Approved IRB Protocol

Based on type of approval, does not have annual status reports or continuing review. Initial approval and approval of last modification included below.

Noting that redactions including private but non-essential information such as clinic and trainee names

IRB APPROVAL OF APPLICATION

May 31, 2017

Katherine Anne Comtois
325 9th Ave
Seattle, WA 98104
+1 206 897-4225
comtois@uw.edu

Dear Katherine Anne Comtois:

On 5/31/2017, University of Washington IRB Committee J reviewed the following application:

Type of Review:	Initial Study
Title of Study:	Preventing Addiction Related Suicide (PARS) - Controlled Trial of Secondary Suicide Prevention
Investigator:	Katherine Anne Comtois
IRB ID:	STUDY00001966
Funding:	Name: National Institute on Drug Abuse (NIDA), Grant Office ID: A109927, Funding Source ID: 1R01DA041486-01A1
IND, IDE, or HDE:	None

IRB Approval

Under FWA #00006878, the IRB approved your activity from 5/31/2017 to 5/30/2018.

- Your application qualified for expedited review ("minimal risk"; Categories 5 and 7).

Determinations, waivers, and regulations

Because entire clinics are randomized to receive the intervention, all patients in an intervention clinic receive the intervention whether or not they agree to be in the study. We have determined that a waiver of consent is not needed for non-subjects. A waiver would be needed for people who meet the regulatory definition of "human research subject"—people whose private identifiable information is obtained for or by the study, or from whom any information is obtained via interaction. The non-subjects will receive the intervention, but you will not obtain any data from or about them.

Location of documents

Use the consent, parental permission, and assent forms that were approved and stamped by the IRB. They can be downloaded from the **Documents tab** in Zipline.

In addition, HSD has uploaded the following signed document to the **Documents tab** in Zipline:

- Individual Investigator Agreement for Lakeside-Millam Recovery Centers.

Four clinical organizations are engaged in this study because their employees will deliver the study intervention. At the time of this approval letter, only Lakeside-Millam has a fully executed Agreement delegating IRB review to the UW. Therefore, **even though the study is approved, you are not allowed to begin study activities at the other three clinical sites until their Agreements have been signed off by the UW and uploaded to your application**.

Thank you for your commitment to ethical and responsible research. We wish you great success!

Sincerely,

Deborah Dickstein, MSPH
Human Subjects Review Administrator, Team J
(206) 543-5971 dickstei@uw.edu

IRB APPROVAL OF MODIFICATION

February 19, 2019

Dear Katherine Anne Comtois:

On 2/19/2019, University of Washington IRB Committee J reviewed the following application:

Type of Review:	Modification/Update
Title of Study:	Preventing Addiction Related Suicide (PARS) - Controlled Trial of Secondary Suicide Prevention
Investigator:	Katherine Anne Comtois
STUDY ID:	STUDY00001966
MOD ID:	MOD00003633
Funding:	Name: National Institute on Drug Abuse (NIDA), Grant Office ID: A135509, Funding Source ID: N/A; Name: National Institute on Drug Abuse (NIDA), Grant Office ID: A109927, Funding Source ID: 1R01DA041486-01A1
IND, IDE, or HDE:	None

IRB Approval

Under FWA #00006878, the IRB approved modifications to your research. The expiration of the current IRB approval period remains 5/14/2019.

- Your modification(s) to the research qualified for expedited review ("minimal risk"; "minor change").
- Your study now automatically has a Certificate of Confidentiality (CoC) because you have added NIH funding. A description of the CoC protections and responsibilities has been placed in your study's Documents section.
- If you plan to continue data collection past the expiration of your NIH funding and the CoC, contact the Human Subjects Division prior to the end of your funding. We will help you determine whether you need to apply for a CoC extension.

Determinations, waivers, and regulations

The IRB made the determinations and waivers listed in the table below for the modification(s).

Requirement	Determination or Waiver
Documentation of consent	Waived. Information sheet used for Cultural Tailoring of the Preventing Addiction Related Suicide (PARS) Intervention

Location of documents
Use the revised consent forms that were approved by the IRB. They can be downloaded from the Final column under the **Documents tab** in Zipline.

In addition, HSD has uploaded the following documents to the **Documents tab** in Zipline:

- Certificate of Confidentiality Acknowledgement Letter

Thank you for your commitment to ethical and responsible research. We wish you great success!

Sincerely,

Lindsey Westlake
Review Administrator
206-897-1748
scaggl@uw.edu

INSTRUCTIONS

- **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.

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1 OVERVIEW

Study Title: Preventing Addiction Related Suicide (PARS) - Controlled Trial of Secondary Suicide Prevention

1.1 Home institution. Identify the home institution of the lead researcher as listed on the IRB application. 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 **POLICY: Use of the UW IRB.***

University of Washington, Department of Psychiatry and Behavioral Sciences

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.

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

[redacted] has met with us by phone and reviewed our protocol resulting in substantial changes.

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

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

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

[ ] **No**
[x] **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.

We have a pilot study IRB#48457 Feasibility of Pilot Survey Protocol that was designed to develop pilot online assessment protocols. The NIDA grant funding this application is a funding amendment to 48457 while we finalize those procedures. However, in proceeding with the main study, we are submitting this new proposal for the full RCT (rather than continue further as amendments to a protocol designed to be a feasibility study).

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.

[x] **No**
[ ] **Yes** → If yes, briefly describe the urgency or deadline as well as the reason for it.

N/A

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).

The goal of this study is to evaluate the effectiveness and utility of "Preventing Addiction Related Suicide" (PARS), a single session suicide prevention intervention, to increase help-seeking by clients in community addiction treatment. Evaluation is conducted through a Stepped wedge controlled trial with the following aims:

Aim 1: Compare the effectiveness of Intensive Outpatient Program (IOP) integrating PARS to TAU to change beliefs about suicide and suicide prevention.

Hypothesis 1a: Clients who receive PARS will know more accurate information about suicide

Hypothesis 1b: Clients who receive PARS will have less maladaptive attitudes about suicide

Aim 2: Compare the effectiveness of IOP integrating PARS to TAU to increase help-seeking behaviors for clients and for clients' friends or family at risk of suicide.

Hypothesis 1c: Clients who receive PARS will show greater help-seeking for themselves and others

Aim 3: Evaluate whether changes in beliefs about suicide and suicide prevention—particularly regarding warning signs for suicide, including addiction, intoxication, and relapse, as well as beliefs that suicide is preventable when action is taken—are possible mechanisms by which PARS increases help-seeking behavior.

Hypothesis 2: The effect of PARS vs. TAU on changes in help-seeking will be mediated by improved information and attitudes

Exploratory Aim 4: Evaluate possible clinic-level dose effects of PARS administration such that participant outcomes improve the longer PARS is implemented within clinics.

Exploratory Aim 5: Compare the effects of PARS vs. TAU on clients' suicidality and substance use in the follow-up period.

Administrative Supplement Aim 1: Tailor PARS to be culturally appropriate, acceptable, and feasible for use in ANAI communities.

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.

