Department of Veterans Affairs	VA PUGET SOUND HEALTH CARE SYSTEM (663) RESEARCH CONSENT FORM	
SUBJECT NAME		SSN:
TITLE OF STUDY	**Clinical trial of the adrenergic alpha-1 antagonist prazosin for alcohol dependence**	
PRINCIPAL INVESTIGATOR	**Tracy Simpson, PhD**	

LAY TITLE: Prazosin for alcohol dependence

Researchers:

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24-hour emergency contact:

- **During business hours (8:00 a.m. – 4:30 p.m.),** please call the Study Research Assistant, Ian Pocock at (206) 277-4872.
- **After business hours (nights and weekends),** 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, a research clinician 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 the research clinician. 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.

STUDY TITLE: Clinical trial of the adrenergic alpha-1 antagonist prazosin for alcohol dependence

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 in individuals 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). The use of prazosin for PTSD nightmares is an off-label use. That means that the FDA has not approved prazosin for PTSD nightmares. The current study is evaluating an "off-label" use of prazosin to determine whether it is helpful in decreasing alcohol consumption among people 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 approximately 200 participants in this study, which will run over approximately 5 years. Study participants will be involved in the study for 16 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 a research clinician to determine if you are eligible to continue in the study prior to receiving any medication. A research 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 performed 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 since you need to be completely sober to participate in the screening appointment. At future appointments, your blood alcohol level must be below .05, or they will need to be rescheduled.

At the screening visit, you will also be asked to provide urine samples to check kidney function and to analyze for the presence of controlled substances. Completing the medical interview, blood drawing, breath analysis, urine sample, and questionnaires will take approximately 1½ – 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. These procedures are part of the research and they are not intended to be treatment.

The research clinician 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 (VA Puget Sound). 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, Medication 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 16 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?"* and *"Have you had thoughts of suicide?"*

Study Medication Procedures: During the first 12 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 will 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 are actually receiving.

During the first 2 weeks that you are on the medication (or placebo), 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 medication exactly as prescribed. If you miss a dose, leave it in the mediset so staff can see exactly which 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 carry a study alarm watch with you 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. The watch will be yours to keep after the end of your participation in the study.

Daily Phone Monitoring: Beginning the day of Study Visit 2, you will be asked 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, and general emotional well-being over the preceding 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 hear each day is to remind you to take your study medication as well as to call the phone monitoring system. You will be asked to call into the monitoring system each day for the entire 16 weeks of the study. Daily phone calls may take about 3 – 5 minutes each day with a total commitment of 5½ – 9½ hours over the 16 weeks to complete all daily phone calls.

Medical Management (MM) Visits: Beginning with Study Visit 2, there will be eight 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, 6, 8, 10, and 12 weeks after starting study medication will last 10 – 15 minutes. During this study, we ask that you not take part in other counseling therapy or take any other medication treatment for alcoholism. However, you may go to self-help groups like Alcoholics Anonymous (AA). If we learn during an MM visit that you are drinking a dangerous amount of alcohol, we may remove you from the study for safety reasons as you would need more intensive treatment than we are providing through this study.

The baseline assessment and the daily telephone monitoring are part of the research and are not intended to be treatment. The study medication procedures and the Medical Management visits are intended to be treatment.

Study Visits 3–17 (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 10 weeks of the study, for a total of 14 more visits. You will also come back for one final follow-up visit 1 month after discontinuing the 12-week medication phase (Study Visit 17). At these visits, a study research 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. Visits 3-9 and 11-15 will last 15 to 30 minutes while Visits 10 and 16 will last 45 to 90 minutes. Visit 17 will last for about 1 hour.

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 monthly urine pregnancy tests 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, 12, and 16 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 12 weeks of the medication phase of the study.

As noted previously, the Medical Management visits are intended to be treatment as are the lab visits and checks for side effects. The final study visit is for both treatment and research purposes.

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 16-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 and is not intended to be treatment.

All procedures will be performed at the VA Puget Sound Health Care System.

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 and having survived an earthquake, an assault, or a rape. You will be asked whether something of this nature has happened to you and, if so, any reactions you might have had, or might still be having, to the experience (for example, repeated nightmares about it, avoidance in 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
- 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
- Nosebleeds

As with any drug, 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.

