An electrophysiological predictor of SSRI response in Veterans with PTSD (MHBB-028-17F)

NCT ID number: NCT04183205

ICF Document date: 6/26/2024

Participant Name:Click or tap here to enter text. Date:Click or tap to enter a date.

Title of Study: An Electrophysiological Predictor of SSRI Response in Veterans with PTSD

Principal Investigator: Suzanne Pineles, Ph.D. VA Facility: VA Boston

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the Veterans Affairs Clinical Sciences Research and Development Service. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn if a brief screening method can predict which people are most likely to show a positive response to selective serotonin reuptake inhibitor (SSRI) medications. This brief screening method involves using electrodes attached to your scalp to measure electrical brain activity in response to a series of loud tones. Your participation in this research will last about 17-21 weeks if you decide to stay for the whole study.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You might choose to volunteer in the study because you are interested in trying an SSRI as a treatment for PTSD. For a complete description of benefits, refer to the Detailed Information section of this informed consent form.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may choose not to volunteer to be in the study because of the potential side effects of sertraline, the SSRI that will be prescribed in this study. For a complete description of risks, refer to the Detailed Information section of this form.

Other treatment options available for treatment of PTSD can be psychological or pharmacological or both. For a complete description of alternate treatment/procedures, refer to the Detailed Information section of this consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

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.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Suzanne Pineles, Ph.D., at the VA Boston Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: 617-435-8742.

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

By conducting this research project, we hope to test a brief screening method that may predict which people with posttraumatic stress disorder (PTSD) and depression are most likely to show a positive response to selective serotonin reuptake inhibitor (SSRI) medications. This method involves using electrodes attached to your scalp to measure electrical brain activity in response to a series of loud tones.

SSRIs are recommended as treatments for psychological disorders such as PTSD and clinical depression. Currently, there is no rapid and uncomplicated way to determine who will benefit from SSRIs and who will not. In this study, men and women with PTSD symptoms who are interested in trying an SSRI medication will participate in eleven or twelve sessions over the course of a trial of sertraline administered and overseen by a study psychiatrist. At the beginning of the trial, participants will be either prescribed sertraline or a placebo. During this study, which will last approximately 17-21 weeks, almost all participants will ultimately be prescribed sertraline and dosing decisions will be made in the same ways as these decisions are made in usual clinical care, meaning they will be made collaboratively between you and the study physician based on your symptom improvement and side effect profile.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 5 years and we expect approximately 47 men and 47 women to participate in this study. Your individual participation in the project will take 17-21 weeks.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

<u>The first two visits will focus on determining your eligibility for study participation</u>:

<u>Visit 1</u> (approximately 4 hours; This session will be conducted remotely; some parts of this session may be conducted in person if you prefer).

You must be between the ages of 18 and 75. Certain prescribed or over-the-counter medications can be taken, but first must be approved by the study doctor. Otherwise, you must be free of medications for at least one month before the study.

Psychiatric, trauma, and substance abuse histories will be obtained through interview and questionnaires. You do not need to answer any questions you do not want to on the questionnaires or during the interview during this visit or future visits. This part of the screening exam will be audio recorded. The tape will be used to help the researchers make more accurate psychiatric diagnoses. These recordings will be kept as part of this study and may be re-scored. If you meet the eligibility criteria assessed during this session, you will be scheduled for a second screening session focused mostly on assessing medical eligibility criteria and providing you with information to determine whether or not you wish to try sertraline. We will aim to schedule this session within two weeks of the first screening session.

Visit 2 (approximately 2.5 hours; This session is conducted in-person)

During this session, our study physician will conduct a medical examination, will review your clinical lab results, and assess if sertraline is potentially a good treatment option for you.

Your hearing will also be tested. Four tubes of blood will be drawn for routine medical tests to ensure that you are physically healthy. You will also give a urine sample for a urinalysis and a urine test for illegal drugs, cannabis, and to measure how much tobacco you typically use. The urine screen for illegal drugs and cannabis will be repeated before each in-person study session. If positive (for illegal drugs), you will not be able to continue in the study.