Pragmatic clinical trial of PARS compared to Treatment-as-Usual (TAU) using a Stepped wedge design with 900 clients enrolled in 15 community addiction treatment sites.

For those unfamiliar with Stepped wedge design, a figure is provided. The Stepped wedge design has the 15 sites randomized into 5 groups and groups are then randomly ordered from 1 to 5. At Step 1, all groups are assessed as control (i.e., TAU). Starting in Step 2, Group 1 moves from control to experimental with the 3 Group 1 sites implementing PARS and the rest continuing TAU. At each Step, the next group begins implementing PARS till by Step 6 all sites have moved to the experimental treatment. Primary outcomes compare TAU vs. PARS.

	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6
Group 1 (3 sites)	TAU	PARS	PARS	PARS	PARS	PARS
Group 2 (3 sites)	TAU	TAU	PARS	PARS	PARS	PARS
Group 3 (3 sites)	TAU	TAU	TAU	PARS	PARS	PARS
Group 4 (3 sites)	TAU	TAU	TAU	TAU	PARS	PARS
Group 5 (3 sites)	TAU	TAU	TAU	TAU	TAU	PARS

Key notes regarding study setting and design: Four community substance abuse treatment agencies have partnered with the research team for this study. These four agencies have 1-9 sites each that are scattered around Western Washington for a total 15 sites. Each site varies from 1-3 Intensive Outpatient Program (IOP) groups which run simultaneously. Each IOP has approximately 24-36 sessions of 2-3 hours each (72 hours total). Once they complete all sessions, the IOP restarts. New IOP clients enter the program at any time and stay till they have attended all 24 or 36 sessions. Thus, each Step in this Stepped Wedge design will be an entirely new set of clients.

Only one IOP for each site will be selected to be the focus of this study (Selected IOP). All client participants will be recruited and consented by research staff and the interventions (TAU vs. PARS) will be in the Selected IOP.

Within each Step, data collection will be as follows. Two weeks prior to the week Standard/PARS session is to be conducted in the selected IOP, research staff will connect with counselors at that site to (a) set up a plan for client recruitment and (b) have counselors complete online assessments themselves. One week prior to the Standard/PARS session, the research staff will come to the program 1-3x to recruit participants with the goal of recruiting all willing participants enrolled in that Selected IOP. Baseline assessments completed at recruitment. Follow-up assessments online or by phone two weeks, then one, three, and six months after recruitment.

Administrative Supplement: We will conduct a sub-study to culturally tailor PARS for use in Alaska Native and American Indian (ANAI) communities. This will be conducted in three ANAI communities with whom Dr. Comtois and/or Ries are currently collaborating.

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. Develop information about a drug or device through its prospective use and assignment to subjects, which will then be submitted to the Food and Drug Administration (FDA) in support of a marketing or research application for an investigational drug or device, or for changes to the purpose, population, or dose for an already-approved drug or device.
☐	6. 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.
☐	7. 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.
☐	8. 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.
☐	9. Preliminary, exploratory, or research development activities (such as pilot and feasibility studies, or reliability/validation testing of a questionnaire)
☐	10. Expanded access use of a drug or device not yet approved for this purpose
☐	11. Use of a Humanitarian Use Device
☐	12. Other. Explain:

N/A

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.

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.

1. Suicidal behavior is prevalent and costly in substance-abusing populations.
Suicide and suicidal behaviors are over-represented in populations with substance use disorders (SUDs) compared to the general adult population. Recent reviews find that the risk of suicide is 14 times higher for people injecting drugs, 10 times for alcohol use disorders, and 17 times for polydrug users. Clients receiving alcohol treatment are about 10 times more likely to endorse of a lifetime history of suicide attempts (43%) compared to a nationally representative sample of adults (4.6%). Moreover, prospective data shows that individuals in addiction treatment had five times the odds of suicide attempt over five years compared to those not in treatment.

2. Community addiction treatment is an ideal setting for targeting suicide risk in this high-risk group.
Every year, approximately 2.5 million people in the United States enter specialized addiction treatment programs. By far, the most common modality of publicly funded addiction treatment available is group-based Intensive Outpatient Programs (IOP). Thus, adding evidence-based, transportable suicide prevention strategies into the standard IOP treatment package has the potential to reach an enormous number of people who are at very high risk for suicide. Moreover, entering addiction treatment may represent a key window for intervention to reduce suicidal behaviors, as this transition is marked by high rates of suicidal thinking and behavior. Individuals often enter addiction treatment in the context of multiple increased risk factors for suicide: when substance use is out of control and/or is resulting in particularly severe impairment (e.g., marital or financial difficulties, severe depressive symptoms). Clients with addiction also connect with each other during treatment, in twelve-step meetings, and in drug use. Improving accurate information and adaptive attitudes toward suicide prevention as well as how to effectively reduce risk and reach out for help may not only increase their access to care if suicidal, but also increase access to care of their friends and family who are often also at risk.

3. Addiction treatment providers need additional training to prevent suicidal behavior.
Unfortunately, most chemical dependency counselors feel unprepared, inadequately trained, and uncomfortable addressing the issue of suicide. This selected suicide prevention program has the potential to serve a dual purpose of providing prevention for clients and providing ongoing education and training for the addiction treatment staff tasked with delivering the program.

4. PARS was developed to be transportable, disseminable, and community-friendly.
PARS is taught as a single module that is integrated within standard IOP therapy group treatment. It was developed with suicide prevention experts as well as leaders in the addiction treatment community of Western Washington. All feasibility testing of PARS was conducted in community treatment programs.

Administrative Supplement: [redacted]

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.

A pre-post pilot study of PARS was conducted with clients attending group-based IOP addiction treatment.

Thirteen IOP counselors were recruited and trained to administer PARS. After completing informed consent and receiving training, counselors answered a survey about PARS acceptability and utility in the standard working conditions at their sites. PARS was found to be acceptable to counselors and leadership at these agencies.

This pilot study of PARS also demonstrated significant post-intervention increases in accurate information and decreases in maladaptive attitudes toward suicide among 79 client participants. Significant gains compared to pre-intervention were maintained at 1-month follow-up for both information and maladaptive attitudes. Help-seeking was also significantly improved. Compared to the month before PARS, in the month following PARS, pilot participants were twice as likely to ask friends and family to seek help as well as to seek help themselves. This also highlights the fluidity of suicide risk during addiction treatment — although outpatient SUD treatment providers attempt to screen out acutely suicidal individuals at intake, instead referring them to a higher level of care, this is nonetheless a high-risk population and suicidal thoughts and behavior are not uncommon during community addiction treatment.

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** The research involves Department of Defense funding, facilities, data, or personnel.	*ZIPLINE* SUPPLEMENT: Department of Defense
☐	**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	*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
☐	**Participant results sharing** Individual research results will be shared with subjects.	*ZIPLINE* SUPPLEMENT: Participant Results Sharing
☒	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.

Client participants (N=900) will be adults with a substance use disorder (SUD) that resulted in their admission to the selected IOP (Selected IOP). All clients enrolled in the Selected IOP will be recruited to participate.

