Department of Veterans Affairs	VA PUGET SOUND HEALTH CARE SYSTEM (663) RESEARCH CONSENT FORM
SUBJECT NAME	SSN:
TITLE OF STUDY	Reducing Alcohol Use and PTSD with Cognitive Restructuring and Experiential Acceptance
PRINCIPAL INVESTIGATOR	Tracy L. Simpson, PhD

LAY TITLE: Acceptance and Cognitive Restructuring for AD and PTSD

Researchers:

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24-Hour Emergency Number: (206) 762-1010 (VA operator--ask for the Psychiatrist on call)

SUBJECT'S IDENTIFICATION **(I.D. plate or give name-last, first, middle)**

STUDY TITLE:

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 signed copy of this form for your records.

1. Purpose of research study and how long it will last:

This research is sponsored by the National Institute on Alcoholism and Alcohol Abuse (NIAAA). The purpose of this research study is to see how two different types of coping strategies, acceptance and cognitive restructuring, impact negative feelings, ability to cope with cravings, and avoidance behaviors in individuals who have both Posttraumatic Stress Disorder and Alcohol Dependence. The effectiveness of the two coping strategies will be compared to each other and also to the effects of learning the "plate method" of daily food proportions. Acceptance is a coping strategy that people can use to be aware of their thoughts, feelings, and memories in the present moment, as they are, without attempting to change them or avoid them. Cognitive restructuring is a coping strategy that people can use to get a different, more balanced, perspective on their thoughts. Learning the "plate method" can lead to healthier food choices, but is not known to be associated with changes in thoughts or feelings, including craving for alcohol. This study will investigate the impact of acceptance, cognitive restructuring, and learning the "plate method" in a laboratory setting by randomly assigning (like pulling a number out of a hat) participants to use either acceptance or cognitive restructuring or their own form of coping ("plate method" group) when they are remembering recent situations that led to alcohol cravings or a desire to drink. This study will also involve examining the impact of acceptance, cognitive restructuring, and using the "plate method" to improve nutrition in people's everyday lives by asking participants to monitor their own experiences over a six-week period.

You have been asked to participate in this study because you are at least 18 years old, you are either in treatment or seeking treatment for Alcohol Dependence and Posttraumatic Stress Disorder, your drinking in the last year has caused you problems or concern, you have been drinking alcohol in the last month, and you desire to stop or decrease drinking behavior. We expect approximately 160 participants in this study.

Description of the study including procedures to be used:

All of the procedures involved in this study are intended only for research purposes, though it is possible that learning new coping or nutrition strategies may be helpful or therapeutic for you.

Study Involvement Overview: If you decide to participate in this study and sign this consent form, you will be evaluated by study staff to determine whether you are eligible to continue in the study.

This would usually take place the same day you are reading this consent form and would be the Screening Session. If the initial tests show that you are eligible to continue in the study and you choose to continue your involvement with the study, we would ask you to complete a psychiatric interview and several paper-and-pencil questionnaires at that time as well. You may refuse to answer any question or item in any test, inventory, questionnaire, or interview. If you do continue in the study you will be a participant for the next 6 weeks. During that period, you will be asked to come back to the research clinic on two more days for two to three hours. In addition, once each week you will be asked to have a brief (no more than 15 minute) phone conversation with the Research Assistant about applying the coping or "plate method" strategy you learned in your daily life. You will also be asked, starting the day after the Screening Session, to call a toll free 800 number to provide daily information about your symptoms and your coping efforts each day for the 6 weeks of the study.

Screening Session and Baseline Assessment: A study investigator will complete an initial screening to see if you are a good fit for the study. The initial screening will consist of questions regarding your current therapy and medication treatment, whether you have various mental health problems, and what your drinking has been like over the past year and the past month. In addition, you will be asked to complete a psychiatric interview and to complete a set of questionnaires. These questions will include your employment, family and psychiatric history. You will also be asked to indicate the types of traumatic events that you have experienced or witnessed. You will be asked questions about your experience with symptoms associated with Posttraumatic Stress Disorder and with Alcohol Dependence. Examples of the kinds of questions you will be asked are: *Have you been having recurrent bad dreams or nightmares about the trauma? Have you been continuously irritable or have outbursts of anger? In the last year have you needed increased amounts of alcohol to feel the effects? In the last year have you wanted to quit or cut down on your drinking but have been unable to?* You are free not to answer any questions that you do not wish to answer.

