# Efficacy and Safety of Stellate Ganglion Block for Post-traumatic Stress Disorder in Veterans

NCT05169190

IRB Approved on May 06, 2025

Participant Name: _____ Date: _____

Title of Study: Efficacy and Safety of Stellate Ganglion Block for Post-traumatic Stress Disorder in Veterans

Principal Investigator: _____ VA Facility: _____

Principal Investigators for Multisite Study: [redacted]

## KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the VA Clinical Science Research & Development Program. 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 determine the effectiveness and safety of Stellate Ganglion Block (SGB) for Post-traumatic stress disorder (PTSD). Your total participation in the study will be about 30 weeks. You have been asked to participate in this research study at the [XXXXX insert site name here] because you are a Veteran between the ages of 18 to 80 and are seeking treatment for PTSD. We will recruit up to 600 participants from six VA Hospitals in Long Beach, California; Tampa, Florida; White River Junction, Vermont; Minneapolis, Minnesota; Salt Lake City, Utah; and Madison, Wisconsin.

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

Veterans who have been diagnosed with PTSD and have not been helped by traditional treatment such as trauma focused psychotherapy and medication may benefit from Stellate Ganglion Block treatment. It is not a cure for PTSD, and the treatment may not work for you. You may choose to volunteer to determine if it helps you. You may also volunteer to help this research which in turn may help other Veterans with PTSD in the future.

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

You may already be happy with your treatment and are not interested in trying SGB. Also, any procedure has possible risks and discomforts. The procedures in this study may cause physical or psychological risks. For a complete list, please refer to the risks section below.

Alternative treatments for PTSD are available to you at the VA in the form of therapy performed by a clinician or medication prescribed by your doctor. You may choose to seek no treatment at all. For a complete description of alternate treatments, refer to the Detailed Information section of this consent.

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Principal Investigators for Multisite Study: [redacted]

## DO YOU HAVE TO TAKE PART IN THE STUDY?

No, all research participation is voluntary. 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 [XXX Insert name of LSI XXX]. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study you may contact [XXX insert contact information here XXX].

## DETAILED INFORMATION ABOUT THE STUDY

## WHAT IS THE PURPOSE OF THIS STUDY?

This research is being conducted to learn about the usefulness, short term durability, and safety of Stellate Ganglion Block (SGB) for post-traumatic stress disorder (PTSD).

The Stellate Ganglion is a collection of nerves in the neck and is part of the sympathetic nervous system which regulates one's fight or flight response. SGB temporarily numbs up the nerves to reduce fight or flight reactions. The doctor injects a local anesthetic around the nerve tissue like a dentist delivers numbing medicine before a dental procedure. The numbing goes away in a few hours, but the positive effects on PTSD may last for weeks or months. The procedure has been used for decades for other conditions such as cardiac conditions and nerve pain. SGB has been found to provide immediate and prolonged improvement for some who suffer from PTSD, but a great study on the efficacy and safety of SGB has not been done yet.

## HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take four years. Your individual participation in the project will last about 30 weeks.

**WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?**

If you decide to participate in the study, you will meet with a study staff member to enroll in the study. If you are a female of childbearing potential (meaning you are able to get pregnant), you will be asked to take a urine pregnancy test and not become pregnant for the duration of the study. If it is determined you are pregnant, you will not be able to enroll in the study.

Study Visits

In the first appointment, study staff will review this consent form with you and make sure all of your questions are answered before you sign. They will then evaluate you to determine if you have any medical conditions that would make you ineligible for the study. You will need to advise the research team of any medications you may be currently taking including over the counter drugs. A staff member will ask you some questions and have you fill out questionnaires assessing your traumatic experiences, and PTSD, depression, anxiety, and physical symptoms. This first visit will take 1-2 hours. The questionnaires will be given to you at nine additional time points throughout the study; the questionnaires alone will take up to 1 hour.

After this visit, you will have a phone assessment. The phone assessment is a clinical interview with a study psychologist to evaluate your mood and PTSD symptoms. You will receive a phone call and be asked a series of questions that will be repeated once in each phase of the study. The first phone assessment will take up to 4 hours, the phone assessments in Phases I and II will take 1-2 hours. You may refuse to answer any questions that you so choose, and the interview will be stopped if you do not want to continue answering questions. This phone assessment will be digitally recorded to ensure the quality and reliability of services being provided to you.

