Official Title: Interventions to Improve the HIV PrEP Cascade Among Methamphetamine Users

NCT Number: NCT03584282

Study Protocol

Document date: 3/14/2022

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: Interventions to Improve the HIV PrEP Cascade among Methamphetamine Users
Short title: Hit Me Up study

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

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

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

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

University of Washington

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

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

☐ **No**

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

In June of 2017 we corresponded with Amanda Guyton about the formative, qualitative work we have done to inform this upcoming study. Our qualitative work was aimed at better understanding the needs of the target population (cismen and transgender individuals who have sex with men and use methamphetamine) in order to design an intervention to support adherence to pre-exposure prophylaxis (PrEP) for this population that is effective and culturally-competent. We included those activities in another IRB study (#54) since that project included PrEP-related qualitative activities with the same target population. At this time, we are submitting a new study IRB application for the randomized trial that we are planning, which is informed by the qualitative work in study #54.

We also corresponded with Amanda and Kristen Wittmann in February 2018 as we were preparing our protocol and consent form for this submission, regarding the use of a text platform that is not HIPAA-compliant and the best way to describe the potential risks of insecure communication in our consent form. We also communicated with UW Medicine Compliance regarding this issue and believe the submitted consent form describes these potential risks.

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.

The related study is titled "PrEP Among Meth-using TG/MSM" (study #54), with PI Joanne Stekler. This other study is a formative study that aims to better understand the knowledge, interest, and use of PrEP for HIV prevention among MSM and transgender individuals (MSM/TG) who use methamphetamine (meth). We have conducted surveys, focus groups, and interviews under this project. These activities have helped inform this proposed study, and how to try to support PrEP delivery to meth users. We also specifically conducted focus groups and interviews reviewing the materials and text messages that we plan to use in this proposed study, which helped ensure their effectiveness and cultural-competency.

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.

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

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

This project aims to conduct a pilot randomized control trial (RCT) to evaluate the acceptability and feasibility of a peer navigation intervention for meth-using MSM/TG.

As additional qualitative work for this study, we aim to understand the challenges/barriers to engaging and retaining MSM/TGP who use methamphetamine into the PrEP care continuum.

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.

The study design is a randomized trial using a 2 x 2 factorial design, whereby participants will be randomly assigned to one of two interventions: standard of care, or peer navigation.. We will also have end-of study interviews with study participants who choose to participate.
As additional activities to the primary study, we seek to also complete interviews with MSM/TGP who use methamphetamine who are not on PrEP, MSM/TGP who use methamphetamine who are on PrEP, eligible MSM/TGP who declined participation in the study previously, and PrEP providers (prescribers, PrEP educators and navigators, etc) who engage MSM/TGP patients who use methamphetamine.

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

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

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

☐ 11. Other. Explain:

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

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

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

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

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

There is an urgent need to find ways to successfully target HIV prevention strategies to cisgender men and transgender individuals who have sex with men (MSM/TG) who use methamphetamine (meth). Meth-using MSM/TG are at particularly high risk for HIV acquisition. Public Health – Seattle King County (PHSKC) has estimated that MSM/TG who use meth are 5 times more likely to be diagnosed with HIV than non-meth using MSM/TG. Daily, oral pre-exposure prophylaxis (PrEP) with Truvada is a highly-effective strategy for the prevention of HIV in adults and its use is increasing in Seattle and the United States. However, despite overall increases in PrEP use, high HIV risk among meth-using MSM/TG, and high interest in PrEP among MSM/TG, there is a smaller than expected number of meth-using MSM/TG who are enrolling in local PrEP programs. Effective HIV prevention efforts will need to decrease barriers to PrEP uptake and better target PrEP delivery to meth-using MSM/TG.

In addition, MSM/TGP who use meth and have initiated PrEP often have challenges with persistence and adherence. Importantly, PrEP's efficacy is related to adherence, and if people take too few pills or discontinue PrEP they receive limited or no benefit from it and can be at risk for HIV infection. Work is needed to monitor and support adherence among meth-using MSM/TG who initiate PrEP.

Building on our preliminary work, we plan to develop and pilot interventions for meth-using MSM/TGP with potential to be cost-effective, scalable, and easily adaptable. Peer navigation has been studied in antiretroviral (ARV) treatment and has been proposed for PrEP.

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.

We have conducted two surveys, five focus groups, and interviews with the target population under study #54. Through this work, barriers that meth users face to both initiate and adhere to PrEP have been discussed. We have received positive feedback from both the peer educators and other community members that text messages and peer navigation would be acceptable interventions to evaluate for PrEP use with this population and would likely help people take their PrEP. Furthermore, we have asked members of the target population for feedback regarding our messages, educational materials, and what activities the peer should provide, and have incorporated those suggestions into the study to help increase acceptability and usefulness to the participants.

As the study enrollment date is ending, we hope to gather further qualitative information from 2 populations of interest to better understand the challenges/barriers to engaging and retaining MSM/TGP who use meth in the PrEP continuum through in-depth interviews.

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, and you are asking the UW to provide the required certification or to ensure that the consent forms can be certified	*ZIPLINE* SUPPLEMENT: Genomic Data Sharing

☐	**Medical device** Procedures involve the use of any medical device, even if the device is not the focus of your research, except when the device is FDA-approved and is being used through a clinical facility in the manner for which it is approved	*ZIPLINE* SUPPLEMENT: Devices
☐	**Multi-site study** (You are asking the UW IRB to review one or more sites in a multi-site study.)	*ZIPLINE* SUPPLEMENT: Participating Site in Multi-Site Research
☐	**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.

Participants will be HIV-negative MSM/TG who use methamphetamine and present to a provider/organization in King County seeking PrEP.

Additional interviews will be conducted with members of populations representing study participants: MSM/TGP who were offered study participation but declined, HIV-negative MSM/TGP who use methamphetamine who are not receiving PrEP, and HIV-negative MSM/TG receiving PrEP who were not enrolled in the main study. We will also interview PrEP providers (prescribers, PrEP educators, navigators, and other persons who work with MSM/TGP who use methamphetamine.

2.2 Inclusion and exclusion criteria.

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

This study will enroll eligible and interested participants starting PrEP. First, eligible participants must meet the study site's PrEP eligibility criteria, and then they must meet the additional study eligibility criteria. Once clinic staff determines that the potential participant meets criteria for PrEP, they will assess if they meet the study inclusion criteria, which follow:

- 18 years of age or older
- HIV-negative or test sent at the enrollment visit
- Cisgender man or individual on the trans gender variant spectrum who has sex with cisgender men, transgender men, or transgender women
- Ability to understand, read, and speak English
- Reports meth use in the past 3 months
- Has a phone and is able to receive and make calls and/or text messages
- Intends to remain in the area for at least 6 months

New qualitative work will enroll MSM/TGP who either declined participation in the HMU study or who would have been eligible but were not engaged in the study (both on PrEP and those not on PrEP) and PrEP providers,(prescribers, peer educators, PrEP navigators, etc). Once clinic or research staff determines that the

potential participant fits into one of the above categories for an in-depth interview, they will assess if they meet the additional study inclusion criterion, which follow.

