Project Title:	**An efficient, exposure-based treatment for PTSD compared to Prolonged Exposure: A non-inferiority randomized trial**	
Principal Investigator:	**Denise Sloan, Ph.D.**	**Version #: 2**

1. Overview of the Research Study:

We are asking you to be in a research study that is being supported by Department of Veterans Affairs. Before you decide to take part, you should know why the study is being done and what it will involve. This form tells you what to expect if you agree to be in the study. Taking part in this study is completely voluntary; it is your decision whether or not to participate in the study.

We are doing the research to see if a brief treatment for PTSD is equally effective as a more time intensive treatment. If you agree, you will be assigned to one of two treatments and complete several assessment sessions. You will be in the study for 8 months if you decide to stay for the whole study. We will describe your involvement in more detail later in this form.

You might choose to volunteer in the study because both treatments in the study are recommended for the treatment of PTSD. You will find more information about benefits later in this form.

You may choose not to volunteer to be in the study because you may experience increased anxiety or discomfort associated with the treatment and assessment sessions. You will find more information about these risks later in this form.

The treatments offered in this study, along with additional treatment options, are available through the VA. You will find more information about alternate treatment/procedures later in this form.

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

2. WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study funded by Department of Veterans Affairs. This study is designed to look at whether Written Exposure Therapy is as effective in treating posttraumatic stress disorder (PTSD) as a more time intensive Prolonged Exposure treatment. This study is taking place at three sites, VA Boston Healthcare System, Ralph H. Johnson VA Medical Center (Charleston, SC), and William S. Middleton Memorial Veterans Hospital (Madison, WI). We plan to enroll up to 180 male and female adults who have a diagnosis of PTSD.

You are being asked to participate in this study because you: (1) are a veteran; (2) experienced a traumatic event, (3) have a probable diagnosis of PTSD. This study involves individual treatment for PTSD. Two treatments are included in this study. These treatments are a Written Exposure Treatment and Prolonged Exposure Therapy. You will be randomly assigned (i.e., flip of the coin) to one of the two treatments.

3. HOW LONG WILL I BE IN THE STUDY? WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

This study will last for approximately 8 months and will be divided into three parts – initial assessment, treatment, and follow-up assessment. You will complete the initial assessment and then, if you are eligible, you will be asked to complete one of the two treatment conditions and additional assessments. The Written Exposure Therapy will consist of 5-7 weekly or twice weekly treatment sessions. The first session will require one hour of time and the remaining sessions will require approximately 40 minutes each session. The Prolonged Exposure therapy will consist of 8-15 weekly sessions that requires one and a half hour each session. The number of sessions completed will depend on response to the treatment. All participants, regardless of what treatment they are assigned to, will be asked to complete several assessment sessions. These assessments will take place 10-, 20-, and 30-weeks following your first treatment session. Thus, there are a total of 4 assessment sessions included in this study.

Initial Assessment

First, you will complete the initial assessment. This assessment will last approximately 3 hours and will help us assess whether you meet the eligibility criteria of the study. You will be interviewed by a clinician to assess the presence of certain psychological symptoms. You will also be asked to complete a series of surveys that ask you about your mood and aspects of your personality. Regardless of whether or not you are eligible to participate further, you will be compensated for your time with $50 paid in the form of a check mailed to your preferred address.

You will *not* be eligible to participate in the treatment component of the study as well as the follow-up assessments if you have: a current diagnosis of psychotic disorder, severe alcohol or substance use disorder, high risk for suicidality; or if you are currently participating in a psychosocial treatment (i.e., individual or group therapy led by a clinician) for PTSD. You will still be eligible to participate if you are currently participating in psychosocial treatment for a condition other than PTSD.

If you are not eligible to participate in the treatment portion of the study, you will be given appropriate clinical referrals.

Treatment

If you are eligible to participate in the remainder of the study, you will be asked to continue in the treatment phase of the study. You will be randomly assigned (i.e., flip of the coin) to one of the two intervention conditions, Written Exposure Therapy or Prolonged Exposure therapy. You will have the option of completing sessions either in person at VA Boston Healthcare System or remotely via a secure virtual platform (i.e., VA Video Connect, Doximity). Both treatments in the study are recommended interventions for PTSD. If you participate in the Written Exposure Therapy you will be asked to write about your traumatic experience at each treatment session. Prolonged Exposure therapy

involves repeatedly describing your trauma experience to the therapist during the sessions. In addition, Prolonged Exposure therapy will require you develop a list of situations you currently avoid because of the trauma experience, and to gradually confront these situations over the course of treatment. Lastly, Prolonged Exposure therapy will require you to complete assignments in between treatment sessions in order to master skills taught in the treatment.

