedback) and phase 1 activity of a usability study with 15 young adults to test the programmed intervention, feasibility of study design, and to complete a phone interview to assess overall impression and feedback of the intervention. We are now submitting documentation for approval of a phase 2 activity of the small pilot study.
The specific aims of this research are as follows:
Phase 1. Develop an interactive web-based intervention with text-message reminders for young adults with alcohol-related consequences who report a pattern of drinking to cope. Conduct a series of focus groups and rapid prototyping sessions with young adults to further refine the intervention and obtain user feedback.
Phase 2. Conduct a pilot test to determine feasibility, acceptability, utilization of coping skills, and preliminary alcohol outcomes. A total of 120 young adults will be randomized to the 4-week, web-based drinking to cope intervention (n=60) or an assessment only control (n=60) where they will complete 4 weekly assessments on knowledge, acquisition, and use of coping skills and a 1- and 3-month follow-up

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.

Phase 1 of this study utilizes focus groups and rapid prototyping sessions with young adults to refine the intervention and obtain user feedback, and a usability study to test the programmed intervention modules, study procedures, and obtain user feedback.
Phase 2 will be a small pilot study to test the intervention.

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: • Are expected to be applicable to a larger population beyond the site of data collection or the specific subjects studied, or • 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 your 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 your proposed activity, based on existing literature (or clinical knowledge). Describe the gaps in current knowledge that your 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.

b. Experience and preliminary work. Briefly describe experience or preliminary work or data (if any) that you or your team 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: You have already conducted a Phase 1 study of an experimental drug which supports the Phase 2 study you are now proposing to do; you have already done a small pilot study showing that the reading skills intervention you plan to use is feasible in an after-school program with classroom aides; you have experience with the type of surgery that is required to implant the study device; you have a study coordinator who is experienced in working with subjects who have significant cognitive impairment.

1.9 Supplements. Check all boxes that apply, to identify Supplements you should complete and upload to the **Supporting Documents** SmartForm in ***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**	*ZIPLINE* SUPPLEMENT: Department of Defense

	The research involves Department of Defense funding, facilities, data, or personnel.	
☐	**Department of Energy** The research involves Department of Energy funding, facilities, data, or personnel.	*ZIPLINE* SUPPLEMENT: Department of Energy
☐	**Drug, biologic, botanical, supplement** Procedures involve the use of any drug, biologic, botanical or supplement, even if the item is not the focus of your research	*ZIPLINE* SUPPLEMENT: Drugs
☐	**Emergency exception to informed consent** Research that requires this special consent waiver for research involving more than minimal risk	*ZIPLINE* SUPPLEMENT: Exception from Informed Consent for Emergency Research (EFIC)
☐	**Genomic data sharing** 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 you are asking the UW to provide the required certification or to ensure that the consent forms can be certified	*ZIPLINE* SUPPLEMENT: Genomic Data Sharing
☐	**Medical device** Procedures involve the use of any medical device, even if the device is not the focus of your research, except when the device is FDA-approved and is being used through a clinical facility in the manner for which it is approved	*ZIPLINE* SUPPLEMENT: Devices
☐	**Multi-site study** You are asking the UW IRB to review one or more sites in a multi-site study.	*ZIPLINE* SUPPLEMENT: Participating Site in Multi-Site Research
☒	None of the above	

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 young adults between the ages of 18-25 years old at study entry.

2.2 Inclusion and exclusion criteria.

a. Inclusion criteria. Describe the specific criteria you will use to decide who will be included in your study from among interested or potential subjects. Define any technical terms in lay language.

Inclusion criteria include: 1)18-25 years old; 2) Reside in the state of Washington, 3) Have a valid email address and phone number, 4) report at least 1 alcohol-related problem in the past month, 5) report using alcohol to cope with distress via negative reinforcement (i.e., to provide relief or reduction of stress or depressed mood) in the past month.

b. Exclusion criteria. Describe the specific criteria you will use to decide who will be excluded from your study from subjects who meet the inclusion criteria listed above. Define any technical terms in lay language.

Doesn't meet inclusion criteria, unwillingness to participate, failure to provide consent.

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

a. Will you recruit or obtain data from individuals that you know 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 WORKSHEET: Prisoners for the definition of "prisoner".

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

i. Describe the type of prisoners, and which prisons/jails:

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

iii. Describe what you will do to make sure that (a) your 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 your research will involve prisoners in federal facilities or in state/local facilities outside of Washington State: check the box below to provide your assurance that you will (a) not encourage or facilitate the use of a prisoner's participation in the research to influence parole 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.

[ ] **Confirmed**

b. Is your research likely to have subjects who become prisoners while participating in your 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 your study, will you continue the study procedures and/or data collection while the subject is a prisoner?

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

2.4 Protected populations. IRB approval is required for the use of the subject populations listed here. Check the boxes for any of these populations that you will purposefully include in your research. (In other words, being a part of the population is an inclusion criterion for your 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 you think may be relevant for the IRB to consider.

n/a

2.5 Native Americans or non U.S. indigenous populations. Will you actively recruit from Native American or non-U.S. indigenous populations 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 you will obtain tribal/indigenous approval before beginning your research.