For MSM/TGP participants:

- 18 years of age or older
- Cisgender man or individual on the trans gender variant spectrum who has sex with cisgender men, transgender men, or transgender women
- Ability to understand, read, and speak English
- Reports past or current methamphetamine use
- Interested in participating in an in-depth interview

For PrEP providers (prescribers, peer educators, and PrEP navigators):

- 18 years of age or older
- Has worked with getting MSM/TGP patients who use meth on to PrEP care
- Interested in participating in an in-depth interview

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

Individuals who are screened and meet ANY of the following criteria will not be eligible for study enrollment:

- PrEP use in the prior month
- Discomfort or anxiety with regards to text messaging
- At study entry has any circumstances that, based on the opinion of the clinical staff, would preclude provision of informed consent, make participation unsafe, or make it unlikely the participant would be able to participate for 6 months

For new activities, individuals who are screened and meet ANY of the following criteria will not be eligible for in-depth interview:

- At study entry has any circumstances that, based on the opinion of the clinical staff, would preclude provision of informed consent or make participation unsafe.

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

a. Will you recruit or obtain data from individuals that you know to be prisoners?

For records reviews: if the records do not indicate prisoner status and prisoners are not a target population, select "No". See the WORKSHEET: Prisoners for the definition of "prisoner".

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

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

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

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

iv. If your research will involve prisoners in federal facilities or in state/local facilities outside of Washington State: check the box below to provide your assurance that you will (a) not encourage or facilitate the use of a prisoner's participation in the research to influence parole decisions, and (b) clearly inform each prisoner in advance (for example, in a consent form) that participation in the research will have no effect on his or her parole.

☐ **Confirmed**

b. Is your research likely to have subjects who become prisoners while participating in your study?

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

☐ **No**
☒ **Yes** → If yes, if a subject becomes a prisoner while participating in your study, will you continue the study procedures and/or data collection while the subject is a prisoner?

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

It is possible that the peer navigator may reach out to the participant after they are in jail due to being unaware of their current incarcerated status. However, they will not have access to their phones while in jail/prison so they will not see these texts.

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

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

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

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

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

[X] **No**
[ ] **Yes** → If yes, name the tribe, tribal-focused organization, or similar community based organization. The UW IRB expects that you will obtain tribal/indigenous approval before beginning your research.

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

"Identifiable" means any direct or indirect identifier that, alone or in combination, would allow you or another member of your research team to readily identify the person. For example, suppose that you are studying immigration history. If you ask your subjects several questions about their grandparents but you do not obtain names or other information that would allow you to readily identify the grandparents, then you are not collecting private identifiable information about the grandparents.

[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.

[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*
Standard of care group	20
Peer navigation group	20
End-of-study interviews	40 (same participants as included in above 4 groups)
MSM/TGP participants who declined participation in HMU study	up to 25
MSM/TGP on PrEP who report recent meth use	up to 25
MSM/TGP not on PrEP who report recent meth use	up to 25
PrEP prescribers	up to 10
PrEP peer educators and navigators	up to 10

3 NON-UW RESEARCH SETTING
Complete this section only if your research will take place outside of UW and Harborview

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

We will still operate the study out of Gay City and Kelley-Ross pharmacy, and the reasons for selecting those sites are below. At this time we propose to broaden study sites to any provider or organization in King County who provides PrEP to someone who is eligible (for example, Madison Clinic at Harborview, Public Health King County STD clinic, private practitioners) and contacts us if the person is interested in participating. During the

first few months of this study we have seen a very small number of eligible people at Gay City and Kelley-Ross (recent methamphetamine use and seeking PrEP). We have brainstormed and asked community partners regarding approaches to broaden our reach to engage with more individuals who may be eligible and interested to enroll in the study. We have provided study information to colleagues and community partners and believe that some may have persons who seek PrEP from them and would be interested in participating in this study. Furthermore, aside from the consent process and fingerstick dried blood spot collection all research procedures (e.g., peer navigation, surveys) are done outside of the study site.

We selected two non-UW sites to participate in this study: Gay City and Kelley-Ross. These sites were selected for several reasons. First, both Gay City and Kelley-Ross have dedicated PrEP clinics, where meth-using MSM/TG (the target population) seek PrEP. Second, the UW research team has existing relationships with both clinic's leadership, and the PI, Dr. Stekler, is the Medical Director and PrEP provider at Gay City. Finally, in the surveys we did as part of study #54, we asked meth-using MSM/TG where they would like to access PrEP and both Gay City and Kelley-Ross were in the top half in both surveys with 33% saying they would like to get PrEP at Gay City and 27% saying Kelley-Ross in our final survey.

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

One important component of protecting our participants will be ensuring that the research study does not stigmatize them for their drug use, MSM/TG identities, or any other identity that they have. It will be important to work with sites that have experience seeing meth-using MSM/TG and creating a non-judgmental environment for this population to seek health services. Both Gay City and Kelley-Ross already see meth-using MSM/TG, and as mentioned above were preferred places to seek PrEP among meth-using MSM/TG survey respondents in Seattle. In addition community partners we have reached out to with study information have experience providing non-judgmental care to MSM/TG individuals. We believe that they provide non-stigmatizing care to meth-using MSMT/TG and will be optimal locations to do this project.

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.

This project will take place in Seattle and will follow the same local laws as projects that are conducted at UW and Harborview.

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.

There are no additional administrative or ethical requirements that would affect our research at any study site.

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.

Participants will be recruited at sites in King County that offer PrEP, including Gay City and Kelley-Ross. Clinic staff will identify eligible participants who meet the clinic's criteria for PrEP and report meth use in the prior 3 months, are MSM/TG, have a cell phone, are over 18 years old, and understand English. The clinic staff will be able to identify eligible participants based on the clinical intake questions that are asked as part of regular PrEP screening. Clinic staff will inform potential participants that they are eligible to receive PrEP and will discuss PrEP initiation prior to inviting them to participate in the study. Once clinic staff recognize that someone may be eligible for the study they will inform them of the study and ask if they want to hear more about it.

We may also use recruitment materials at the clinics (e.g., in the waiting room) that describe the study, so a potential participant may inquire about the study prior to the clinic staff bringing it up. Written materials describing the study may be especially important, as anecdotally we have heard that meth users who are currently in the PrEP program at Kelley-Ross have disclosed their meth use after they initiated PrEP, at a follow-up appointment. Since people for this study are only eligible at the visit they are starting PrEP, we may include materials in the waiting room that describe the study to support disclosure of meth use at their first PrEP visit if someone reads about it and is interested in participating in the study.

In addition, during routine clinical care visits, calls, or other points of contact, Gay City clinic staff may tell patients about the study and refer them to the study team for more information.

