Subject's Name: **Date:**

Principal Investigator: Lisa McTeague, Ph.D

Study Title: Telehealth-delivered Massed Imaginal Exposure for PTSD: Toward Increasing Access to Alternative, Evidence-based Treatment Schedules for Virtual Care

Introduction. The purpose of this form is to provide you information that may affect your decision as to whether or not to participate in this research study. The person performing the research will answer any of your questions. Read the information below and ask any questions you might have before deciding whether or not to take part. If you decide to be involved in this study, this form will be used to record your consent.

SUMMARY

The purpose of this study is to investigate a brief daily 1-week treatment called Imaginal Exposure therapy – a main component of Prolonged Exposure therapy (PE), which has been demonstrated to be an effective treatment for post-traumatic stress disorder, or PTSD. This treatment involves repeatedly approaching your trauma memory in imagination, in order to produce a reduction in PTSD symptoms. All visits for this study will be conducted virtually using a VA-approved telehealth platform. Telehealth visits are visits that are conducted through the internet, rather than a face-to-face visit. All participants in this study will receive 6-daily treatment sessions, and will also complete clinical interviews, self-report questionnaires, and video-based measures of emotional and physical reactions, such as heart rate and breathing rate. The main goals are to determine the safety, acceptability, and effectiveness of delivering this therapy through telehealth and to provide an alternative treatment schedule for potentially more rapid reductions in PTSD symptoms and personalized care.

If you agree to participate, you will undergo an initial research visit to assess your trauma-related symptoms that takes about 2 ½ hours. If you qualify based on this initial visit, you will be invited to begin the treatment phase of the study. You will receive six, 60-minute daily sessions of imaginal exposure within a 10-day period. The initial research assessments completed before treatment will be repeated again at 1-week and 1-month following your last treatment session. These two visits will take about 1 ½ hours each.

You may experience emotional distress when recalling personal experiences during some of the assessments and interviews. Your response to treatment will be monitored by your clinical care team throughout the study. If you do not show a significant response to treatment, you will be offered additional sessions with your provider. If additional sessions are needed, this would not be part of the research, but rather would be part of your usual or routine treatment. You do not have to participate in this study to receive treatment, and there are effective alternatives. It is unknown whether imaginal exposure therapy is effective when delivered by telehealth, rather than in-person. You may benefit from participating in terms of a reduction in trauma-related symptoms, although this cannot be guaranteed. Other effective alternatives can be offered to you by your therapist or another provider. Effective alternatives to include Cognitive Processing Therapy, or CPT, which is a very similar and effective treatment relative to imaginal exposure and Prolonged Exposure therapy, but has a stronger focus on changing problematic beliefs associated with past traumatic experiences.

Subject's Name: **Date:**

Principal Investigator: Lisa McTeague, Ph.D

Study Title: Telehealth-delivered Massed Imaginal Exposure for PTSD: Toward Increasing Access to Alternative, Evidence-based Treatment Schedules for Virtual Care

A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. As your study mental health care providers 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 appear to be experiencing significant trauma-related PTSD symptoms. The investigator in charge of this study at the Ralph H. Johnson VA Medical Center is Dr. Lisa McTeague. The study is sponsored by a grant from the Charleston Health Equity and Rural Outreach Innovation Center (HEROIC) by supporting study staff, and to cover study-related costs, including compensation for completing each of three outcome assessments. The study is being done at the Ralph H. Johnson VA Medical Center with the PTSD Clinical Team. Approximately 25 volunteers will take part in this study.

