Concise Summary of Important Information

This information gives you an overview of the research. More information about these topics may be found in the pages that follow. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with us or the military.

1. What problem is this study trying to solve?

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future. The goal of this research study is to determine if Written Exposure Therapy for Suicide (WET-S) is an effective treatment for suicide thoughts and behaviors and posttraumatic stress symptoms for people receiving treatment as an inpatient. For more information, please see the ***Why is this Study being Done*** section below.

2. What will happen to me during the study and how is this different from continuing with usual care? What are all my options for treatment, including the pros and cons?

If you consent to participate in this study, you will speak with an interviewer about your suicidal thoughts and behaviors and experiences with traumatic events and fill out questionnaires related to these experiences and any related difficulties. If you are eligible for the study, all participants will receive the usual care offered at the hospital. Half of the participants will be randomly assigned to receive additional treatment with Written Exposure Therapy for Suicide (WET-S). This additional treatment consists of five hour-long sessions occurring 1-2 times a day where you write about your feelings related to some of your life experiences and then meet with your study therapist. After treatment is complete you will be assessed again at your last treatment session, as well as at 1- and 4-months after treatment to see how you are doing. Participants who receive Written Exposure Therapy for Suicide (WET-S) will receive it in addition to usual care. Participants who do not receive WET-S will receive usual care only. You do not have to participate in this study and, if you decide not to participate, you will still receive usual care. For more information, please see the ***What will be done if you decide to be in the research*** section below.

3. How much time will I spend on the study?

You will be asked to meet 5-11 times with research staff depending upon which group you are assigned. Typically, WET-S is delivered in 5 sessions. The first screening assessment to determine if you qualify to participate will take about 3 hours. The assessment at your post-treatment session will take about 15 minutes. The 2 follow up meetings for assessments will each take about 3 hours for a total of 9 hours and 15 minutes. If you are assigned to receive the Written Exposure Therapy for Suicide (WET-S) in addition to Usual Care, the WET-S treatment meetings will each take about 1 hour, with the exception of the first treatment meeting which could last approximately 90 minutes, for a total of approximately 5 hours. Your participation in this study will last 4-5 months.

4. Could taking part in the study help me and are there risks?

Participating in this research could help you feel better. However, there can also be risks to taking part in this research study. Everyone taking part in the study will be watched carefully for any side effects, but the study staff do not know all the possible side effects that may happen. Be sure to tell your study therapists immediately, about any side effect that you have while taking part in the study. For more information, please see ***How could you or others benefit from your taking part in this study*** section below. For details and a list of risks you should know about, please see the ***What are the risks of participation in the research*** section below.

5. What else should I consider before I make my decision?

This research is supported by the Department of Defense and is part of an effort to improve care for service members who feel suicidal. Study assessments and treatments will be conducted by staff specially trained and experienced working with military service members and their families.

Title of Study: Decreasing Suicide Risk among Service Members with Posttraumatic Stress Using Written Exposure Therapy

Please review the rest of this document for additional details about these topics and other information you should know before making a decision about participating in this research.

Consent to be part of a Research Study
To be conducted at Carl R. Darnall Army Medical Center

Information about this Form

You may be eligible to take part in a research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

General Information – "Who is conducting this research?"

Principal Investigator
The Principal Investigator (PI) is the researcher directing this study. The PI is responsible for protecting your rights, safety, and welfare as a participant in the research. The PI for this study at the University of Texas Health Science Center at San Antonio (UTHSCSA) is Alan Peterson, Ph.D., ABPP, Department of Psychiatry, Division of Behavioral Medicine. The Overall PI for this study is Brian Marx, PhD, a psychologist who works at the National Center for PTSD at the VA Boston and at the Boston University School of Medicine.

Site Investigator
The Site Investigator works at the Carl R. Darnall Army Medical Center (CRDAMC) and is responsible for activities for this study at Fort Hood. The Site Investigator for this study is Brooke Fina, LCSW, who works for the University of Texas Health Science Center at San Antonio Division of Behavioral Medicine at Fort Hood.

Funding
The Department of Defense awarded research funding to the Military Suicide Research Consortium headquartered at the Florida State University (https://msrc.fsu.edu/about-msrc) which in turn funded this project to be done at CRDAMC.

Purpose of this study – "Why is this study being done?"

You are asked to participate in this research study to test a new treatment for suicidal thoughts or behaviors as well as posttraumatic stress symptoms (PTSS) in active duty service members, veterans, and DEERS eligible beneficiaries. Currently, there are no treatments for suicidality that treat posttraumatic stress symptoms at the same time. The study investigators have adapted an effective, short treatment for PTSS to also address feelings and behaviors of suicidality. This adapted treatment, called Written Exposure Therapy for Suicidality or WET-S, is designed to be delivered in one-hour sessions during hospitalization. The purpose of this study is to see whether WET-S is as effective in reducing suicidal feelings and posttraumatic stress symptoms as the usual treatment given to service members and veterans hospitalized at CRDAMC for suicidality and PTSS. One to two sessions per day of WET-S will be done. Typically, five sessions of WET-S are given, but for this

study you may receive up to two additional sessions to be sure you understand how the treatment works and receive a full course of treatment.