2.6 Third party subjects. Will you collect private identifiable information about *other individuals* from your 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 your research team to readily identify the person. For example, suppose that you are studying immigration history. If you ask your subjects several questions about their grandparents but you do not obtain names or other information that would allow you to readily identify the grandparents, then you are not collecting private identifiable information about the grandparents.

☒ **No**

☐ **Yes** → If yes, these individuals are considered human subjects in your study. Describe them and what data you will collect about them.

2.7 Number of subjects. Can you predict or describe the maximum number of subjects (or subject units) you need to complete your 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 your research. 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 you plan to study in the context of risks and benefits. Unless otherwise specified, if the IRB determines that your research involves no more than minimal risk: there are no restrictions on the total number of subjects you may enroll in the study. If your research involves more than minimal risk: you may only enroll the number of subjects described here in your application. Submit a Modification if you wish to increase the number of subjects. Exceeding the IRB-approved number (over-enrollment) will be considered non-compliance.

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

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

☒ **Yes** → If yes, for each subject group, use the table below to provide your 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 ***For clinical trials: provide numbers for your site and for the study-wide total number***
Focus Groups	60
Rapid Prototyping Sessions	10
Usability Study	15
Pilot Study	120

3 NON-UW RESEARCH SETTING

Complete this section only if your research will take place outside of UW and Harborview

3.1 Reason for sites. Describe the reason(s) why you selected the sites where you will conduct the research.

N/A

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 your research, how it is conducted, or how you obtain or document consent.

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

N/A

3.3 Site-specific laws. Describe any local laws that may affect your 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.

N/A

3.4 Site-specific administrative or ethical requirements. Describe local administrative or ethical requirements that affect your research.

Example: A school district may require you to obtain permission from the head district office as well as school principals before approaching teachers or students; a factory in China may allow you to interview factory workers but not allow you to pay them.

N/A

3.5 Students: Does your research involve traveling outside of the US?

[x] **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 your 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 you will identify, recruit, and screen subjects. 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.

Ads will be placed in online social networking sites (e.g., Instagram) and other media outlets (newspapers, community ads) that attract a broad spectrum of young adult drinkers. An online study profile will be developed for Facebook and Instagram, as in our previous studies. Other methods of recruitment will include placing ads on Craigslist, in local university, community college, and trade school newspapers, and advertising in local newspapers and placing flyers in local coffee shops and other places where young adults frequent. In these ads, individuals are asked to call or view the study website to complete the screening. Additionally, we will use in-person techniques such as tabling at colleges or local community events.

Both Instagram and Facebook recruitment ads will provide a hyper-linked website address (URL) for more information and eligibility screening. Potential participants will first be presented with an information statement briefly describing the screening and consent process. If interested, individuals may complete the screening online.

All contacts with participants will:

- Inform/remind participants of the voluntary nature of their participation
- Review the length and content of the focus groups/rapid prototyping sessions
- Provide incentive information
- Provide study contact information
- Provide information for contacting the IRB with any questions or concerns

We are requesting general approval with flexibility to make minor changes that do not substantially alter the scope or content of our recruitment/retention contacts with participants.

The information statement will contain all elements of consent and what they will be asked to do if they choose to participate.

At the end of the screening survey, participants who do not meet eligibility criteria will be informed that they have completed their participation in the study.

4.2 Recruitment materials.

a. What materials (if any) will you use 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.

Ads will be placed in online social networking sites (e.g., Instagram) and other media outlets (newspapers, community ads) that attract a broad spectrum of young adult drinkers. An online study profile will be developed for Facebook and Instagram. Other methods of recruitment will include placing ads on Craigslist, in local university, community college, and trade school newspapers, and advertising in local newspapers and placing flyers in local coffee shops and other places where young adults frequent. In these ads, individuals are asked to call or view the study website to complete the screening. Additionally, we will use in-person techniques such as tabling at colleges or local community events. Participants who meet eligibility criteria will immediately be invited to participate in the study. Study staff will make phone call reminders and participants will be given the opportunity to ask any questions they have about the study or their participation.

b. Upload descriptions of each type of material (or the materials themselves) to the **Consent Forms and Recruitment Materials** SmartForm of ***Zipline***. If you will send letters or emails to the subjects, these should include a statement about how you obtained the subject's name and contact information. However, no sensitive information about the person (such as a diagnosis of a medical condition) should be included in the letter.

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:

- *You could 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, you might 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). In doing so, you would not need to submit a Modification if/when the study phone number or contact person changes. Also, instead of listing the inclusion/exclusion criteria, you 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, you might 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).

[s] **No**

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

4.4 Payment to participants. Describe any payment you will provide, including:

- The total amount/value
- 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 information about the number and amount of payments, and especially the time 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.

Do not include a description of any expenses that will be reimbursed.

We have provided a table summarizing participant payments for this study below. All payments will be in the form of Amazon.com electronic gift cards.