Having an established psychiatric provider at this point is not mandatory for you to enroll in the study. However, if you already have a psychiatric provider outside of VA, you will be asked to sign a release of information (ROI) to contact your provider and study enrollment is contingent upon contacting your provider about the appropriateness of your participation in the study. We will share the following information with your current provider: information about the design of the study, inclusion and exclusion criteria, your psychiatric and medical diagnoses as well as illness severity, as assessed in the screening evaluation, and any history of safety issues such as risk to self or others. If you don't sign a ROI to contact the provider, you will not be entered into the study.

Female participants enrolling in this study must have a negative pregnancy test and indicate that they are willing to practice one of the following methods of contraception for the duration of the study. Acceptable contraceptive methods include: hormonal forms of birth control, spermicide and barrier (such as condom or diaphragm), intrauterine device, spousal/partner sterility, or abstinence with agreement to continue abstinence or to use an acceptable method of

contraception should sexual activity occur. Nursing mothers may not participate in this study. A urine pregnancy test will also be done at each session while you're in the study to ensure that you do not become pregnant.

Information you provide during Visits 1 and Visit 2 will be used to determine eligibility for the remainder of the study. After these sessions, you will be told if you are eligible to participate in the remaining study sessions within one week and we will aim to start your participation within two weeks of this second screening session.

Study Procedures for Qualifying Participants: If you qualify, you will be scheduled for the 14-17 week predictor of sertraline effectiveness study.

Visit 3 [This session may include both in-person and remote data collection; the in-person appointment will be about 90 minutes, and the remote portion of the appointment will be about 60 minutes]: This session marks the start of the portion of the study where you will begin to take either sertraline or placebo.

During the in-person portion of this appointment, you will be fitted with a nylon cap (like a swim cap) embedded with recording electrodes that will measure electrical brain activity. These electrodes will be attached to the surface of your hair. They will record electrical activity from various sites on the front, top and back of your scalp. During the procedure, you will listen to loud tones through headphones. The tones will be presented at different volumes for about 13 minutes. You will then complete a task in which you will count numbers presented on a computer screen.

You will also provide a blood draw for us to test for additional predictors of medication response and to provide baseline levels of neurobiological measures that may change in response to sertraline use. If you agree below, an additional tube of blood will be drawn for genetic testing. Additional visits for repeat clinical labs may be required.

During the remote portion of this appointment, a study clinician may also interview you regarding your current psychological symptoms and you will be asked to complete a set of questionnaires. Finally, a study physician will meet you to provide instructions and answer questions regarding how/when to take the study medication. In later sessions, the study physician will also assess symptom change and side effects.

During session 3, there is a possibility that you might be determined ineligible to continue in the study. This would occur if your symptoms reported during this session have decreased such that you are only experiencing minimal or no symptoms of PTSD or depression. If this occurs, you would likely not benefit from the study medication and you will be withdrawn from the study.

If you do not already have a psychiatric provider established at this time, the study team will begin working with you during this visit to facilitate referrals with the goal of you establishing a relationship with a provider before the end of the study. These discussions will continue throughout the course of the study. Once a referral is made, we will ask you to sign a ROI (if the clinician is outside of VA) for study staff to contact your provider and share information about the design of the study, inclusion and exclusion criteria, your psychiatric and medical diagnoses as well as illness severity, as assessed in the screening evaluation, and any history of safety issues such as risk to self or others.

Visit 4 [This session will be conducted remotely; about 2 weeks after Visit 3]: This study visit will include completing self-report measures, completing clinician-administered assessments and a brief check-in with the study physician focused on medication instructions, response, and side effects. You may also be asked to have your medication bottle accessible so you can count your pills.

Visit 5 [This session will be conducted remotely and will take about 45 minutes; about 2 weeks after Visit 4]: This study visit will focus on assessing symptoms, side effects, medication use, and for collaborative decisions regarding medication dosing.

Visit 6 [This session will be conducted remotely; about 2 weeks after Visit 5]: Procedures for study visit 6 include all of those administered during study visit 4.

