UNIVERSITY OF WASHINGTON
CONSENT / INFORMATION FORM

Harm Reduction with Pharmacotherapy (HaRP)

University of Washington Researchers:

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**Note: We cannot guarantee the confidentiality or security of email communication.

In case of a study-related emergency, please contact 911, your case manager or call the Harborview Emergency Room at 206-744-3074.

Case Manager: _____

Researchers' Statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called 'informed consent.' You will receive a copy of this form for your records.

PURPOSE OF THE STUDY

This is a combined medical and behavioral research study. The purpose of this study is to determine whether or not the study medication (Vivitrol®) and counseling are effective in reducing the harms associated with alcohol use among people who are dependent on alcohol and have been or are currently homeless. We plan on having 300 participants complete this study. The information you provide for this study will help us determine whether the study medication and/or counseling may help active drinkers reduce their alcohol-related harm.

STUDY TREATMENTS

The **study medication** is a 30-day, extended release form of naltrexone, which blocks opioid receptors in the brain. The study medication is given monthly via an injection into the gluteal (buttocks) muscle. The Food and Drug Administration (FDA) has approved the study medication for the treatment of alcohol dependence. Research has shown that the study medication may decrease alcohol cravings, alcohol use and alcohol problems as well as improve people's quality of life. In **harm-reduction counseling**, health-care professionals help people reduce their alcohol-related harm and improve their quality of life. Harm reduction counseling does not require that people stop using alcohol or other drugs. In this study, staff will ask you about your personal and drinking goals. They will then help you figure out ways to work towards those goals. They will also talk to you about how to be safer if you choose to drink.

STUDY PROCEDURES

First, you will meet with UW research staff who will tell you more about the HaRP study. You will receive $5 just for meeting with the UW research staff—even if you decide not to participate. If you do decide to participate, you will be interviewed by research staff, which will take approximately 30 minutes. We will ask you about some personal characteristics (age, gender). We will also ask you about your alcohol use and your thoughts about your alcohol use. Some of these questions may seem private or uncomfortable. **You are free to not answer any question you do not want to answer.** Your answers to these questions will remain confidential and known only to the research staff. Then, you will be interviewed by the study physician/nurse, have a physical exam and provide urine and blood samples (we will draw 2 small tubes of blood or 3 teaspoons) for lab tests including tests to find out if you are pregnant or if there are any opioid based medications in your bloodstream.. This will take about 60 minutes. The results of these tests will remain confidential and will only be used by research staff to determine if you are a good fit for this study and to track your progress over

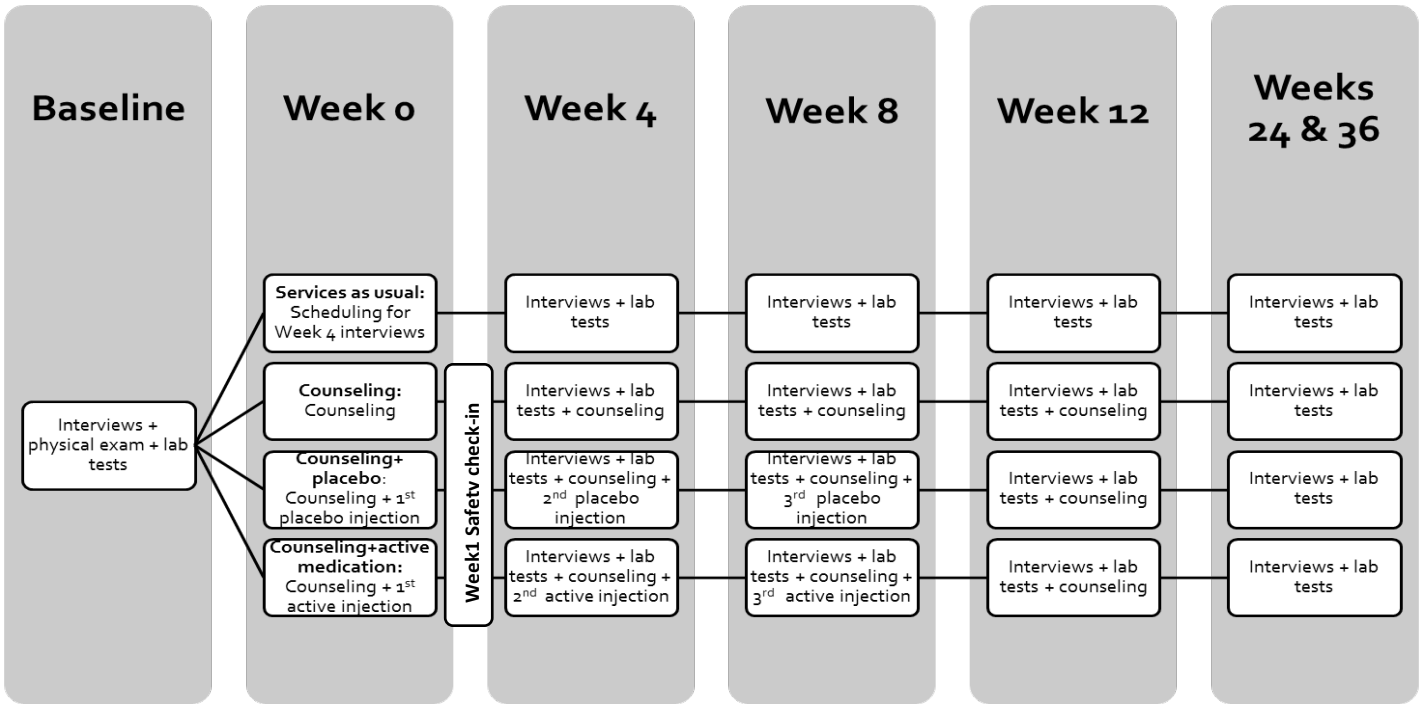
time. You will be scheduled to return one week later for another 45-minute meeting to discuss the findings with the research staff (Week 0).