Counselor participants (N=~50, maximum 200) are chemical dependency providers and/or clinicians working at the study sites. To determine effects of PARS implementation beyond the Selected IOP all counselors who work at all the sites will be recruited to participate including any counselors newly hired across the course of the study.

Administrative Supplement: [redacted]

2.2 Inclusion and exclusion 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.

Assumed by virtue of placement that they would be eligible (refer to section 4.1)

Client Participant Inclusion Criteria

1. Enrolled client in one of the community treatment settings
2. Over 18 years of age (no maximum age)
3. Ability to understand written and spoken English

Client Participant Exclusion Criteria

1. Any clinical medical/psychiatric condition, severity of that condition, or life situation that in the opinion of the counselors or Drs. Comtois or Ries would compromise safe and voluntary study participation (e.g., psychosis, custody conflict). This is expected to be a rare circumstance and will be known prior to the recruitment session. If a counselor does not want someone involved, they will not be. If counselor is unsure, Dr. Comtois or Ries will facilitate decision with counselor ahead of time to assist in the decision.

Counselor Participants – Inclusion Criteria:

1. Hired as regular staff counselor at one of the partner agencies
2. "Engagement staff": anyone who has a clinical treatment relationship with clients (CDPs, counselors, etc.).
3. Ability to understand written and spoken English

Counselor Participants – Exclusion Criteria:

1. Determined by agency administrator as not appropriate to participate (do not have specific expectation this will occur but want to provide agencies with possibility of excluding counselor at their discretion)

Stakeholder Participants – Inclusion Criteria:

1. Stakeholders for the Administrative Supplement will be [redacted]

Stakeholder Participants – Exclusion Criteria:

1. None

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:

N/A

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?

N/A

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.

N/A

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.

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

If we know someone is a prisoner, we will not continue follow-up assessments until after their release. However, it is possible (although unlikely) that our text message or email and online follow-up assessment system will reach a participant while a prisoner (e.g. in King County jail) and we do not know that they are. This is unlikely as cell phone and computer access is not available during incarceration. Most likely these messages will be discovered by the participant after release at which time they are no longer

prisoners. While there is no easy way to prevent this occurrence, we do not believe there is any way the participant would feel coerced into participation so the risk to the participant would be low and there is no way that this could have a role in parole or other legal decisions.

In order to ensure this, our consent form also contains this information. The client consent form states that "If you become incarcerated over the course of the study, we will not be able to contact you or collect any information from you until you are released. Depending on the circumstances, it may be possible that we will need to stop any further follow up assessments".

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 or submitted.

Population	Worksheet
☐ Children	WORKSHEET: Children
☐ Children who are wards	WORKSHEET: Children
☐ Fetuses in utero	WORKSHEET: Pregnant Women
☐ Neonates of uncertain viability	WORKSHEET: Neonates
☐ Non-viable neonates	WORKSHEET: Neonates
☐ Pregnant women	WORKSHEET: Pregnant Women

"Children" are defined as individuals who have not attained the legal age for consent to treatments or procedures involved in the research and its specific setting. This will vary according to the location of the research (that is, for different states and countries).

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**

[X] **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.

[redacted] (representing a large number of Alaska Native and American Indian tribes in the [redacted]

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.

[X] **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. You may submit a Modification to increase this number at any time after you receive IRB approval. If the IRB determines that your research involves no more than minimal risk: you may exceed the approved number and it will not be considered non-compliance. If your research involves more than minimal risk: exceeding the approved number 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.

N/A

[x] **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*
Treatment as Usual (TAU)	450
PARS (experimental condition)	450
Counselor Participants	200
Stakeholder Participants for Administrative Supplement	

3 INTERNATIONAL RESEARCH SETTING

Answer the questions in this section ONLY if your research will occur at sites outside of the United States

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 or how it is conducted.

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.

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

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.

Client Participant Recruitment:
A week ahead, counselors will inform clients from each selected IOP that research staff will be coming by providing them the PARS client recruitment flyer (attached). Using the same flyer a week later, all clients will be reminded about the study and told to stay at the end of a group if they would like to hear more about it.

Using the recruitment flyer for talking points, the research staff will come at the end of group to explain what the study is and recruit participants.

(If a client participant does not meet study criteria, the IOP counselor will call that client aside as the IOP group ends to explain this to them privately and the client will not stay to hear about the study or participate.)

Counselor Participant Recruitment:
The agency leadership will inform counselors from each site that research staff will be coming by providing them the PARS counselor recruitment flyer (attached).

Using the recruitment flyer for talking points, the research staff will come to explain what the study is and recruit counselor participants.

All counselors (defined as staff with a treatment relationship with clients) will be invited to participate at the beginning of the study. At each subsequent Step, if new counselors have started they will be recruited at that time and will complete the remainder of the study.

(If a counselor participant does not meet study criteria, the agency staff will call that counselor aside to explain this to them privately and the counselor will not stay to hear about the study or participate.)

Stakeholder Recruitment for the Administrative Supplement: [redacted].

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.

As noted in 4.1 above, there will be two recruitment flyers – one for client participants and one for counselor participants. Both are attached.

We would like to request flexible approval of recruitment strategy and materials, specifically to create or update recruitment materials without submitting a modification to the application so long as the overall content does not go outside the scope and range of what is already approved. Any substantive change to content would be submitted as a formal modification.

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 to the subjects, the letter should include a statement about how you obtained the subject's name, contact information, and any other subject-specific information (such as a health condition) that is mentioned 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).

[ ] **No**
[X] **Yes** → If yes, describe the nature of the relationship.

Dr. Ries works extensively with substance abuse treatment sites in Western Washington and has or may consult with them on challenging cases etc. over the next five years. It is unlikely that one of the client participants will be someone he consults on, but this is not impossible. It is somewhat more likely that he would consult with a counselor participant. These consultations are at the agency's request and they are under no obligation to do so.

Dr. Ries also has a longstanding consultation relationship with the [redacted] Indian Tribe. Dr. Comtois has been conducting another research study with both the [redacted] in which we have conducted a cultural tailoring process comparable to the one proposed here.

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.

<u>Client participants</u> will be reimbursed $30 (in a choice of gift cards) for the baseline assessment. The initial client follow-up assessment one week after the Standard/PARS session is shorter so reimbursed at $20. The 1, 3 and 6 month follow-up assessments are reimbursed $30 each.

In addition, to minimize attrition, client participants will also be offered an additional incentive to be paid at the final 6-month assessment (or end of the 6-month assessment window if they do not complete it). The additional incentive (also in gift cards) will be $20 for completing 2 of the 3 outcome assessments and $30 for completing all outcome assessments.

<u>Counselor participants</u> will be reimbursed $30 (in a choice of gift cards) for the baseline and follow-up assessments (i.e. every four months). Additionally, the counselor leading the study PARS group will receive an additional $20 for completing the brief acceptability questionnaire after the first PARS group.

<u>Stakeholder Participants</u> [redacted]

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.

As reimbursement for attending and completing PARS Training, counselor participants will receive free National Association of Social Work CE Credits for the hours they participate in the PARS training.

4.6 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, you must still answer question **4.7** below.
☒ **Yes** → If yes, describe the consent process.

