Consent to participate as a Research Subject in:

Evaluation of a Brief Individual Therapy for Veterans with Post Traumatic Stress Disorder (PTSD)

We are inviting you to be 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.

Your participation in this study is entirely voluntary. Please take as much time as you need to discuss the study with your doctors, family, and friends. The decision to participate or not is yours. If you choose to participate, you have the right to withdraw from the study at any time.

This study is being conducted by the Health Services Research and Development Department at the VA Puget Sound Health Care System (VA Puget Sound).

Principal Investigator:
Tracy Simpson, PhD

Research Staff:
Scott Michael, PhD
Supervising Clinical Psychologist

Sarah Campbell, PhD
Co-Investigator

Holly Rau, PhD
Co-Investigator

Lisa Batten, MHA, MPH
Study Coordinator/Assessor

Study Title:
Open Trial of Behavioral Activation and Social Engagement (BASE) for PTSD

1. Who can I contact with questions while I am in this research study?

During business hours (8:00 a.m. – 4:30 p.m.), please call Lisa Batten, the Study Coordinator at (206) 277-1377.

After business hours (nights and weekends), please call the VA's Psychiatric Emergency Services at (206) 764-2600 (Seattle Division) or (253) 583-1680 (American Lake Division).

The study researcher(s) listed above must be contacted immediately if:

- You think you may have been harmed or injured as a direct result of this research.
- You have any questions regarding your medical care issues.

You may also contact the Institutional Review Board (IRB) 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.
- Have questions about your rights as a research subject.

If you begin to feel suicidal or have other adverse reactions, please let us know. Dr. Michael is a psychologist who is well trained in managing emotional crises, should any arise. You can reach Dr. Michael at (206) 277-4386. You can also contact the VA and ask for the on-call psychiatrist or call the Veterans Crisis Line at (800) 273-8255. In case of a life-threatening emergency, call 911.

2. What is the purpose of this research study?

We are conducting a research study to evaluate the effectiveness of an individual therapy called "Behavioral Activation and Social Engagement for PTSD" (also called "BASE for PTSD"). This therapy is geared for Veterans with Posttraumatic Stress Disorder (PTSD) who seek treatment in a primary care setting.

"BASE for PTSD" is a shorter adaptation of a treatment that has proven to be effective in improving the quality of life for Veterans with PTSD who sought care in our Mental Health Services and Primary Care Services outpatient programs.

The purpose of the study is to see if "BASE for PTSD" will be able to help Veterans with PTSD by:

- helping them better understand how PTSD affects them.
- reducing ways in which they feel impaired by their PTSD symptoms.
- enabling them to do more of the things that they really care about.
- improving, strengthening, and building up their social supports.

We are asking you to participate because you are a Veteran with PTSD and have sought physical or mental health treatment in a Primary Care clinic. Over a one-year period, we are approved to enroll 50 subjects in this study. If you enroll, you will need to participate for 3 months, which will include 10 study visits (6 visits for individual therapy and 4 visits for assessments). The average duration of the visits will be 40-60 minutes; however, one visit may last up to 2 hours.

3. What will I be asked to do in this research study?

STUDY SCHEDULE

Study Week	Study Visit	Duration	Study Activity
Week 0	Visit 1	1 hour	• Provide informed consent • **Complete Screening & Pre-Treatment Assessment** • Schedule first individual therapy session
Week 1	Visit 2	45 minutes	• Attend an individual therapy session in person or participate by phone (Session 1)
Week 2	Visit 3	45 minutes	• Attend an individual therapy session in person or participate by phone (Session 2)
Week 3	Visit 4	45 minutes	• Attend an individual therapy session in person or participate by phone (Session 3)
Week 4	Visit 5 Visit 6	45 minutes 1 hour	• Attend an individual therapy session in person or participate by phone (Session 4)

			• **Complete Mid-Treatment Assessment**
Week 6	Visit 7	45 minutes	• Attend an individual therapy session or participate by phone (Session 5)
Week 8	Visit 8 Visit 9	45 minutes 1½-2 hours	• Attend the final individual therapy session or participate by phone (Session 6) • **Complete Post-Treatment Assessment** • Complete post-treatment interview
Week 12	Visit 10	1 hour	• **Complete Post-Treatment Follow-Up Assessment**
Week 16	No visit. Medical Chart review only		• Research staff will collect information from your electronic medical record (medication and treatment received during the study)

You will have the option to participate in person or by telephone for all study visits, except for Visit 1, which must be attended in person. Because in-person sessions are more beneficial than phone sessions, we do not encourage phone sessions, except in exceptional circumstances and when assessed by a clinician to be appropriate.

If you decide to participate via telephone for your individual therapy sessions and assessments (Mid-Treatment, Post-Treatment, and Post-Treatment Follow-Up Assessments), a study staff member will mail the study materials to you to your verified address prior to your sessions and assessments to help you understand the questions you will be asked. If you decide to attend your therapy sessions by phone, we will ask you to mail some study materials to the study clinician prior to your therapy sessions.