If you are not eligible for the study, we will discuss your lab test findings and give you a recommendation for next steps, including a referral for further care. Regardless of the outcome, you will be paid $20 for the Week 0 session.

If you are eligible for the study, you will be assigned at random (like flipping a coin) to:

- be interviewed,
- receive counseling,
- receive counseling + placebo (an injection with no medication in it)
- receive counseling + study medication

once a month for 3 months. Neither you nor the researchers will know which injection you are receiving (placebo or active injection). If you would like to know your group assignment, please let us know and will we provide that information to you at the end of the study. Each group's experience is outlined in the figure below. At the end of each session, you will receive $20 for your time.



COMMUNITY SERVICES DATA

To keep you safe during the study, we will access records where you get your supportive and health care services (Downtown Emergency Service Center, Evergreen Treatment Services-REACH, Neighborcare Health, Catholic Housing Services, UW Medicine and/or other medical centers as applicable) about "adverse events" (hospitalization or illness) you have experienced from two years before the study (10/14/11) through the study end date (9/30/18). With your permission, we will be given records that show illnesses you have experienced, where you have used other treatment/hospitalization services, how many times you have used services, how long the services lasted, and what types of services you received. We will not share your personally identifiable private information with anyone but will use this data to compile reports to be sure the medication is safe for you to continue. This research study will have no effect on your ability to use community services in the future or the quality of services that you will receive. Finally, the site where we meet with you will write in your client file that you are participating in this study. However, we will not share any other study information with site staff without your permission, except in case of a serious or life-threatening situation.

We also want to learn about other community services that you have used and will use during the course of the study. Community services will include:

- Harborview Medical Center inpatient, outpatient, Psychiatric Emergency Services, Emergency Department
- King County Medic One/Emergency Medical Services

- King County Correctional Facility
- Washington State Comprehensive Hospital Abstract Reporting System (CHARS)

To do this, with your permission, we will be given records that show where you have used services, how many times you have used services, how long the services lasted, and how much these services have cost. For these records, we will not record specific treatment or diagnosis information beyond type of service (like ER visit), how many times you used it, and how much it cost. We will request this information for the two years prior to your study participation through your final follow-up appointment. We will not share information from one agency with another agency. This study will have no effect on your ability to use community services in the future or the quality of services that you will receive. You may also change your mind about this later and may write a letter to Dr. Susan Collins at 325 Ninth Ave, Box 359911, Seattle, WA 98195 to say that you do not want any more information about you shared.

AUDIO RECORDINGS OF SESSIONS

We would also like to audio record sessions during the study to:

- Be sure that the research staff are conducting the assessments and treatment sessions correctly and in the same way every time.
- Train staff on how to do the sessions.
- Assess how the sessions are being delivered by staff and received by you so we can change them in order to better fit your needs.

Participating in audio recording is optional. You don't have to give us permission to audio record if you don't want to. If you do allow us to audio record sessions, you can review and delete any portion of the audio recordings at any time during the study. At the end of this consent form, we will ask you to mark whether or not you would like to participate in audio recording your sessions. Even if you choose to audio record now, you can change your mind at any time, and may also take away permission for us to keep any audio recordings.