There is no eligibility screening. See Section 2.1 and 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***.

4.7 Data and specimens for recruiting and screening. For studies where you will obtain consent, describe any data and/or specimens (including any PHI) you will obtain for recruiting and screening (prior to obtaining consent) and whether you will retain it as part of the study data.

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.*

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.

There is no eligibility screening. See Section 2.1 and 4.1.

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), 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.*

Study Interventions

In this study, we are using a Stepped wedge design that randomizes at the site level. That means that all clients will receive whichever intervention their site is providing at the time they enroll. This will be Treatment as Usual (TAU) until the Stepped wedge design randomization selects that site to implement PARS at which point all clients will receive PARS till the end of the study. This will be true for all clients and counselors whether or not they choose to participate in the study. Thus, the study is restricting the choice of interventions for study participants and non-participants.

This is described in the consent form for participants. However, because of the study design, non-subjects will also experience randomization and exposure to the intervention. We request a waiver of consent for this.

Clarification of IOP Treatment in which both study interventions are embedded

Intensive Outpatient Program (IOP) guidelines in Washington State are based on State requirements. Within these guidelines, agencies typically offer IOP consisting of three-hour groups, three times a week, over eight weeks, for a total of 24 groups (72 hours total). Some programs meet less often for a longer time window up to 12 weeks. The 24-36 session series runs and then starts over continuously. Clients can enter the IOP at any time in the 24 session series and stay until they have attended all 24-36 sessions. Thus, within 24-36 sessions, all IOP clients will have completed (or dropped) from the program and a new group of IOP participants will be in the program. In our Stepped wedge design, each step is 4 months, which means that when we return to the site at each step, we will be recruiting from a different pool of clients.

Although at least one monthly individual counseling session is required, the primary modality is a group format. Each group session is 2-3 hours long and a combination of didactic information and process discussion. IOP programs are required to provide education on specific topics, e.g., alcohol and drug education, relapse prevention, risks of drug or alcohol use during pregnancy, blood borne pathogens (including HIV/AIDS and Hepatitis), emotional, physical, and sexual abuse, and nicotine addiction. However, within a 24-36-session curriculum, IOP programs have wide latitude in determining group content since the required topics typically represent less than 50% of the 24-36 sessions. Therefore the content in IOP programs across our sites is expected to be variable while the structure of session hours will be consistent. While IOP programs from our partner agencies include mental health topics, currently no IOP includes a suicide prevention focused session.

Control: Treatment as Usual (TAU)

At the beginning of the study, each site will select a particular group session in their 24-36-session schedule to be their TAU session for this study. To minimize variability between sites, the TAU session will be one regarding grief, depression, or coping with negative emotions. All sites have a TAU session on

one of these topics. They will continue to present this TAU session at the same point in the 24-36-session schedule as long as their site is randomized to TAU.

Intervention: Preventing Addiction Related Suicide (PARS)

At the Step where the site is randomized, that site will begin implementing Preventing Addiction Related Suicide (PARS) instead of the identified TAU session.

PARS is a single session that includes a specified combination of didactic presentations and group discussions. PARS topics include: Goals and Objectives; Suicide Overview; Addiction and Suicide: A Strong Relationship; Suicide Myths and Facts; Suicide Risk Factors; Suicide Protective Factors; Common Triggers of Suicidal Thoughts and Behaviors; Warning Signs and Guidelines for Preventing Addiction Related Suicide. The PowerPoint slides of the PARS curriculum and the PARS counselor adherence measure are attached.

All IOP counselors will be trained in the Step where they are randomized to implement PARS. In this way, the study sites are "engaged" in the research as counselors on site will provide the study interventions. The agencies will be deferring human subjects review to the UW and have completed an Institutional Agreement for IRB Review (IAIR) with each site.

Dr. Ries, who developed PARS, will provide all the training. To maximize the value to our community partners and assure a counselor trained in PARS is available on the day the PARS module is scheduled, all consenting counselors will be offered the opportunity to participate in the training so that someone can substitute if the designated PARS counselor is unavailable.

PARS counselor adherence will be evaluated at the first PARS administration by having an adherence coder sit in on the PARS session. Observation is the method requested by the agency treatment partners as least disruptive and most acceptable to clients. As adherence coders will have participant contact and be hearing the treatment session, they will complete any training on specific agency procedures regarding treatment observers with regard to client PHI so the adherence coders meet all agency standards. No client PHI will be collected as part of adherence coding – the focus is on the counselor's level of adherence to PARS and not client identity nor comments.

Both Conditions:

Any additional treatments outside of the IOP program (e.g., mental health-oriented counseling, pharmacotherapy) will be available during all phases of the Stepped design. Washington State mandates self-help group attendance in addition to attendance of group and individual IOP sessions; this will also remain consistent throughout each site's participation (regardless of when PARS is implemented at each site).

Client Participant Assessment Procedures:

Reminder – clinics are randomized at the clinic level. Clients and counselors have no choice in if they receive the intervention. This randomization effects clients and counselors regardless of whether they are study participants or not. As noted above, participants are informed about this in the consent form and we request waiver of consent for the non-participants.

Baseline Assessment

Will always occur one week prior to session intervention.

Will be conducted by in-person group administration. Assessments will be completed on paper or tablet computers. Expected to take 15-30 minutes.

If the individual does not have time or requests an individual assessment, this will be offered at a later time or in a different room at the same time.

Post-Intervention Assessment

Will be conducted one week after the PARS or TAU group session (i.e., 2 weeks after baseline). Assessments will be completed using online assessment. Participant will receive a text message or email (their preference) with a link to the assessment. If a participant prefers, follow-up assessments can be conducted by phone in which case research staff will call participant when the assessment is due. Expected to take 5-10 minutes.

Long-Term Follow-Up Assessments

Will be conducted 1, 3, and 6 months after the baseline assessment. Participants will receive a text message or email (their preference) with a link to the assessment. If a participant prefers, follow-up assessments can be conducted by phone in which case research staff will call participant when the assessment is due. Expected to take 10-15 minutes.

Following their completion of the 6-month assessment, participants have the option of checking a box—or verbally agreeing if the survey is conducted via phone—at the end of the survey to request the correct answers to the PARS Suicide Knowledge Scale questions (description of measure in Section 5.13 of current protocol). We will not provide the participant's individual survey responses during this process.

Counselor Participant Assessment Procedures:

Baseline Assessment

Will be conducted by in-person group administration. Assessments will be completed on tablet computers or paper versions. Expected to take 10-20 minutes.

If the individual does not have time or requests an individual assessment, this will be offered at a later time or in a different room at the same time.

Additionally, at the beginning of each Step, the Research Coordinator (or site-assigned RA) will reach out to the Site Administrator and Treatment Coordinator to ask if any new clinical staff have joined (or left) the site since the last Step. To clarify who was there previously, the Research Coordinator will provide a list of counselors who have been approached (regardless of whether they completed or refused).

Post-Training and Post-Intervention Follow-Up Assessment

Will be conducted immediately after the PARS training (when this is scheduled according to the Stepped wedge design) and immediately after the first administration of PARS, only for the counselor leading the PARS session. Assessments will be completed using online assessment using a tablet computer or paper version. Expected to take 5-10 minutes.