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.

Information about Study Participants – "Who is participating in this research?"

You are being asked to be a participant in this study because you are an active duty service member, or veteran, or DEERS eligible beneficiary receiving treatment for suicidality on the CRDAMC inpatient psychiatric unit and also experiencing symptoms of posttraumatic stress.

How many people are expected to take part in this study? This study will consent up to 140 individuals.

Information about Study Procedures – "What will be done if you decide to be in the research?"

Screening: After you sign this consent, assessments will be done to find out if you qualify for the study and can be treated as part of this study; this is called screening. The assessment will include filling out questionnaires on-line and talking with a study interviewer through telehealth. The interviewer will ask you to share your suicidal thoughts and behaviors, past deployment and life experiences, and current symptoms of posttraumatic stress to determine if you are eligible for the study. The research assessment procedures will take about 3 hours.

Our preference for your and our safety during the COVID-19 pandemic is for you to do the assessments on-line and the interview using a secure telehealth platform. But if we, or you, have difficulty connecting to the internet, we will have you complete the assessments on paper taking appropriate physical distancing precautions.

If it would not be appropriate for you to continue in the study or if you choose not to enroll, the researcher will discuss the reasons with you and you will continue to receive care on the hospital unit outside of this study.

Assignment to Study Groups: Everyone will receive Usual Care on the CRDAMC inpatient psychiatry unit. If it is determined that you are eligible for the study, you will be assigned by chance (like flipping a coin) to either receive Usual Care alone or Usual Care plus Written Exposure Therapy for Suicide (WET-S).

Study Procedures: As a participant, you will undergo the following procedures:

- **Everyone will receive Usual Care at CRDAMC** in person, which includes: medications, psychoeducation groups, nurse case management, and discharge planning.
- If you are assigned to also receive **Written Exposure Therapy for Suicide or WET-S,** you will develop a crisis response plan to use if you feel suicidal in the future with your study therapist and practice using this plan as well as attend 5 one-hour treatment sessions where you will write about your thoughts and feelings related to specific life experiences guided by your study therapist. Treatment sessions will be scheduled while you are in inpatient care. This means that you may have 1-2 treatment sessions each day depending on how long you are hospitalized. While typically, five sessions of WET-S are given, you may receive two additional sessions to be sure you understand how the treatment works and receive a full course of treatment. If we cannot complete the 5 WET-S sessions while you are hospitalized, we will expect you to complete the remaining treatment sessions as an outpatient using your own computer.
- Regardless of which group you are in, the research team will communicate with your medical team to coordinate your care.

Assessments: After treatment is complete you will be assessed on the last day of treatment and again at 1- and 4-months later to see how you are doing. The assessment on the last day of treatment will only take about

15 minutes, but the 1- and 4-month assessments will take about 3 hours. Even if you choose to stop treatment, we ask that you complete the follow-up assessments. This will help us understand how the treatment works or doesn't work for different types of people. Your participation in all parts of the study is very important.

Because of the physical distancing recommendations in place with the COVID-19 pandemic, assessment and treatment sessions will occur using a computer or tablet talking over a secure line in real-time with the research staff using a computer in his or her office. However, paper assessments may be used in the event of technical difficulties. The video telehealth platform used for these communications is HIPAA-compliant. While you are in care at the CRDAMC inpatient unit the computer or tablet will be supplied for you to use for study procedures only. For sessions or assessments that occur after you are discharged from inpatient care, you will need access to a computer with high speed internet access to support the telehealth platform. The computer must be equipped with speakers or a standard headphone jack to be able to hear and speak with the research staff. You will also need to have access to a private location with the ability to control access during assessment and treatment sessions to ensure your privacy and confidentiality. If you don't have access to a computer in a private location, you can come to the STRONG STAR offices located at the Shoemaker Center on Fort Hood and use a computer in one of our offices.

Recordings: All assessment interviews and WET-S treatment sessions speaking with your therapist will be recorded to make sure that the study staff members are correctly following study procedures. These recordings will be reviewed by research experts who are a part of the research team.

Time Commitment:
You will be asked to meet 5-11 times with research staff depending upon which group you are assigned. The first screening assessment to determine if you qualify to participate will take about 3 hours. The assessment at your post-treatment session will take about 15 minutes. The 2 follow up meetings for assessments will each take about 3 hours for a total of 9 hours and 15 minutes. If you are assigned to receive the Written Exposure Therapy for Suicide (WET-S) in addition to Usual Care, the WET-S treatment meetings will each take about 1 hour for a total of 5-7 hours. Your participation in this study will last 4-5 months.