B. PROCEDURES

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

1. You will need to complete an initial research visit using a VA-approved videoconferencing platform to find out whether you can be in this study. This visit will take about 2 ½ hours, and will involve a clinical interview, completing questionnaires about your medical and mental health, PTSD and other trauma-related symptoms, and a physical assessment in which we will measure your emotional and bodily reactions to your trauma-related symptoms. Throughout your participation, you will be asked to answer questions about your trauma-related symptoms and reactions. For the physical assessment, we will use a specialized computer program to measure your heart rate, respiration rate, and emotional expressions from video recordings of the standard trauma interview. These assessments will be repeated at your pre-treatment visit, and at 1-week and 1-month following treatment completion. These procedures may produce temporary emotional and physical distress.
2. If you qualify based on this initial assessment, you will be invited to the treatment phase of the study. In this phase, you will receive six, 60-minute therapy sessions, delivered via a VA-approved video-conferencing platform. These visits must be completed within 10 days of starting the first treatment session. Before the start of each visit, you will complete self-report outcome assessments to assess changes in trauma-related symptoms. Additionally, your treatment provider will check-in with you briefly (~5-10 min.) in the evening following each treatment visit using a secure VA-approved telehealth or secure messaging platform to offer you additional support as you progress through the treatment phase. A secure messaging platform is a internet based method of contacting your provider that helps ensure confidentiality and privacy of your communications.

3. Once you complete treatment, which will take up to 10 days, you will be asked to attend two additional virtual visits 1-week and 1-month after treatment to assess the same clinical, physical, and self-report assessments that you completed at your initial pre-treatment visit. These visits will take about 1 ½ hours each to complete.
4. You are free to choose to take part in this study and can decide to stop participating at any time without interfering with your usual care or any benefits or services for which you are usually entitled. The researchers may also decide to withdrawal you from the study if there is a good reason to do so based on how you respond to the therapy, or if it is otherwise in your best interests.

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.

C. DURATION

Participation in the study will take about 9 visits over a period of two months. The first study visit is the longest, lasting about 2 ½ hours. The next six treatment visits will take about 60 minutes each, which will be scheduled within one week from the initial visit and completed within 10-days of the first treatment visit. The final two visits should take place 1-week and 1-month after the last treatment visit and will take about 1 ½ hours each.

D. RISKS AND DISCOMFORTS

Confronting your trauma memory and answering questions about your symptoms might cause temporary discomfort. However, there is a lot of evidence that approaching and talking about a past distressing trauma is helpful for overcoming PTSD symptoms. In fact, this is the main reason why imaginal exposure therapy is believed to help –practicing repeatedly confronting your trauma memory, and related thoughts, feelings, and situations should be expected to reduce your emotional and physical reactivity with time, and help you think about your trauma and its impact in new ways. Most individuals with PTSD experience symptom relief from receiving similar exposure-based treatments, such as Prolonged Exposure therapy, but this cannot be guaranteed. If you do not respond to treatment, you will be offered additional treatment sessions, or another evidence-based treatment, such as Cognitive Processing Therapy, or CPT.

Your privacy and the confidentiality of the data obtained during your participation in the study will be protected, but there is a risk of a loss of confidentiality of your personal information as a result of

participation in this study. This risk is not any greater than the level of risk associated with usual care from your medical and mental health care providers, and several procedures will be in place to protect the privacy of your research records.

As required by the VA, a note indicating your participation in this study will be included in your VA medical records for each study visit. Steps for protecting your privacy and the confidentiality of your research data records include the following. First, you will be assigned an ID number that will be included with your research data records. A separate data file will be used to link your ID number to your identifying information. Information that could identify you, such as your name, social security number, phone number, and driver's license, will not appear in your data records, including any responses to questionnaires or other recordings of your physical and emotional reactions over the course of your participation. Second, all of your research data records will be kept on protected Ralph H. Johnson VA Medical Center network storage. Third, once all data are collected, any link between your identifying information and your data will be destroyed.

Are there any exceptions to my information remaining confidential and private?
Yes. During the course of your participation, if you express to research staff that you have been having thoughts of wanting to harm yourself or others, or if you inform the research staff about possible abuse or neglect of a child, elderly, or disabled person, your information may be disclosed to appropriate authorities for the purpose of keeping you and others safe, or to stop ongoing abuse or neglect.

What other risks are possible?
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

As required by the VA, a note indicating your participation in this study will be included in your VA medical records for each study visit.