Ongoing Follow-Up Assessments

Will be conducted every 4 months (i.e., at each Step in the Stepped wedge) and one at the end of the study (after Step 6). Participants will receive a text message or email (their preference) with a link to the assessment. If a participant prefers, follow-up assessments can be conducted by phone in which case research staff will call participant when the assessment is due. Expected to take 10-15 minutes. (NOTE: for Step 1, counselors consented to 6 assessments and they were every 6 months. They also did not consent to the assessment at the end of the study. The PARS counselor Step 1 Re-Consent IRB ver-1 8-

21-17 document clarifies the questions to be asked at the Step 2 follow-up to re-consent these counselor participants. Also noted in Section 8.)

Study Locations

Location	Activities
Harborview Pat Steel Building	Study management, data management, entry, and analysis
Evergreen Recovery	Main Agency
Everett Outpatient	Recruitment, baseline assessment, study intervention
Lynnwood Outpatient	Recruitment, baseline assessment, study intervention
Lakeside Milam Recovery Center	Main Agency
Auburn	Recruitment, baseline assessment, study intervention
Edmonds	Recruitment, baseline assessment, study intervention
Everett	Recruitment, baseline assessment, study intervention
Issaquah	Recruitment, baseline assessment, study intervention
Kirkland	Recruitment, baseline assessment, study intervention
Puyallup	Recruitment, baseline assessment, study intervention
Renton	Recruitment, baseline assessment, study intervention
Seattle	Recruitment, baseline assessment, study intervention
Tacoma	Recruitment, baseline assessment, study intervention
Northwest Integrated Health	Main Agency
Tacoma	Recruitment, baseline assessment, study intervention
Puyallup	Recruitment, baseline assessment, study intervention
Lakewood	Recruitment, baseline assessment, study intervention
Olalla Recovery Centers	Main Agency
Gig Harbor	Recruitment, baseline assessment, study intervention

Note that for the Administrative Supplement, we are describing the PARS intervention to them but there is no trial of the intervention, *per se*.

5.2 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 will collect questionnaire data on REDCap on a tablet or paper (baseline) or online (follow-up). Follow-up interviews will be conducted by phone if so requested by a participant. The content of the questionnaires and description of most sensitive items are described below in Section 5.13.

Our goal is to attempt recruitment of all counselors at each site at each Step of the study. At Steps 2-6, the study therefore reaches out to the site's point of contact to determine if there are any counselors who have left or new counselors hired since the previous Step. New counselors can then be recruited. To prevent inadvertent re-recruitment of counselors who refused to participate at an earlier Step: we request to retain the names of counselors who refuse so that the research staff can provide a complete list of counselors from the previous Step to the site point of contact and clarify who refused so they won't be re-recruited.

We will also obtain the medical record for each participant for their treatment at the site that includes the IOP program and an ancillary services. This will allow us to determine how many IOP sessions they attended and whether they completed the program, what other services they received, what diagnoses and problems were identified for that client and whether they resolved during the course of treatment, and what their disposition plan was following the IOP program. If any of this information is not clear in the medical record, a research assistant will ask the counselor to clarify or add needed information verbally.

We believe that losing a client to suicide at a site could change the responses that participants give at a given Step of the study. Therefore, at the beginning of each step, we will ask if a client at the site died by suicide since our last assessment and if so, was it someone in the target group from which we are recruiting client participants. (We may well learn from other sources that our participant died by suicide (i.e., when they do not respond to outcome assessments), but the purpose of this procedure is to be aware of a potential confounder of study results – that is, that a suicide at the site might change suicide-related study results at that Step. Of course, if we learn a study participant then we will submit an adverse event report to the IRB.)

For the Administrative Supplement, [redacted]

5.3 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.

Participant questionnaires, medical record (plus verbal consultation with counselor, if needed)

For the Administrative Supplement, [redacted]

5.4 Retrospective/prospective. For all types of data and specimens that you will access or collect for this research: Describe which data are:

- Retrospective (i.e., exist at the time when you submit this application)
- Prospective (i.e., do not yet exist at the time when you submit this application)
- Both retrospective and prospective (for example, past and future school records)

Retrospective. (NOTE: Their medical history in the records preceeds study constent; but their records are obtained after consent.)

5.5 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 identify 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.*

5.10 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.

Participants will be contacted by text message (using Twillio within the REDCap system) or email (their preference) with a link to the online REDCap survey unless they request contact by phone to do a phone interview. If they do not complete the survey when expected, research staff will contact them to remind them, solve any technical difficulties, or complete the assessment by phone. Using the follow-up locating consent form and associated contact information form (attached), research staff will reach out through the means they approve to locate them for follow-up interviews. This includes phone, email, texts, letters, private messages to social media, or contacting a friend or treatment provider they authorized us to speak to. (As noted in 8.2b below, we separate the follow-up locating consent from the main consent so that we can show it to people providing contact information to assure them we have the participant's permission without sharing any details about the study.)

5.11 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.

Client participants opted in/out of the following statement at the time of consent: "It is possible that, depending on the results of the study, the research team may want to interview you again in the future. Please initial here _____ if you are willing to be contacted in the future about participation in a follow-up study. You are not required to participate in further research if contacted in the future." No such study, nor contact with participants, will be performed without explicit review and approval by UW HSD. Only the research team will have this information. It will not be shared.

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

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

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

N/A

5.13 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 would like to request flexible approval of recruitment instruments. Specifically, we would like to request that the IRB will approve the general content of our questionnaires rather than the specific forms themselves. This will allow us to create or update recruitment instruments without submitting a modification to the application - so long as the overall content does not go outside the scope and range of what is already approved. Any substantive change to content would be submitted as a formal modification.

Please find below a description of each questionnaire and the most sensitive item for each.

Client and Counselor Measures:

Accurate Information about suicide. The PARS Suicide Knowledge Scale assesses factual understanding of warning signs, triggers, and interventions for suicide. Items include: *"Relapsing on drugs or alcohol is a common trigger for suicidal thoughts/feelings. 1 = True , 2 = False, 99 = I cannot/do not want to answer"*

Attitudes toward suicide. The PARS Attitude Scale, originally adapted from the 14-item Staff Suicide Prevention Survey, is rated on a Likert-type scale from 1 (Strongly Disagree) to 5 (Strongly Agree). This scale evaluates stigma and bias toward suicidal acts or persons, as well as perceptions that suicide is preventable if appropriate action is taken. Items include: *"Talking about suicide might give a person unwanted ideas about suicide."*

PARS Demographic Form: The PARS Demographic Form assesses demographic information to better classify clients and counselor identifying criteria (Age, Gender, etc.). Most sensitive item on client version: *"In the past 5 years, have you had consensual sex with". Is rated on the criteria of: Only females…Only males… Both*

males and females… No consensual sex past 5 years… I cannot/do not want to answer." Most sensitive version on counselor version: *"Do you consider yourself to be: Heterosexual/straight… Gay/lesbian/homosexual… Bisexual… Other Describe: _____ …I cannot/do not want to answer"*

Client Only Measures:

Help-seeking behavior. The PARS Behavior Scale – Client Version consists of four items assessing help-seeking behavior for self and others. Participants report the frequency of help-seeking behavior from never ("0 times/none") to "more than 3 times." Items include: *"In the past month, have you: (1)… asked a friend to get help because you were worried that he or she was having suicidal thoughts/feelings; (2)… asked a family member or relative to get help because you were worried he or she was having suicidal thoughts/feelings; (3)… asked for help because you were having suicidal thoughts/feelings; and (4)… called a crisis line/suicide hotline?"* If items 1 to 3 are endorsed, participants will also be asked to report whom they asked for help.