RISKS, STRESS, OR DISCOMFORT

The Food and Drug Administration (FDA) has approved the study medication for the treatment of alcohol dependence. We are using the study medication off-label, and have submitted our protocol for FDA review. The risks associated with blood draws include pain at the place where the needle is inserted as well as the possibility of bruising and a risk of infection at the place where the needle is inserted. Some people feel anxious with blood draws and may faint. The side effects of the study medication may include headache, dizziness, decreased appetite, depressed mood, muscle cramps, nausea, fatigue, vomiting, painful joints.There may be pain, tenderness, swelling, bruising, and itching/irritation at the injection site which may be severe. If you experience any of these common side effects, you should contact Dr. Collins (206-744-9181). We will arrange for you to come in and be checked by a study physician/nurse and will help you manage the side effects. More serious adverse events experienced by a very small number of people in studies involving naltrexone have included liver damage or hepatitis, eosinophilic pneumonia or allergic reactions. If you experience these serious adverse events, we may contact your case manager/health-care provider to explain the situation and get you the proper follow-up care. Further, if we learn information during the study about conditions that pose immediate danger to your health and safety if you participate, we will share this information with you, and if necessary, agency staff and/or other public safety and health-care personnel to ensure your health and safety are protected. If a serious and/or life-threatening event happens during the study, we will also discuss relevant information we have with agency staff and/or other public safety and health-care personnel, as necessary, to help keep you and other participants safe. In case of emergency, please contact 911, your case manager/health-care provider, or Harborview Medical Center (206-744-3074).

The study medication should not be taken by people who are physically dependent on opioid-based medications (oxycodone, methadone) or street drugs (heroin) because it can trigger opioid withdrawal symptoms. Because the study medication blocks opiates from working, it may also reduce the effectiveness of pain medications. Please let the study staff know promptly if you are taking any type of pain medication or other opiates.

Because the risks to the unborn baby from exposure to the study drug are unknown, pregnant or nursing women may not participate in this study. Women in their childbearing years must agree to use a reliable method of birth control while participating in this study. Reliable methods of birth control include birth control pills, intrauterine device, injectable or implanted contraceptives, tubal ligation, true abstinence, or diaphragm and condom plus spermicidal foam. We will also ask you to take a urine pregnancy test before starting to take the study medication, and throughout the 3-month treatment period, if you are assigned to counseling+study medication or counseling+placebo groups. If you suspect you have become pregnant while participating in this study, you should promptly contact the research staff and let us know.

Other risks associated with participation are primarily related to the sensitivity of some of the questions. You will be asked about your alcohol use as well as thoughts, feelings, and personal difficulties that may be private. These questions may make you feel uncomfortable or seem intrusive, or you may become concerned about your alcohol use as you answer the questions. In addition, you will be asked to report on potentially illegal behaviors, such as opiate and other drug use. Answers to these questions could pose a risk if the information were known and linked to identifiable individuals.

You may find that having your assessments and medication management sessions audio recorded during the study is a violation of your privacy. Participating in the audio recorded sessions is optional. We will make every effort to keep the information you give us secure. You can review and delete any portion of the audio recordings at any time during the study. If you choose to participate now, you can change your mind at any time.

ALTERNATIVES TO TAKING PART IN THIS STUDY

Other kinds of treatments for alcohol dependence may be available to you outside of this study. If you choose not to participate in this study but have questions about alcohol or other health-related behaviors, we can provide you with information about resources located within the community.

BENEFITS OF THE STUDY

There may be no direct benefit to you for participating in this research, however, you may benefit by learning more about yourself through completing the study. If you are in a group receiving the medication and/or counseling, you may also notice a reduction in your alcohol cravings, alcohol use and/or alcohol problems. Because individuals respond differently to treatment, no one can know for sure if the study medication and counseling will be helpful in your particular case. However, research studies have shown that the study medication and brief counseling are safe and effective treatment for alcohol dependence. It has been FDA approved for this use. Benefits to society include the opportunity to contribute to research to test if the study treatments reduce alcohol-related harms for people who are currently using alcohol.

SOURCE OF FUNDING

The researcher for this study, Dr. Susan Collins, is receiving payment from the study sponsor, the National Institutes of Health, to support the study staff and study procedures. The study medication is being provided free of cost by Alkermes, Inc.

FINANCIAL INTEREST

Richard Ries, MD, has a financial relationship with Alkermes, Inc., who makes Vivitrol® (injectable naltrexone). Dr. Ries has attended trainings and given talks for Alkermes, Inc. Dr. Ries has received compensation for these activities in addition to his salary from the University of Washington. This financial interest and the design of the study have been reviewed and approved by the University of Washington. A Management Plan was developed to minimize any possible effect of this financial interest on your safety or welfare. The Plan will also protect the quality and reliability of the research.

CONFIDENTIALITY OF RESEARCH INFORMATION

All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities to keep you and others safe.

Your name and other identifying information will be linked to a unique study ID number. The ID number is randomly generated for research purposes. Your study ID will not include any information that can identify you and will only be known to you and the researchers. All of the data and samples (blood and urine) we collect from you will be coded with your study ID.