Ending Participation Early. Could your participation end early? There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:

- The researchers believe that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is stopped.

The researchers will discuss your options for medical care if your participation in this study ends.

We will tell you about any significant new findings which develop during this research which may relate to your willingness to continue taking part.

Risks – "What are the risks of participation in the research?"

Risks from the Research. There are risks to taking part in this research study. Everyone taking part in the study will be watched carefully for any side effects. However, the study staff do not know all the possible side effects that may happen. Be sure to tell your study therapists immediately about any side effect that you have while taking part in the study.

Likely, but Not serious (expected to occur in more than 20 out of 100 participants):

- Emotional distress or an initial increase of posttraumatic stress symptoms due to writing about specific life experiences as part of both the assessments for all study participants and the Written Exposure Treatment for Suicide (WET-S) if assigned to this treatment condition.

Rare and Serious

- It is possible that technical difficulties will result in missing a scheduled treatment session. The research team will work closely with you to solve technical problems to minimize missed treatment time and also to re-schedule and conduct missed treatment sessions due to technical difficulties as soon as possible
- Unintentional disclosure of private information or breach of confidentiality by the research team.
- For assessment or therapy sessions conducted via video telehealth, there are risks to confidentiality if others nearby can hear what is being said during the encounter. While you are an inpatient, the staff will work with you to find a quiet location to participate in the study. Once you are discharged, to minimize the risk of breach of confidentiality, you are encouraged to use headphones and to find a quiet location to hold the encounter
- Also, although the information provided during the video telehealth sessions is transmitted securely, there is always a risk that others (not affiliated with this research) could access the information. It is important to have virus protection on your computer to minimize this risk. The inpatient computers have virus protection. If you don't have virus protection on your home computer, there are free products available. We will talk with you about the virus protection you have on your computer and can work with you to be sure protection is installed and turned on
- Due to the use of online conferencing systems, your privacy and confidentiality is not guaranteed.

Risks whether you participate in this research or not:

- Participating in usual mental health treatment can increase some symptoms and increase the risk of feeling emotionally uncomfortable in the short term.
- Individuals with suicidal thoughts and behaviors as well as with posttraumatic stress symptoms may attempt suicide. This is a risk to you whether you are receiving mental health treatment or not. Therefore, the risk of suicide to you is not any higher being in the study than it would be if you were not in the study. Your treatment may require you to talk about some things that might be painful or uncomfortable for you, which can cause increased emotional distress and the possibility of wanting to kill yourself, which can result in death.

If at any time you are feeling significant distress or if you are having thoughts of hurting yourself or someone else while you are hospitalized, please notify a member of the CRDAMC staff as soon as possible. After you are discharged from the hospital, if you have these feelings please contact a member of the research team right away. We may discuss or develop a Crisis Response Plan with you and/or refer you to local resources. You can also be seen in the Urgent Care and Triage Center during duty hours and in the Fort Hood Emergency Room after 1630 and on weekends and holidays at any time.

For more information about risks and side effects, ask one of the researchers or study staff.

Are there Risks related to withdrawing from the study? If you decide to withdraw from this study early, please discuss your decision with the research team. If you decide to withdraw, we will ask you if you to participate in a brief assessment with a study clinician, either in-person or by phone to assess your condition and make appropriate referrals if necessary. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

What if a research-related injury occurs? The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please

immediately contact your study therapist. See the section "Contact Information" below for phone numbers and additional information. You should also tell your regular doctors.

In the event of injury resulting from this study, the extent of medical care provided is limited and will be within the scope authorized for Department of Defense (DoD) health care beneficiaries. If you sign this form, your authority as a service member to seek compensation based on a service-connected injury is not changed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"

A possible benefit of your participation in this study is the lessening of your suicidal thoughts and behaviors and a reduction of your posttraumatic stress symptoms, which may positively affect your overall health and feelings of well-being. There is no guarantee you will receive any benefit from taking part in this study. We hope that information gained from this study will improve treatment for military service members and others with suicidal thoughts and behaviors and posttraumatic stress, even if you do not experience any improvements yourself.

Alternative procedures or course of treatment – "What other options are there to participation in this study?"

There are other options available to you. Your other choices may include:

- Getting treatment as usual without being in this study.
- Seeking alternate forms of treatment.

Payments – "Will there be any payments for participation?"

You will not receive any payments for your participation in this study.

Costs – "Will taking part in this study cost anything?"

There are no costs to you for taking part in this study.

Confidentiality – "How will your records be kept confidential?"