Suicidal ideation and behavior. At baseline, we will as about a lifetime history of suicidal and non-suicidal self-harm. Items will include *"Have you ever thought about or attempted to kill yourself?. With responses of: Never…It was just a brief passing thought…I have had a plan at least once to kill myself but did not try to do it …I have had a plan at least once to kill myself and really wanted to die…I have attempted to kill myself, but did not want to die…I have attempted to kill myself, and really hoped to die…I cannot/do not want to answer".* At each follow-up, we will ask similar question, but only pertaining to a history of suicidal and non-suicidal behaviors since the last assessment. Items will include *"How often have you thought about killing yourself IN THE PAST MONTH? : 0=Never, 1=Rarely (1 time), Sometimes (2 times) 3=Often (3-4 times), 4=Very Often (5 or more times)".*

Drug and alcohol use. To assess days of drug/alcohol use in past 30 days will ask clients to self-report a numerical value of "*How many days in the past 30 have you used alcohol? _____"* and "*How many days in the past 30 have you used drugs? _____"*.

To assess baseline substance use problems, participants will complete a modified version of the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST), a modified 23-item screening tool developed by the World Health Organization to examine lifetime and recent (past three months) substance use. Most sensitive item "*Have you ever used any drug by injection (NON-MEDICAL USE ONLY)?"*

To assess baseline alcohol and substance use problems, participants will complete the Short Inventory of Problems – Alcohol/Drug (SIP-AD) which measures negative consequences from drug or alcohol use. Most sensitive item "*I have taken foolish risks when I have been drinking/using drugs."*

Depression, Physical and Mental Health. Two screening measures will be used to assess covariates and potential moderators (depression, physical health, mental health) of PARS outcomes. The two-item Patient Health Questionnaire (PHQ-2) assesses recent depressive symptoms. The most sensitive item is *"Over the last 2 weeks, how often have you been bothered by any of the following problems? Feeling down, depressed, or hopeless" Not at all… several days… more than half the days…. Nearly every day.*" The EQ-5D is a widely used, and psychometrically validated, self-administered measure of health status. Most sensitive item: *"I have severe problems washing or dressing myself"*

Counselor Only Measures:

In order to assess a counselor's confidence in discussing client suicidality, we have developed a four item measure, PARS Confidence in Suicide Prevention Measure. Items include *"I am confident in dealing with the needs of suicidal clients. ____" and rated on a 0-10 scale.*

PARS Acceptability. Counselors will complete the PARS Counselor Acceptability Scale, a 13-item survey that was developed in our pilot trial to measure acceptability, ease, and perceived effectiveness of incorporating PARS into day-to-day IOP procedures. Items are measured on a Likert scale from strongly agree to strongly disagree. Most sensitive item: *"In general, the prevention program described was an intrusive procedure"*

Measures for Administrative Supplement:

Interview Guide. In order to understand the stakeholder participants' understanding and opinions about the PARS intervention and to evaluate their perception of the usability and understandability of the culturally tailored PARS-ANAI version, we have developed a PARS-ANAI Interview Guide. Items include "What are some suggestions to make the currently-used treatment workbooks more culturally appropriate". The most sensitive item: "If you were a customer-owner/tribal member seeing this module how would you feel if this were presented to you"

Demographics. A basic demographic measure is included. Given the topic, it also includes items regarding the participant's experience with or exposure to suicidal behavior and substance abuse. The most sensitive question: "Which of the following services have you received for suicidal thoughts or behaviors".

5.14 Send HSD a Confidentiality Agreement if you will obtain or use any private identifiable UW records without subject's written consent (for example, screening medical records or class grades to identify possible subjects).

The Confidentiality Agreement form must be completed, printed, signed, and mailed to the Human Subjects Division at Box 359470. Your IRB application cannot be approved until we receive the Confidentiality Agreement.

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. See the **WORKSHEET: Children** for details.
- The generic age of consent may be different in other states, and in other countries.

[X] **No** → If no, go to Section 8.

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

N/A

[ ] **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.

7.5 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.

N/A

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.

N/A

7.6 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 usually (but not always) includes an opportunity for subjects to ask questions. It does not necessarily include the signing of a consent form. This question is about the consent process.
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.
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.
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. 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 4.6. 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).*
- *Whether/how you will provide an opportunity for questions*
- *How you will provide an adequate opportunity for the subjects to consider all options*

Client Participants

Research staff will describe the study to the clients after their treatment group (or at a different time, if requested by a potential participant). Uninterested clients will then leave. There are three consent forms (a) the main consent, (b) follow-up locating consent form and (c) release of information form for their agency to release the medical record to the study. Research staff will distribute and review the consent forms with all interested clients. Clients will then be directed to review the consent forms individually and ask any questions they have about the study. Potential participants willing to participate will be asked to sign the consent form and then complete Contact Information Form and gift certificate reimbursement information.

Counselor Participants

Research staff will describe the study to the counselors. Uninterested counselors will then leave. Research staff will distribute and review the consent form with all interested counselors. Counselors will then be directed to review the consent form individually and ask any questions they have about the study. Potential participants willing to participate will be asked to sign the consent form, provide an email or phone number to be texted or called for follow-up assessments, and the gift certificate reimbursement information.

If either client or counselor participants do not want their agency to know that they did not want to participate, they will be told they are free to write random words on the consent form and/or questionnaires so no one else will know they were not participating.