Mid-treatment and Follow-up Assessments

All individuals who participate in the treatment will be asked to complete a number of assessments after starting treatment. These assessments will take place 10-, 20-, and 30-weeks after the first treatment session. These assessments will consist of fewer questions regarding current psychological symptom than the initial assessment, and will require no more than 2 hours of your time.

During each of the assessment sessions you may refuse to answer any question that you do not feel comfortable answering. At any time during any session you are free to withdraw from the study. You will not have to tell the staff your reasons for ending your participation.

During each assessment session you will be assessed for distress and suicidal risk. If you are experiencing daily thoughts of suicide for extended periods of time as well as experiencing detailed, intense, and intrusive suicidal thoughts and imagery, then you will be removed from the treatment component of the study. If such an event were to occur, a licensed psychologist would meet with you to discuss what you are experiencing and a plan of action will be developed that will be discussed with you. If you are experiencing high distress without any thoughts or threats of suicide, then a licensed psychologist will meet with you to determine whether or not you should be removed from the treatment component of the study. In the event that you are removed from the treatment component of the study, we will make the appropriate clinical referrals for you. We would still like you to participate in additional assessment sessions if you are willing.

4. WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

This study involves answering questions about your traumatic experience, as well as about your reactions to the traumatic event, which may be upsetting. If you participate in treatment you will also be asked to recall your trauma memory, which you may find upsetting. Regardless of the treatment condition, you may experience some disruption of daily activities due to scheduling of treatment sessions. Some participants may feel uncomfortable about the assessment sessions and treatment sessions being audio-recorded. However, this is required for adequate supervision of the clinicians. The treatment and assessment may involve risks that are currently unforeseeable. In addition to the risks listed above, you may experience a previously unknown risk or side effect. If you are or become

pregnant, the treatment or assessment might involve risks to the embryo or fetus, which are currently unforeseeable.

5. WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no known direct benefits to you for being in this study.

6. DO I HAVE TO TAKE PART IN THE STUDY?

Participation in the study is completely voluntary. Refusing to take part in the study or deciding to drop out of the study will involve no penalty or loss of benefits to which you are otherwise entitled. For veterans who are employees, refusing to take part in the study will in no way influence employment status.
You may also withdraw from the study and still receive the same standard of care that you would otherwise receive.
If you decide to withdraw from the study, data that has already been collected will continued to be reviewed but no further information will be collected.

7. WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

Other treatment to that described above may include other types of psychotherapy or psychopharmacology and will be under supervision of your doctor or caregiver. If you are eligible for the treatment portion of the study, you will be required to not participate in any additional clinician-led psychosocial treatments for PTSD during the course of the treatment portion of the study. If you do not meet the eligibility criteria for the study, if you decide to withdraw from the study, or if you require additional treatment after completion of the study, we will provide you with appropriate clinical referrals within and outside of the VA system.

8. RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

We may terminate your participation in the study. Termination would occur if you repeatedly don't attend treatment sessions and do not respond to contact attempts to reschedule sessions, or if you verbally or physically assault a member of the research team. We would also terminate your participation if you are hospitalized due to severe substance use or suicidality. In such instances, attending to these issues would take priority over the treatment study.
Termination from the study may adversely affect you in terms of not receiving treatment for PTSD. However, we will provide you with appropriate clinical referrals.

9. HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Information collected for the purpose of this research study will be kept confidential as required by law. The results of this study may be published for scientific purposes, but your records or identity will not be revealed unless required by law.

Information about you is protected in the following way: We will store your information in ways we think are secure. Procedures to maintain confidentiality of data and your privacy include: using a code rather than your name, keeping your name separate from your coded data, and reporting group, not individual, data. All information will be password protected and accessible only to research personnel with IRB approval to access the data. All digital audio recordings of assessment and treatment sessions will also only be coded with an identification number. After audio files are downloaded and store to a password protected VA server, digital recordings will be deleted from recorders. Digital recordings will continue to be stored on the password protected VA server that is accessible only to study staff with IRB approval to access the data.

Identifiers might be removed from the identifiable private information that are collected. After that removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

While this study is being conducted, you will have access to your research related health records. This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care.

For supervision purposes, we need to digitally audio-record all assessment and treatment sessions. Only study personnel will have access to the recordings. All recordings will be identified only by subject identification codes and stored in a password-protected folder and accessible only to research personnel with IRB approval to access the data. After audio files are downloaded and stored on a password protected VA server, digital recordings will be deleted from recorders. Digital recordings will continue to be stored on the password protected VA server that is accessible only to study staff with IRB approval to access the data. **As digital audio-recording is required for this study, if you refuse to be audio-recorded you will not be able to participate in this study.**

To help protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes or Health. With this Certificate, we cannot be forced, even by a court subpoena from any Federal, state, or local civil, criminal, administrative, legislative, or other proceeding, to disclose information that may identify you. We will use this Certificate to resist any demands for information that would identify you, except as explaiend below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for audting or evaluting Federally funded projects, or for information that must be disclosed to meet the requirements of the Federal Food and Drug Adminsitration (FDA).