Visits 7,8, and 9 [This session will be conducted remotely and will take about 45 minutes each; about 2 weeks after prior visit]: Procedures for these visits are identical to those administered during study visit 5.

Visit 10 [This session may include both in-person and remote data collection; about 2 weeks after Visit 9 or at the point you wish to discontinue the study medication]:

Procedures for study visit 10 are identical to those administered during study visit 3. This visit will mark the end of the part of the study in which you are prescribed sertraline.

Most study participants will discontinue sertraline at study visit 10. You will be instructed in how to reduce and ultimately discontinue sertraline. During this period of reducing your sertraline dose, you will have weekly phone calls with the study physician and a remote appointment two weeks later (Visit 11 and in some cases Visit 12).

However, if you wish to continue taking sertraline and not discontinue sertraline at the end of the study, this will only be possible if you a) have an established relationship with a provider

who is willing to manage your psychopharmacological treatment, b) this provider has communicated with our study team his or her willingness to coordinate care and continue prescribing this medication after study visit 10, and c) you have an appointment with this provider within four weeks of study visit 10. If these conditions are not met, you will not have the option of continuing to be prescribed sertraline through this study

Because it often takes time to make an initial appointment with a new VA provider, we will start working with you to facilitate referrals at the time of study enrollment if you do not have an established relationship with a VA primary care provider or psychiatrist.

We may end your participation in the study early if you are unable to respond to interview questions (for example, due to substantial cognitive or psychological impairment, extreme drowsiness, or due to the immediate effects of substance use) or displays aggressive or inappropriate behavior towards study staff. We may also discontinue your participation in this study if you are at immediate risk of harming yourself or others. In that event, we will follow all applicable laws and assist you in obtaining appropriate clinical care.

You may choose to stop the study at any time by alerting the study staff that you will to do so.

Schedule of study visits

Visit #	Approximate Duration of Session	Time Elapsed Since Previous Session
1. (screening session 1)	4 hours (some parts of this session may be conducted in person if you prefer)	
2. (screening session 2)	2.5 hours in-person and remote	Less than 2 weeks
3. Study Visit	In-person: 1.5 hours Remote: 1 hour	Less than 2 weeks
4. Study Visit	Remote: 1 hour	About 2 weeks
5. Medication check-in	Remote: 45 minutes	About 2 weeks
6. Study Visit	Remote: 1 hour	About 2 weeks
7. Medication check-in	Remote: 45 minutes	About 2 weeks
8. Medication check-in	Remote: 45 minutes	About 2 weeks
9. Medication check-in	Remote: 45 minutes	About 2 weeks
10. Study Visit	In-person: 1.5 hours Remote: 2.5 hours	About 2 weeks
11. Medication check-in, if discontinuing sertraline	Remote: 45 minutes	About 2 weeks

12. Medication check-in if sertraline discontinuation is not complete	Remote: 45 minutes	About 2 weeks

NOTE: Pending current VA Safety Guidelines, you may have the option of completing some or all remote components of study visits 3, 4, 6, and 10 in-person.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

Below are a list of responsibilities and expectations of all participants who take part in this study:

- Take the study drug as instructed, inform study staff of any side effects.
- Keep the study drug in a safe place for your use only and away from children.
- Keep your study appointments. If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
- Tell the investigator or research staff if you believe you might be pregnant or might have gotten your partner pregnant.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- 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.
- Refrain from consuming any illegal drugs for the duration of the study. Refrain from consuming alcohol or marijuana before any remote or in person study appointments.
- If you have non-VA providers who are involved in your psychiatric care that the study team needs to communicate with, you will be asked to sign a VA Form Letter 10-212 for each medical office the study team will communicate with. You must sign this form in order for the study team to talk to your medical providers.

