SUBJECT NAME		SSN:
TITLE OF STUDY	**A Placebo-Controlled Trial of Prazosin in Individuals with Co-occurring Alcohol Dependence and PTSD Seeking Abstinence**	
PRINCIPAL INVESTIGATOR	**Tracy Simpson, PhD**	

LAY TITLE: Prazosin for alcohol dependence and PTSD

Researchers:

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24-hour emergency contact: In case of an emergency, please call (206) 762-1010 and ask the operator to page the on-call psychiatrist.

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. After reading and signing this consent, research staff will ask you a series of true/false questions to make sure you understand important details of this study. Any questions that you are not able to answer will be reviewed with you by study staff. 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 purpose of this study is to see whether the drug prazosin will decrease drinking of alcohol and symptoms related to PTSD in individuals with PTSD who are dependent on alcohol and have last used alcohol at risky levels in the past 90 days. Prazosin is a medication that is FDA approved for treating people with high blood pressure. Some studies have shown that prazosin may also decrease nightmares and improve sleep in Veterans suffering from Posttraumatic Stress Disorder (PTSD), and there is preliminary

evidence that it can be helpful in reducing alcohol consumption among individuals who are alcohol dependent. The use of prazosin for PTSD nightmares and for alcohol dependence is an off-label use. That means that the FDA has not approved prazosin for PTSD nightmares or for alcohol dependence. The current study is evaluating an "off-label" use of prazosin to determine whether it is helpful in decreasing alcohol consumption and symptoms associated with PTSD among people with PTSD who are alcohol dependent.

This study is sponsored by the National Institute on Alcohol Abuse and Alcoholism (NIAAA). You have been asked to participate in this study because you are 18 years of age or older, are seeking treatment for alcohol dependence, and have last used alcohol in the past month. We expect to enroll approximately 90 participants in this study and the study will run over approximately 2 years. Study participants will be involved in the study for 8 weeks or until they complete the follow-up assessment.

2. Description of the study including procedures to be used:

STUDY VISIT 1
(Screening Assessment)

If you decide to participate in this study and sign this consent form, you will be evaluated by study staff to determine if you are eligible to continue in the study prior to receiving any medication. A study clinician will complete a medical interview, psychiatric interview, and a complete physical examination. This will include taking vital signs (such as blood pressure and heart rate), height, weight, possibly an electrocardiogram (ECG) which checks the electrical activity in your heart, and blood tests (about 2 tablespoons) to check blood count, liver function, and kidney function.

A breathalyzer will be used to check the level of alcohol on your breath. If your blood alcohol level is over 0.0 today, you will be asked to reschedule this screening appointment as you need to be completely sober to participate in the screening appointment. At each future appointment, your blood alcohol level must be below .05 or you will be asked to reschedule or wait for your blood alcohol level to drop below .05 if time allows.

At the screening visit, you will also be asked to provide urine samples to check kidney function and to analyze for the presence of illegal drugs. Completing the medical interview, blood draw breath analysis, urine sample, and questionnaires will take approximately 1½ to 3 hours. You will also be asked about potentially traumatic experiences that may have occurred in your lifetime as well as past and current reactions to any such experiences. You may refuse to answer any question or item in any test, inventory, questionnaire, or interview, but we will need enough information to determine whether you are eligible for the study. If we cannot determine that you are eligible from the information you are willing to give us, you won't be able to continue in the study.

Also, we want you to know that if you are eligible for the study and you receive a positive diagnosis for PTSD by the research study staff, you will be considered for participation in prazosin for alcohol dependence and PTSD, which this consent form is about. If you do not receive a PTSD diagnosis but you are otherwise eligible for the study, you will be considered for participation in the sister

study that is evaluating prazosin for alcohol dependence without PTSD. We will disenroll you from the alcohol and PTSD study and we will ask you to sign another, nearly identical, consent form for the alcohol dependence study. The sister study is longer in duration and has more study visits. These differences will be reviewed in detail if you do not receive a PTSD diagnosis and wish to be considered for the other study. The initial screening procedures are part of the research and they are not intended to be treatment.

The study staff will review the results of all these tests. If they believe that continued participation in this study may cause you harm, you will not be able to continue in the study. In this case, if you are a Veteran, you will be provided with standard mental health and substance abuse treatment at the VA Puget Sound Health Care System (VAPSHCS. If you are not a Veteran, you will be provided with referrals to community mental health and substance abuse treatment centers.

