Subject's Name: **Date:**

Principal Investigator: Kathleen T. Brady, MD, PhD

Study Title: Mindfulness Based Recovery in Veterans with Substance Use Disorders

A. PURPOSE AND BACKGROUND:

You are being asked to volunteer for a research study. This research is sponsored by the Department of Veterans Affairs. The purpose of this study is to evaluate the efficacy of mindfulness-based relapse prevention (MBRP) compared to 12-Step Facilitation (TSF) in military Veterans following completion of intensive outpatient treatment for substance use disorders at the Ralph H. Johnson VA Medical Center.

You are being asked to participate in this study because you are a Veteran who is completing an intensive substance use disorder outpatient program at the Ralph H. Johnson VA Medical Center.

The investigator in charge of this study is Kathleen T. Brady, MD, PhD. Karen Hartwell, MD is the investigator in charge at the Ralph H. Johnson VA Medical Center. This study is being done at 2 sites and will involve approximately 308 volunteers. We plan to enroll approximately 154 volunteers at the Ralph H. Johnson VA Medical Center.

B. PROCEDURES:

If you agree to be in this study, the following will happen:

Baseline/Screening visit: Approximately one to two weeks before completion of the intensive outpatient treatment program (IOP), you will come in for a screening visit to see if you qualify for the study.

At this visit the following will happen:

- A urine sample will be collected by the research staff for a urine pregnancy test, a urine drug screen and a test to measure recent alcohol use. The urine pregnancy test will be done before the urine drug screen. If the pregnancy test is positive, you will not be eligible to participate in the study and no further study procedures will be conducted.
- An alcohol breathalyzer will also be done to determine recent alcohol use.

- A psychiatric evaluation will be done which will include interviews and questionnaires (approximately 5 interviews and 5 questionnaires), which will take approximately 2-21/2 hours). You will be asked questions about your drug and alcohol use as well as about your mood, your nerves, quality of life, current medications and other areas of functioning.

- At the end of this visit, if you continue to meet study requirements, you will be randomly assigned to one of two groups. This means that you have a 50/50 chance (like flipping a coin) of being in either group. The two treatment groups are Mindfulness-Based Relapse Prevention (MBRP) and Twelve-Step Facilitation Intervention (TSF).

Treatment visits: Following the Baseline/Screening visit, and completion of the IOP treatment program at the VA, if you are randomized to the Mindfulness-Based Relapse Prevention (MBRP) group, you will attend an introductory session before attending your first group therapy session. If you are randomized to the Twelve-Step Facilitation Intervention (TSF) group, you can begin attending group therapy sessions immediately after you complete the VA IOP treatment program. Once you begin attending the weekly therapy group, you will be expected to attend 8 weekly group therapy sessions and brief study assessment visits on the same day, if possible.

During the 8 weekly group therapy sessions and study assessment visits the following will happen:

- You will attend your MBRP or TSF therapy session which will be delivered in a group setting. If you are in the TSF therapy, your last session may be delivered in an individual or small group setting.

- You will provide a urine sample for drug testing.

- An alcohol breathalyzer will be done prior to attending the group therapy sessions to determine recent alcohol use.

MUSC MEDICAL UNIVERSITY of SOUTH CAROLINA
IRB Number: Pro00035024
Date Approved 6/1/2016

- You will be asked questions about your drug and alcohol use since your last study visit as well as questions about your mood, current medications, and changes in your physical health.
- You will be asked for information about any work (paid or volunteer) you've done since your last study visit. You will also be asked about any mental health or substance use treatment you received since your last study visit. This includes treatment at the VA and treatment outside of the VA, such as AA/NA meetings.
- If you are not able to come to the site to attend a study visit and you agree, some assessments and questionnaires may be conducted by phone.

  After you complete the final weekly group therapy session (session 8), the assessment visit for that week will include all of the above procedures, in addition to a urine test for recent alcohol use. You will also be asked to complete questionnaires and asked questions about your drug and alcohol use as well as about your mood, your nerves, current medications, quality of life and other areas of functioning in your life.