The questionnaires, medication review, and phone assessment will determine if you are eligible for Phase I and the Phase I, Week 8 phone assessment determines eligibility for the Phase II “open-label” SGB. In Phase I it is not guaranteed you will receive the ropivacaine injection because you will be randomized into one of three groups: SGB, placebo, or waitlist. Randomization will be further explained in the following section. Phase II is called the "open label" in which there will be no randomization. In Phase II you and the clinician know you will be receiving the SGB with ropivacaine injection.

Randomization for Phase I

If you are eligible once the questionnaires and phone assessment are complete you will be randomized into one of three groups because the study is a "randomized clinical trial."

Randomization is like flipping a coin to determine which group you are in. In this study there will be three groups that you may be randomized to. The three groups you may be put into are:

1. SGB Group
2. Placebo Group
3. Waitlist Control Group

The first group will have the SGB with what we think is "active" medicine (ropivacaine, like Novocain you get at a dentist to numb you) which has been found to be effective in preliminary research. The second group will have the same SGB procedure but with saline instead of ropivacaine, so we call this the “placebo” group. It could be that saline works just because of the volume of fluid around the Stellate Ganglion. The third group is called the "wait list control group," and those randomized to this group will have assessments like the other groups but will not receive the procedure in Phase I of this study.

For safety purposes, it is possible you will need to have an electrocardiogram (ECG) completed. The ECG is a painless, noninvasive way to assess heart functioning and ensure you don’t have any heart troubles that would make it unsafe to have the SGB injection. Additionally, it is possible you may need a blood draw for routine medical tests to participate.

If you are randomized to the SGB group or the Placebo group, you and the doctor administering the procedure will not know which type of injection you are receiving. Of course, if there is any problem or side-effect during or after the procedure, the doctor will be able to immediately know which group you are in to take care of you. Regardless of which group you are in, your general treatment and participation in this study will be the same.

There are visits at the following time points in Phase I: Week 1, Week 4, Week 8, and Week 12. The questionnaires are completed at every visit and there is the separate phone assessment at the Week 8 visit. If you agree to an optional assessment, there will also be a psychophysiological responses (PPR) assessment between randomization and Day 0, and during both the Phase I and Phase II Week 8 visits, all in-person at the [XX insert site name XX].

The psychophysiological assessment will be the same each time. It will last 60-75 minutes. This assessment allows researchers to measure certain functions of your nervous system. It is a standard, non-painful, and non-invasive procedure where sensors, such as electrodes, are taped to your skin. This is non-invasive because no electricity is being applied and no sensor will be inserted into your skin. Theses sensors will measure galvanic skin response, which is how much sweat is produced (such as on the palm of your hand), heart rate, and blood pressure.

Phase II

After the Week 12 questionnaires, Phase I is complete. Phase II begins immediately after the completion of Phase I. In Phase II, all eligible participants will be offered the SGB with ropivacaine. Both you and the doctor will know you are getting the SGB with ropivacaine. If you are offered the procedure and choose not to have it, you will be asked to complete the Phase II assessments without procedure. There are visits at the following time points in Phase II: Week 1, Week 4, Week 8, and Week 12 after the procedure visit which begins Phase II. The questionnaires are completed at every visit and there is the separate phone assessment at the Week 8 visit. If you agree to an optional assessment, there will also be the PPR assessment at the [XX insert site name XX] during the Week 8 visit.

SGB Injection

In Phase I, both the doctor and the participant (you) will be blinded as to if they are receiving a ropivacaine injection (active SGB) or a saline injection (placebo SGB). Twelve weeks following enrollment Phase II will begin. In Phase II, all eligible and interested participants from all groups will receive the SGB procedure with ropivacaine. Eligibility will be determined by our study psychologist conducting the phone assessment prior to entering Phase II.

You will be asked to fast before the procedure. More information about fasting will be provided to you when the procedure is scheduled.

During the procedure, you will meet with:

- A trained doctor having the necessary knowledge to perform the procedure and handle any complications that may occur
- Nurses or other medical assistants who will assist you during the injection and with any nervousness that may occur
- A radiology technician will assist the doctor with the ultrasound

- An individual will transport you to the procedure, and from the procedure to a recovery area for safe monitoring. In the recovery area, you will be monitored for about thirty minutes to ensure your safety.