We will also provide a small incentive ($10 gift card) to Project NEON peer educators who refer an eligible individual to us who completes screening. We may increase the incentive amount to $15 for peers who refer multiple individuals to us and we may provide an extra gift card to peers who refer the most individuals in a certain time period (e.g., 3 months). We have successfully worked with the peers to recruit for surveys among the same population, which overlaps with their contacts (study #54).

All study participants who complete their participation in the study (i.e., complete the 6-month survey) or who discontinue the study early will be recruited for an end-of-study interview. The research coordinator will contact them via text or email and invite them to participate in an interview.

"New activities for all MSM/TGP" and "New activities for PrEP providers, (prescribers, caseworkers and peer educators/navigators, etc):"

For MSM/TGP:

Participants will be recruited from Gay City and Kelley-Ross. Clinic staff will identify eligible participants who report meth use in the prior 3 months (or at the time of prior offer of the study), are MSM/TGP, are over 18 years

old, and understand English. The clinic staff will be able to identify eligible participants based on the clinical intake questions that are asked as part of regular PrEP screening.

In addition, during routine clinical care visits, calls, or other points of contact, staff may tell potential participants about the study and refer them to the study team for more information. Based on participant preference, if the potential participant would rather contact study staff on their own, participants will be given a "business card" (attached in the modification submission as "HMU business card_Dana and Kimiam") with the research coordinators contact information. MSM/TGP participants will reach then out via the contact details provided where we will then set up an interview time and date. If the study participant would prefer to have the research study team contact them first, clinic staff will ask potential participants for their consent to share contact information directly with the research staff, who will then reach out via the contact information provided by clinic staff.

Another form of participant recruitment will be in reviewing previous text messages from interested participants through the texting platform used through Grindr and Adam4Adam recruitment. Previously, potential participants who reached out via text through the Grindr/Adam4Adam ad communicated with study staff but ultimately did not elect to enroll in the study. We will obtain a waiver of consent prior to re-contacting these individuals.

The research coordinator will contact all interested participants via phone call, text or email and invite them to participate in an interview.

For PrEP providers, (prescribers, caseworkers and peer educators/navigators, etc):

Participants will be recruited at sites in King County that offer PrEP, including Gay City and Kelley-Ross. Eligible clinic staff will be identified by the PI, Joanne Stekler and approached via phone call or email to ask about their interest in participating in an in-depth interview.

The research coordinator will contact all interested PrEP providers via email or phone to schedule and complete the interview.

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 mentioned above we may have materials in the waiting room that describe the study for participants to read before their appointment. In this way, someone who is interested in participating, and potentially receiving text messages or peer support for PrEP use but who otherwise may not have disclosed their meth use, may end up discussing their eligibility and interest with clinic staff.

We have existing PrEP educational materials targeted to meth users that were originally developed under study #54, we may add the study name and additional study information to these materials. We will also develop new cards for the study that only have study information (e.g., reference to study eligibility, purpose, and contact information for clinical sites). We will provide these cards to community partners to hand out or have at their clinics/organizations to inform people about the study. We may also hand out these materials in other settings, such as health fairs or community events.

We will also send out information via email to community partners who may interface with people who may be interested in PrEP, use meth, and would be interested in this study. We will share information that is consistent with the messages in the talking points included in 'Recruitment Materials' in Zipline (e.g., study purpose, location, length, overview of procedures, and reimbursement). We may also post this information on social media pages that may reach people who are eligible and interested (e.g., Facebook). Finally, we may have a flyer describing the study hanging in the waiting rooms of one or both clinics.

New activities for MSM/TGP participants and PrEP providers:

For MSM/TGP participants, we will have a recruitment script for clinic staff to use when approaching possible participants. Clinic staff will refer interested participants to research staff who will be able to schedule in-depth interviews.

We will share information that is consistent with the accompanied "Recruitment Script – Participant MSM/TGP" in Zipline.

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**

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

The study PI, Dr. Stekler, is a PrEP provider at Gay City Health Project and is present for all initial PrEP appointments. Therefore, she will be the one to identify eligible participants about the study and inform them about it. Dr. Stekler will emphasize that the study is completely voluntary and in no way would impact someone's ability to obtain PrEP from the clinic. In addition, Dr. Stekler will be contacting PrEP providers and prescribers who may be of interest to interview. As with any MSM/TGP participants, Dr. Stekler will emphasize that the study is completely voluntary and in no way would impact their employment status or existing relationships with her or their place of employment.

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

- The total amount/value
- Whether payment will be "pro-rated" so that participants who are unable to complete the research may still receive some part of the payment

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

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

We will ask participants to take a survey at baseline, month 3, and month 6 (end of study). They will be provided a $20 Amazon gift card for each completed survey via email, and therefore up to $60 in Amazon gift cards if they complete all three. We will provide each participant who completes an end-of-study interview a $40 Amazon gift card.

New activities for all MSM/TGP participants and PrEP providers:
We will ask participants to partake in an interview. MSM/TGP participants will be provided with a $40 Amazon gift card after the completion of the interview. Non-prescriber PrEP providers will be provided with a $20 Amazon gift card after the completion of the interview. PrEP prescribers will not receive compensation.

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.

There will be no form of non-monetary compensation for participating in this study.

4.6 Will you access or obtain data or specimens for recruiting and screening procedures prior to enrollment?

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

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

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

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

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

Examples:

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

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

☐ **Yes** → If yes, describe the consent process.

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

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

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

5 PROCEDURES

5.1 Study procedures. Using lay language, provide a complete description of the study procedures, including the sequence, intervention or manipulation (if any), drug dosing information (if any), use of records, time required, and setting/location. If it is available and you think it would be helpful to the IRB: Upload a study flow sheet or table to the **Supporting Documents** SmartForm in ***Zipline***.

*For studies comparing standards of care: It is important to accurately identify the research procedures. See UW IRB **POLICY: Risks of Harm from Standard Care** and the draft guidance from the federal Office of Human Research Protections, **"Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care";** October 20, 2014.*

This research study will be conducted in addition to standard of care procedures for PrEP use. Therefore, clinical procedures, including blood draws for laboratory testing, STI screening, PrEP prescriptions, and adherence counseling will be performed in accordance with the clinic's standard of care. Participants will be followed in this study and have visits at entry (baseline), and then at months 1, 3 and 6.