Payments	
Survey	**Compensation**
Focus Group	$20
Rapid Prototyping Session	$20
Usability Study	$50
Pilot Study	$65

4.5 Non-monetary compensation. Describe any non-monetary compensation you will provide. Example: extra credit for students; a toy for a child. If you will be offering class credit to students, you must provide (and describe) an alternate way for the students to earn the extra credit without participating in your research.

n/a

4.6 Will you access or obtain data or specimens 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.

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

[ ] **Yes** → If yes, describe any data and/or specimens (including PHI) you will access or obtain for recruiting and screening and whether you will retain it as part of the study data.

4.7 Consent for recruiting and screening. Will you obtain consent 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**.
☒ **Yes** → If yes, describe the consent process.

Consent via online information statement described in 4.1

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

☐ **No** → If no, describe the information you will provide during the consent process and for which procedures.

☐ **Yes** → If yes, upload the consent form to the **Consent Forms and Recruitment Materials** page of ***Zipline***.

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), use of records, time required, and setting/location. If it is available and you think it would be helpful to the IRB: Upload a study flow sheet or table to the **Supporting Documents** SmartForm in ***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.*

Ads will be placed in online social networking sites (e.g., Instagram) and other media outlets (newspapers, community ads) that attract a broad spectrum of young adults. Online and print ads will highlight our study and provide a hyper-linked website address (URL) for information and to complete the brief screening survey. An information statement will describe all elements of informed consent, including a description of the study procedures, incentive structure, and potential risks to participants. Individuals will then complete a brief on-line screening survey to assess for study eligibility. Those that meet the eligibility criteria will be invited to participate in a focus group or rapid prototyping session and will complete an electronic informed consent page for the focus group or rapid prototyping session.
A research assistant will then call individuals who meet eligibility criteria. In this call, participants will be asked to

verbally confirm several pieces of information obtained from screening (including name and date of birth), and once this is confirmed they will schedule a time to participate in the focus group or rapid prototyping session.

Due to the novel coronavirus (COVID-19) outbreak, all focus group and rapid prototyping sessions will be completed via Zoom (video conferencing). Participants will be emailed the Zoom password for the meeting and the 'wait room' feature will be utilized.

The purpose of the focus group is to receive feedback on the prototype of the intervention modules. Focus groups will last up to 90 minutes, and be digitally recorded. Participants will receive $20 compensation. We will conduct 6 focus groups, with a maximum of 10 young adults per group.

The purpose of the rapid prototyping sessions is to further adapt and refine the intervention modules. These individual sessions will consist of a semi-structured interview and provide the opportunity for the participant to fully engage with the modules and provide feedback. Participants will be asked about general satisfaction with the design and usefulness of the modules and skills. Rapid prototyping sessions will last up to 60-minutes, and be digitally recorded. Participants will be compensated $20 for their time. A total of 10 participants will complete rapid prototyping.

For the usability study and for Phase 2 (small pilot study), a research assistant will call and email individuals who meet eligibility criteria and invite them to participate in a training session and to verify eligibility. The training session will be completed via Zoom (video conferencing). Participants will be emailed the Zoom password for the meeting and the 'wait room' feature will be utilized. During the training, participants will be asked to verbally confirm several pieces of information obtained from screening (including name and date of birth), and then will be provided with more information about the study design, timeline, and payment. This training should take no longer than 15 minutes.

After the training is complete, participants will be emailed a link to complete the baseline survey.
A total of 15 participants will participate in this usability study where they will receive 2 modules a week for a total of 4 weeks (8 modules total) and complete a phone interview at the end of the study to assess overall impressions with the modules and provide feedback.

For the small pilot study, a total of 120 young adults will be randomized to receive the 8 health-related modules or assessment only control group.

The 8 web-based modules include skills to improve mood and adaptive strategies instead of drinking alcohol to cope with negative emotions (e.g., drinking alcohol when feel sad). Each module will take between 5-10 minutes to view. The modules are focused on: 1) education on drinking to cope with negative emotions, 2) identifying triggers for drinking and engaging in more helpful behaviors, 3) goal setting, 4) emotion regulation, 5) mood booster activities, 6) more helpful thinking, 7) social support, and 8) problem solving.

All participants will complete online follow-up assessments at 1 and 3 months.

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

[ ]	**No**	→ If no, go to question **5.3**.
[x]	**Yes**	→ If yes, describe what you will record (if not already described in 5.1) and answer question **a**.

a. Before recording, will you obtain the consent of subjects and any other individuals who may be

recorded?

☐ **No** → If no, email hsdinfo@uw.edu before submitting your application in Zipline. In your email, include a brief description of your research and a note that you intend to record individuals without their 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).

☒ **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 a 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. 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 your MRI scan(s). Describe the dose you will use and (if it is more than the standard clinical dose recommended by the manufacturer) why it is necessary to use a higher dose. If you plan to use a linear GBCA, explain why you cannot use a macrocyclic GBCA.

2.) Information for subjects. Confirm by checking this box that you will either provide subjects with the FDA-approved Patient Medication Guide for this GBCA you are using or that the same information will be inserted into the consent form.