The master list linking your identifying information to your study data and samples will be kept in a separate, secure location. Your name and contact information will be accessible only to research staff (including the UW Investigational Drug Service pharmacy) for the purposes of contacting you to complete the study, conducting random assignment and dispensing the study medication. We will keep your name and contact information until December 31, 2021 to ensure safety during the study and to ensure your payments and any messages about your participation can be delivered. As necessary, we will contact you using the information you provide us with and using your preferred contact methods (i.e., by phone, email, in person or via agency staff that you have designated in writing). The link between your identifying

information and study data/samples will be destroyed on December 31, 2021. Your coded blood and urine samples will be destroyed after tests are completed.

Audio recordings will be coded with your study ID only and will not include any information that can identify you. We will store the audio recordings on password protected computers and on a secure server supporting 128-bit encryption. The audio recordings will be transcribed and used for research purposes. De-identified transcriptions of audio recordings will be kept indefinitely.

Your coded data may be shared with other researchers doing similar work at other hospitals, and/or be combined with data from other hospitals in some research reports. You will not be personally identified in any research reports or presentations of this research. Coded research data will be retained indefinitely.

Government or university staff sometime review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm. The U.S. Food and Drug Administration (FDA) reserves the right to review study data that may contain identifying information.

We will do everything we can to keep others from learning about your participation in this study. To further help us protect your privacy, we have obtained a Certificate of Confidentiality from the United States Department of Health and Human Services (DHHS).

With this Certificate, we cannot be forced (for example by court order or subpoena) to disclose information that may identify you in any federal, state, local, civil, criminal, legislative, administrative or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except to prevent serious harm to you or others, and as explained below.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family, from voluntarily releasing information about yourself or your involvement in this study.

If an insurer, employer or health-care, service or treatment provider learns about your participation and obtains your consent to receive research information, then we may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

There are some limits to this protection. We will voluntarily provide the information to:

- DHHS employees for the purpose of audit or evaluation;
- individuals at the University of Washington or the funding agency if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- the appropriate authorities to prevent serious harm to yourself, children or others. For example, if we learn of child abuse/neglect, elder abuse, or the intent to harm yourself or others.

OTHER INFORMATION

We have taken steps to protect you from the risks mentioned above. Your participation in this research study is voluntary, and you are free to skip over any questions you do not want to answer. You may refuse to participate, and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

If it is more convenient for you and logistically possible for the research team, we may conduct interviews at a location outside of the study sites (e.g., shelters, housing, drop-in centers, medical clinics). If you do meet at a location outside of the study sites, there is a chance that others may become aware of your participation in the research.

You or your insurer will not be charged for any study-related procedures. There are different pay schedules depending on the group you are assigned to, because some groups have a different number of sessions. If you are assigned to the counseling+medication or counseling+placebo groups, you can receive up to $165 for participating ($5 for the information session and $20 for completion of each of the eight meetings). If you are in the counseling-only or services-as-usual groups, you will receive up to $145 for participating ($5 for the information session and $20 for completion of each of the seven meetings). You will receive payment in cash at the end of each meeting you attend.

To thank participants for their ongoing study participation, we will offer drawings every three months to win the participant's choice of a Subway or Starbucks gift card worth $50. If you complete all appointments from baseline through week 12 you will receive one drawing entry. If you complete the week 24 appointment, you will receive an additional drawing entry. If you complete the week 36 appointment, you will receive yet another drawing entry. This makes for 3 possible entries over the course of the study. We will have a drawing once every three months through the end of the study. The odds of winning depend on the number of participants who complete the study in the specified time. Winners of the drawing will be notified through the contact methods given to us for appointment reminders.
If you are in one of the two groups receiving an injection, we will give you ID tags and wallet cards. We will ask that you keep them on your person during the 12-week treatment period. They indicate you may be on the study medication and have Dr. Collins's contact information for you and medical personnel, if necessary.

If, at any time, you do not want to participate, or you have questions about the study, please contact Dr. Susan Collins at (206) 744-9181 or email her at collinss@uw.edu. In case of emergency, please contact 911, your case manager/health-care provider, or Harborview Medical Center (206-744-3074).

COMPENSATION FOR INJURY

If you think you have an injury or illness related to this study, please contact Dr. Susan Collins. She will arrange for you to come in and be checked by a study physician. We may then refer you to your assigned agency staff member or primary care physician for appropriate treatment and follow-up care. In the case you do not have a primary care provider at the time, we will refer you to primary care clinics at Harborview Medical Center or the Pioneer Square Clinic. Your health insurance will be billed for your medical care in this case. No money has been set aside to compensate for things like lost wages, lost time, or pain. However, you do not waive any rights by signing this consent form. The UW will compensate up to $10,000 to reimburse for treatment of injury or illness resulting from the study.

Printed name of study staff obtaining consent Signature Date

Participant's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research participant, I can call the Human Subjects Division at (206) 543-0098. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

___ Yes
___ No

Please mark whether or not you would like to participate in the audio recording sessions.

Printed name of participant Signature of participant Date

Copies to: Researcher
Participant