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

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

Reasonably foreseeable discomforts or inconveniences of the study:

There may be some discomfort from the placement of the recording electrodes. This involves the use of mild abrasion and alcohol to cleanse the surface of the skin, mild rubbing of the scalp, and the use of salt water on the scalp. You may find some of the loud tones distressing. There may also be some discomfort during the administration of the EKG. When conducting the EKG, you will be required to remove your shirt, and may be asked to shave areas where the EKG stickers will be placed. You can be provided with a medical covering upon request, and female research technicians will be administering the EKG unless otherwise requested. Some of the questions that you will be asked are of a personal nature (e.g., questions about medications and diagnoses), and you may experience some discomfort in answering them. There will be questions asked specifically about your trauma experience that may be emotionally upsetting. If you become extremely distressed during the study, you will be asked to meet with Dr. Suzanne Pineles, the Principal Investigator, or another study clinician, to discuss your feelings. You may also be asked to schedule a follow-up appointment with a study clinician so that your level of distress can be monitored.

This study involves answering questions about past experiences, current life circumstances, and aspects of your physical and mental health. Some participants may feel uncomfortable about the interview sessions being audiotaped. However, this will be a required procedure. For all aspects of the study, confidentiality will be respected, and both informed consent and authorization for recording will be obtained as per requirements put forth by the Health Insurance Portability and Accountability Act (HIPAA). These audio recordings will be kept on a secure server with only your subject number as a label. Only members of the research team will have access to the audio recordings. Should you feel uncomfortable with these interviews being recorded, you can end your participation in the study now or at any time without penalty.

You may experience discomfort from the blood draws and a temporary bruise or “black and blue mark” may develop. You may also experience discomfort from needing to provide urine samples for toxicology screens, and this may also be inconvenient.

It also may be inconvenient to take a daily medication for several months during this study.

Reasonably foreseeable risks of study:

Because this study involves the physician-monitored administration of sertraline, risks for this study include risk for the possible side effects of sertraline, including:
constipation (3-8%), nausea (13-30%), dizziness (6-17%), headache (25%), insomnia (12-28%), drowsiness (2-15%), fatigue (12%), tremor (5-11%), diarrhea (13-24%), abnormal ejaculation (7-19%), and reduced libido (11%).

There are also several unlikely (<1%), but more significant, potential side effects including: easy bruising/bleeding, muscle cramps/weakness, shaking (tremor), and unusual weight loss.

Additional relatively rare risks of sertraline include the risk (especially in people younger than 25) of worsening depression, other mental/mood symptoms, or suicidal thoughts/attempts.

Finally, rare but serious side effects include: black/bloody stools, vomit that looks like coffee grounds, eye pain/swelling/redness, widened pupils, vision changes (such as seeing rainbows around lights at night, blurred vision), hemorrhage, dermatologic (Steven-Johnson syndrome), hyponatremia, musculoskeletal, seizure, and painful or prolonged erections. It is important to note that the risk of hemorrhage is increased with frequent aspirin use.

This medication may increase serotonin and rarely causes a very serious condition called serotonin syndrome/toxicity. To reduce risk for this, we are excluding participants who are using other serotonergic drugs (e.g., fentanyl, lithium, tramadol, buspirone, tryptophans, and St. John's wort) and MAOs.

A very serious allergic reaction to this drug is rare; symptoms include: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, and trouble breathing.

If you think you are having symptoms of a very bad allergic reaction or the rare but serious side effects listed above, you should get immediate medical help, which may include calling 911.

You should inform either Dr. Pineles, the study psychiatrist, or study staff as soon as possible if you experience any of these possible side-effects of sertraline. If it is after hours, you should call the psychiatry fellow on call. All of these numbers are listed below in the section titled "WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?"

Potential Risks other than Possible Side Effects of Sertraline:

Risks of Placebo: At the beginning of the trial, you may be treated with a placebo for a short

time. This means that you will not be receiving medications or other therapies intended to treat your PTSD or depression for several weeks during the study. During this time, it is possible that your PTSD or depression symptoms may stay the same, get worse or improve.

Risks of Drawing Blood: The risks associated with drawing your blood include pain, bruising, and rarely, fainting or infection. To minimize these risks, only a qualified, experienced health professional will draw your blood.

Drug Interactions: For your safety, you must tell the study doctor or nurse about all the prescription drugs, herbal products, over-the-counter drugs, vitamins and natural remedies that you are taking before you start the study and before taking any of these products while you are on the study.