If the results from this initial screening indicate that you are a good fit for the study, you will be invited to complete the Baseline Assessment questionnaires. These questionnaires inquire about recent experiences with craving alcohol or desires to drink alcohol, the ways that you cope with negative emotions, and your readiness to change your drinking habits. You will also be asked to provide details about two recent situations that led you to feel cravings for alcohol or to have a desire to drink, one positive and one negative situation. This information will then be compiled into a brief one-minute script that study staff will use in the next study session. The script will be audio recorded so that we can make sure that each one is delivered in one minute and to standardize how quickly the script is read. The script will not contain any identifying information, but will include details of your personal recent situations. The scripts will be stored on CDs in a locked filing cabinet and only study staff will have access to them. These recordings will be destroyed in accordance with the record control schedule after completion of the study. Completing the Screening Session and the Baseline Assessment will take approximately two and one-half hours to three and one-half hours.

You will also be taught how to use the toll free telephone daily monitoring system, which is described in more detail below, and you will be asked to start calling in to the system once a day beginning tomorrow.

Second Study Session: The second study session will happen approximately one week after the initial screening session and the final follow-up visit (described below) will happen six weeks after the first study session. During this study session, you will be asked to complete many of the same questionnaires that you completed during the Baseline Assessment. You will also be randomly assigned to one of the three study groups (acceptance, cognitive restructuring, or learning the "plate method") and you will be taught how to use the strategy that you are assigned to, followed by a survey about your understanding of the strategy. You will then be asked to imagine being in the two recent situations that led you to crave alcohol that you described in the baseline assessment session. While you are imagining your craving situations, you will be asked to use the strategy you were taught or your own strategy (for those in the "plate method" group) to cope with the cravings and any negative emotions that you feel. You will then be asked to complete questionnaires regarding your experiences of positive and negative mood and craving and about the strategy(s) you used to cope.

During study session #2, we will audio record the part of the session when the Research Assistant is teaching you one of the three conditions (acceptance, cognitive restructuring, or learning the "plate method"). The recordings will be done with a CD recorder and the CDs will be saved in a locked filing cabinet. The audio recordings will be done to insure that the Research Assistant is teaching the conditions correctly and one of the investigators will review the recordings to make sure that the conditions were delivered properly. Your voice would likely be on the recording as there is opportunity to interact with the Research Assistant during this part of the session. However, your name or other identifying information will not be included with the audio file and only study staff will have access to the recordings. The recordings will be stored in a locked filing cabinet in accordance with the record control schedule after the end of the study. At the end of that time the audio recordings will be destroyed by VA computer staff using a special method of completely erasing the files.

Daily Monitoring: We are also interested in better understanding the coping strategies that individuals with Posttraumatic Stress Disorder and Alcohol Dependence use and whether the interventions mentioned above are useful coping strategies in people's everyday lives. Therefore, we will ask you to report once per day on your experiences for a six week period. You will be asked to call a toll-free 800 number once each day to answer a series of automated questions about your alcohol cravings, alcohol use, mood, level of distress, posttraumatic stress symptoms, and coping strategies during the previous day. Daily phone calls may take between 3-5 minutes each day with a total commitment of 2-3.5 hours over the 6 weeks to complete all daily phone calls.

In order to help you remember to complete the daily report of your experiences, you will be asked to wear an alarm watch. The watch will signal you one time a day in the morning to remind you to complete the daily questions and either to use the new coping strategy that you were taught or to be aware of the coping strategies that you are using already. The watch will be yours to keep after the

end of your participation in the study. If you miss a daily call, the study staff will call you to both gather any missed information and help solve any problems with the system that might have come up. We will ask that you continue to complete daily monitoring in this manner over a 6-week period.

Self-report Assessment: In order to see how the interventions mentioned above may be working after a couple of weeks of practice, we will ask you to complete six short paper-and-pencil questionnaires two weeks after Study Visit #2. You will have the option of having us mail you the questionnaires to complete and mail back to us or coming into the office to complete them.