☐ **Confirmed**

c. 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)
- ☐ 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:

Personnel. For MRI scans that will be conducted at the DISC or BMIC research facilities: The role, qualifications, and training of individuals who will operate the scanner, administer the GBCA (if applicable), and/or insert and remove the IV catheter should be listed on the Study Team addendum.

5.4 Data variables. Describe the specific data you will obtain (including a description of the most sensitive items). If you would prefer, you may upload a list of the data variables to the **Supporting Documents** SmartForm instead of describing the variables below.

We are requesting permission to make additions and minor edits to the questionnaires without re-submitting documents to the IRB. For changes that go outside the range and scope of what is approved we will submit a modification. The types of measures we will include are: alcohol use & consequences and drinking to cope behaviors.
A phone interview will consist of qualitative data from the participants.

5.5 Data sources. For all types of data that you will access or collect for this research: Identify whether you are obtaining the data from the subjects (or subjects' specimens) or whether you are obtaining the data 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.

We will be obtaining data 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 to assist you in identifying 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 your 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 <u>access</u> to any direct or indirect identifiers?

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

Name and contact information (phone numbers, address, email addresses) will be entered, downloaded, and stored separately from research data. All data will be identified only by a PIN, which will be randomly generated for study purposes. A master list of names and PINs will be stored in a locked research staff office in a password-protected database and on password-protected computers with restricted access, and will be available only to research staff on this project.

[ ] **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 you have access.
- [ ] You have (or will have) entered into an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to you under any circumstances.

  You should be able to produce this agreement for IRB upon request. 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 to you. Describe them below.

b. Will you obtain any direct or indirect identifiers?

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

Yes, name and contact information (phone numbers, address, email addresses) will be collected and stored separately from research data and identified only by a PIN, which will be randomly generated for study purposes.

☐ **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 you have access.

☐ You have (or will have) entered into an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to you under any circumstances.

You should be able to produce this agreement for IRB upon request. 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 to you. Describe them below.

c. If you obtain any identifiers, indicate how the identifiers will be stored (and for which data). NOTE: Do not describe your data security plan here – we will ask for that information in section 9.6.

☐ You will store the identifiers with the data. Describe the data to which this applies:

☒ You will store identifiers and study data separately but you will maintain a link between the identifiers and the study data (for example, through the use of a code). Describe the data to which this applies:

Name and contact information will be entered, downloaded, and stored separately from research data. All data will be identified only by a PIN, which will be randomly generated

for study purposes. A master list of names and PINs will be stored in a locked research staff office in a password-protected database and on password-protected computers with restricted access, and will be available only to research staff on this project.

☐ You will store identifiers separately from the study data, with no link between the identifiers and the study data. Describe the data to which this applies:

d. Research collaboration. Will individuals who provide you with coded information or specimens for your 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 one outside the UW research team will have access to identifiers.

5.7 Protected Health Information (PHI). Will you access, obtain, use, or disclose a participant's identifiable PHI 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. ***If you will use UW Medical Records, you must answer yes to this question.***

☒ **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 you will access or obtain, and the reason for obtaining it. *Be specific.*

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

☐ **No**

☐ **Yes**

c. Describe how you will access or obtain the PHI. *Be specific. For example, you might: directly view records; search through your department's clinical database; submit a request to Leaf.*

d. For which PHI will you obtain HIPAA authorization from the subjects by having them sign a HIPAA Authorization form, before obtaining and using the PHI?

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

☐ **Confirmed**

e. For which PHI will you NOT obtain HIPAA authorization from the subjects?

Provide the following assurances by checking the boxes.

☐ You will access, obtain and/or use only the minimum necessary amount of PHI to accomplish the purposes described in this application.

☐ 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.

☐ You will fulfill the HIPAA "accounting for disclosures" requirement. See UW Medicine Compliance Policy #104. THIS IS ONLY FOR UW RECORDS.

☐ 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 you obtain or generate genomic data (as defined at http://osp.od.nih.gov/scientific-sharing/genomic-data-sharing-faqs/)?

☒ **No**
☐ **Yes** → If yes, answer the question below.

a. Do you plan to send genomic data from this research to a national database (for example, NIH's dbGaP database)?

☐ **No**
☐ **Yes** → If yes, complete the ***ZIPLINE* SUPPLEMENT Genomic Data Sharing** and upload it to the **Supporting Documents** SmartForm of ***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. Are you likely to use the information, specimens, or subject contact information you obtain or collect 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 you, colleagues, or others for research purposes
- Sharing with others for their own research

You are strongly encouraged to consider the broadest possible future plans you might have, and whether you will obtain consent now from the subjects for future sharing or research uses (which you may or may not be able to describe at this time). Answer **YES** even if you will only share information without identifiers. Answer **NO** if you are unlikely to do any sharing, or if your 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 your banked data/specimens with other investigators; establishing a repository from which you formally share with others through written agreements; or sending your 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 <u>what you will store for future use,</u> including whether any direct or indirect (e.g., subject codes) identifiers will be stored.

Indirect identifiers (PINs) will be stored with the data set.