Unknown Risks:

The safe use of sertraline in pregnant women and nursing mothers has not been established. Consequently, there may be risks to you (or to your embryo or fetus) if you are or may become pregnant that are unknown. Women of childbearing potential enrolling in this study must (i) have been using a birth control measure (an intrauterine device (IUD), birth control pills, a condom, diaphragm, or abstinence) for the previous three months, (ii) must have a negative pregnancy test, and (iii) must agree to continue to use a birth control measure for the duration of the study. If, while participating in the study, you suspect you have become pregnant, please contact the study physician immediately. Women are considered to be of childbearing potential unless they have been surgically sterilized (for example tubal ligation or hysterectomy) or are post-menopausal, that is, no menstrual period for more than 6 months. Nursing mothers may not participate in this study.

If you become pregnant during the study, you will be immediately withdrawn from the study due to the unforeseeable risks to the embryo or fetus.

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 research consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no direct/personal benefits to you from your taking part in this research study. However, the information we get from this study might help others with your condition(s).

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

Participation is voluntary. Refusal to take part in the study will involve no penalty or loss of benefits to which you are otherwise entitled.

Other treatment to that described above may include psychological treatments, pharmacological treatments, or both and will be under the supervision of your doctor or caregiver.

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 on protected VA servers and locked cabinets in a locked office located within VA Boston. Only the research team will have access to the information collected from you for this study. The paper data collected from this study will be kept in a locked cabinet in a locked office, while the electronic data will be coded and stored without personal identifiers. Any personally identifiable information will be kept on a separate drive of the computer with password protection or in a locked cabinet in a different locked office from the other information collected in this study.

Identifiers might be removed from the identifiable private information or identifiable biospecimens that are collected. After that removal, the information or biospecimens 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,

We will store biological samples taken from you (such as urine, blood, or tissue). Blood samples labeled with only your subject code will be processed and stored using the appropriate procedures in the MAVERIC biorepository located within VA Boston. The blood samples will be sent for measurement of sertraline levels and serotonin levels from the VA MAVERIC bio-repository to the CAVHS. The blood samples will be sent for measurement of stress hormones and other chemicals to VA or non-VA laboratories. These samples will be labeled only with your research code. Researchers at these laboratories will not have access to your identity or any

individual private, protected health information. Blood samples, as well as general data from the study also may be sent to other, not yet selected, non-VA laboratories or researchers for analysis. Again, these samples and data will carry only your research code and will not carry any personally identifying information. Samples will be kept at these laboratories for up to 3 months, after which they will be returned to the VA Boston MAVERIC Bio-repository or destroyed.

While this study is being conducted, you will not 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.

Clinical interviews will be audiotaped for training and reliability purposes, and to help clinicians make accurate psychiatric diagnoses. These audio files will be saved on a limited access folder on a secure VA server with only your subject number as a label. Only members of the research team will have access to the audio recordings. Any personally identifiable information (i.e., this signed Informed Consent Form) will be kept in a locked cabinet in a different locked office from the other information collected in this study. Digital audio recordings will be deleted from the recording device.

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 explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing 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.

We will record information from this study in your medical record, such as information related to your medical care. Please ask us if you have any questions about what information will be included in your medical records. You should know that once information has been put into your medical records, it is not covered by the CoC. However, information in your medical records is protected in other ways.

Your research records will be kept indefinitely or until the law allows their destruction per the VA Record Control Schedule. ***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 (photographs, x-rays, scans, video/audio recordings, etc) will be destroyed in a manner such that they cannot be retrieved.
- Audio/visual recordings and/or printed photographs will be shredded.

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.

We will include information about your study participation in your medical record.

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

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

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 co-payments for VA care and medications that are not part of this study.

You will be compensated $560 for your time and effort taking part in this study. Based on where you live, you may be eligible for additional travel compensation (detailed below).

You will be paid $60 for the first screening evaluation session and $50 for the second evaluation visit.

