Department of Veterans Affairs	VA PUGET SOUND HEALTH CARE SYSTEM (663) RESEARCH CONSENT FORM	
SUBJECT NAME		SSN:
TITLE OF STUDY	Considering Healthier Drinking Options in Collaborative Care	
PRINCIPAL INVESTIGATOR	Katharine A. Bradley, MD, MPH	

LAY TITLE: CHOICE

Researchers:

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24-hour emergency contact: Please call the CHOICE pager at (206) 416-1722 and enter in your 10-digit phone number after the beep.

You are being invited to participate 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. Please read this 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 whether you want to be in the study. You are free to discuss this with friends or family. This process is called "informed consent." We will give you a copy of this form once it is signed for your records.

1. Purpose of research study and how long it will last: The CHOICE Study is funded by the National Institutes of Health (NIH). This research study will test a new program to improve the delivery of effective medical care for Veterans who drink alcohol. We expect to enroll about 400 patients from the Veterans Affairs Puget Sound Health Care System (VAPSHCS).

Why is the study being done? This study is for VA patients who drink alcohol. We know that alcohol affects many health conditions and can interact with medications. The purpose of the study is to test a program designed to improve the health of Veterans who drink alcohol.

How are you eligible? We are inviting you to participate if you were recently seen at a VA primary care clinic and reported drinking at levels that can affect your health. You must be 75 years of age or younger to be eligible.

2. Description of the study including procedures to be used: If you wish to join the study and sign this consent form, we will ask you to complete a series of surveys. We will ask you to complete an in-person baseline appointment, two telephone interviews, and two blood draws over a year. We will also be checking the long-term effects of the study through reviews of medical records.

Some patients will be offered support services that this study is testing to address any health problems that may be affected by alcohol. Research appointments and all blood draws will be at either the Seattle or American Lake divisions of VAPSHCS.

The CHOICE Support Program ***(for patients who by chance are offered extra care)***

This research will compare different types of patient care. If you choose to take part, you will be assigned by chance to one of two groups – Group A or Group B. As with the flip of a coin, you will have a 50/50 chance of being in either group.

If you are assigned to **Group A**:

- You will continue to receive regular care from your VA primary care provider.

If you are assigned to **Group B**:

- You will continue to receive regular care from your VA primary care provider; and
- You will also be offered extra services as part of the support program we are testing in this study to see if it will benefit patients. However, you do not have to accept any of the extra support that is offered to you.
- The services you would receive if you are in Group B will depend on *your preferences* and your personal health conditions.

All Group B patients will be offered the following services:

- An initial appointment with a CHOICE nurse, in person or by phone depending on your preference.
- An initial appointment with a nurse practitioner (NP) who will review your medical records and go over laboratory tests done for the study. The NP would also discuss your health conditions that might be worsened by drinking or medications that might interact with alcohol.

- Up to 16 visits with the CHOICE nurse. These visits would typically be weekly for 1 month, every 2 weeks for 1 month, and monthly thereafter for the year of the study, but the exact frequency would depend on your preference. Each nurse visit would be between 5 to 30 minutes.
- The 16 visits with the CHOICE nurse could include any of the following:
  - Review and monitoring of abnormal lab tests that can indicate harm due to drinking
  - Review and monitoring of the effect of alcohol on your health conditions.
  - Review and monitoring of alcohol's interactions with medications you take.
  - Education about how drinking may affect your health conditions.
  - Helping you to set personal goals and planning activities to help you manage your physical health conditions and decrease your drinking, if you choose.
  - The study nurses will coordinate care with your VA primary care provider.
- Some Group B patients will be offered optional medications to help decrease drinking. If you were offered medications, the NP will discuss three medication options with you that are approved by the U.S. Food and Drug Administration *(naltrexone, disulfiram,* and *acamprosate).*
  - If a medication is recommended for you and you wish to try it, you will receive detailed information about the possible benefits and risks of that particular medication at the time it is prescribed.
  - If you choose to take one of these medications, you will need to schedule meetings with the NP to start or adjust medications.