The study procedure will take place at the [XX insert site name XX]. The full appointment for the procedure will take a minimum of three hours, including preparation and recovery time. Throughout the procedure, you will have continuous monitoring of your vital signs to ensure your safety. *(Include if applicable:* One to four static x-ray images may be taken to ensure the needle is in the correct position.*)* An ultrasound will be administered to guide the needles into the right place around the Stellate Ganglion. The procedure itself takes about 15-20 minutes. Once the procedure is complete, you will be transferred to an area to be observed for about thirty minutes to ensure that no complications have occurred, and you are safe.

Receiving the SGB procedure for PTSD is considered investigational at this time. The study doctor will monitor tests that are done for the purpose of standard of care as well as those that are done for research and will alert you if there are any problems. The study doctor or a member of the study staff can answer the questions you may have about the procedures that are not part of your standard care.

Summary of Timeline:

| Phase | Visit | Order of Assessments |
|---|---|---|
| Screening | Consent-Randomization | ▪ Consent<br>▪ Questionnaires<br>▪ Telephone Assessment<br>▪ Randomization (if eligible)<br>▪ *Optional PPR Assessment*<br>▪ Compensation -- $25, additional $25 for optional PPR |
| Phase I | Day 0 | ▪ Procedure day |
| | Week 1 | ▪ Questionnaires |
| | Week 4 | ▪ Questionnaires |
| | Week 8 | ▪ Questionnaires<br>▪ Telephone Assessment<br>▪ *Optional PPR Assessment* |
| | Week 12 | ▪ Questionnaires<br>▪ Compensation -- $100, additional $25 for optional PPR |
| Phase II | Day 0 | ▪ Procedure, if eligible and interested |
| | Week 1 | ▪ Questionnaires |
| | Week 4 | ▪ Questionnaires |
| | Week 8 | ▪ Questionnaires |

| | | |
|---|---|---|
| | | ▪ Telephone Assessment<br>▪ *Optional PPR Assessment* |
| | Week 12 | ▪ Questionnaires<br>▪ Compensation -- $75, additional $25 for optional PPR |

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

- All responsibilities and expectations of you during your participation in the study include*:*
    - Keep your study appointments. If you need to miss an appointment, please contact the local site coordinator at [XX phone number XX], to reschedule as soon as you know you will miss the appointment.
    - Tell the research staff if you believe you might be pregnant.
    - Ask questions as you think of them. A whole team is dedicated to ensuring that you are receiving proper treatment and understand the procedures taking place.
    - While participating in this research study, we ask that do not take part in any other research projects without approval from the investigators. This is to protect you from possible injury from things such as extra blood draws, 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.
    - While participating in this research study we also ask that you do not engage in any evidence-based practice psychotherapies for PTSD or do not start or stop any psychotropic medications during your study enrollment.

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

Blood Draw and ECG

The side effects of having blood drawn are typically minimal and non-life threatening. Some side effects may include bruising or swelling at the injection site, dizziness, and lightheadedness. There is also a rare possibility of infection at the needle site. There are few risks related to an ECG. Some people may experience a skin rash where electrodes were placed, but this usually goes away without treatment.

Questionnaires and Phone Assessment

It is possible that some participants may find answering questions and discussing their symptoms and traumatic experience(s) distressing. All clinicians are trained to address any distress that may occur. Your telephone assessment recordings will be reviewed by study doctors to make sure the assessment is given reliably. You have the right to discontinue the interview at any time. These recordings will not be released outside of the study. The recordings will be kept behind the VA firewall and only attached to your study ID.

Asking about your traumatic experience can cause you to remember those experiences and may worsen your symptoms. If this should happen, we will have you evaluated by the study doctor, and he/she will address your concerns and provide any services that are necessary, such as crisis intervention to ensure your safety and well-being. If it is determined that hospitalization is needed to ensure your safety the research staff can provide access to hospitalization.

SGB Procedure

It is possible that some participants may experience side effects or risks caused directly from the procedure. Common risks (experienced by more than 15 people out of 100) include changes in the appearance of your eye or changes in your vision. These are usually transient and resolve in a few hours without any treatment. Occasional risks (experienced by 4 to 14 people out of 100) include significant nausea and vomiting, paresthesia (nerve tingling) during needle positioning, pain at the injection site, varying rates of drowsiness, dizziness, hoarseness, increased pain, headache, dysphagia (trouble swallowing), hematoma, dyspnea (shortness of breath), shivering, cold feeling, sensation of warmth in your face, face swelling, facial numbness, and blurred vision, with the most common being pain at the injection site. Rare risks (experienced by fewer than 4 in 100 people) include bruising, bleeding, and infection and injury to the airway, nerve, blood vessel, or other nearby structures. Other risks include an allergic reaction, heart rhythm abnormality, change in blood pressure, breathing problems, or neurologic issues such as stroke, numbness, or weakness. In 1,000 people, 1 or fewer people may experience convulsions. There is also one known rare incidence of death and another single rare incidence of quadriplegia caused during or shortly after the SGB procedure in many thousands of procedures. 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.