Brief Weekly Coaching Calls: If you participate in this study, you will be asked to arrange a time once per week starting after the first study visit to talk on the phone with the study Research Assistant about the coping strategy or "plate method" information you were taught and how you are using it in your daily life. The phone calls will be brief, lasting no more than 15 minutes, and will provide you with a chance to ask questions and trouble-shoot applying the strategies in your life.

Follow-up Visit: The final visit will involve completing a psychiatric interview and questionnaires. These will be used to examine the impact of the interventions on participants' symptoms of Alcohol Dependence and Posttraumatic Stress Disorder. This assessment will include the same measures that are involved in the screening and baseline assessment session. Similar to the screening/baseline session, examples of the kinds of questions you will be asked are: *Have you been having recurrent bad dreams or nightmares about the trauma? Have you been continuously irritable or had outbursts of anger? In the last month have you wanted to quit or cut down on your drinking but have been unable to?* You are free not to answer any questions that you do not wish to answer. In addition, you will be given information regarding the interventions that some participants were taught during the study and additional information on the current knowledge of acceptance and cognitive restructuring interventions. Completing the follow-up visit will take approximately one and one-half to two and one-half hours of your time.

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 the study interviews and questionnaires to be upsetting. Trained and experienced staff will complete all interviews with you to lessen this possibility. You could also feel some embarrassment related to questions about your symptoms of PTSD, alcohol and drug use, mental health problems, and personal habits. The study does involve answering questions about potentially illegal activities (e.g., you will be asked whether you have used any illicit drugs such as marijuana or cocaine as part of the assessment procedures). Such questions could lead to some discomfort.

Some people may experience stress and discomfort in describing and imagining previous situations that led to cravings for alcohol or a desire to drink. However, the stress and discomfort you may experience should be temporary and trained and experienced staff will work with you to lessen this possibility.

4. Potential risks of the study:

Loss of confidentiality (people not involved in the research study 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 also put a note in your computerized VA record that says you are participating in a research study, and that you may be taught a brief intervention of acceptance or cognitive restructuring or how to use the "plate method" for improving nutrition. The study title "Reducing Alcohol Use and PTSD with Cognitive Restructuring and Experiential Acceptance" will be included in that note. This means that anyone who has access to your 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.

You will be given an opportunity to have the written materials detailing your previous negative and positive life events destroyed once you have completed the study. If you choose to have these materials destroyed, the investigator will characterize these events in a general way (e.g., having an argument with a friend; playing with a child) so that we know the types of previous life events that people described.

Any significant new findings developed during this research, which may relate to your willingness to continue, will be provided to you. The study may contain unforeseeable risks and should any such risk(s) arise you will be informed as soon as they are identified.

5. Potential benefits of study:

You may benefit from participating in this study if you are randomly assigned to learn a new coping strategy, either acceptance or cognitive restructuring, that decreases your experience of craving, negative mood, distress, or drinking behaviors associated with Alcohol Dependence and Posttraumatic Stress Disorder. You may also derive some benefit if you are assigned to learn how to use the "plate method" as this can lead to healthier food choices. Further, it is possible that neither acceptance nor cognitive restructuring impact symptoms associated with Alcohol Dependence or Posttraumatic Stress Disorder, and, therefore, your participation in this study might not provide you with any direct benefits. Potential benefits to society from your participation in this study may include greater knowledge and understanding of effective coping strategies for individuals who suffer from Alcohol Dependence and Posttraumatic Stress Disorder. The results of this study may help develop a new therapy for others with similar problems.

6. Other treatment available:

If you choose not to participate in this study, you will receive the same standard care of mental health treatment at the VA Puget Sound Health Care System if you are a veteran. If you are not a veteran and you choose not to participate in this study, you may access care in the community of your choosing. We will be happy to provide you with resource information if you wish.

You may wish to discuss this study or alternative treatments with your regular provider at the VA Puget Sound Health Care System or in the community.

7. Use of research results/Confidentiality: Although the information obtained about you during the research study will be kept confidential, the following people or groups may know that you are in this study and have access to identifiable data about you: the research team members; Seattle Institute for Biomedical and Clinical Research (the nonprofit institute that works with the VA to conduct research); the study sponsor The National Institute on Alcohol Abuse and Alcoholism (NIAAA); 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); 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.