The research procedures, in addition to informed consent, that all participants will get in addition to the standard of care, are the following:

- Randomization: After consent has been obtained the clinical site will send documentation of eligibility (checklist) and the signed informed consent, HIPAA authorization, and ROI to the study team at UW. The site will either email the documents or provide them in person to a study team member. Once these documents are received, the research coordinator will send the participant a link to the baseline survey. After completion of the baseline survey, the participant will be randomized to one of the two intervention groups: standard of care, or peer navigation. The research coordinator will open a sequentially numbered, sealed envelope with the study allocation (generated by site using blocked randomization with variable block sizes and random number generator). They will record the treatment assignment of the participant in their de-identified chart and send a text or email to inform the participant of their assignment.
- Surveys: Participants will be asked to complete an online survey at the entry visit (baseline) and at 3 and 6 months. They will be sent a unique link to the survey by text and reminders if they do not complete it. If a participant does not complete their baseline survey within 7 days they will be replaced in the study. Extenuating circumstances (such as sudden job loss, health emergencies and legal issues for robberies) can be made to extend this baseline survey deadline within a reasonable timeframe at the discretion of the PI.

- Fingerstick for dried blood spots: At all follow-up visits (1 month, 3 months, and 6 months) we will collect a blood specimen via fingerstick and use it to obtain dried blood spots, which will be used to test for the presence of the medications in PrEP (tenofovir and emtricitabine).

- Intervention groups:
  - Standard of care: The up to 20 participants who are assigned to the standard of care, will only be asked to participate in the research procedures described above.
  -
  - Peer navigation: For the up to 20 participants who are assigned to the peer navigation group, they will receive peer support. These activities include, but are not limited to, in-person meetings, appointment reminders and escort, refill assistance, and check-ins about adherence. The activities that the participant receives will be in response to their needs and requests. The peer will introduce themselves to participants in this intervention arm within 2 business days of when the participant completes the survey, via their preferred method of contact (as recorded at the clinic during the entry visit). The peer will schedule their first in-person meeting within 1 week of enrollment. As some meth users will have greater functioning than others, the peer will create an individualized plan for each subject and tailor activities and resources based on acuity. Individualized plans will be completed at study enrollment and exit to be able to record needs and progress during the study. Additional individualized plans may be completed during follow-up at the discretion of the peer and depending on the needs and acuity of the participant.

If a participant decides to stop getting PrEP at one of our study clinics, and gets PrEP somewhere else during their 6-month study participation, we will ask them to take the remaining online study surveys and to complete an ROI between their new clinic and the study site where they enrolled. If they are in one of the groups that receive text messages or peer navigation, we will also ask that they continue to receive these interventions to try and support their PrEP use at the other provider. If a participant leaves the study early (before 6 months) we will attempt to complete a study exit visit that will have the same procedures as a visit at months 3 or 6 (survey and dried blood spot).

Finally, the research coordinator will conduct semi-structured interviews with all willing study participants after they finish study follow-up to better understand the acceptability and feasibility of the study interventions and participants experience with PrEP. Interviews will be digitally audio-recorded and transcribed verbatim, and identifying information will be deleted. The information sheet and interview guide for these interviews have been uploaded to Zipline. Once a participant completes their final, 6–month survey, or if a participant discontinues the study early, the research coordinator will contact them and ask if they would like to participate in an end-of-study interview. Interviews can be conducted in-person, by phone, or by Zoom videoconference. If the interview is conducted by phone or Zoom the research coordinator will email the information sheet to the participant prior to the interview and will ensure that all questions are answered and verbal consent is obtained at the start of the interview before asking any interview questions. If the interview is done in-person the information sheet will be reviewed at the beginning of the interview and verbal consent will be obtained prior to asking any interview questions. $40 Amazon gift cards will be provided for each completed interview, which will either be handed to participants or emailed.

Procedures	Enrollment[1]	Month 1	Month 3	Month 6	Early Discontinuation
Clinical Procedures					
HIV Testing	X	X	X	X	X
HBsAg Testing	X				
Creatinine Testing	X	X	X	X	X
STI Screening	X		X	X	X
Adherence Counseling	X	X	X	X	X
Research Procedures					
Research Consent	X				
Online CASI	X		X	X	X
Blood collection for DBS		X	X	X	X
Blood volume (mL)	15	7	15	15	15
Clinic visit length (min)	90	30	30	30	30

[1] The research procedures of the enrollment visit may be performed on the same day of the initial PrEP clinical visit, or on the following day.

New activities for all MSM/TGP participants and PrEP providers:

The research coordinator will conduct semi-structured interviews with all willing study MSM/TGP participants and PrEP provider (prescribers, caseworkers, peer educators, and PrEP navigators) participants to better understand the challenges and barriers to PrEP initiation and engagement in the PrEP care continuum. Interviews will be digitally audio-recorded and transcribed verbatim, and identifying information will be deleted. The information sheet and interview guide for these interviews have been uploaded to Zipline. Interviews can be conducted in-person, by phone, or by Zoom videoconference.

Note: Remote interviews will be preferred, however an in-person option is being made available due to potential access issues. It is anticipated that most (if not all) will be remote. Attention will be paid to COVID safety protocols and guidelines including symptom screening if an interview is done in-person.

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 obtain contact information from the clinic at enrollment and all participants will complete an ROI so we can obtain their clinical information related to PrEP. We will also obtain drug level testing results (tenofovir and emtricitabine) once the study is over.

The data we will obtain from the baseline and follow-up surveys are uploaded in Supporting Documents.

The peer will complete individualized plans for each participant assigned to peer navigation. The peer will also complete a contact log with all of the participant contacts they have that are not already recorded in the text platform, individualized plans, or the peer's cell phone. Examples of the individualized plan and contact log have been uploaded in the Supporting Documents SmartForm.

We will obtain interview data from participants who consent to participate in an end-of-study interview. An interview guide has been uploaded in the Supporting Documents SmartForm with interview questions.

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.

We are obtaining the data from the subject (contact information, self-reported survey data, dried blood spots, reported behavior and PrEP adherence, etc.). We will also obtain PrEP pharmacy refill data as available. We will also collect data recorded by the peer (individualized plan, contact log). and data recorded on the text platform (number of texts, content, etc.). Correspondence between the peer and the participants assigned to the peer navigation group will also be considered study data. We will count the frequency of contacts of different types (e.g., text, call, in-person) and describe the contact (e.g., call to pharmacy to help with refills).

5.4 Retrospective/prospective. For all types of data and specimens that you will access or collect for this research: do all data and specimens to be used in the research exist (for example, in subjects' medical records) at the time this application is being submitted for initial review?

[X] **No**
[ ] **Yes**

Include any necessary comments or explanation below (Note that for most studies this can be left blank):

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

a. Will you or any members of your team have <u>access</u> to any direct or indirect identifiers?

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

We will have access to all participant's names, date of birth, and contact information (email, phone, address, and other contact information, e.g. Facebook or Skype, that the participant chooses to provide). Participants will sign an ROI at study entry, so all identifying information in their clinical chart related to their PrEP follow-up will be accessible to the study team at UW.

New activities for all MSM/TGP" and "New activities for PrEP providers, (prescribers, caseworkers and peer educators/navigators, etc):

We will have access to all participant names and contact information (email and/or phone number). Information will be deleted as we complete interviews, so name and contact information will not be accessible past the completion of interviews. Recordings and transcriptions will have no association with participant names and contact information, and will only be labeled as the interview date. An ROI is not needed due to the limited nature of this data and it not being tied to clinical chart information.