For individuals who qualify and choose to participate in the remaining visits, you will receive $120.00 for study visit 3, $40.00 for study visit 4, $40.00 for study visit 6, and $150.00 for study visit 10. Because study visits 5,7, 8, 9, 11 (and 12 for participants with longer sertraline discontinuation procedures) are primarily for the purpose of monitoring your response to sertraline in order to optimize the treatment efficacy and are typically short in duration, you will receive $20.00 for each of these visits. Thus, you will be compensated $560 if you participate in all study procedures through visit 11 (and $580 if you participate in all study procedures including visit 12). Any additional visits for repeat clinical labs required will be compensated with $10 and travel costs (except for repeat labs solely due to failed drug screen).

As discussed above, if your home address on file is a distance of 50 miles or greater (round trip) from VABHS, you are eligible to receive $5 for each 10 miles of travel above 50 miles, for a maximum of $50 (or 100 miles) per visit. If you chose to pay for a rideshare or taxi to attend in-person appointments, you are eligible to receive additional compensation; you would be compensated for the amount ride fare minus $10. For example, if the rideshare to the appointment was $15 (one way), you would be compensated an additional $20 – to offset the cost of the $30 roundtrip fare. If you choose to attend the consenting appointment in person, you will be paid $10 (or more depending on travel compensation rules listed above) to compensate for your travel.

If you are excluded from the study because you don't meet study inclusion criteria, if you withdraw from the study, or if we terminate your participation, you will be compensated only for the sessions you have participated in, but not for future sessions.

You consent to the release of personally identifying information about you including your name, address, social security number and bank information (bank name, routing number, and account number) to the VA so that we may provide compensation to you. You will receive payment within 7 to 10 days.

If payment is made to you by the VA (whether by direct deposit, or a VA issued debit card), an IRS Form 1099 will be generated regardless of the amount you are paid. The government may garnish the compensation against outstanding debts a veteran has to the federal government.

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

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY:

[redacted]

AFTER HOURS:

[redacted] and ask for the fellow on call for the Psychiatry Service

DO I HAVE TO TAKE PART IN THE STUDY?

Participation is voluntary. Refusal to take part in the study will involve no penalty or loss of benefits to which you are otherwise entitled.

If you are a VA employee or student, refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress.

You are free to withdraw from this study at any time. However, we urge you to work with the study team to gradually reduce the study medication rather than abruptly stopping the medication.

Should you choose to withdraw from the study, the study investigators may continue to review the data already collected for the study but cannot collect further information. Blood and urine samples already collected cannot be withdrawn.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

We may end your participation in the study early if you are unable to respond to interview questions (for example, due to substantial cognitive or psychological impairment, extreme drowsiness, or due to the immediate effects of substance use) or displays aggressive or inappropriate behavior towards study staff. As mentioned above, you also could be terminated from study if you fail the drug or alcohol screens. We may also discontinue your participation in this study if you are at immediate risk of harming yourself or others. In that event, we will follow all applicable laws and assist you in obtaining appropriate clinical care.

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.** [redacted] during normal working hours.

I understand that if I have any general questions about this research study, I can call **Dr.** [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 [redacted] and ask for the fellow on call for the Psychiatry Service.

If you have questions about your rights as a study participant or any complaints, concerns, or suggestions about this study, you may contact the Institutional Review Board at (617) 637-3794. The Institutional Review Board is responsible for overseeing the safety of human participants in this study.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

Sometimes during the course of a research study, new information becomes available about the study drug that is being studied that might change a person's decision to stay in the study. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw from the study, the study team will arrange for your clinical care to continue. If you decide to continue in the study, you might be asked to sign an updated informed consent form. Your research psychiatrist could also decide it to be in your best interests to withdraw you from the study. If so, he or she will explain the reasons and arrange for your usual medical care to continue.

Data collected during your study participation will not be disclosed to you.

WHO COULD PROFIT FROM THE STUDY RESULTS?

The samples collected in this study may not be used for commercial profit. If any commercial product is developed related to the findings from this study, participants will not share in the profit.

DOES THIS STUDY INVOLVE GENETIC RESEARCH AND HOW WILL MY GENETIC INFORMATION BE PROTECTED?