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

It is possible that only the de-identified data set will be shared with study collaborators. However, no direct identifiers are stored with the data and all identifying information will remain safeguarded and maintained confidentially with restricted access to only the research team.

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

The Project Coordinator and Research Investigator.

d. Describe <u>the possible future uses</u>, 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.

De-identified data will be shared with members of our Center or the broader research community upon request for legitimate scholarly research purposes.

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

[x] **No**

[ ] **Yes** → If yes, be sure to include the information about this consent process in the consent form (if there is one) and in your 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?

[ ] **No**

[x] **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.

Participants can choose to withdraw their data or stop participating at any time.

g. Agreements for sharing or release. Confirm by checking the box that you will comply with UW (and, if applicable, UW Medicine) policies that require a formal agreement between you and 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 your 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) you 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.

We will have contact with participants via emails, text messages, and phone calls through-out the study. Participants will be encouraged to contact the research team via phone or email with any questions or concerns throughout their participation.

5.12 Future contact with subjects. Do you plan to retain any contact information you obtain for your subjects so that they can be contacted in the future?

[ ] **No**

[x] **Yes** → If yes, describe the purpose of the future contact, and whether use of the contact information will be limited to your team; if not, describe who else could be provided with the contact information. Describe your 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.

It is possible that participants who indicate willingness to be contacted for future research study participation will be contacted again in the future by the study team or other researchers in our lab

5.13 Alternatives to participation. Are there any alternative procedures or treatments that might be advantageous 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 the Supporting Documents SmartForm of ***Zipline*** all data collection forms (if any) that will be directly used by or with the subjects, and any scripts/talking points you will use 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 you will cover 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 your research, provide a description of the process by which you will establish the data collection/questions as you interact with subjects, how you will document your data collection/questions, the topics you plan to address, the most sensitive type of information you will plan to gather, and the limitations (if any) on topics you will raise or pursue.*

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 you will use for data that will be gathered in an evolving way.
- The general content of questionnaires, surveys and similar instruments for which you are seeking general approval. (See the **NOTE** bullet point in the instructions above.)

We have provided the following items with our Zipline application:

- Screening Invitation Email and general communication with participants
- Pilot study: Screening measures
- Pilot study: Baseline measures
- Pilot study: Follow up measures
- Usability study: Phone interview measures

We would also like to request general approval to make minor changes to measures, scripts, text messages, and intervention content without submitting a formal modification so long as those changes do not alter the range and scope of what is currently approved. For changes that go outside the range and scope of what is currently approved we will submit a modification.

6 CHILDREN (MINORS) and PARENTAL PERMISSION

6.1 Involvement of minors. Does your 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.

☒ **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 your population(s). If there is more than one answer, explain.

☐ **Don't know** →This means is it not possible to know the age of your subjects. For example, this may be true for some research involving social media, the Internet, or a dataset that you obtain 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 you obtain parental permission for:

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

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

☐ Some of your research procedures → Use the table below to identify the procedures for which you will not obtain written parental permission.

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 you will not obtain parental permission	Will you inform them about the research?[3] YES	NO
			☐	☐

	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐

Table footnotes

1. *If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.*
2. *If you plan to obtain identifiable information or biospecimens 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 you inform them about the research beforehand even though you are not obtaining active permission?*

b. Indicate by checking the appropriate box(es) your plan for obtaining parental permission

☐ 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 you checked both boxes, 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). Your answer 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

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 you obtain assent for:

☐ All of your research procedures and child groups	→ Go to question **7.2.**
☐ None of your research procedures and child groups	→ Use the table below to provide your 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 you will not obtain assent.

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 you will not obtain assent

Table footnotes

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

7.2 Assent process. Describe how you will obtain assent, for each child group. If your research involves children of different ages, answer separately for each group. If the children are non-English speakers, include a description of how you will ensure that they comprehend the information you provide.

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

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

7.5 Documentation of assent. Which of the following statements describes whether you will obtain documentation of assent?

☐ None of your research procedures and child groups	→ Use the table below to provide your justification, then go to question **7.5.b**
☐ All of your research procedures and child groups	→ Go to question **7.5.a**, do not complete the table
☐ Some of your 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 your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.*

a. Describe how you will document assent. If the children are functionally illiterate or are not fluent in English, include a description of what you will do.

b. Upload all assent materials (talking points, videos, forms, etc.) to the **Consent Form and Recruitment Materials** SmartForm of ***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 you did not at the beginning of their participation).
Children who reach the legal age of consent: You must obtain informed consent 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 your plans (if any) to re-obtain assent from children.

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

- If you plan to obtain consent, describe what you will do about now-adult subjects whom you are unable to contact.
- If you do not plan to obtain consent or think that you will be unable to do so, explain why.

7.7 Other regulatory requirements. (This is for your 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:
	• Consent must be legally effective.
	• The process minimizes the possibility of coercion or undue influence.
	• Subjects or their representatives must be given sufficient opportunity to discuss and consider participation.
	• The information provided must:
	  ○ Begin with presentation of key information (for consent materials over 2,000 words)
	  ○ Be what a reasonable person would want to have
	  ○ Be organized and presented so as to facilitate understanding
	  ○ Be provided in sufficient detail
	  ○ 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. **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 your 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 you will obtain consent 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 you will not obtain consent?