STUDY VISIT 2

(Baseline Assessment, begin medication, Medical Management therapy, start daily monitoring)

If the tests show that you can continue in the study and you choose to enroll, you will be a participant in the study for the next 8 weeks. Following the initial medical screening, you will come in for a second appointment to provide additional information, to get started with the study medication and the Medical Management (MM) therapy, and to start the daily symptom monitoring via an automated Interactive Voice Response (IVR) telephone system. At this appointment, study staff members will interview you and ask you to complete questionnaires. You will be asked questions about your substance use and problems that may have occurred as a consequence of your substance use. These questions will include your employment, family, legal, and psychiatric history. Examples of the kinds of questions you will be asked are: *Have you ever been abused? Have you had thoughts of suicide?*

- **Study medication procedures.** During the first 6 weeks of the study, you will either receive prazosin or a placebo medication beginning the day of Study Visit 2. The placebo medication will be a pill in capsule form that looks exactly like the prazosin medication that will be given to participants in the study, but the placebo medication does not contain any active ingredient and will have no direct physical effect on participants who take it. You will be randomly assigned (like flipping a coin) to take either the prazosin or the placebo medication by a computer program. Both of the medications will look the same so neither you nor the study staff will know which medication you will actually receive. During the first 2 weeks that you are on the medication, the amount will be slowly increased to the target dose of 4 mgs in the morning, 4 mgs in the afternoon, and 8 mgs at night. It is very important that you take the medication exactly as prescribed. If you miss a dose, leave it in the mediset so staff can see exactly what dose was missed. If you miss a dose, skip it and take the next dose at the usual time. Never "double up" your medication as this could lead to a significant increase in side effects. You will be asked to wear a study wristwatch so that we can remind you to take your study medication three times each day (at 9 a.m., 3 p.m., and 9 p.m.) and to provide information once per day to the study's automated telephone monitoring system (see next section for details).

- **Daily phone monitoring.** Beginning the day after Study Visit 2, you will be asked daily to call a toll-free number each morning to report on your alcohol craving, alcohol use, marijuana craving, marijuana use, cocaine craving, cocaine use, medication compliance, PTSD symptoms, and general emotional well-being over the last 24 hours in order to better track your response to the study medication. If you fail to call the number as scheduled, the study coordinator will attempt to contact you within 2 working days to obtain your report on your cravings and use of alcohol or drugs. The first alarm you receive each day reminding you to take your study medication will also remind you to call the phone monitoring system. You will be asked to call into the daily monitoring system each day for the entire 8 weeks of the study. Daily phone calls may take between 3-5 minutes each day with a total commitment of 4 to 5½ hours over the 8 weeks to complete all daily phone calls.

- **Medical Management (MM) visits.** Beginning with Study Visit 2, there will be four MM visits. MM visits will focus on medication issues. This includes things like side effects and issues related to taking medications. MM will also provide support and encouragement for you to avoid alcohol use and to attend Alcoholics Anonymous (AA) or other self-help meetings. The first MM visit, which will occur on the day you start study medication (Study Visit 2), will last 30-45 minutes. Later MM visits at 1, 2, 4, and 6 weeks after starting study medication will last 10-15 minutes. During this study, we ask that you not take any other medication treatment for alcoholism or participate in trauma-focused treatment for PTSD (for example, prolonged exposure treatment, cognitive-processing treatment, EMDR). However, you may go to self-help groups like Alcoholics Anonymous (AA) or attend other talk treatments for alcohol problems or to get support for PTSD issues. If we learn during an MM visit that you are drinking a dangerous amount of alcohol, we may remove you from the study and provide you with referrals to more intensive treatment for your safety.

STUDY VISITS 3-11

(MM appointments, lab visits, checks for side effects, and final study visit)

We will ask you to come back to the research clinic twice a week for the first 2 weeks and once each week thereafter for the next 4 weeks of the study, and a final visit 8 weeks after you start, for a total of 10 more visits. It is critical you attend all study appointments so that we can closely monitor your responses to the study medication. For safety reasons, the study staff may discontinue your participation in the study if you do not make at least half of your scheduled visits while the study medication dose is slowly being increased to its target dose (Study Visits 3-6), and attendance is required for Study Visit 6. Additionally, if you do not come in for scheduled study visits for 18 consecutive days during the medication maintenance period where your medication remains consistent (Study Visits 7-11), the study staff may discontinue your participation in the study for safety concerns.