We will audio-record the individual therapy sessions and a portion of the Post-Treatment Assessment procedures. We will later transcribe (write out word for word) the recording of only the Post-Treatment Assessment so that approved study staff members will be able to review your responses as part of the data collected for the study. Additionally, approved study staff may review the recording during data analysis to make sure that the transcript accurately captured what you said and how you said it.

STUDY VISIT 1 (Screening & Pre-Treatment Assessment)

At this appointment, we will go over this Consent Form and answer any questions you have about the study. We will then ask you to complete a short quiz to make sure that all the important elements of the study are clear to you.

We will then have you complete questionnaires that will include screening questions about any hospital stays related to emotional distress and assessment questions related to PTSD. Additionally, we will ask questions about your employment, psychiatric history, history of stressful events, and recent symptoms. Examples of the kinds of questions you will be asked are:

- *In the last month, how often were you bothered by repeated, disturbing, and unwanted memories of the stressful event?*

- *Have you ever experienced an assault with a weapon (for example, being shot, stabbed, threatened with a knife, gun, bomb)?*

Based on your answers, we may find that the study is not a good fit for you and your participation will end at this point. If the study is a good fit and you would like to continue, we will ask you to answer additional questions about your relationships, your preferred ways of coping with stress, and your level of daily activity.

We will then schedule your first individual therapy session during this visit.

STUDY VISITS 2–5 and STUDY VISITS 7–8 (individual therapy sessions)

At each of these six study visits, you will need to complete an individual therapy session. You will have the option to attend these sessions in person or via telephone. During these sessions, the following will be covered:

- We will explain the ways in which PTSD symptoms can influence how you live your life.
- We will help you learn how to reconnect to things that really matter to you.
- We will outline ways for you to improve, strengthen, and build up your relationships with other people.

STUDY VISIT 6 (Mid-Treatment Assessment)

At this study visit, we will have you complete questionnaires that are similar to the ones you completed during Study Visit 1. The questionnaires will include questions regarding your PTSD symptoms, your relationships, your preferred ways of coping with stress, and your level of daily activity.

STUDY VISIT 9 (Post-Treatment Assessment and Post-Treatment Interview)

At this study visit, we will have you complete questionnaires that are similar to the ones you completed during Study Visit 1. Additionally, we will ask you questions about your overall experience of the individual therapy sessions. Sample questions include:

- *What is the most important thing you will take away from this therapy?*
- *How easy was it for you to participate in this therapy?*

STUDY VISIT 10 (Post-Treatment Follow-Up Assessment)

At this study visit, we will have you complete questionnaires that are similar to the ones you completed during Study Visit 1.

Possible discomforts or inconveniences with the research activities listed above:

You may feel uncomfortable when answering questions about emotional topics or symptoms. However, you are free to refuse to answer any of the questions in the questionnaires. Doing so will not affect your participation.

If you begin to feel suicidal or have other adverse reactions, please let us know. Dr. Michael is a psychologist who is well trained in managing emotional crises, should any arise. You can reach Dr.

Michael at (206) 277-4386. You can also contact the VA and ask for the on-call psychiatrist or call the Veterans Crisis Line at (800) 273-8255. In case of a life-threatening emergency, call 911.

4. What are some risks of joining this research study?

The procedures in this study may involve risks that are currently unknown. We may need to contact you if we learn of a new study risk, even if you have completed the study. You may be asked to sign an updated Consent Form to document that this new information has been explained to you.

- **Loss of confidentiality.** There is the risk that a breach of confidentiality could occur. However, every effort will be made to prevent this from happening. Your personal information will be kept secure and only accessed by authorized study staff as needed to conduct this study. Detailed information is outlined in Section 7 of this Consent Form.

- **Audio-recording.** Your name or any identifying information will not be included on the audio-recording. However, please note that your voiceprint is considered a "personal identifier" according to the patient privacy rules, so the research team will ensure the security of these recordings. The recording will either be made with a digital recorder or via the computer in the office. We will either erase the recording from the digital recorder or from the computer desktop after it has been transferred electronically to a secure VA server. Our methods of securing your privacy and confidentiality are described in Section 7. Both the individual therapy sessions and the Post-Treatment Assessment will be audio recorded, but only the Post-Treatment Assessment will be transcribed (copied word for word).

If any of the risks included in this Consent Form become significantly updated during this study, we will let you know.

5. What are some benefits of joining this research study?

It is possible that your participation in this study will not provide you with any direct benefits. While similar therapies have benefited patients by improving functioning and reducing PTSD symptoms, no one can know in advance if it will be helpful in your particular case.

By participating in the study, your study data will be a contribution to the research results that may potentially improve ways in which to improve the quality of life for Veterans with PTSD.

6. Are there other ways I could receive these benefits?

Possible alternatives to study participation include participating in outpatient individual and/or group therapy through the Primary Care Mental Health Integration Clinic, General Mental Health Clinic, or PTSD Outpatient Clinic at VA Puget Sound in Seattle. We also welcome you to seek care at Vet Centers in the community.

7. Who will see my information and where will it be stored?

Your research information will be kept confidential. However, some data will be shared, communicated, or stored during or after this research study.