If you agree, a small sample of your blood will be banked for potential use in genetic studies of PTSD. The intent of this sample is to measure genes or gene expression involved with the serotonin system that might influence your response to sertraline. However, future research might include whole genome sequencing. Blood samples will be processed and stored using appropriate procedures in the MAVERIC biorepository located within VA Boston and/or the biorepository at CAVHS. This sample will be labeled with your subject code and, as discussed above, the master list matching codes to identifying information will be kept on a secure computer server under password protection. These results will be used for research purposes only and will not appear in your medical record or be released to you or your physician. The results of these genetic tests are not expected to influence any future employers or insurers or to have any psychological implications. We do not expect the genetic testing done in this study to become part of treatment for PTSD at any time during this study or in the next few years to come. You are welcome to contact the Principal Investigator at any point if you wish for this sample to be destroyed. The Principal Investigator's contact information is listed in this form.

Federal laws and policies provide you with protection from discrimination by health insurance companies, group health plans, and most employers based on your genetic information. A federal law called the Genetic Information Nondiscrimination Act (GINA) generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information obtained from this study.
- Health insurance companies and group health plans may not use your genetic information obtained from this study when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information obtained from this study when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. It also does not prohibit discrimination on the basis of already known genetic disease.

FUTURE USE OF DATA AND RE-CONTACT

Your data (not including the audio recordings) will be entered into a data repository and may be used for future studies approved by an IRB. This data repository is called the Biological Predictors of PTSD and Treatment Data and Specimen Repository. Dr. Suzanne Pineles is the Principal Investigator of this repository and it is located at VA Boston Healthcare System. Only

authorized personnel on the Biological Predictors of PTSD and Treatment Data and Specimen Repository (R&D #1592602) will have access to the data in this data repository.

TISSUE BANKING

We will store your blood and genetic (if provided) samples in a secure location at the MAVERIC Core Laboratory located at VA Boston Healthcare System or the Central Arkansas VA Healthcare System laboratory (CAVHS). Samples will be stored for use in future studies related to genetic and neurobiological markers of PTSD, treatment response, and other related problems. Electronic data from these biological samples will also be stored in the Biological Predictors of PTSD and Treatment Data and Specimen Repository (R&D #1592602) may be combined with data from other projects for large-scale analyses including with large, international collaborative research groups. Any future studies that make use of your samples will be reviewed by the IRB at VA Boston Healthcare System.

Please read each sentence below, think about your choice, and mark "**YES**" or "**NO**". **No matter what you decide to do, your decision will not affect your medical care or your participation in the study already described.**

May the VA Boston Healthcare System or its research partners in this study retain your blood specimen(s) after the end of the study for use in future research?

☐ **YES** **My specimen(s) may be saved for future research as follows:**

Check all restrictions that apply:

☐ **None. My specimen may be used for any future research**
☐ **Only research by the current principal investigator**
☐ **Only research that does not involve genetic testing**
☐ **Only research that involves the disease or condition to which this study pertains**

OR

☐ **None of the above. The specimen may only be used under the following conditions:**

_____

☐ **NO** **My specimen(s) must be destroyed at the end of this research study.**

If yes, may the VA Boston Healthcare System or its research partners in this study keep your name and other identifying information with your specimen(s)?

☐ **YES** **My personal identifiers and medical information can be kept with my specimen(s). All information will be kept secure and confidential.**

☐ **NO** **My name and identifiers must be removed from my specimen(s). My specimen(s) cannot be linked back to me.**

If you gave consent for the specimen(s) to be used in future research by the VA Boston Healthcare System or its research partners, an Institutional Review Board (IRB) may review and approve each new study. The IRB may require that you be contacted for your consent prior to the use of the specimen(s) in a new study if it decides such consent is required for your protection.

You have the right to withdraw your consent in the future and have your specimen destroyed. You need to notify the investigator of your decision. If you decide to remove identifiers from your specimen(s), you will not be able to withdraw your specimen later because it cannot be linked back to you.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

An appropriately trained study staff member has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information to this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this form.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

FOR IRB USE ONLY