[x] **No**

[ ] **Yes** → If yes, use the table below to identify the procedures for which you will not obtain consent. "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 you will not obtain consent	Will you provide subjects with info about the research after they finish? YES	NO
			☐	☐

	☐	☐
	☐	☐
	☐	☐
	☐	☐

Table footnotes

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

b. Describe the consent process**,** if you will obtain consent 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 you will provide sufficient opportunity for the subjects to discuss the study with the research team and consider participation*

Participants will be directed to a Screening Information Statement detailing all procedures, obligations, and timeline associated with the study. It is made clear that participants can rescind consent and decline further participation at any time. Participants are provided with information for contacting the study team with any questions and will be asked to consent online if interested in participating.
Eligible participants will then be directed to an electronic Informed Consent page for the usability study and pilot study.
Audio recordings will begin with an announcement that the conversation is now being recorded.

c. Comprehension**.** Describe how you will ensure or test the subjects' understanding of the information during the consent process.

Participants are encouraged to ask any questions they have about the study prior to consenting to participate. Participants are provided with information for contacting the study team with any questions.

d. Influence**.** Does your research involve any subject groups that might find it difficult to say "no" to your research because of the setting or their relationship with you, even if you don't pressure them 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.

☒ **No**
☐ **Yes** → If yes, describe what you will do, for each of these subject groups, to reduce any effect of the setting or relationship on their 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 how you have ascertained that the information you will provide to subjects (via written or oral methods) is what a *reasonable member of the subject population(s)* would want to know. If you have consent materials that contain a key information section, also describe how you have identified 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, you may have consulted 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.

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

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.

☐ **No** → If no, skip to question 8.4

☒ **Yes** → If yes, answer questions **a** through **e**

a. Describe your 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.

The Screening Survey will include electronic consent. Participants are provided with a single page online information sheet detailing the study, participant obligations, potential risks, payments, and schedule of participating in the study. It is described at the top of the information sheet that it should take about 5 minutes to complete, and potential participants are encouraged to contact the study team with questions and/or concerns.
Focus group and rapid prototyping sessions, and usability study and pilot study, will also include electronic consent.

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?*

The screening consent form can be accessed via email and closed and accessed at a later time. All of the information is on one page, so they do not need to navigate forward or backward.

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, if anything, you will do 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.

Potential subjects are presented with an information statement detailing the purpose of the study, study procedures, payment information, information on risk, stress, or discomfort, alternatives to participation, benefits of the study, description of the source of funding, information on confidentiality, and the ability to consent or decline participation. The contact information of the entire research team is clearly available, and participants are encouraged to ask questions at any point in their consent process or participation to ask questions. We also encourage participants to contact Human Subjects Division if subjects have questions about their rights as a research subject. We also encourage them to keep a copy of the consent form, and offer to provide a copy, to be able to reference the information and the contact information.
Young adults completing the online screening survey and meeting eligibility criteria will be presented with an electronic consent form for the usability study and pilot study.

d. What will you do if you encounter individuals who wish to participate but who do not have access to the methodology you are using 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, you cannot exclude these individuals from your study unless you have 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.

It is not possible to participate in the study without completing the online screening.

e. How will you provide additional information, including any significant new findings (such as new risk information) to subjects during the research? If this is not an issue, explain why.

We do not anticipate additional relevant findings will come up during the research that requires dissemination to participants. However, we would contact subjects via email.

8.4 Written documentation of consent. Which of the statements below describe whether you will obtain documentation of consent? 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. Are you obtaining written documentation of consent for:

None of your research procedures → Use the table below to provide your justification then go to

x	question **8.5.**
☐ All of your research procedures	→ Do not complete the table; go to question **8.4.b.**
☐ Some of your research procedures	→ Use the table below to identify the procedures for which you will not obtain written documentation of consent from your 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 you provide them with a written statement describing the research (optional)? YES	NO
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐

Table footnotes

1. *If your answer is the same for all adult groups or all procedures, you can collapse your 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?

- *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, describe the methodology you will use.

See the GUIDANCE: Electronic Informed Consent for information about options (including the DocuSign system available through UW-IT) and requirements.

b.1 Is this method legally valid in the jurisdiction where the research will occur?

☐ **No**
☐ **Yes** → If yes, what did you use as your source of information about legal validity?

b.2 Will you obtain verification of the subject's identity 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 your rationale for why this is appropriate. Also, what would be the risks to the actual subject if somebody other than the intended signer provides the consent signature?

☐ **Yes** →If yes, how?

b.3 How will you meet the requirement 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 you enroll adult subjects who do not speak English or who lack fluency or literacy in English?

☒ **No**
☐ **Yes** → If yes, describe the process you will use 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 you will provide interpretation 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 you will obtain translations of all study materials (not just consent forms) and how you will ensure 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 your 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 you are not obtaining written documentation of consent for any part of your 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.