You will also need to come back for one final follow-up visit 2 weeks after discontinuing the 6-week medication phase (Study Visit 11). At these visits, a study clinician will meet with you to measure your heart rate and blood pressure and to ask you if you have had any side effects from the medication. You will be asked to complete a brief measure of PTSD symptoms along with three

brief measures of sleep difficulties, wake difficulties, and anxiety. You will also be asked to provide a urine sample at each of these visits to monitor your use of illegal drugs. Any use of illegal drugs during this study will be kept confidential and, except for drug use that could have bad effects when taken with the study medication or present an immediate risk to your life, their use will *in no way* affect your eligibility to participate in the study. If we do determine that you are using drugs or alcohol at levels that are unsafe for you to continue in the study, we will provide more appropriate treatment referrals to you. If you are a woman and can bear children, we will also do urine pregnancy tests monthly throughout the study in order to ensure that if you become pregnant, you discontinue the study medication immediately. In addition, we will also have you provide a blood sample (about 1-2 tablespoons) at the screening assessment, and then again at 6 and 8 weeks into the study. These blood samples will be used to check your liver functions and other markers of alcohol use. As noted above, you will also receive MM treatment at visits bi-weekly throughout the 6 weeks of the medication phase of the study. At Visits 10 and 11, we will ask you to complete some of the same assessments on alcohol consumption and PTSD symptoms that you completed at Study Visit 2 (the Baseline Assessment). The Medical Management visits are intended to be treatment, as are the lab visits, and to check for any side effects.

Follow-up Tracking

If you are a Veteran, we would like to access your VA electronic medical record for 90 days after you have completed the 8-week study so that we may continue to monitor for side effects associated with the medication. This will also allow us to monitor you for any sign of relapse. The follow-up tracking is for research purposes only.

Overview of Study Involvement

All of the study procedures are related to research and none of them are standard care either at the VAPSHCS or in the community. To summarize the information above, if you choose to participate in this clinical research study, you would do the following activities over the 8 weeks of the study:

- Complete several interviews and questionnaires about your drinking and PTSD three times
- Have your blood drawn three times
- Have two physical exams
- Be randomly assigned to take either prazosin or a matched placebo medication for 6 weeks
- Come in to the VAPSHCS in Seattle VA one or two times per week for study visits to check your blood pressure, any side effects of the study medication, as well as your PTSD symptoms
- Participate in medication management (MM) sessions with the study clinician

- Complete daily calls to a telephone data collection that would take 3 to 5 minutes every day for 8 weeks

All of the study procedures will take place at the VA Puget Sound Health Care System in either the Addiction Treatment Center (Building 24) or in the lab in the main hospital (Building 100).

3. Description of any procedures that may result in discomfort or inconvenience: Some people may find interviews and questionnaires upsetting. Trained and experienced staff will complete all tests and interviews to lessen this possibility. You could also feel some embarrassment related to questioning about your personal habits, lifestyle, and drug or alcohol use.

The questionnaires about past potentially traumatic experiences cover such things as having been in combat, having survived an earthquake, an assault, or a rape. You will be asked whether something of this nature has happened to you, and you will be asked about any reactions you might have had to the experience or might still be having to the experience (for example, repeated nightmares about it or avoiding talking or thinking about it). Based on the answers you provide us, it is possible that one of our trained study clinicians may give you a diagnosis of Posttraumatic Stress Disorder (PTSD).

4. Potential risks of the study: The most common side effects of prazosin include dizziness, drowsiness, lightheadedness, headache, nausea, lack of energy, weakness, and palpitations (abnormal heartbeat). Other side effects (less than 4% of people) include vomiting, diarrhea, constipation, drop in blood pressure when standing up, indigestion, fainting, vertigo, shortness of breath, depression, nervousness, rash, increased urinary frequency, blurred vision, reddened eyes, dry mouth, nasal congestion, and nosebleeds. There may also be unanticipated side effects to the drug prazosin.

Dizziness or drowsiness may occur after the first dose of the medicine. You should take your first dose of medication just before you go to bed for the night. Avoid driving or performing hazardous tasks for the first 24 hours after taking the medicine or when the dose is increased. Dizziness, lightheadedness, or fainting may occur, especially when getting up from a lying or sitting position. Getting up slowly may help lessen the problem. We will call you the day after you take your first dose to make sure you are tolerating the medication.

It is not safe to be in this study if you have a history of allergy to prazosin.

Additionally, it can be unsafe for men to take both prazosin and medications for erectile dysfunction, such as sildenafil (Viagra), tadalafil (Cialis), or vardenafil (Levitra), and we ask study participants not to use them during the course of the study.

The study drug should only be taken by the person for whom it has been prescribed. It should be kept out the reach of children or anyone who cannot read or understand instructions. You are also

cautioned not to take anyone else's prazosin even if you run out or cannot access your study medications as it could be dangerous to you if you are in the placebo condition.