If we learn you intend to harm yourself or others, we must report this information to appropriate authorities.

The following list of people or groups may know that you are in this study. They may have access to your research records, which may include your medical records:

- Research team members
- Other 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), the VA Office of the Inspector General (OIG), and the Government Accountability Office (GAO)
- The VA committees that oversee research
- The VA Puget Sound Fiscal Department and U.S. Department of the Treasury 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 access to your records, including your medical records, could be either for study-related purposes or to make sure your study record meets all legal, compliance, and administrative requirements. The reviewers will protect your privacy.

Medical Record

If you consent to join the study, we will review your medical record for documentation of prior PTSD treatment and record this treatment along with your questionnaires in your de-identified file.

We will also write progress notes in your medical record. The first progress note will simply state when you joined the study and the last progress note will state when your participation was complete. The progress note will also include the name of the study. We will not put any questionnaire results or additional study data into your medical records.

Two months after you have completed the study, we will consult your medical record to see if you have decided to pursue any additional therapy or if you have started taking medication for PTSD.

Study Code

Your privacy is important to us. We will not place your name on any research data. To make sure no one other than study personnel can match you to your data, we will use a unique study code instead of identifying information, such as your name or social security number, to code (label) your study data, including any self-report questionnaires and other data collection forms. We will keep a master list that links study participants' names to study codes separate from the study data in a secure VA database with restricted access.

Safekeeping / Storage

To protect the confidentiality of the information obtained about you during this research study, we take many preventative measures. Any paper study documents we have, received, or created will be secured in locked file cabinets accessible only to study staff. Any electronic study records will be kept in electronic folders on the secure VA network with access to the specific folders restricted to designated study staff.

A member of the research staff will listen to the recording and then transcribe it. The transcribed files will be stored along with all other study data on the secure VA network. Therefore, the transcriptions will be labeled with your study code and will not contain your name, social security number, or other identifying information. The audio-recorder will be stored in a locked cabinet when not in use and accessible only to authorized study staff. Alternatively, audio will be recorded directly to a password protected computer, transferred to a secure folder, and deleted from the computer desktop.

Current VA regulations require us to keep audio-recordings and transcripts for at least six years after the close of the study. All audio-recordings will be kept in their entirety in accordance with VHA policy on quality assurance of records. Requests for amendment to the recordings will be documented in a transcribed version of the recording.

After study completion

Once this study is completed, we will not use the study code linking you to your data for any additional research. We will store the code linking you to your data in a secure database or in a locked filing cabinet in accordance with the VA records retention policy (which will be a minimum of 6 years after the study has been completed). We will keep your coded data for at least six years after the close of the study.

In the future, researchers may write about the information collected from this research study. Any future publications or articles will not include any identifying information about you without your approval in writing.

We will use the information that we collect for this study only for research purposes, not for profit. However, researchers may use this research information in the future for the development of new ways to treat PTSD and substance use disorders. Neither you nor your family will gain financially from discoveries made using the information that you provide.

8. What are some other things to think about before I decide to join this research study?

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 $120 if you complete the entire 12-week study. You will receive payment for completing each of the four assessments as follows:

- $30 for Study Visit 1 (Screening & Pre-Treatment Assessment)
- $30 for Study Visit 6 (Mid-Treatment Assessment)
- $30 for Study Visit 9 (Post-Treatment Assessment)
- $30 for Study Visit 10 (Post-Treatment Follow-Up Assessment)

In order to receive payment, we will mail you a check within 8 weeks after each session.
To comply with Internal Revenue Service (IRS) guidelines, we will collect your social security number. You may receive an IRS Form 1099.

9. What will happen if I decide I don't want to be in this research study later?

You do not have to take part in this study. If you are in this study, you can withdraw at any time. If you decide not to participate or to withdraw, no action will be taken against you; for instance, you will not lose your VA benefits.

The study therapist has the right to terminate your participation in this study if he or she feels that it is not in your best interest to continue in the study. This termination will not require your consent.

You may be withdrawn from the study if your study therapist believes that your symptoms are getting worse due to your participation in the study.

If you decide to withdraw from the study, no new information will be collected from you, but data already collected will continue to be part of the analyses.

If you decide to withdraw, or if you are terminated from the study, a person from the study team may need to meet with you to discuss the steps that are necessary to end your participation in the study.

10. What will happen if I am hurt in this research study?

If you are injured as a result of participation in a VA-approved research study, the VA will provide you with the necessary medical treatment. You will not be charged for this treatment. Veterans who are injured because of being in this study may receive payment under Title 38, United States Code, Section 1151. Veterans or non-Veterans who are injured may receive payment under the Federal Tort Claims Act.

You do not waive any legal rights by signing this Consent Form.

11. What am I agreeing to by signing this form?

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 I may encounter in the study, of the possible benefits of the study, and of the other choices of treatment that are 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 copy of this Consent Form.

I agree to participate in this research study as described in this document.

_____ _____

Subject Signature Date

_____

Print Name of Subject

_____ _____

Signature of Person Obtaining Consent Date

_____

Print Name of Person Obtaining Consent