We estimate that being in the support program will typically take 6 to 12 hours over the next year. At the end of the one-year period, the support program will end. If this study is stopped early, these services will no longer be provided.

If you are in Group B, digital audio recordings may be made of your nurse visits. Recordings will be used to verify the nurse visits are following the study protocol and to advise the nurses. Supervisors will review the audio files to rate and provide feedback to the study nurses. Only approved research staff will have access to the computer audio files.

The following are research procedures that both Groups A and B will complete:

<u>In-Person Research Appointment</u>

You recently completed a telephone interview. You were asked questions about your alcohol use. The next step in the enrollment process is your in-person interview with the enrollment coordinator. If you agree to take part, the coordinator will ask you to complete the following *at that appointment:*

- A brief screen to determine if you are eligible for the study. You will be asked questions that are similar to ones that you have already answered over the phone. *Time estimate: 5 minutes*

  Example question: *We will ask you to remember three objects and ask you what they are a few minutes later.*

- A written survey that asks about your drinking patterns, depression, post-traumatic stress disorder, and prior alcohol treatment. *Time estimate: 20 minutes*

  Example question: *"How often during the last year have you had a feeling of guilt or remorse after drinking?"*

- An in-person interview with the enrollment coordinator. Questions will be about your health, how you feel, family history of alcohol use, past treatment for alcohol use, and other information such as your education and race. *Time estimate: 30 minutes*

  Example question: "*Have you felt sad, low, or depressed most of the time for the last 2 years?"*

Medical Records

If you are by chance offered to receive services from the support program, CHOICE nurses and the nurse practitioner will document all clinical care in your VA medical records.

To understand the effects of the program we are testing, we will need to collect health care information. This information will be from your VA electronic medical records and from your Washington State health records. We would like to see your lab test results, which VA services you use, the kinds of medications you take, health care costs, and any hospitalizations inside or outside the VA. If you do not allow us to see your medical records, you will not be able to join this study. If you agree to be in this study, we will collect this information from your electronic medical records for 2 years before today's date and 11 years after today's date.

Telephone Interviews

The Group Health Research Institute (GHRI) Survey Research Program will conduct all telephone interviews. An interviewer from GHRI will call you for two phone calls:

- The first phone call will happen 3 months after your in-person research appointment. *Time estimate: 20 minutes*
- The second phone call will be 12 months after your in-person research appointment. *Time estimate: 45 minutes*

Example question: *"How often during the last year have you had a feeling of guilt or remorse after drinking?"*

Lab Visits

During your in-person research appointment, the enrollment coordinator will walk you to the lab for a blood draw. VA lab personnel will draw blood (1-2 tablespoons) from a vein for three lab tests. These tests will give us more information about how alcohol affects your body.

Two of these tests are part of routine care at VAPSHCS. The results will be included in your medical records and made available to your VA provider. One test is not used at VAPSHCS. It will be analyzed at the Clinical Neurobiology Laboratory at the Medical University of South Carolina. The results of this lab test will only be used for research purposes. However, if you are offered extra support and choose to keep track of these labs, they will all be included in your medical records and made available to your VA provider. *Time estimate: 15 minutes*

After 12 months, you will need to give us another blood sample (1-2 tablespoons) for the same three lab tests. As before, two lab results will be included in your VA electronic medical records. The third will be sent to the lab in South Carolina to be used for research. *Time estimate: 15 minutes*

Summary of Research Activities	Baseline Appointment (or soon after)	In 3 Months	In 12 Months
Written survey	X		
In-person interview	X		
Telephone interview		X	X
Blood draw	X		X

3. Description of any procedures that may result in discomfort or inconvenience: You may be inconvenienced during the study when you are called to complete telephone surveys.