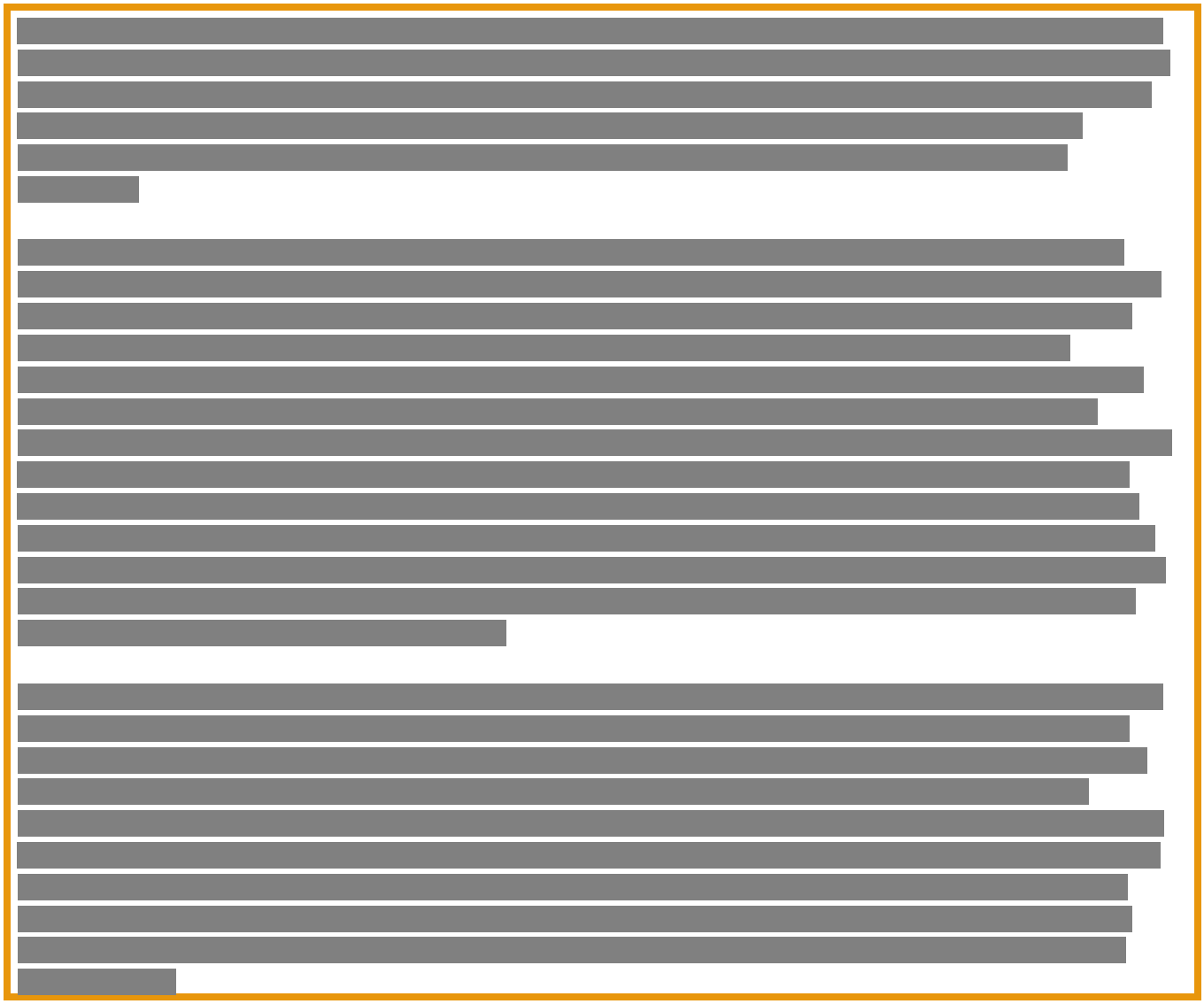
Our goal is to attempt recruitment of all counselors at each site at each Step of the study. At Steps 2-6, the study will reach out to the site's point of contact to determine if there are any counselors who have left or new counselors hired since the previous Step. New counselors can then be recruited. To prevent inadvertent re-recruitment of counselors who refused to participate at an earlier Step, we will retain their names only in our records so that the research staff can provide a complete list of counselors from the previous Step to the site point of contact and clarify who refused so they won't be re-recruited.

Follow-up Locating Consent Form to Prevent Client Participant Attrition.

Our goal is for all participants to complete all outcome assessments regardless of treatment participation. Therefore, informed consent will include a separate locating consent form on which client participants choose locating strategies they consent to have used (e.g., obtaining forwarding address from post office, checking social media) and provide alternative contacts to whom the study can reach out in case the participant moves or changes contact information.

This form is separate from the main consent so that if we have to provide to a contact so they know we have permission to get the client's contact information, we are not sharing any information about the study, their drug use, etc. We have used this locating consent form for over 20 years of research. It finds an excellent balance between obtaining detailed information and allowing participants to only provide information they are comfortable providing.

Administrative Supplement



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

The main points of the consent form will be reviewed with opportunities to ask question before the participants are asked to review and sign the informed consent form to assure that they understand.

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.

All client participants will be asked by their counselors at the end of a standard treatment group in their IOP if they would like to volunteer for a study that involves staying after that group (or participating before or after one of the other IOP groups that week, if that day is not convenient). Client participants will be told by the agency and the study that this study is voluntary and will not affect their treatment nor will any data provided be shared with the agency unless the client reports suicide risk in which case the study will coordinate with the client and agency to assure adequate care. As noted above, if either clients or counselors do not want to participate, they can write nonsense on the forms so others do not know they are declining.

See 8.2b above for how this is addressed for the administrative supplement.

e. 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.

Participants are free to stop participating any time as described in the consent form. If a participant no longer wishes to participate, they can decline when we contact them for follow-up assessments. We will ask them to elaborate on why they would like to discontinue participation in the study as this will help with current and future retention, but they are free to say that it is for no reason or they do not want to give a reason.

8.3 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 4.6.

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 question **8.4.**
☐ All of your research procedures	→ Do not complete the table; go to question **8.3.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
Counselor Participants	We have decided that the study Steps will be 4 months in duration instead of 6 months as is currently approved.	☒	☐
Counselor Participants	We have decided to add a final (7th) assessment for Counselor participants to allow us to determine the impact of Step 6.	☒	☐
	Also see 'Procedure Stage' in Section 5.1	☐	☐

Stakeholder Participants	As described in 8.2b, there is no reason to increase confidentiality risk for study participants in the Administrative Supplement focus groups and cognitive interviews by de-anonymizing them for the purpose of written consent.	X	

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.*

8.4 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?

[X] **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.

N/A

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.

N/A

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.

N/A

8.5 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; excluding individuals who cannot read and understand the consent form.

If a participant is unable to read a consent, due to visual impairment, study staff will read the consent to the participant. We will have the participant sign to the best of their ability, and then printed by the research

study team. We will also have a witness sign the consent for added precaution. All of this will be clearly documented within our tracking systems to ensure clarity.

8.6 Deception. Will you deliberately withhold information or provide false information to any of the subjects?

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

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

N/A

a. Will you debrief the subjects later? (Note: this is not 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***.

N/A

8.7 Cognitively impaired adults, and other adults unable to consent.

a. **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 **8.8**.
[ ] **Yes** → If yes, answer the following questions.

a.1. Rationale. Provide your rationale for including this population in your research.

N/A

a.2. 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. 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 re-assess decision-making capacity and consent during that time.

N/A

a.3. 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".*

N/A

a.4. 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.

N/A

a.5. 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.

N/A

8.8 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.*

Questionnaires with a blank cover sheet will be provided. Client participants will be told by the agency and the study that this study is voluntary and will not affect their treatment nor will any data provided or shared with the agency unless the client reports suicide risk, in which case the study will coordinate with the client and agency to assure adequate care. Counselor participants will be told by the agency and the study that this study is voluntary and participation, or non-participation, will not affect their job nor will any data provided be shared with the agency.