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

☐ There will be no identifiers.

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

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

You should be able to produce this agreement for IRB upon request. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.

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

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

b. Will you <u>obtain</u> any direct or indirect identifiers?

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

We will obtain direct identifiers, including all participant's names, date of birth, and contact information (email, phone, and address). Participants will sign an ROI at study entry, so all identifying information in their clinical chart related to their PrEP follow-up will be accessible to the study team at UW.

New activities for all MSM/TGP" and "New activities for PrEP providers, (prescribers, caseworkers and peer educators/navigators, etc):

We will have access to all participant names and contact inofmation (email and/or phone number). Information will be deleted as we complete interviews. An ROI is not needed due to the limited nature of this data not being tied to clinical chart information.

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

☐ There will be no identifiers.

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

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

You should be able to produce this agreement for IRB upon request. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.

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

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

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

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

Participants identifiers that are recorded on the enrollment forms (e.g., consent form, contact information, HIPAA authorization) will be stored in a folder in a locked file cabinet in the PI's secure office on a secure floor at the Ninth and Jefferson Building, with the study code on the folder.

We will store text messages, phone calls, and emails with identifiers of participants who are in the peer navigation groups for the duration of the corresponding participant's participation. Since this study is assessing the acceptability and feasibility peer navigation, characteristics of these data sources, including quantity, frequency, subject, are important to assess the study aims. Correspondence data includes identifying contact information (e.g., phone number, email address), so this data will be stored with identifiers.

For participants in the peer navigation group, sources of data with identifiers that cannot be removed will be stored after they complete their participation.

New activities for all MSM/TGP" and "New activities for PrEP providers, (prescribers, caseworkers and peer educators/navigators, etc):

Interested participants will be given a date for their interview. No participant identifiable information will be documents or recorded. Once an interview is completed, the audio recordings will be uploaded to a secure transcription service and labeled only by the interview date to avoid any direct or indirect identifiable information. This process of labeling will be the same for transcripts. Once transcriptions are returned and reviewed for accuracy, the audio file will be permanently deleted.

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

All participants' emails will be entered into our survey platform so we can send them survey links. We may also store participant phone numbers in an online text message platform, listed only by their participant code number, to limit identifying information. For participants assigned to peer navigation, the peer navigator will store their phone number and email on an encrypted study cell phone so they can communicate with participants in the peer navigation group. Their code will not be stored on the cell phone.

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

New activities for all MSM/TGP" and "New activities for PrEP providers, (prescribers, caseworkers and peer educators/navigators, etc):

Interested participants will be given a date for their interview. No participant identifiable information will be documents or recorded. Once an interview is completed, the audio recordings will be uploaded to a secure transcription service and labeled only by the interview date to avoid any direct or indirect identifiable information. This process of labeling will be the same for transcripts. Once transcriptions are returned and reviewed for accuracy, the audio file will be permanently deleted.

The demographic survey information will be entered in by a study staff coordinator and will not be tied to any participant identifiable information. It will only be tied to the interview date to avoid any direct or indirect .

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

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

No, individuals who provide us with coded information or specimens will not collaborate on other activities for this research.

5.6 Newborn dried blood spots. Will you use newborn dried bloodspots collected in the United States on or after March 18, 2015?

[X] **No**
[ ] **Yes** → If yes, is this research supported by any federal funding (including any fellowship or career development award that provides salary support)?

[ ] **No**
[ ] **Yes** → If yes, describe how you will ensure that the bloodspots were collected with parental permission (in compliance with a 2015 law that applies to federal-funded research).

5.7 Protected Health Information (PHI). Will you access, obtain, use, or disclose a participant's identifiable PHI for any reason (for example, to identify or screen potential subjects, to obtain study data or specimens, for study follow-up) that does not involve the creation or obtaining of a Limited Data Set?

PHI is individually-identifiable healthcare record information or clinical specimens from an organization considered a "covered entity" by federal HIPAA regulations, in any form or media, whether electronic, paper, or oral. ***If you will use UW Medical Records, you must answer yes to this question.***

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

[X] **Yes** → If yes, answer all of the questions below.

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

We will obtain the health information that is in the clinical charts at the study sites were participants are enrolled that is relevant to PrEP follow-up. All participants will sign a HIPAA Authorization and an ROI at study entry. This data will include appointment dates, behavioral eligibility for PrEP, any reported side effects from PrEP, prescription orders and refills, reported PrEP adherence, any discontinuation of PrEP and reason, and other information that may be recorded regarding their PrEP use and follow-up.

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

[ ] **No**

[X] **Yes**

c. Describe how you will access or obtain the PHI. *Be specific.*

At study entry, all participants will sign a HIPAA Authorization and an ROI between the clinic site and the UW study team to share PrEP-related clinical records.

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

We will ask participants to authorize us to access their PrEP-related medical records using both a HIPAA Authorization and an ROI prior to obtaining any PHI.

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

[X] **Confirmed**

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

None.

Provide the following assurances by checking the boxes.

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

[X] You will fulfill the HIPAA "accounting for disclosures" requirement. See UW Medicine Privacy Policy #25. THIS IS ONLY FOR UW RECORDS.

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

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

[X] **No**
[ ] **Yes** → If yes, answer the question below.

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

[ ] **No**
[ ] **Yes** → If yes, complete the ***ZIPLINE* SUPPLEMENT Genomic Data Sharing** and upload it to the **Supporting Documents** SmartForm of ***Zipline***.

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

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

[X] **No**
[ ] **Yes**

5.10 Data and specimen sharing/banking. Are you likely to share some or all of the data, specimens, or subject contact information with other researchers or a repository/database for research purposes not related to this study, or to bank them for your own future unspecified research uses? **You are strongly encouraged to consider the broadest possible future plans you might have, and whether you will obtain consent now from the subjects for future sharing or unspecified uses.** Answer **YES** even if you will only share information without identifiers. Answer **NO** if you are unlikely to do any sharing, or if your only sharing will be through the NIH Genomic Data Sharing described in question 5.8.

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

[X] **No**
[ ] **Yes** → If yes, answer all of the questions below.

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

b. Describe what will be shared, including whether direct identifiers will be shared and (for specimens) what data will be released with the specimens.

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

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

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

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

☐ **No**
☐ **Yes** → If yes, be sure to include the information about this consent process in the consent form (if there is one) and in your answers to the consent questions in Section 8.

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

☐ **No**
☐ **Yes** → If yes, describe how, and whether there are any limitations on withdrawal.

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

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

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

☐ **Confirmed**

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

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

For all participants we will send them a link to the survey at baseline, month 3 and month 6 and reminders if they do not complete it. For the participants assigned to the standard of care group, we will not have additional contact. For participants in the peer navigation group, the peer navigator will have varied communication (in-person, email, phone, text) in response to the requests of the participant. Once participants have completed their 6-month survey, or if they discontinue the study early, we will contact them and ask if they would like to participate in an end-of-study interview.

