Subject's Name: **Date:**

Principal Investigator: Daniel Gros, Ph.D.

Study Title: Comparing Group Therapies for Veterans with Depression and PTSD

SUMMARY

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this study is to determine whether a new form of group psychotherapy for Veterans with major depressive disorder (MDD) and/or posttraumatic stress disorder (PTSD) is effective.

Participants will complete an initial screening involving an interview and questionnaires. Once screening is complete, participants will complete 12-weekly sessions of group psychotherapy, with additional screenings after week 6, week 12, and 6-months after the week 12 screening. All appointments should take about 2 hours to complete. All appointments will be offered in-person or via VA-approved telehealth technologies, based upon your preference and the group schedule. Total study duration is about 9 months.

Participation in this study may improve your mental health symptoms, but that cannot be guaranteed. The greatest risk of this study is some physical or emotional distress during the interview process as well as the therapy sessions and the loss of confidentiality. You do not have to participate in this study to have your condition(s) treated. Alternative treatments include psychotherapy and medication options within the mental health service line at the Ralph H. Johnson VAMC.

If you are interested in learning more about this study, please continue to read below.

A. PURPOSE OF THE RESEARCH

This research is sponsored by the Department of Veteran Affairs Rehabilitation Research & Development. The purpose of this study is to determine whether a new form of group psychotherapy for Veterans with depression and/or PTSD is effective. The new form of group psychotherapy, Group Transdiagnostic Behavior Therapy (G-TBT), was designed to treat a wider range of common disorders and related symptoms than is typical among the existing forms of evidence-based psychotherapy. We are interested in learning if G-TBT reduces symptoms of PTSD, depression, avoidance, and related impairment.

Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. You are being asked to participate in this study because you are 18 – 80 years of age and may have symptoms consistent with MDD and/or PTSD.

The study is sponsored by the Department of Veterans Affairs Rehabilitation Research and Development program. The investigator in charge of this study at the Ralph H. Johnson VA Medical Center is Daniel Gros, Ph.D.. The study is being done at the Ralph H. Johnson Veterans Affairs Medical Center. Approximately 326 people will take part in this study.

B. PROCEDURES

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

1. All procedures will take place at the Ralph H. Johnson VAMC in Charleston, SC. You will come in to the VAMC for an interview with the study coordinator for a review of the study procedure and informed consent will be obtained. You also will be asked to complete questionnaires asking about, for example, your age, employment, relationship status, and education. You will also be asked to complete several questionnaires and a diagnostic interview to assess your symptoms of anxiety, depression, and related conditions in order to determine if you are eligible for the study.

2. If you have recently started taking a prescription medication, you may be asked to wait 4 weeks until you start the therapy so that the effects of this medication will be stable and will not affect the study results.

3. If you are eligible, you will be randomly assigned to one of two treatment conditions ("randomly assigned" means that you have a 50/50 chance, like a coin toss, of being placed in one or the other treatment condition). If you are assigned to Treatment 1, you will be asked to participate in the newer G-TBT for the treatment of the depressive and anxiety disorders. If you are assigned to Treatment 2, you will be asked to participate in an established disorder-specific evidence-based psychotherapy (e.g., Group Cognitive Behavior Therapy for Depression or Group Cognitive Processing Therapy for PTSD), for the treatment of the diagnosed the MDD or PTSD. Both Treatment 1 and 2 have been shown to be helpful in treating the symptoms of the depressive and anxiety disorders and will be delivered by a well-trained therapist working under the supervision of the Principal Investigator. Both Treatment 1 and 2 will consist of 12 weekly group psychotherapy sessions scheduled over a 12-week period.

4. After your initial visit (baseline), you will meet with the study therapist weekly for the group psychotherapy sessions. Of note, the group psychotherapies will begin once at least 6 participants are ready to attend the groups, potentially resulting in a wait of a few weeks between

baseline and the start of group psychotherapy. All appointments will be offered in-person or via VA-approved telehealth technologies, based upon your preference and the group schedule.

5. Group psychotherapy sessions will consist of: (a) education about the common symptoms and reactions to stress, as well as explaining the components of the psychotherapy itself, (b) goal setting and tracking, and (c) learning, assigning and practicing cognitive and behavioral therapeutic techniques (e.g., practices exposures, assigning pleasant activities, challenging negative thought patterns). These types of psychotherapeutic techniques have been shown to be effective in reducing the symptoms of anxiety and depression. Periodically, brief self-report measures of your symptoms will be completed and your VAMC medical record may be reviewed to monitor your treatment progress.

6. All clinical interviews and psychotherapy sessions will be audio recorded to ensure that interviews and psychotherapy sessions are being delivered in accordance with the manuals. All recordings will be kept in a locked cabinet or in a study-specific folder on encrypted VA server (//v07.med.va.gov/cha/mh gros research) that are only accessible by study staff.

7. You will be asked to complete additional assessments upon the completion of psychotherapy and at 6-months post-treatment. The assessments will be the same for both groups and will include measures that assess your symptoms of anxiety, depression, and related conditions. These appointments also will be delivered either in-person and via VA-approved telehealth technologies, based upon your preference.

If during treatment you indicate to us that you might harm yourself or someone else, we may ask you to complete and sign a safety plan. This safety plan involves several steps including calling us, your other mental health providers at the VAMC, Veterans Crisis Hotline (1-800-273-8255 – press 1), emergency numbers and/or 911. All of these contact numbers will be on the safety plan.