You may be asked questions of a sensitive nature. You may experience discomfort or distress while answering questions about your alcohol use. However, these questions are similar to the questions asked as part of routine clinical care and ones you have already been asked during your pre-screening telephone call. You are free to skip any questions that you don't want to answer.

You may become tired while answering the survey questions. We encourage you to take a break if you become too tired. You can schedule a time to finish the survey on another day.

Having your blood drawn can be uncomfortable and can sometimes cause a bruise. You may become faint or dizzy when blood is drawn. It doesn't happen often, but the puncture site can become infected. Only trained VA lab personnel will draw your blood. If your regular provider has ordered lab tests, the study tests can be drawn at the same time.

4. Potential risks of the study: There is a risk of loss of privacy (confidentiality). We have extensive measures in place to keep this from happening and expect these measures to protect your personal information.

If you are assigned to Group B, the CHOICE nurse will work with you to determine if your health might be harmed by alcohol. You will have the option of telephone calls with the nurse to discuss your health, lab tests to check for harm due to drinking, and prescribed medications to decrease your drinking. We cannot guarantee that support from the CHOICE nurse or medications from the nurse practitioner will help to improve your health.

If you are offered medications through Group B and choose to take them, there are some *known side effects* that may occur if you take *disulfiram, naltrexone,* or *acamprosate.*

Common Side Effects:

Common side effects of *naltrexone* are symptoms of nausea, abdominal pain/cramps or vomiting, diarrhea or constipation, joint and muscle pain, anxiety, depression, and difficulty sleeping. In rare cases, naltrexone can damage your liver.

Common side effects of *disulfiram* are skin rashes or itching, metallic aftertaste, headache, or drowsiness. Serious side effects include liver damage, blurred vision and, in rare cases, seizures and bipolar disorder.

Common side effects of *acamprosate* include skin rashes or itching, mild diarrhea, nausea, headache, depression, dizziness, dry mouth, or insomnia.

Other Cautions:

- If you take any of these medications and are capable of becoming pregnant, you should be using an effective method of birth control. If you become pregnant, you should let the study nurse know immediately and stop taking these medications.
- You should not take *naltrexone* if you have acute hepatitis or liver failure.
- If you are taking opiates to treat chronic pain, you should not take *naltrexone* because it blocks the effects of these medications.

- If you use opiate medications or drugs (morphine, methadone, oxycodone, hydrocodone codeine, or heroin), you should stop using these drugs at least 7 days before starting *naltrexone.* You must carry a wallet card or wear a medical bracelet at all times to alert clinicians that you are taking naltrexone in the event of an emergency.

- If you drink alcohol when you take *disulfiram,* it can make you feel sick. The most common effects of an interaction with alcohol include vomiting, blurred vision, chest pain, drowsiness, headache, and tremors. It should not be taken while intoxicated.

- You should always inform your health care providers of the medications that you are currently taking so that possible interactions can be monitored.

As with all medications, there may also be *unanticipated side effects*. The nurse practitioner and CHOICE nurse will ask you about undesired side effects that you may have and try to minimize them. You would need to tell the study nurse and your regular provider immediately if you have a reaction to these medications. If you are selected for Group B, you can decide with the nurse practitioner if medications to help reduce your drinking are right for you. If you are prescribed these medications, you may decide to stop taking them at any time.

The particular treatments or procedures in this study may involve risks that are currently unforeseeable. We will contact you as soon as possible if new findings occur during this research that may pose a risk to you.

5. Potential benefits of study: The study goal is to learn more about the drinking patterns of Veterans over a period of time. We would like to see if a support program will bring about higher quality health care and improve health conditions of these Veterans.

Your health may improve by being in the study. However, we cannot guarantee this. You may not benefit directly by participating in this study. We hope that this research will benefit other Veterans by showing whether added primary care support can minimize health risks from alcohol in the future.

6. Other treatment available: Taking part in this study does not stop you or your primary care provider from trying other kinds of treatment. You may always seek care you and your provider desire, whether or not you are being offered any extra health services in this study.