New activities for all MSM/TGP participants and PrEP providers:

Interested participants for the in-depth interview will be contacted by the study team or PI and asked if they would like to participate in the population-appropriate in-depth interview.

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

[X] **No**
[ ] **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.

5.13 Alternatives to participation. Are there any alternative procedures or treatments that might be advantageous to the subjects?

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

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

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

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

Use this text box (if desired) to provide:

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

5.15 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.
- The generic age of consent may be different in other states, and in other countries.

☒ **No** → If no, go to Section 8.

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

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

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

a. Will you obtain parental permission for:

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

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

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

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

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

Table footnotes

1. *If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.*
2. *If you plan to obtain identifiable information or biospecimens without parent permission, any waiver granted by the IRB does not override parents' refusal to provide broad consent (for example, through the Northwest Biotrust).*
3. *Will you inform them about the research beforehand even though you are not obtaining active permission?*

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

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

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

This is all that is required for minimal risk research.

If you checked both boxes, explain:

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

☐ **No**

☐ **Yes** → If yes, an advocate may need to be appointed for each child who is a ward. The advocate must be in addition to any other individual acting on behalf of the child as guardian or in loco parentis. The same individual can serve as advocate for all children who are wards.

Describe who will be the advocate(s). Your answer must address the following points:

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

7 ASSENT OF CHILDREN (MINORS)

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

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

a. Will you obtain assent for:

☐ All of your research procedures and child groups	→ Go to question **7.2.**
☐ None of your research procedures and child groups	→ Use the table below to provide your justification, then skip to question 7.5.
☐ Some of your research procedures and child groups	→ Use the table below to identify the procedures for which you will not obtain assent.

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

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

Table footnotes

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

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

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

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

☐ None of your research procedures and child groups	→ Use the table below to provide your justification, then go to question 7.4.a.
☐ All of your research procedures and child groups	→ Go to question **7.4.a**, do not complete the table
☐ Some of your research procedures and/or child groups	→ Complete the table below and then to go question 7.4.a

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

Table footnotes

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

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

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

7.5 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.

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

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

7.6 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. **NOTE**: If you plan to obtain identifiable information or identifiable biospecimens without consent, any waiver granted by the IRB does not override a subject's refusal to provide broad consent (for example, the Northwest Biotrust).

WAIVER OF DOCUMENTATION OF CONSENT means that there is IRB approval for not obtaining written documentation of consent.

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

[X] Adult subjects

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

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

8.2 The consent process. 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*

In order to obtain consent, the clinical/study staff will meet with an interested and eligible participant in a private setting and review the UW HSD-approved consent form with them. If the staff has a time conflict or are at a site outside of Gay City or Kelley-Ross the clinic staff will reach out to the UW study team (Principal Investigator, Study Coordinator and/or Peer Navigator) to provide consent. In these cases one of the UW study team members will consent the individual within 7 days at either at the study site or in another private location at UW or with a community partner (e.g., a private room at Gay City). All personnel who perform consent will ensure that the participant knows that participating in research is voluntary and that they can stop their participation at any time. Specifically, the clinical/study staff will inform the individual that they can receive PrEP at the clinic without participating in the study, if they would prefer not to participate. Once the consent is reviewed, all questions have been answered, and the staff is confident the client understands the procedures, the client and the staff will both sign and date the consent form.

The Gay City PrEP clinic also offers PrEP visits by telemedicine for people who cannot come to the Wellness Center during the weekly clinic hours and at outreach settings where Gay City offers HIV testing, including UTOPIA in Kent, WA. Telemedicine visits are only done for the initial PrEP visit for clients; for follow-up PrEP visits the HIV tester will see the client without the provider's presence via telemedicine. During the initial visit the HIV tester is with the client in-person and uses a HIPAA-compliant telemedicine platform (Zoom) through their UW Net ID account to connect with the provider. Together, the tester and provider conduct the visit, including informing the client about PrEP, assessing for eligibility, and determining next steps (e.g., how to help client with insurance/financial assistance for PrEP; if behaviorally eligible, provider will prescribe PrEP once eligibility is confirmed after reviewing lab results). The tester performs any specimen collection, weight measurements, etc. The tester and provider are in private settings during telemedicine appointments to ensure the privacy of the client.

For people who have a telemedicine appointment and are eligible for and interested in the study, the HIV tester will hand the client a paper consent form and the provider will review the consent form with the client via telemedicine. Since video is used, she will be indicate visually to the client where in the consent form certain things are described. If the client is eligible and wants to participate, she will ensure that all the client's questions are answered and the client understands the study. The participant and the tester (on a specified signature line) will sign two consent forms and the participant will be given one of them. The tester will bring the other consent form back to Gay City. Study staff will pick up the consent form and the provider will sign it. We will then either mail the consent form with all three signatures to the participant or bring it to them at their next visit (approximately 1 month later) if they do not want us to mail it to them.

We will use an information sheet for the end-of-study interviews and obtain verbal consent. We would like to have as many participants as possible participate in these interviews to learn about their experience in the study and to better understand in a qualitative/in-depth way the acceptability and feasibility of the study procedures (peer navigation). Since people may be more likely to participate via phone or Zoom than having to go somewhere in person and these participants may not have the capability to print, sign, and scan a consent form, we will use an information sheet, review it with the participant to ensure comprehension, and obtain verbal consent.

Consenting Process for MSM/TGP and PrEP providers:

If the interview is conducted by phone or Zoom the research coordinator will email the information sheet to the participant prior to the interview and will ensure that all questions are answered and verbal consent is obtained at the start of the interview before asking any interview questions. If the interview is done in-person, the information sheet will be reviewed at the beginning of the interview and verbal consent will be obtained prior to asking any interview questions.

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

The staff will ensure that the individual is aware of what the research procedures and risks/benefits are and that all questions are answered before obtaining consent.

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**

[X] **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.

The lead researcher is also the prescribing physician at the Gay City Health Project. If she has a potential client who is eligible to participate, she will inform them of the study and emphasize that they can continue to get PrEP at Gay City without participating if that is their preference. The Gay City PrEP clinic is not a primary care clinic, but instead is a safety net clinic that follows people who initiate PrEP until they can be linked to a primary care provider for continued use (typically up to a few months) and assists with this linkage. So the PI is not the primary care provider for the Gay City PrEP clients. All clients who decide not to initiate PrEP are provided information on other locations to get it if they so choose to in the future.

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.

The clinical staff will be in ongoing communication with participants throughout their PrEP follow-up. Participants are always welcome to communicate that they no longer want to participate to the clinic staff, who can communicate that to the UW study team. Finally, the 20 that are in the peer navigation group will be in close contact with the peer, who will be checking in on how they are doing throughout their participation, and they can communicate to the peer if they want to stop participating. For any participant who stops the study early, we will ask them for the reason of early discontinuation.