In the event that you are one of the few people who experience a serious problem from the drug, a research clinician will evaluate your condition and, if necessary, decrease your medication dose or discontinue the medication. Please call Ian Pocock, Study Research Assistant, at (206) 277-4872 to report any adverse reactions to the medication that are concerning you and he will make sure that a study clinician gets back to you promptly.

In case of a life-threatening emergency, you may also call 911 for immediate assistance. 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; for example, sildenafil (Viagra), tadalafil (Cialis), or vardenafil (Levitra). We ask study participants not to use them during the course of the study.

Individuals with a lifetime-use history of prazosin are at increased risk for intraoperative floppy iris syndrome and are encouraged to alert their doctor prior to eye surgery to minimize risks.

The study drug should only be taken by the person for whom it has been prescribed. It should be kept out of 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 since 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 monthly urine pregnancy test to assure that we discover a pregnancy as soon as possible.

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 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. 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) as an alternative, and we can let the

ATC 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:

- Research team members
- Seattle Institute for Biomedical and Clinical Research (the nonprofit institute that works with the VA to conduct research) will be provided with your full name, address, phone number, and social security number in order to authorize payment for your participation in this study
- The National Institute on Alcohol Abuse and Alcoholism (NIAAA), the study sponsor
- Federal agencies including, but not limited to, 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 FDA may also choose to inspect research records that include your personal medical records. The reviewers will protect your privacy.

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. 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.

All hard data (that is, completed questionnaires, completed interviews) except for identifiable information linking you to the hard data will be kept in accordance with the record control schedule after all subjects complete the study. As noted above, the master sheet connecting your name to your data will be destroyed in accordance with the record control schedule after the last subject finishes the study. Databases created by the study data will not contain any identifiable information and will be maintained indefinitely in accordance with the record control schedule.

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.

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.

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 received a Certificate of Confidentiality (CoC) issued by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) of the National Institutes of Health (NIH). This Certificate, however, does not imply that the Secretary of the Department of Health and Human Services (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 that 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 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 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 (IRB)/Human Studies Subcommittee of the VA Medical Center may also review records but must maintain the confidentiality of your research records.

Even with a CoC 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.

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 $597 if you complete the entire 16-week study.

The total amount of money you can receive for completing all of the **study visits** is $325. You will receive:

- $ 45 for the initial screening assessment
- $ 45 for the baseline/randomization visit
- $ 15 for the 6-week assessment
- $ 50 for the 12-week assessment
- $ 50 for the final 16-week follow-up
- $120 for the 12 remaining weekly blood pressure check and urinalysis visits ($10 each)

You will have the option to receive these reimbursements either entirely by check 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 $272 for perfect compliance and the schedule is as follows:

- $112 (or $1 for each completion of daily IVR)
- $160 bonus (or $10 for each week when you make all seven required calls). During the 16 weeks of the study, you can miss 1 day each week and still earn $7 in bonus money for the weeks where you missed.

About every month or so, you will be given partial reimbursements for the telephone monitoring. IVR payments will also be made in check form.

You will be asked to be involved in the study for 16 weeks, or until you complete the follow-up assessments if scheduling conflicts arise. If you participate for longer than the originally scheduled 112 days, you will be asked to continue to complete the daily IVR phone calls and you will be paid $1 for each of the additional calls that you make. You may receive an Internal Revenue Service (IRS) Form 1099. If so, your social security number will be used for this purpose.

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, the date you signed the consent, the date you were randomized for study medication and ended medication, and finally at the end of your involvement, an indication that you have completed the study. No information that is specifically about you will be entered into your VA medical record (that is, 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.

You may continue to receive the standard medical care at the VA Puget Sound Health Care System and the Addiction Treatment Center if you are a Veteran; if you are not a Veteran, 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 Ian Pocock at (206) 277-4872.

We will inform you if any information is discovered that may affect your willingness to continue to participate. Study staff will be monitoring your safety regularly through their contact with you at study visits and from your responses to the daily monitoring. 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.

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. 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.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. It may be many years; however, before research results are posted.

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.

In the event of any research-related injury or adverse reaction and for information as to what medical treatments are available if any research-related injury occurs, please contact one of the study staff listed at the beginning of this consent form. If you experience an adverse effect or research injury that requires immediate attention, please call the 24-hour emergency number listed at the top of this consent form. In case of an emergency in which you are unable to reach one of the researchers, please call 911 or go to the nearest emergency room.

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