Standard care is available to Veterans who drink alcohol and have health issues. Standard care includes brief alcohol counseling with referral to an addictions specialist when needed.

7. Use of research results / Confidentiality: The information obtained about you will be held confidential. However, for purposes of this study, the following list of people or groups may know

that you are in this study. They will have access to your records, which may include your medical records:

- Research team members
- Seattle Institute for Biomedical and Clinical Research (the nonprofit institute that works with the VA to conduct research)
- The GHRI Survey Research Program
- The National Institutes of Health (NIH)
- Federal agencies including, but not limited to, the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP), the VA Office of Research Oversight (ORO), and the VA Office of the Inspector General (OIG), Government Accountability Office (GAO)
- The VA committees that oversee research, including the Institutional Review Board that oversees the safety and ethics of VA studies
- The Group Health committees that oversee research, including the Group Health Institutional Review Board and supporting staff, will have access to your study records but not your medical records

The purpose of this access is to review the study and make sure that it meets all legal, compliance, and administrative requirements. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy.

Your privacy is important to us. Study data will be stored on a secure computer within a password-protected database. Only approved research staff may access it. We will not place your name on any research data. Instead, we will assign a code number whenever possible to identify your information, such as on your lab tests and questionnaires. We will keep the master list that links your name to your code number in a secure-access computer specifically for research data. The master list will be stored in password-protected folders and will only be accessed by the Data Manager.

Once this study is completed, we will not use the code linking you to your data for any additional research. The code linking you to your data will be held in a secure database until the VA receives authorization to destroy it in accordance with federal records regulations. It may be several years before the code linking you to your data is actually destroyed. All coded data will be stored on secured computers or in file cabinets in locked offices. This coded data will be kept indefinitely.

A portion of all blood samples will be sent to the Clinical Neurobiology Laboratory at the Medical University of South Carolina for lab work to conduct a lab test. Samples will be mailed using a secure method and will not include your name. A unique study identification number will be used to label all your samples. Your blood samples will not be used for additional research and will be destroyed after the lab tests are completed.

Your name, address, and telephone number will only be shared with researchers at the Group Health Research Institute (GHRI) Survey Research Program. Survey interviewers will be collecting

sensitive data during telephone surveys. They will be contacting you to complete telephone surveys at baseline, 3 months, and 12 months. All telephone survey information will be stored on password-protected computers that are only accessible to authorized personnel. All data will be sent to the Data Manager at VA's Health Services Research and Development Service (HSR&D) through a secure method at the end of each quarter.

The audio recordings of the nurse visits will be de-identified. The audio files will be labeled with your unique study code number and will not contain your name, social security number, or other identifying information. The audio files will be stored on a secured computer server protected by a VA firewall in password-protected folders accessible only to approved research staff. The digital recorders used to audio record interviews will be kept with the research staff or stored securely at all times. Please note that your voice is technically identifiable according to HIPAA patient privacy rules, so we will do everything possible to protect your voice identity. The nurse will review a "Consent for Use of Picture and/or Voice" with you and ask for your consent before your nurse visit is recorded.

To help us protect you and the information we will be collecting from you, this study has been given a Certificate of Confidentiality by the National Institutes of Health. This Certificate means that the researchers cannot be forced, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, to disclose any information that may identify you. The researchers will use the Certificate to resist any demands of information that would identify you, except as explained below.

Exceptions: A Certificate of Confidentiality does not prevent researchers from disclosing certain information about you for legal or ethical reasons. For example, we will report information about child abuse, elder abuse, or intent to hurt yourself or others. 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 research. If an insurer, employer, or other person obtains your written consent to receive research information, we cannot use the Certificate to withhold that information.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally-funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

In addition, any study test results or information that is included in your VA medical record will not be covered by the Certificate of Confidentiality and may be released if requested by a lawful subpoena or other lawful and appropriate request for the information.

Persons who have access to your medical record will have access to any research-related information or documents that are in your record. Access to your medical records is governed by Washington State law (RCW 70.02) and by the federal HIPAA law.