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 **8.4.**
☒ 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
40	End-of-study in-depth interviews	☒	☐
25	MSM/TGP who previously declined participation in HMU study	☒	☐
50	MSM/TGP who use methamphetamine, not on PrEP or on PrEP who never knew about HMU study	☒	☐
10	PrEP Prescribers	☒	☐
10	Peer Educators, Peer Navigators	☐	☐

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?

☒ **No**

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

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

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

8.5 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 before they sign it; excluding individuals who cannot read and understand the consent form.

Since peer navigators may potentially communicate with participants via text, participants must be able to read.

8.6 Deception. Will you deliberately withhold information or provide false information to any of the subjects? *Note: "Blinding" subjects to their study group/condition/arm is not considered to be deception.*

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

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

a. Will you 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***.

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

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

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

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

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

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

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

8.8 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.*

At all study sites providers meet with clients in a private room when they initiate PrEP. We will perform screening and consent in these offices or another private location at UW or with a community partner. We will encourage participants to answer the survey in a private setting. The peer will encourage participants to meet with them in private settings. This may not always be possible if the peer is accompanying the participant to the pharmacy, for example, but the peer will only engage in activities that the participant requests, and will ensure that privacy is protected as much as possible.

For the end-of-study interviews done in-person they will be done in a private setting. For interviews done via phone or Zoom, the interviewer will be in a private setting and will encourage the participant to also be in a private setting.

Interviews done in-person will be done in a private setting. For interviews done via phone or a HIPAA compliant Zoom account, the interviewer will be in a private setting and will encourage the participant to also be in a private setting.

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

[X] **No**
[ ] **Yes** → If yes, will you obtain subject consent for this use?
  [ ] **Yes**
  [ ] **No** → If no, describe the steps you will take to protect subjects (or small groups of subjects) from being identifiable.

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

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

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

[ ] **No**
[X] **Yes** → If yes, the UW IRB expects you to inform subjects of this possibility in the consent form or during the consent process, unless you provide a rationale for not doing so:

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

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

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

See the "Research Data and Records" information in Section 8 of this document for the retention schedules for UW Medicine Records: ***http://www.uwmedicine.org/about/Documents/UWM-Records-Retention-Schedule-v1.6.pdf***

[X] **Confirm**

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

[X] **No**
[ ] **Yes**

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

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

Since this study will enroll people who use meth, the data collected is extremely sensitive (level 5), since it regards illegal activity.

b. Use this space to provide additional information, details, or to describe protections that do not fit into one of the levels. If there are any protections within the level listed in 9.6.a which you will *not* follow, list those here.

When participants enroll in the study, the clinical sites will share the participants identifying information with the UW study team (name, contact information, etc.). For all participants this information exist in two locations: 1) the identifying folder in the locked cabinet in the PI's office will have the study code on it and 2) in a password protected file that is stored securely in a locked file cabinet in the PI's office. We will open a de-identified chart and use a code, which will be linked to the participant's identifying information. This link will be password protected and stored on a secure server at UW with limited access. We will collect a HIPAA Authorization and ROI at study entry to obtain clinical records and will ensure that these records are stored securely at UW. Self-reported meth use on the online surveys will be stored with REDCap, a secure HIPAA-compliant platform. We will send a unique survey link to each participant so that we can track who has completed the surveys without them needing to enter any identifying information. Dried blood spot specimens will be labeled with a name at the point of collection since they will be done at the clinic, but once transferred to the research team will be relabeled with the participants study code, so no identifying data will be on stored specimens.

For participants in the peer navigation group, we will also describe the risks associated with unsecured communication in the consent form. The peer will communicate with the participant based on their preferences. The peer will also have an encrypted, HIPAA-compliant app option that they can use to correspond with participants who wish to use the same app for communication. Participants in the peer navigation group will be encouraged to use this HIPAA-compliant app, and the peer will aid them in downloading it and using it as needed.

For specific types of study data, we will not be able to separate it from personal identifiers. This includes the data related to correspondence with participants assigned to receive peer support.

The correspondence the peer has with participants assigned to receive peer support will also link study data and personal identifiers. The method of and type of correspondence will be in response to the needs and requests of the participant. We anticipate that the peer and participant will correspond by email, text, and phone. We will store the peer and participant's correspondence, which will have identifiers (e.g. name, phone number, email address) in order to characterize the intervention to meet study aims (e.g. frequency of communication, method, general subject area). Study data will be downloaded from portable devices once every month.

Any fax communications that are sent for study purposes will be collected from the fax machine within 24 hours and stored per study protocol. The fax machine used for this study is a shared fax on a secure floor (13th) of the Ninth and Jefferson Building. Everyone who has access to the floor, and therefore the fax machine, is a UW employee with a badge. The fax machine is in a low traffic area, in the corner of the building near the administrative desks and is used regularly by a small number of UW employees for patient and participant communications. We check the fax machine as soon as possible if we are expecting a fax (e.g., a scheduled enrollment) and at least daily for unexpected faxes.

For the end-of-study interviews, we will encourage the participant not to use their name or the name of anyone else. If they do, we will omit those names during the transcription process and replace them with a de-identified label (e.g., "Interviewee", "Friend of Interviewee"). We will delete the audio recordings once the transcriptions have been reviewed against the audio recording for accuracy.

10 RISK / BENEFIT ASSESSMENT

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

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

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

- Fingerstick: The fingerstick for blood collection may cause a small amount of pain or bruising, and the site may bleed slightly after collection. The study staff will follow standard procedures for collecting blood specimens from participants and attempt to minimize any chance for discomfort or bruising.

- Sensitive Information: The survey will ask questions about drug use and sexual practices. Participants could experience some discomfort while taking the survey, due to the sensitive nature of some of the questions. Participants will be encouraged to find a private space they can take the surveys. Surveys will also be de-identified.

  In particular, the study surveys ask about depression, including whether participants have had thoughts that they would be better off dead or hurting themselves. This is a question in the Patient Health Questionnaire 9 (PHQ-9), which is a validated and widely used survey to screen for depression. The study surveys will be completed online and not at the study clinic. We therefore will not be able to reply in person to responses indicating that a participant wants to hurt themselves. If people report this on a study survey, we will build in a skip pattern so that the King County Crisis Line number becomes available to them. All clinical and study staff will be aware of the King County Crisis Line and other local resources that can be provided to participants if they indicate that they are experiencing depression or suicidality. If a participant contacts the study team (PI, study coordinator, or peer) indicating that they are experiencing depression or suicidality the study team member will provide appropriate referrals. The study team members will receive training on how to provide these referrals. Study site staff have experience responding to the varied needs and requests of their patients/clients and have their own clinic trainings and processes to appropriately respond to requests, including for referrals for mental health concerns.