The risks to the embryo from exposure to prazosin are unknown. For this reason, pregnant women or nursing mothers may not be in this study. Women who can bear children must agree to use a reliable form of birth control while participating in the study, such as birth control pills, intrauterine device (IUD), implanted contraceptive (such as Implanon), vasectomy, or diaphragm and condom. If you suspect that you have become pregnant while participating in this study, you should tell someone on the study team right away. As noted above, we will include a urine pregnancy test monthly to assure that we discover a pregnancy as soon as possible.

Research shows that some people who take prazosin have an increase in the occurrence of Intraoperative Floppy Iris Syndrome (IFIS). IFIS is a complication that can occur during cataract surgery, and we recommend that you inform your doctor of your use of prazosin prior to any eye surgery.

The riboflavin trace that is added to the medication so that we can monitor whether study participants are taking their prescribed study medications is harmless, but it will turn urine bright yellow. We ask that study participants not take any daily vitamin formulations that contain riboflavin during the course of the study so that there is no interference with the riboflavin trace in the study medications.

Some discomfort may be associated with the drawing of blood samples. There is a minor risk of bleeding, bruising, or infection at the site of the needle insertion.

The evaluations you receive as part of the study could disclose a medical condition that you might not have been aware of previously. We will share such information with you.

Loss of confidentiality (people unintentionally finding out personal information about you) is another risk of participating in this study. The data will be coded so as not to identify you, but confidentiality cannot be guaranteed. We will put a note in your computerized VA record that says you are participating in a research study and that you may be taking prazosin. This means that anyone who has access to your VA medical records (your other VA health care providers or people that you give permission to see your medical records) will know that you have participated in this study. Notes about the study visits will also be placed in the VA medical records.

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 as a risk to you.

5. Potential benefits of study: You may benefit from participating in this study if it decreases your cravings or decreases your alcohol consumption and symptoms associated with PTSD. However, it is also possible that your participation in this study will not provide you with any direct

benefits. Individuals respond differently to medications, and no one can know in advance if it will be helpful in your particular case. Potential benefits to society from your participation in this study may include greater knowledge and understanding of alcohol cravings and how to prevent them. The results of this study may help develop a new therapy for others with similar problems.

6. Other treatment available: Your participation in this study is voluntary and optional. You are free to choose to discontinue the study and seek other treatment alternatives.

For Veterans, you are free to access care at the Addictions Treatment Center (ATC) or in the Mental Health Service (MHS) as an alternative, and we can let the ATC or MHS coordinator know if this is your preference or you can contact him/her directly.

For non-Veterans, you are free to access care at an appropriate community mental health and substance abuse treatment center or private treatment provider as an alternative. We will be happy to provide you with resource information if you wish.

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:

- The specific research team members
- Seattle Institute for Biomedical and Clinical Research (the nonprofit institute that works with the VA to conduct research)
- The National Institute on Alcohol Abuse and Alcoholism (NIAAA), the study sponsor
- 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 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. The FDA may also choose to inspect research records that include your personal medical records.

Privacy and confidentiality will be maintained throughout the study. All samples and data will be stored by subject code and no identifying information will be included with them. Data will be stored in a locked filing cabinet in a locked office and in a computer with restricted access. Databases created by the study data will not contain any identifiable information. Only the investigators and their research assistants will have access to the original research data.

Once this study is completed, we will not use your data (or the code linking it to you) for any additional research. Your data and code will be held in a secure database until VA receives

authorization to destroy them in accordance with federal records regulations. It may be several years before the data and code are actually destroyed, but they will not be used for research after this study is completed.

The results of this study may be published, but your identity will not be revealed in any publication without your written permission. The data may also be used to gain support for other studies in the future and additional questions may be asked of the dataset beyond whether prazosin is effective for treating alcohol dependence (for example, *How does alcohol craving change over time in early recovery?*). You will not be identified individually in any summary of this study.

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 that you provide.

If you decide to take part in this research study, you will be asked to give us information about your substance use and behavior. We have applied for a Certificate of Confidentiality (CoC) issued by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) of the National Institutes of Health. This Certificate, however, does not imply that the Secretary, DHHS, approves or disapproves of the project. 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 CoC to resist any demands of information that would identify you, except as explained below.