8.7 Deception. Will you deliberately withhold information or provide false information 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.*

- [x] **No**
- [ ] **Yes** → If yes, describe what information and why.

Example: you may wish to deceive subjects about the purpose of the study.

a. Will you inform subjects 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 you debrief the subjects later? (Note: this is not necessarily required.)

- [ ] **No**
- [ ] **Yes** → If yes, describe how you will debrief the subjects. Upload any debriefing materials, including talking points or a script, to the **Consent Form and Recruitment Materials** SmartForm of ***Zipline***.

8.8 Cognitively impaired adults, and other adults unable to consent. Do you plan to include such individuals in your research?

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

x	**No**	→ If no, go to question **8.9**.
	Yes	→ If yes, answer the following questions.

a. Rationale. Provide your rationale for including this population in your research.

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

b.1. If you will have repeated interactions with the impaired subjects over a time period when cognitive capacity could increase or diminish, also describe how (if at all) you will reassess decision-making capacity and obtain consent during that time.

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

*For research conducted in Washington State, see the **SOP: 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 you will use to obtain and document assent from the subjects.

e. Dissent or resistance. Describe how you will identify the subject's objection or resistance to participation (including non-verbal) during the research, and what you will do in response.

8.9 Consent-related materials. Upload to the **Consent Forms and Recruitment Materials** SmartForm of ***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 you will use.

- *Translations must be included. However, you are strongly encouraged to wait to provide them until you know that the IRB will approve 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. 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.*

9 PRIVACY AND CONFIDENTIALITY

9.1 Privacy protections. Describe the steps you will take, 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 procedures (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.*

Procedures for minimizing risks: We have taken steps to protect participants against potential risks posed by their participation in this research. In the consent form, participants will be fully informed of the range of items and the most sensitive and personal items, and will also be informed that they are free not to answer any question they wish not to answer and can refuse to participate or withdraw from participation at any time without penalty. Participants are encouraged to contact the investigators at any time to discuss any concerns they might have.

All data and other information in this study will be maintained confidentially, but will not be anonymous due to the longitudinal nature of participation. In order to protect against risks posed by a potential loss of confidentiality, we will take the following steps. First, participants will be assured that they are free to refrain from answering any question they do not wish to answer. Second, all data will be identified only by a unique personal identification number (PIN), which will be randomly generated for study purposes. Identifiable information entered online (such as contact information) will be downloaded and stored separately from participants' responses, but will be identified by the PIN. A master list of names and PINs will be stored in a password-protected database, on a password-protected computer with restricted access, and will only be available to senior research staff under the supervision of the Principal Investigator. Data will be retained on computers with restricted and password protected access, without links to the master code list. Third, all members of the research team have received or will receive training that includes emphasis upon the importance of confidentiality of information, and all personnel on the project will complete the required NIH training in protection of human research

participants. All staff will sign confidentiality statements. Fourth, to maintain confidentiality of data submitted over the internet, participants will be required to log into a secure server (site certificate provided by GeoTrust) using a unique PIN created for study purposes. Data transfer will be protected using a Secure Socket Layer with 128-bit encryption. The SSL certificate will ensure that data moving from the participant to the server (i.e., participant responses) will be encrypted using a 128-bit minimum encryption key. This is the same level of encryption used for most banking transactions and offers the highest degree of protection available for data transfer. The server is physically located in a secure, commercially protected co-location facility with 24 hour locked and monitored key-card access, within a locked room, within a locked server rack, with a locking face-plate protecting the server itself from physical access without authorization. Electronic protection is provided by a commercial-grade firewall, with continuous monitoring of the server for any attempts at electronic invasion Finally, we will obtain a Federal Certificate of Confidentiality through the Department of Health and Human Services. This certificate offers the highest protection available by law for research data.

Participants will be informed of these risks and protections in the informed consent process. All recruitment contacts will emphasize the voluntary nature of participation to reduce risks of experienced coercion. Participants will be notified of the potential risk that the information provided may not be helpful, and will be provided with information about where they might seek information about alcohol use, or receive alcohol-related services if desired. Participants are encouraged to contact the investigators at any time to discuss any concerns they might have.

9.2 Identification of individuals in publications and presentations. Do you plan to use potentially identifiable information about subjects in publications and presentations, or is it possible that individual identities could be inferred from what you plan to publish or present?

[x] **No**

[ ] **Yes** → If yes, will you obtain subject consent for this use?

- [ ] **Yes**
- [ ] **No** → If no, describe the steps you will take 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 your research team likely to learn of any of the above events or circumstances while conducting your research **AND** feel obligated to report it to state authorities?