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, the findings will be presented as grouped data and you will not be individually identified. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study. Representatives of the Department of Defense will have access to all research records as a function of providing funding for the protocol.

Limits of Confidentiality. Even without your consent, suspected or known abuse or neglect of a child, the disabled, or elderly, threatened violence to self or others, or other local health reporting requirements will be reported to appropriate authorities by law.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study.

Protected Health Information (PHI) – "What is Protected Health Information (PHI)?"

Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use

about you will include: your name, social security number, medical identification number, dates of birth and care, phone number, email address, home address, and audio-recordings of treatment sessions (if you are assigned to the WET-S condition). We need this information to make study appointments, document your care and progress in your medical record, and contact you if we do not hear from you when we are expecting to.

We will get this information by asking you and by looking at your military medical records if needed.

How will your PHI be shared? Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- The members of the research team at the National Center for PTSD at the Boston VA and the University of Texas Health Science Center at San Antonio.
- The Institutional Review Board and the Compliance Office of the University of Texas Health Science Center at San Antonio, and other groups that oversee how research studies are carried out.
- The Research Offices at the University of Texas Health Science Center at San Antonio.
- Researchers working at Florida State University (FSU) who are maintaining the data collected for the Military Suicide Research Consortium under a protocol they have approved by their Institutional Review Board number FSU HSC#2018.23936. Sending a limited set of the data we collect from study participants, including you, is a requirement of receiving the funding to conduct this study. This data will include the dates we collected data from you but will not include any identifiers such as your name or social security number that could link you to your data.
- Representatives of the Department of Defense who have access to all research records as a function of providing funding for the protocol.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. The researchers and those listed above agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and federal law. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. You need to be aware that some parties receiving your protected health information may not have the same obligations to protect your protected health information and may re-disclose your protected health information to parties not named here. If your protected health information is re-disclosed, it may no longer be protected by state or federal privacy laws.

How will your PHI be protected? To protect your PHI and privacy, the study staff will use code numbers, instead of your name, to identify your research information. This code number will be used on any photocopies of your study records, and other study materials containing health information that is sent outside of the CRDAMC and the University of Texas Health Science Center at San Antonio for review. However, if we publish the results of the study in a scientific journal or book, the findings will be presented as grouped data and you will not be individually identified.

Do you have to allow the use of your health information? You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties, but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to:

Dr. Alan Peterson
University of Texas Health Science Center at San Antonio
Department of Psychiatry – Mail Code 7747
7550 IH10 West, Suite 1325, San Antonio, TX 78229-5820

If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study? The federal regulations say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

How long will your PHI be used? By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends, and all required study monitoring is over.

Long-Term Study Data Storage. We will be asking your permission to store your questionnaire answers and interview data linked to your personal health identifiers after this study is completed in the STRONG STAR Repository to be used for other research investigating the causes, consequences, and treatment of suicidality, posttraumatic stress, and related conditions. Your consent to allow us to store your information, or request not to keep your information, will be given in a separate consent document. Your participation in the current study does not depend on your decision to participate or not in the Repository. Please note however that if you decide not to participate in the Repository, the researchers intend to keep and use the information collected as part of this study, but your personal identifiers (such as your name, social security number, and contact information) will be permanently destroyed so that it can never be linked to you again.

Contact Information – "Who can you contact if you have questions, concerns, comments or complaints?"

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints in the future or you wish to report a problem which may be related to this study please contact:

- Site Investigator at CRDAMC: Brooke Fina, LCSW, phone 254-288-1638 at Fort Hood, TX
- Principal Investigator at UTHSCSA: Dr. Alan Peterson, phone (210) 562-6700 in San Antonio, TX
- Overall Study Principal Investigator: Brian Marx, PhD, phone (857) 364-6071 at the VA Boston Healthcare Organization

The University of Texas Health Science Center committee that reviews research on human subjects (Institutional Review Board) can answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the IRB by calling (210) 567-8250, or by mail to IRB, UTHSCSA, Mail Code 7830, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900.

Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research, please sign this section. You will be given a signed copy of this form to keep. You may request a copy of your signed consent form at any time until study is ended. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE

- You have read the above information.
- Your questions have been answered to your satisfaction about the research and about the collection, use, and sharing of your protected health information.

Adult Signature Section

- You have voluntarily decided to take part in this research study.
- You authorize the collection, use, and sharing of your protected health information as described in this form.

Printed Name of Subject	Signature of Subject	Date	Time AM PM

Printed Name of Person Obtaining Consent and Authorization	Signature of Person Obtaining Consent and Authorization	Date	Time AM PM

☐Consent and authorization was obtained from this individual who is unable to read and/or write but can otherwise communicate and/or comprehend English. The method used for communication with the subject was: _____.
The specific means by which the subject communicated agreement to participate was:
_____