You should understand that this Certificate does not prevent you from voluntarily releasing information about you or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the reserachers cannot use the Certificate to withhold that information.

The Certificate does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a reserch participant under the following circumstances: in the event that you report engaging in behavior that constitutes child or elder abuse as defined by the Commonwealth of Massachusetts; or if you are deemed at immediate risk of suicide; or if you are deemed to be at risk of doing bodily harm to a specifically identifiable individual.

Your research records will be kept indefinitely or until the law allows their destruction per the VA Record Control Schedule (www1.va.gov/VHAPUBLICATIONS/RCS10/rcs10-1.pdf). Records will be destroyed, when allowed, in the following manner.

- Paper records will be shredded
- Electronic records will be destroyed in a manner in which they cannot be retrieved.
- Digital images (e.g., audio recordings) will be destroyed in a manner such that they cannot be retrieved.

Your research records and the information within them will not be used for any purpose other than that described in this study as approved by the IRB.

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history, drug treatment, alcohol treatment, and mental health treatment.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the Centralized Data Monitoring Committee; Institutional Review Board, Research & Development Committee, Research Compliance Officers, Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO).

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Denise M. Sloan, Ph.D., and her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

To comply with laws and regulations, we may need to share safety-related information such as that relating to child abuse or neglect; elder or disabled person abuse; specific reportable diseases; harm to self or others.

An unsigned copy of this consent form will be posted on clinicaltrials.gov or Regulations.gov after all study participants have completed the study.

10. WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

You will be told of any significant new findings that come to light during the course of this study and that may relate to your wanting to stay in the study.

11. WHAT ARE THE COST TO ME IF I TAKE PART IN THIS STUDY?

A participant will not be required to pay for medical care and services received as a participant in an approved VA research study. Some participants are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services (including, but not limited to, dental services, supplies, medicines, orthopedic and prosthetic appliances, and domiciliary or nursing home care) provided by the VA that are not part of this research study.

You will be compensated $50 for each assessment session and $10 for each treatment session for your time and effort taking part in this study. Payment is made at each assessment and treatment session that is completed. Payment is only made for sessions that are completed.

You consent to the release of personally identifying information about you including your name, address, and social security number to the VA so that we may provide compensation to you. You can expect to receive a check within 2-6 weeks. The government may garnish the compensation against outstanding debts a veteran has to the federal government.

You consent to the release of personally identifying information about you including your name, address, and the last 4 of your social security number to the Fiscal Office of the VA Boston Healthcare System so that we may provide compensation to you.

If payment is made to you by the VA (whether by check or cash voucher), an IRS Form 1099 will be generated regardless of the amount you are paid.

12. WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

In the event that you are injured as a result of your being in this research study, you will receive medical care, including emergency treatment. This care or treatment is governed by federal law and VA policy. You would also have the right to file any legal action, as in any instance of alleged negligence.

14. WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

I understand that if I have any medical questions about this research study, I can call **Dr. Denise Sloan** *(857)* [redacted] during normal working hours.

I understand that if I have any general questions about this research study, I can call **Dr. Denise Sloan at** *(857)* [redacted] during normal working hours.

I understand that if I have any medical problems that might be related to this study that **during the day** I can call **Dr. Denise Sloan at *(857)*** [redacted] and **after hours** I can call the VA Medical Center operator at ***(617)*** [redacted] and ask for the fellow on-call for psychiatry.

I understand that, if at any point during or after this study I have any questions about my rights as a research participant or I want to discuss problems, complaints, concerns, and questions about the research, obtain information, or offer input, I may contact the Research Compliance Officer at (857[redacted].

15. AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

I have read or have had read to me all of the above. Study staff have explained the study to me and answered all of my questions. I have been told of the discomforts and risks of the study. I have been told of other choices of treatment that I could have.

I understand that my participation in this study is voluntary, that I do not have to take part in this study and that, if I do take part, I may withdraw from the study at any time. I also understand that, if I refuse to take part or if I decide to withdraw, I will not suffer any penalty, loss of rights, or loss of VA or other benefits that I have a right to receive.

I voluntarily consent to be in this study. I will receive a signed copy of this consent form.

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Participant's Signature **Month Day Year** **Name (print)**