There may be publications about this study in the future. If so, your identity will be held confidential. No personal information will be given in a publication without your approval in writing.

Your study information will be used only for research purposes and will not be sold. Information gained from this research may be used commercially for the development of new ways to diagnose or treat diseases. However, neither you nor your family will gain financially from discoveries made using the information and/or specimens that you provide.

8. Special circumstances: The VA requires some Veterans to pay co-payments for medical care and services. You will still have to pay these co-payments as long as they are not related to this research study.

You may have time and travel expenses due to coming in for the enrollment interview, completing phone surveys, returning for lab tests, or for appointments with study nurses. We will make every effort to schedule the final lab test at a time that is most convenient for you and when you will be traveling to the VA for an appointment.

You will be reimbursed:

- $2 pre-incentives for your telephone assessments with GHRI.
- $10 for the in-person baseline appointment.
- $10 for your time after you complete the baseline assessments, which include the enrollment interview, written survey, and baseline lab test.
- $10 for completing the 20-minute telephone survey at 3 months.
- $15 after 12 months for completing the 45-minute telephone survey.
- $15 for the final lab test at 12 months.

Cash will be mailed to your permanent mailing address after you complete each telephone assessment. It typically takes between 2 and 4 weeks for you to receive the payment, but it could take longer.

Per VA policy, if you agree to participate we will document your consent to participate in the study in your VA electronic medical record. All authorized users of the national VA medical records system can have access to your medical record. This may include health insurance companies who are being billed for medical costs. This record will be kept forever.

9. Withdrawal from the study: You do not have to take part in this study. If you are in this study, you can withdraw at any time. You will not be penalized for your decision to not participate or withdraw nor will you lose your VA or other benefits if you decide to do so.

Your doctor has the right to terminate your participation in this study if he or she feels that it is not in your best interest. This termination will not require your consent.

If you decide to withdraw, or if you are terminated from the study, a person from the study team will then need to meet with you to discuss the necessary steps that you may need to take to end your participation in the study.

10. Questions or concerns related to the study: The study researchers (listed below) *must* be contacted immediately if:

- You think you may have been harmed or injured as a direct result of this research; and/or
- You have any questions regarding your medical care issues.

During business hours (8:00 a.m. – 4:30 p.m.)	Call Dr. Diane Greenberg (or covering research investigator) at (206) 764-2965.
After business hours (nights and weekends)	Call the CHOICE pager at (206) 416-1722 and enter in your 10-digit phone number after the beep.

You may contact the Institutional Review Board (IRB) – VA Office at (206) 277-1715 if you:

- Would like to speak with a neutral party who is not involved with this study;
- Have questions, concerns, or complaints about the research;
- Would like to verify the validity of the study; or
- Have questions about your rights as a research subject.

An IRB is an independent body made up of medical, scientific, and non-scientific members, whose job it is to ensure the protection of the rights, safety, and well-being of human subjects involved in research.

11. Research-related injury: Medical treatment will be provided, if necessary, by the VA if you are injured by being in this study. You will not be charged for this treatment. Veterans who are injured because of being in this study may receive payment under Title 38, United States Code, Section 1151. Veterans or non-Veterans who are injured may receive payment under the Federal Tort Claims Act.

You do not waive any legal rights by signing this consent form.

12. Research subject's rights: I have read or have had read to me all of the above. The study has been explained to me, including a description of what the study is about and how and why it is being done. All of my questions have been answered. I have been told of the risks and/or discomforts, possible benefits of the study, and other choices of treatment available to me. My

rights as a research subject have been explained to me and I voluntarily consent to participate in this study. I will receive a signed copy of this consent form.

I agree to participate in this research study as you have explained it in this document.

_____ _____
Subject Signature **Date**

_____
Print Name of Subject

_____ _____
Signature of Person Obtaining Consent **Date**

_____
Print Name of Person Obtaining Consent