If a client participant is not considered appropriate to participate in these procedures, the IOP counselor will call that client aside as the group ends to explain this to them privately and they will not stay to hear about the study or participate.

The primary risks in this study are discomfort with answering questions about suicidality or drug use and a violation of confidentiality. The latter could occur from someone seeing the individual's answers during the group session, seeing the text messages, emails, or online survey at follow-up, or mistakes in data security by the research team.

Should a client express distress about talking about suicide in the PARS intervention, this will be addressed by the counselor leading the group as they would in other IOP sessions (in which many difficult topics including trauma, depression, and sexually transmitted diseases are standard topics). There will be one exception due to the potential for suicide risk. Following group, the counselor will meet individually with the client to address the issue and conduct a suicide risk assessment. Should the client be found to be at risk, standard IOP protocols for suicide risk will be followed by the counselor. Refer to Section 10 for more detail.

Participants are not required to answer any assessment question they choose not or don't know how to answer. This is described in the consent form and the follow-up survey protocol will include a method to opt out if they do not want to answer a specific item. Participants are free to stop at any time and the amount of money per question is low enough that we believe it will not be coercive if they do not want to participate.

All participants are adults and voluntarily participating, but we recognize that clients in addiction treatment and counselors might have specific or idiosyncratic reasons why participation in this study is inadvisable. Therefore, we have included an exclusion criterion for each to exclude anyone the agency or research team believes should not participate. This will be handled subtly, without public announcement that they should not participate, to protect their privacy (e.g., a client is called over by a counselor or a counselor is called over to chat with an agency leader in an innocuous way at the end of the meeting where we were recruiting and taken from public view before telling them that they believe the study is not a fit for them.)

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.

N/A

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.

N/A

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.

N/A

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?

N/A

10.3 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.

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

Although not adverse event, a possible problem is the discovery of suicidality that was previously unknown. In this case, we will facilitate referral back to agency or other treatment options as fits the client's needs using the risk assessment protocol as noted above in 9.3. No other adverse events are expected, but if they occur the participant will be referred back to their agency or other options.

While the discovery of suicidality is not an adverse event, the research team will respond according to our standard suicide risk management protocol. This research team has considerable experience in managing suicidal individuals in study assessments and Drs. Comtois or Ries or Ms. Kerbrat who is a licensed social worker will be available during all baseline assessments.

The research team who is conducting a large clinical trials of suicidal Service Members using text messages through the REDCap platform, the team already has an alert and follow-up system in place to assure immediate response if responses indicating suicide risk occur. When alerts go off, the research team has an alert and back-up system to respond to these messages promptly and use the risk management plan from 9.3 to connect the participant to care.

10.4 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.

N/A

*** 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.*

10.5 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, 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.

Please refer to supporting document.

A Data and Safety Monitoring Board (DSMB) will serve as an oversight committee, reviewing any modifications to the research design and conduct of the study and making recommendations according to the NIH Policies for data and safety monitoring as described below. The DSMB is charged as an external, independent oversight board, to monitor the conduct of the study for ongoing feasibility, data integrity, and safety. The specific goals of this DSMB are to:

1. Review new or modified risk management protocols at both sites.
2. Review procedures and decisions regarding the adequate protection of specific patients when investigators move into risk management protocols because of adverse events.

3. Review progress toward meeting enrollment goals.
4. Review procedures for maintaining the confidentiality of data, and quality of data collection, management, and analyses.
5. When appropriate, serve as final arbiters of whether individual patients should be removed from a protocol.
6. Recommend continuation, discontinuation, modification, or termination of a study based on emerging data (in the study and literature) and evaluation of risk/benefit ratio.
7. Conduct annual reviews to determine whether patient safety has been adequately safeguarded.
8. Meet at least once yearly with the principal investigator to review progress reports and more often as needed if severe adverse events occur which require discussion or changes to protocol.
9. Submit a brief report to NIH yearly summarizing the board's review.

Dr. Comtois has served on the NIMH DSMB-B for multi-site contracts since 2003 and has chaired and participated in multiple DSMBs for other studies of suicidal individuals. She has DSMBs for both of her current clinical trials. We have developed procedures based on this experience that are rigorous but feasible which we will follow in this study. Dr. Comtois will select DSMB members who have appropriate expertise, including in ethics and biostatistics, and no conflicts of interest. These members will monitor the study and ensure that monitoring is timely and effective.

Prior to the start of the study, the DSMB will review the IRB-approved protocol and overall plans for data and safety monitoring and request the desired data and format for reports from the study. The board will then review patient flow and participant entry to ensure adequate recruitment and retention of participants and will monitor the occurrence of adverse events related to participation in the protocol. If a severe adverse event is discovered, it will be communicated to the University IRB as well as the DSMB. The DSMB chair will determine if an immediate meeting to discuss a severe adverse event is needed. If so, a teleconference will be convened by Dr. Comtois. Otherwise, these events will be reviewed at the next scheduled meeting.

The DSMB has been informed of the PARS-ANAI supplement and procedures, and we will follow their guidance as to which Administrative Supplement procedures they want to review as this is outside of the RCT.

10.6 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.

This study does not blind participants from knowing their treatment condition. We do not make telling them an explicit Step in the study (to reduce expectancies that might bias responses) but will tell anyone who asks at any time during the study.

10.7 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.

We do not anticipate a reason to withdraw participants without their consent. Should this be considered, Drs. Comtois and Ries will consult with each other and our treatment partners to determine why such a move is in the best interest of the client and only withdraw them for that reason. The DSMB Chair would be immediately informed as per DSMB protocol.

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

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

The minimal risks to patient-subjects are reasonable in relation to the anticipated benefits because participants in the PARS condition will receive potentially valuable information regarding the relationship between addiction and suicide and what to do if suicide symptoms are seen in themselves or others. There is no anticipated benefit to participants in the TAU condition beyond receiving reimbursement for study participation.

10.9 Individual subjects findings.

a. Is it likely that your research will unintentionally discover a previously unknown condition such as a disease, suicidal intentions, or genetic predisposition?

[ ] **No**
[X] **Yes** → If yes, explain whether and how you would share the information with the subject.

It is possible that suicidality will be uncovered in study assessments or during the PARS intervention that were previously unknown to the treatment team. If this occurs during study assessments, the RA with assistance, as needed, from a licensed member of the research team will intervene as described in section 9.3 and will follow that protocol to assure adequate care for the individual while minimizing disclosure of study information to their treatment team to what they choose to tell. Drs. Comtois and Ries will train and supervise the RAs and intervene as needed to assure an appropriate response. If suicidality is disclosed during the PARS intervention, it will be to the counselor administering the PARS intervention who will follow standard agency procedures to intervene in the face of risk.

b. Do you plan to routinely share the individual results of your study procedures with the subjects – such as genetic test results, laboratory tests, etc.?

[X] **No**
[ ] **Yes** → If yes, complete and upload the **SUPPLEMENT: Participant Results Sharing** to the **Supporting Documents** SmartForm of ***Zipline***

10.10 Commercial products or patents. If a commercial product or patent could result from this study, describe whether subjects might receive any remuneration/compensation and, if yes, how the amount will be determined:

N/A