  It is possible that we will learn about child or elderly abuse or intent to harm oneself or others. If we learn about child or elder abuse or an intent to hurt someone else, we will call the police non-emergency number.

- Loss of confidentiality: The study staff will do everything possible to keep participants' information private; however, there is always the risk of a breach of confidentiality. All identified study documents will be kept in a locked cabinet in the principal investigator's locked office. De-identified study records will be stored in a locked cabinet at the research coordinators' desk and on work computers that are password-protected and encrypted. Participants' phone numbers will be stored in the secure text platform to communicate with participants, and their email will be stored in the survey platform to send links to study surveys.

  All members of the research team are responsible for the security and protection of research records. Procedures of preventing breaches of confidentiality include regular Collaborative Institutional Training Initiative (CITI) training of all study staff, collecting minimum necessary identifiers, limiting access to identifiers, encrypting devices, and using coded data. If there is a breach of confidentiality, we will report this to the IRB as an unanticipated problem within 24 hours and will address the breach to a degree that is dependent on the extent and impact of the breach. Consequences may include staff retraining, changing of staff responsibilities, up to dismissal of study staff for serious violations.

- Unsecured communication: There is also a risk of unsecured communication for the participants who are assigned to receive peer support. The peer will communicate with participants via phone, email, and text. Because unencrypted email, text messaging, and phone conversations are unsecured, there is a risk that this correspondence could be intercepted by a third party. In order to mitigate these risks, we will correspond with their participants in the way they choose, explain these risks in the consent form, and talk with them about ways to reduce these risks (e.g. using an encrypted app on both phones, deleting messages after they receive them, looking at messages in a private setting).

New activities for all MSM/TGP" and "New activities for PrEP providers, (prescribers, caseworkers and peer educators/navigators, etc):

- Sensitive Information: The interview will ask questions about drug use and sexual practices. Participants could experience some discomfort while participating in the interview, due to the sensitive nature of some of the questions. Participants will be encouraged to find a private space where they can speak freely during the interview. Interviews will also be de-identified.

- Loss of confidentiality: The study staff will do everything possible to keep participants' information private; however, there is always the risk of a breach of confidentiality. All identifiable contact information (participant name, email and/or phone number) will be kept in a locked cabinet in the principal investigator's locked office. De-identified study records (the demographic surveys asked at the end of the interview) will be stored in a locked cabinet at the research coordinators' desk and on work computers that are password-protected and encrypted.

  All members of the research team are responsible for the security and protection of research records. Procedures of preventing breaches of confidentiality include regular Collaborative Institutional Training Initiative (CITI) training of all study staff, collecting minimum necessary identifiers, limiting access to identifiers, encrypting devices, and using coded data. If there is a breach of confidentiality, we will report this to the IRB as an unanticipated problem within 24 hours and will address the breach to a degree that is dependent on the extent and impact of the breach. Consequences may include staff retraining, changing of staff responsibilities, up to dismissal of study staff for serious violations.

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

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

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

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

b. Steps to minimize risk. Describe the specific steps you will take to minimize the magnitude, probability, or duration of these risks.

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

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

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

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

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

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

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

10.4 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.

*** 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.

In response to the study sponsor's request we have formed a DSMB for this study. The DSMB will meet prior to the start of the study to review the protocol and annually until study completion. The Data Safety and Monitoring Plan (DSMP) that is uploaded to the Supporting Document SmartForm supersedes the DSMP that was originally proposed in the Funding Application.

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.

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.

While the study team will do their best to retain all participants for the duration of the study, it is possible that participants will discontinue their participation early, before the final 6-month visit. This could occur due to participant choice, study team decision, or experiencing an adverse event (AE). If someone has an AE related to PrEP and is willing to remain in the study, we will discontinue PrEP in that participant, but continue to follow them to monitor the AE and its resolution. If so meone exits the study early, we will attempt to schedule a final visit that will include the same procedures as a scheduled month 3 or 6 visit. If a participant refuses to return for a final visit, we will ask them to at least complete an exit CASI. Reasons for early discontinuation will be recorded on study data collection forms.

In addition, the study team will discontinue participants if they do not complete a baseline CASI within 7 days (with the exception of extenuating circumstances) of their entry visit, in which case they will be replaced. If the study team thinks that the participation of a study participant could cause harm to them or the study

staff (e.g., inappropriate, aggressive behavior), the study team may end participation for that participant early. We do not expect this to occur.

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.

For participants assigned to the peer navigation group, we expect that they may benefit from receiving peer support to take their PrEP and having assistance with other needs they may ask for help with.

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?

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

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

You should answer YES if your consent form says anything about sharing individual information with subjects.

[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. Is it possible that a commercial product or patent could result from this study?

[X] **No**
[ ] **Yes** → If yes, describe whether subjects might receive any remuneration/compensation and, if yes, how the amount will be determined.

11 ECONOMIC BURDEN TO PARTICIPANTS

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

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

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

The only costs associated with participating in this study will be additional costs incurred for receiving text messages or phone calls from the peer navigator whose phone plans charge for receiving text messages.

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

N/A

12 RESOURCES

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

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

12.2 Study team communication. Describe how you will ensure that each study team member is adequately trained and informed about the research procedures and requirements (including any changes) as well as their research-related duties and functions.

☐ **There is no study team.**

The study team will meet regularly (the PI, Research Coordinator, and peer navigator) to review the study progress and participants' disposition. All of the study team has current human subjects protection trainings. The peer will undergo a peer navigator training. The Research Coordinator will ensure that all research procedures and requirements, as well as their changes, are reviewed and approved by the PI and communicated to the peer.

13 OTHER APPROVALS, PERMISSIONS, and REGULATORY ISSUES

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

Do not attach the approvals unless requested by the IRB.

Approval	Research for which this is required
☐ Radiation Safety	Procedures involving the use of radioactive materials or an ionizing radiation producing machine radiation, if they are conducted for research rather than clinical purposes. Approvals need to be attached to the Supporting Documents page in ***Zipline***.
☐ Institutional Biosafety	Procedures involving the transfer/administration of recombinant DNA, DNA/RNA derived from recombinant DNA, or synthetic DNA.
RDRC	

☐	Procedures involving a radioactive drug or biological product that is not approved by the FDA for the research purpose and that is being used without an IND, for basic science research (not to determine safety and effectiveness, or for immediate therapeutic or diagnostic purposes).
☐ ESCRO	Procedures involving the use of some types of human embryonic stem cells.

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

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

13.3 Financial Conflict of Interest. Does any member of the team have a Financial Conflict of Interest (FCOI) in this research, as defined by UW policy GIM 10?

☒ **No**

☐ **Yes** → If yes, upload the Conflict Management Plan for every team member who has a FCOI with respect to this research, to the **Supporting Documents** page of ***Zipline***. If it is not yet available, use the text box to describe whether the Significant Financial Interest has been disclosed already to the UW Office of Research.