All study data will be confidential and labeled with a code instead of with your name or other information that could identify you. Data will be stored in a locked file in a locked office and in a computer with restricted access. Only the investigators and their research assistants will have access to the original research data. All hard data (i.e., completed questionnaires, completed interviews, audio recordings of negative and positive life events) and identifiable information linking you to the hard data will be kept in accordance with the record control schedule after all subjects complete the study. Databases created by the study data will not contain any identifiable information and will be maintained indefinitely. 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. You will not be identified individually in any summary of this study.

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.

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 obtained a Certificate of Confidentiality (CoC) issued by

National Institute on Alcohol Abuse and Alcoholism (NIAAA), NIH. 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 (e.g. your primary mental health clinician, police, Washington State Department of Social and Health Services). This is 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 (RRB)/Human Studies Subcommittee of the VA Medical Center may also review 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.

Although we will make every effort to keep your information confidential, no system for protecting your confidentiality can be completely secure. It is still possible that someone could find out you were in this study and could find out information about you.

8. Special circumstances:
Because this study is not meant to provide you with comprehensive treatment for your PTSD and your alcohol dependence, you are encouraged to seek out any additional treatment that you might need.

Some veterans are required to pay co-payments for medical care and services provided by VA. These co-payments requirements will continue to apply to any of your medical care and services provided by VA that are not part of this research study.

The total amount of money you can receive for completing the entire 6 week study is $322. You will receive $50 for the initial screening and baseline assessment visit, $40 for the second study visit, and $40 for the final follow-up visit. You will receive $20 for completing the paper-and-pencil questionnaires two weeks after Study Visit #2, either by mail or at the VA. You will receive $10 for each of the four weekly telephone coaching calls with the research assistant. Payment for completing

the daily monitoring will be under the following schedule: $1 per day for the completing the telephone monitoring, and if all 7 calls are made in a week you will receive a bonus of $15. If you miss only one day in a week (and that day is not the day after a missed day in the previous or following week), you will receive a bonus of $7 for that week. You can earn up to $132 for perfect compliance with the six weeks of daily monitoring.

You will receive these payments by check. It may take up to two to four weeks from your appointment date for the checks to be processed and issued to you. In order for these payments to be processed, you will be asked to give your full name, social security number, and address. This information will only be used to process these payments. It is also important for you to know that the institution is required to report to the IRS as taxable income all payments to an individual subject totaling $600 or more in a calendar year. This will not be the case for this study but if you are in other studies and the total amount from this institution is $600 or more, it will need to be reported to the IRS. Your name, social security number, address, and amount of payment would be included in the information that goes to the IRS. 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.

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 and at the end of your involvement a second entry will be made indicating that you have completed the study. No information that is specifically about you will be entered into your VA medical record (i.e., 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 and you are free to withdraw at any time. Your decision to not participate or to withdraw will involve neither penalty nor loss of VA or other benefits to which you might be otherwise entitled. You will continue to receive the standard medical and mental health care at the VA Puget Sound Healthcare System if you are a veteran and you will be offered community-based referrals if you are not a veteran.

Should you choose to withdraw from the study you may contact the study Principal Investigator, Dr. Tracy Simpson, at (206) 277-3337.

We will inform you if any information is discovered that may affect your willingness to continue to participate. 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, we may end your study participation early.

Your participation may also be terminated without your consent if your doctor feels that it is in your best interest.

Whether you choose to withdraw or the study doctor withdraws you from the study, the consequences of your withdrawal from the research, if any, and procedures for an orderly termination of participation will be discussed with you by the study physician.

10. Questions or concerns related to the study: If you have any questions about the availability of medical care or if you believe you have experienced a research-related injury as a direct result of participation in the study, you should immediately contact:

Researcher: Dr. Tracy Simpson at (206) 277-3337 during the day and

The VA operator at (206) 763-1010 after hours and ask the operator to page Dr. Simpson.

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

- Wish to contact an impartial third party not associated 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.

10. Research-Related Injury:
The VA will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. 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.

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 investigators 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.

STUDY TITLE:

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.

☐ You may contact me about possible future research studies. Only my contact information will be stored for this purpose.

☐ I do not wish to be contacted about possible future research studies.

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

Subject Signature **Date**

Print Name of Subject

Witness Signature **Date**

Print Name of Witness
(Witness only to subject signing the consent form)

Signature of Person Obtaining Consent **Date**

Print Name of Person Obtaining Consent