Follow-up visits: After your last group therapy session, you will attend follow-up visits at 3 months, 6 months, and 10 months.

At these study visits the following will happen:

- A urine sample will be collected for a urine drug screen and to measure recent alcohol use.
- An alcohol breathalyzer will also be done to determine recent alcohol use.
- You will be asked to complete questionnaires and asked questions about your drug and alcohol use as well as about your mood, your nerves, current medications, quality of life and other areas of functioning in your life.

- If you are not able to come to the site to attend a study visit and you agree, some assessments and questionnaires may be conducted by phone.

You may be withdrawn from the study without your consent if the researchers believe it is in your best interest or if you fail to follow study procedures. You may be withdrawn from the study and referred for more intensive treatment if you:

- Experience increases in your alcohol or drug use leading to the need for a more intensive level of care.
- Have active suicidal or homicidal ideation.
- Are unable to manage psychiatric symptoms and the study doctor decides that you need to be started on medications for anxiety, mood or psychotic symptoms during the course of the study.
- Are unable to return for therapy sessions due to incarceration or hospitalization lasting longer than four weeks.

C. DURATION:

Participation in the study will take about 12 months. You will have a baseline visit to determine eligibility lasting approximately 2 ½ hours, 8 weekly visits including the treatment sessions lasting approximately 90 - 120 minutes, then you will have follow-up visits at 3 months, 6 months and 10 months each lasting about 1 hour.

D. RISKS/DISCOMFORTS:

Possible risks involved in participating in this study may include:

- Risk of loss of confidentiality: There is a chance that your personal information may inadvertently not be kept confidential. Some answers you give during the research visits (like whether you use illegal drugs) may put you at risk if other people find out. To keep what you say private, your study records will use a code number instead of your name. We will protect your records by keeping all your materials in locked file cabinets only accessible by research staff and all computer files will be secure password-protected

files only accessed by research staff. The research staff that will be working with you has been thoroughly trained to keep your information confidential.

- Risk of distress associated with answering questions about your feelings and drug and alcohol use. You can refuse to answer any questions that you do not want to answer.
- There is the risk of another person or parties observing you attending group therapy sessions or learning by other means that you are receiving treatment. You will not be openly identified as a research participant or a participant for psychological intervention.
- There is a risk related to randomization. The treatment you receive may prove to be less effective than the other study treatment.
- If you are or become pregnant and test positive for illegal drugs, it is a law that the South Carolina Department of Social Services (DSS) must be notified. You and your family will be evaluated by the agency. You could be ordered to mandatory drug treatment, lose custody of your children, or possibly be jailed.
- Unknown Risks: The experimental treatments may have unknown side effects. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

E. BENEFITS:

There may be no direct benefit to you from participating in this study. However, possible benefits may include a potential reduction in substance use and related problems. The information we get from this study might help us treat future patients.

F. COSTS:

You will not be charged for any treatments or procedures that are part of this study. You will not be required to pay for medical care or services received as a participant in a VA research project except as follows: Some veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study.

G. COMPENSATION:

You will be paid with vouchers or cash for your participation in this study. If cash is not available at the time of your study visit you will have the option of receiving a voucher or coming back to receive cash when it becomes available (probably within a week of your visit). You will receive $25 for completing the baseline/screening visit, $20 for each of the weekly assessments completed at weeks 1-7 during the active treatment phase and $40 for completing week 8 (end of treatment visit). You will receive $45 for completing the 3-month follow-up visit, $50 for completing the 6-month follow-up, and $60 for the completion of the 10-month follow-up. You are also eligible to receive an additional $10 once you complete a total of 3 weekly assessments and an additional $30 for completing a total of 5 weekly assessments. Thus, the total amount you are eligible to receive for the baseline assessment, treatment and follow-up visits is $400.

The IRS requires a tax form be filed if your compensation exceeds $600.00/year. However, if the payment for participation will be made through Austin Financial Services Center, it may generate IRS Form 1099 automatically, regardless of amount.