Exceptions: A Certificate of Confidentiality (CoC) 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. If any member of the research team is given such information, he or she will make a report to the appropriate authorities (such as your primary mental health clinician, police, Washington State Department of Social and Health Services). In the event you indicate that you are at risk of harming yourself or another person, study staff may escort you to the VA Emergency Room for further evaluation and care. In addition, if you drive to a study appointment and you are found to be over the legal limit of .08 blood alcohol content (BAC), we will work with you to find an alternative way home or have you wait until your BAC is under the legal limit and you are safe to drive. However, if you insist on driving home before you are under the legal limit, we will need to notify the VA police and we will provide them with your name and your BAC reading in order to protect the public safety. These steps would be taken to ensure the safety of all individuals. Also, because this research is funded by NIAAA, staff from that and other DHHS agencies may review your records but they cannot report anything that would harm the research subjects. Additional program and evaluation staff such as those from the Research and Development Committee and/or Institutional Review Board (RRB)/Human Studies Subcommittee of the VAPSHS may also review your records but must maintain the confidentiality of your research records. Even when a CoC is in place, you and your family members must still continue to actively protect your own privacy. If you voluntarily give your written consent to anyone

(such as an insurer or employer) to receive information about your participation in the research, then we may not use the CoC to withhold this information. This protection will not apply until we have obtained the CoC, which may take a few weeks. We will inform you when the CoC has been obtained.

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.

All study tests and procedures will be done at no cost to you. You may be reimbursed up to $395 if you complete the entire 8-week study.

The total amount of money you can receive for **completing all of the study visits** is $260. You will receive:

- $45 for the initial screening assessment
- $45 for the baseline/randomization visit
- $50 for the 6-week assessment
- $50 for the 8-week assessment
- $10 for each of the 7remaining weekly blood pressure check and urinalysis visits.

You will have the option to receive these reimbursements either entirely in check form or you can opt to receive up to $10 cash at the time of your visit and the balance paid by check. It may take up to 2 to 4 weeks from your appointment date for the checks to be processed and issued to you.

The total amount of money you can receive for the **daily phone calls** is $135 for perfect compliance and the schedule is as follows:

- $1 for completion of daily IVR
  - If you make all seven required calls in a week, you will receive a bonus of $10 for that week.
    - During the 8 weeks of the study, you can miss 1 day each week and still earn $7.00 in bonus money for the weeks where you missed only one call.
    - You will be given partial reimbursements for the telephone monitoring approximately monthly.

IVR payments will also be made in check form.

You will be asked to be involved in the study for 8 weeks or until you complete the follow-up assessments if scheduling conflicts arise. If you participate for longer than the originally scheduled 56 days, you will be asked to continue to complete the daily IVR phone calls, and you will be paid for all calls that you make.

In order to reimburse you for these expenses, your name will be provided to SIBCR. If you participate in multiple studies and receive payments totaling $600 or more in a calendar year, SIBCR is required to report this to the Internal Revenue Service as taxable income. If SIBCR reports this income to the IRS, you may receive a 1099 tax form from SIBCR at the end of the year for being in this study. The information that SIBCR would be required to report would include your name, social security number, address, and amount of payments. However, participation in this study alone will not result in enough income to require SIBCR to report it to the IRS as taxable income.

Accounting is done through the Seattle Institute for Biomedical and Clinical Research (SIBCR), a non-profit agency contracted with the Seattle VA. SIBCR will not identify or link a payment to any research study, including this one.

For Veterans, in addition to the medical providers who provide treatment to you, members of the research team will review your VA medical record for information on your medical history and your alcohol and drug use history. We will need access to your medical records for up to 90 days after you complete the study. If you are a VA patient, you already have a VA medical record. If you are not a VA patient, we will create a VA medical record for you. As per VA regulations we will put an entry in your VA medical record that includes the title of the study and the date you signed the consent, the date you were randomized for study medication and ended medication, and an entry at the end of your involvement stating that you have completed the study. No information that is specifically about you will be entered into your VA medical record (the results from your assessments and clinical case notes will not be entered into this 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 in accordance with the record control schedule.

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.

If you are a Veteran, you may continue to receive the standard medical care at the VAPSHCS and the Addiction Treatment Center.

If you are not a Veteran, you may continue to receive the standard medical care at an appropriate community mental health and substance abuse treatment center or private provider.

If you do choose to participate, you may change your mind and withdraw at any time by contacting Bergetta Dietel at (206) 227-4015.

If circumstances occur in which your study participation must be terminated, this may be done without your consent. If the research staff finds that continuing with the study is not in your best interest medically, we may end your study participation early.

Your clinician 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, the study clinician 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. Saxon at (206) 277-3770
After business hours (nights and weekends)	Call (206) 762-1010 and ask the operator to page Dr. Saxon

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