[x] **No**

[ ] **Yes** → If yes, the UW IRB expects you to inform subjects 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 your assurance that you will not destroy any identifiers (or links between identifiers and data/specimens) and data that are part of your research records until after the end of the applicable records retention requirements (e.g. Washington State; funding agency or sponsor; Food and Drug Administration) for your research. If you think it is important for your specific study to say something about destruction of identifiers (or links to identifiers) in your 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***

[x] **Confirm**

9.5 **Certificates of Confidentiality**. Are you planning to obtain a federal Certificate of Confidentiality for your research data? *NOTE: Answer "No" if your study is funded by NIH or the CDC, because all NIH-funded and CDC-funded studies automatically have a Certificate.*

[x] **No**
[ ] **Yes**

9.6 **Data and specimen security protections**. Identify your data classifications and the security protections you will provide, referring to the ***ZIPLINE* GUIDANCE: Data and Security Protections** for the minimum requirements for each data classification level. ***You cannot answer this question without reading this document. Data security protections should not conflict with records retention requirements.***

a. Which level of protections will you apply to your data and specimens? If you will use more than one level, describe which level will apply to which data and which specimens.

We will apply Level 3 protections since we collect information on alcohol use.

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 you will *not* follow, list those here.

We will follow all required Level 3 data security protections.

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 you will manage or reduce the risks. 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.*
- *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.*

There are no known physical risks of participating in this research. It is possible participants may feel uncomfortable participating in the focus groups or rapid prototyping interviews or feel as if they should share opinions they may not want to share. They may feel self-conscious about sharing your feedback and thoughts in front of others.
It is possible participants may not want to answer questions in the usability study or may feel self-conscious sharing their feedback about the intervention materials. Participants will be told they are free to not answer items.

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.

- [x] **No** → If no go to question 10.3
- [ ] **Yes** → If yes, answer the following questions:

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

b. Steps to minimize risk. Describe the specific steps you will take 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 you will require the use of contraception: describe the allowable methods and the time period when contraception must be used.

c. Pregnancy. Describe what you will do if a subject (or a subject's partner) becomes pregnant

For example; will you require the subject to immediately notify you, so that you can discontinue or modify the study procedures, discuss the risks, and/or provide referrals or counseling?

10.3 MRI risk management. *Answer this question only if your subjects will receive MRI scans*. 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. Describe how you will assess the renal function of your subjects prior to MRI scans and how you will use that information to exclude subjects at risk for NSF.

b. Describe your protocol for handling a sever allergic reaction to the GBCA or any other medical event/memergency 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 subjects-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 you checked any of the boxes:
You must provide the name and institutional affiliation of a physician anesthesiologist who is a member of your research team or who will serve as a safety consultant about the interactions between your research procedures and the general or regional anesthesia of the subject-patients. If your procedures will be performed at a UW Medicine facility or affiliate, the anesthesiologist must be a UW faculty member, and you must consult with the Vice Chair of Clinical Research in the UW Department of Anesthesiology and Pain Medicine for feasibility, safety and billing.

*** If you checked the box about radio-isotopes: you are 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 your research, or if you have one regardless, upload your DSMP to the **Supporting Documents** SmartForm in ***Zipline***. If it is embedded in another document you are uploading (for example, a Study Protocol) use the text box below to name the document that has the DSMP. Alternatively, you can provide a description of your DSMP in the text box below.

DSMP is now uploaded to supporting documents.

10.7 Un-blinding. If this is a double-blinded or single-blinded study in which the participant and/or you 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.

n/a

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.

Fraudulent web completers will be withdrawn from the research.

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.

There may be no direct benefit from participation. The knowledge gained from this study may benefit future young adults. Benefits to society include the opportunity to contribute to research that helps to develop substance use intervention programs.

10.10 Return of individual research results.

In this section you are asked to 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. Do you anticipate 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.

[x] **No**

[ ] **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.

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

a.3. Explain which results will not 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*

b. Do you plan to offer 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.

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.

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

f. Check the box to indicate that you have described your plans for return of individual research results 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.*

☐ **Confirmed**

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

☒ **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.

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.

N/a

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).

N/a

11.3 Reimbursement for costs. Describe any costs to subjects that will be reimbursed (such as travel expenses).

N/a

12 RESOURCES

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

N/a

12.2 Study team communication. Describe how you will ensure 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.**

We will have weekly research team meetings to ensure each study team member is adequately trained and informed about the project and its related functions.

13 OTHER APPROVALS, PERMISSIONS, and REGULATORY ISSUES

13.1 Other regulatory approvals. Identify any other regulatory approvals that are required for this research, by checking applicable boxes

Do not attach the approvals unless requested by the IRB.

Approval	Research for which this is required
☐ Radiation Safety	Procedures involving the use of radioactive materials or an ionizing radiation producing machine radiation, if they are conducted for research rather than clinical purposes. Approvals need to be attached to the Supporting Documents page in ***Zipline***.
☐ Institutional Biosafety	Procedures involving the transfer/administration of recombinant DNA, DNA/RNA derived from recombinant DNA, or synthetic DNA.
☐ RDRC	Procedures involving a radioactive drug or biological product that is not approved by the FDA for the research purpose and that is being used without an IND, for basic science research (not to determine safety and effectiveness, or for immediate therapeutic or diagnostic purposes).
☐ ESCRO	Procedures involving the use of some types of human embryonic stem cells.

13.2 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

13.3 Financial Conflict of Interest. Does any 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 your 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 team member who has a FCOI with respect to the research, to the **Supporting Documents** page of ***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.