H. RECRUITMENT OF PARTICIPANTS:

You are invited to participate in the recruitment of other participants for this study. If you choose to participate, we will provide you with business cards that you may give to other Veterans in the Intensive Outpatient Program who you think would be interested in this study. The cards will have our contact information so Veterans can contact us if they are interested in the study. The cards will also have a code that is unique to you and if any of your cards result in successful study recruitment, you will receive $10 for each one. You will receive payment by Electronic Funds Transfer (EFT), which means the money will be electronically deposited into your bank account. Participation in the recruitment process is completely voluntary, and if you elect not to participate your participation in this study will not be affected in any way.

I. ALTERNATIVES:

You may choose not to participate in this study. If you choose not to participate in this study, you could receive other treatments for your condition. The Ralph H. Johnson VAMC offers an aftercare program following the IOP. We will also be happy to provide referrals for other treatment clinics and health care providers in the community if you would like.

Subject's Name: **Date:**

Principal Investigator: Kathleen T. Brady, MD, PhD

Study Title: Mindfulness Based Recovery in Veterans with Substance Use Disorders

J. DISCLOSURE OF RESULTS:
Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law.

K. NEW INFORMATION: If there are significant new findings during the course of the study, you will be notified.

L. EMPLOYEE PARTICIPATION: Your participation or discontinuance will not constitute an element of your job performance or evaluation nor will it be a part of your personnel record at this Institution.

M. CONFIDENTIALITY CERTIFICATE:
A Certificate of Confidentiality has been obtained from the Federal Government for this study to help insure your privacy. This certificate means that researchers cannot be forced to tell people who are not connected with the study, including courts, about your participation, without your written consent. If we see something that would immediately endanger you, your child, or others, we may discuss it with you, if possible, or seek help.

N. RE-CONTACT:
From time to time we have other research studies that you may be eligible to participate in. We are inviting you to allow us to contact you by phone, email, and/or mail to see if you would be interested in participating in any future studies. By checking the "yes" box below, you are indicating that you would like us to contact you by phone, email, and/or mail if another study becomes available that you might qualify for. To maintain your confidentiality, we will not leave identifiable messages or any identifiable information on letters or envelopes that are mailed to you. By checking the "no" box below, you are indicating that you do not want study personnel to contact you for any future studies. You may still participate in the current study if you check "no" and you will not suffer any adverse consequences in doing so.

☐ Yes. I would like to be re-contacted for future studies. I give permission for study personnel to contact me by phone, email and/or mail to inform me of other available studies I may be eligible for. Please initial here_____.

☐ No. I do not wish to be re-contacted for any future studies. Please initial here_____.

O. VOICE VIDEO RECORDING:

We will audio record the therapy sessions to assure treatment quality and adherence to the treatment manual. This could pose a minimal risk to confidentiality although we will take every step possible to ensure that all recordings are stored securely and any risks minimized. To minimize any risk, all recordings will be kept in a locked file cabinet or on a secure and encrypted server and only the project staff and supervisors will have access to the recordings. They will be destroyed after the study has been completed.

CONSENT

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

The VA will provide necessary medical treatment to a research subject injured by participation in a research project. This requirement does not apply to treatment for injuries that result from non-compliance by a research subject with study procedures. If you sustain an injury as a direct result of your study participation, medical care will be provided by this VA Medical Center. Financial compensation is not available for such things a lost wages, disability or discomfort due to an injury.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. The data collected on you to this point remains part of the study database and may not be removed. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

Subject's Name: **Date:**

Principal Investigator: Kathleen T. Brady, MD, PhD

Study Title: Mindfulness Based Recovery in Veterans with Substance Use Disorders

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, or if I have comments, concerns or complaints, I may contact: Dr. Karen Hartwell (843.789.7311). I may contact the VA Medical Center's Medical Director (843.789.7200) concerning medical treatment.

If I have questions, comments, concerns or wish to voice a complaint, I may contact the VA Research Compliance Officer at (843.789.7399).

If I have any questions about my rights as a research subject in this study I may contact the Medical University of SC Institutional Review Board for Human Research at (843.792.4148).

I agree to participate in this study. I have been given a copy of this form for my own records.
If you wish to participate, you should sign below.

Signature of Person Obtaining Consent Date Signature of Participant Date