Subject's Name: **Date:**

Principal Investigator: Lisa McTeague, Ph.D

Study Title: Telehealth-delivered Massed Imaginal Exposure for PTSD: Toward Increasing Access to Alternative, Evidence-based Treatment Schedules for Virtual Care

F. BENEFITS

The main potential benefit of participating in this study is that you may experience relief from trauma-related symptoms over the course of treatment, although this cannot be guaranteed. The study may also provide evidence that imaginal exposure therapy can be effective and safely administered virtually, and thus may provide a benefit to future patients. In addition, it may provide support for developing alternative treatment schedules to allow flexibility and accommodate individual preferences. You may also learn more about your condition, effective ways to cope with trauma-related symptoms, and other effective treatment options.

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. In addition, routine medical care for your condition (care you would have received whether or not you were in this study) may be charged to you or your insurance company. You may wish to contact your insurance company to discuss this further. It is possible that your insurance company will refuse to pay for the costs associated with study participation, in which case you will be held financially responsible. Please ask the main researcher, Dr. Lisa McTeague, if you have questions about which study procedures may be associated with costs to you, and which will be provided at no cost.

H. PAYMENT TO PARTICIPANTS

In return for your time, effort, and travel expenses, you will be paid up to $100.00 for completion of the three assessment visits, including the 2 ½ -hour pre-treatment assessment and both the 1 ½ hour 1-week post-treatment and the 1-month follow-up assessments. If you complete only a portion of the study assessment visits, then you will be paid according to the visits you completed.

Payment will be made for completing each of the three assessment visits, according to the schedule outlined below:

Participant Compensation Schedule

Completed Visit:	Amount to be Paid:
Pre-treatment Assessment Visit	$25.00
1-Week Post-treatment Assessment Visit	$25.00
1-Month Follow-up Assessment Visit	$50.00
All Study Visits (3) Completed (Total):	**$100.00**

Subject's Name: **Date:**

Principal Investigator: Lisa McTeague, Ph.D

Study Title: Telehealth-delivered Massed Imaginal Exposure for PTSD: Toward Increasing Access to Alternative, Evidence-based Treatment Schedules for Virtual Care

Note that 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 that have been determined to be effective for treatment PTSD. If you decide not to receive imaginal exposure therapy, then you can still receive Prolonged Exposure therapy as part of your usual care. You can also speak to your provider about other treatment options. As stated earlier, another effective therapy option for PTSD is called Cognitive Processing Therapy, or CPT, which your therapist may be able to provide.

J. DATA SHARING

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

If you would like to be informed about the results of this study upon completion, you can contact the principal investigator, Dr. Lisa McTeague, by phone (843) 792-8274.

L. SIGNIFICANT NEW FINDINGS

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

M. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

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.

Subject's Name: **Date:**

Principal Investigator: Lisa McTeague, Ph.D

Study Title: Telehealth-delivered Massed Imaginal Exposure for PTSD: Toward Increasing Access to Alternative, Evidence-based Treatment Schedules for Virtual Care

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.

P. PERMISSION TO RECORD SESSIONS AND FUTURE CONTACT

As implemented in our ongoing VA study (PI: Wangelin), we would like to audio and video record assessment and therapy sessions to ensure quality and adherence to our protocol and treatment manual. In addition, these video and audio streams will be used to capture how the physical and emotional reactions change over time as a result of the exposure therapy. Recording is not required for participation, but is very useful to us. 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 that you could be identified, including information regarding alcohol and drug use, or other criminal behavior.

To minimize any risk, all recordings will be kept in a locked file cabinet or on a secure and encrypted server. Only the project staff and supervisors will have access to the recordings. The recordings will also be destroyed after the study has been completed. Please initial by your choice below:

____ Yes, I permit audio or visual recording of my assessment and therapy sessions.

____ No, I do not give permission to have any of my study visits audio or video recorded.

The researcher in charge of this study might also like to contact you in the future about other research opportunities. Please initial by your choice below:

____ Yes, I agree to be contacted. ____ No, I do not agree to be contacted.

Q. 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.

Subject's Name: **Date:**

Principal Investigator: Lisa McTeague, Ph.D

Study Title: Telehealth-delivered Massed Imaginal Exposure for PTSD: Toward Increasing Access to Alternative, Evidence-based Treatment Schedules for Virtual Care

R. VOLUNTEER STATEMENT

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: **Dr. Lisa McTeague at 843-577-5011, extension 205309.**

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.

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