While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury from things such as extra blood drawing, extra X-rays, or potential drug interactions. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

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C. DURATION

The psychotherapy treatment component of the study will last about 12 weeks, with a pre-treatment assessment completed immediately before treatment begins, a mid-treatment assessment completed after 6 weeks of treatment, an immediate post-treatment assessment completed 1 week after psychotherapy is complete, and a follow-up assessment completed 6 months after psychotherapy is complete. Each psychotherapy session will be appropriately 90 minutes and each assessment will take 2-3 hours of your time.

D. RISKS AND DISCOMFORTS

There is a risk that you may become upset by questions asking about your experiences and/or symptoms of anxiety and depression or experience some physical or emotional distress during the interview process as well as the therapy sessions. There is a risk of loss of privacy as a result of participation in the group discussions. There also is a risk of a loss of confidentiality of your personal information as a result of participation in this study. Finally, there is a risk of being randomly assigned to a treatment condition that is less effective than the other.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your healthcare providers if you have any questions about the risks of usual care.

E. MEDICAL RECORDS and/or CERTIFICATE OF CONFIDENTIALITY

If you are a Ralph H. Johnson VA Medical Center patient, you have a VA medical record. If you have never been a Ralph H. Johnson VA Medical Center patient, a VA medical record will be created for the purposes of this study. Results of research tests or procedures will be included in your VA medical record. All information within your medical record can be viewed by individuals authorized to access the record. We will make every effort to keep confidential all research information in the medical record that identify you to the extent allowed by law.

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F. BENEFITS

Our goal is to determine whether this new treatment, G-TBT, is helpful for Veterans. If you are randomized to receive the G-TBT, the potential benefit to you is that the treatment you will receive may prove to be better than standard care, although this cannot be guaranteed. Another benefit is that the information gained from the study will help increase our knowledge about how to best treat future Veterans with symptoms of anxiety, depression, and related conditions. It also is possible that there may be no benefit for participation in the study.

G. COSTS

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these copayments for VA care and medications that are not part of this study.

H. PAYMENT TO PARTICIPANTS

In return for your time, effort, and travel expenses, you will be paid $300 for participation in this study. If you do not complete the study, you will receive the following payments for each completed assessment visit: $40 for pre-treatment, $60 for mid-treatment after week 6, $80 for immediate post-treatment after week 12, and $120 for 6-month post-treatment. 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. This will require the use of your Social Security Number and it may generate IRS Form 1099 automatically, regardless of amount.

I. ALTERNATIVES

If you choose not to participate in this study, you could receive other treatments for your condition. The standard psychotherapy for your condition is individual or group psychotherapy and/or treatment with antidepressant medications. You may receive these options at the Mental Health Clinic at the Ralph H. Johnson VAMC. You also may wish not to seek treatment at all.

J. DATA SHARING

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Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

K. DISCLOSURE OF RESULTS

Results of this research will be used for the purpose described in the study. The information may be published, and if so, your information will not be identified and shall be protected with State and Federal Laws. We suspect that the information obtained in the study will take at least one year to analyze. Once this has been done, the reports will be written, and we will make these reports available to individuals who participate in this study upon request.

L. AUDIO RECORDING

We would like to record the assessment and therapy sessions to assure quality and adherence to the procedures. Recording the sessions is required for participation. This could pose a risk to confidentiality and although we will take every step possible to ensure that all recordings are stored securely and any risks minimized, there is a risk is that you could be identified. To minimize any risk, all recordings will be kept in a locked cabinet or in a study-specific folder on encrypted VA server (//v07.med.va.gov/cha/mh gros research) that are only accessible by study staff.

M. SIGNIFICANT NEW FINDINGS

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

N. 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.

O. CLINICAL TRIALS.GOV

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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P. CONSENT

Your privacy is very important to us and the researchers will make every effort to protect it. Results of this research will be used for the purposes described in this study. These results may be published, but you will not be identified.

The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. 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. There are times when we may have to show your records to other people from Federal agencies that oversee our research such as the Department of Health and Human Service's Office of Human Research Protections (OHRP), the Food and Drug Administration (for FDA regulated research only), the Government Accountability Office (GAO), the VA Office of the Inspector General (OIG), the VA Office of Research Oversight (ORO), our local VA Research and Development Committee, and other study monitors may look at or copy portions of records that identify you. Also, all records in South Carolina are subject to subpoena by a court of law. Any information shared with these outside groups may no longer be protected under federal 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 the Ralph H. Johnson VA Medical Center. Financial compensation is not available for such things as 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. 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.

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.

VOLUNTEER STATEMENT

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Dr./Mr./Ms._____ has explained the research study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

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 the study principal investigator, Daniel Gros, Ph.D., at 843-789-6225.

If I have questions about my rights as a study participant, or I want to make sure this is a valid VA study, I may contact the Medical University of South Carolina's Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. I may call the MUSC IRB (843) 792-4148, or the Ralph H. Johnson VA Medical Center's Research Compliance Officer at (843) 789-7399, if I have questions, complaints or concerns about the study or if I would like to obtain information or offer input.

By signing this document below, I voluntarily consent to participate in this study. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it.

A copy of this signed consent will also be put in my medical record.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date
_____ Name of person obtaining consent	_____ Signature of person obtaining consent	_____ Date