If during the procedure or any time in the 30-minute post-procedure observation period you have any significant adverse effects, such as change in vital signs, unusual pain, hematoma, change in sensorium, significant bleeding, or any other symptom deemed important the doctor will have full authority to break the blind and find out what you were injected with so they can take proper care of you. If at any time during the study there are medical concerns about you that could be due to the intervention, medical treatment will be provided, and the blind will be broken if necessary. The procedure suite will also be equipped with advanced cardiac life support equipment and medications should any complication occur.

The safe use of Stellate Ganglion Block 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 have a negative pregnancy test at the time of the procedure. If, while participating in the study, you suspect you have become pregnant, please contact the study physician immediately. If you become pregnant during the course of the study, you will be withdrawn and transitioned to clinical care.

*(Include if applicable:* Radiation

If you take part in this study, you will have one to four static x-ray images taken with the fluoroscopy machine during each procedure. These static x-ray images would be performed as standard of care if you were to receive this procedure outside of this study. Although x-ray images use radiation, which can cause cancer and other health problems in large amounts, you will be exposed to a very small amount of radiation. Everyone receives a small amount of unavoidable radiation each year from space and from naturally occurring radioactive materials in the environment. Each procedure can give your neck the equivalent of up to 14.1 extra days' worth of this natural radiation. The radiation dose we have mentioned here is what you will receive from each procedure in this study and does not include any exposure you may have received or will receive from other tests or procedures.)

OPTIONAL Psychophysiological Assessment

Each of the tests involved in collecting biological measures such as heart rate, blood pressure, and perspiration is a standard, non-painful and non-invasive procedure and used widely in clinical research and practice. There is no medical risk associated with these measures. During part of the psychophysiological assessment, a puff of air will be blown at your neck at random intervals. The puff of air is like going to the eye doctor where they blow a puff of air into your eye to check for glaucoma. Due to the startling nature of the air puff and noise this may be

distressing to some people. You have the right to discontinue the assessment at any time. Study staff will be available to address any distress that may occur.

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 health care providers if you have any questions about the risks of usual care.

**WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?**

We do not know if you will get any benefits from taking part in this study. However, results from this study are intended to provide a better understanding of the effects of SGB on PTSD and the safety of SGB. This information may enhance the knowledge and shape treatment for PTSD which may potentially help many Veterans suffering from PTSD.

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

Several PTSD treatments do exist. You may choose to seek no treatment at all. You may choose to enroll or continue with treatment for PTSD at [XXinsert name of local siteXX]. You may also seek medication help from your psychiatrist or seek therapy from a trained clinician. You may choose to not participate in the study.

**HOW WILL MY PRIVATE INFORMATION BE PROTECTED?**

All participants will be given a subject ID number (SID) to be used on study materials rather than your name. Any documents with your name will be kept separately from study materials in a locked cabinet, inside a locked office. All electronic material is stored in a password protected file behind the VA firewall. Only research staff approved to work on this study will have access to study materials.

Your information collected as a part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

There are times when we might have to show your records to other people. For example, someone from the Office for Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, the Food and Drug Administration, and other study monitors may look at or copy portions of records that identify you.

The results of this study may be published in the medical literature or presented at scientific, medical, or educational meetings, but your name or identity will not be revealed and your records will remain confidential unless disclosure of your identity is required by law. Because of the need to release information to the parties listed above, absolute confidentiality cannot be guaranteed. The key listing names and code numbers will be kept in a separate locked filing cabinet and separate secured computer drive behind VA firewalls. Access to these files will be limited to staff who need to view the information as needed.

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.

Compensation

You will be compensated for your time spent participating in the study. You will receive $25 after baseline questionnaires and phone assessment, $100 after completion of Phase I, and $75 after Phase II at study completion. If you complete each phase, you may be eligible for a maximum of $200. If you choose to participate in the optional PPR assessments, you will be paid an addition $25 for each completed assessment. You will only be compensated for the assessments and phases completed. Compensation for your participation will be provided to you *[select all that apply and remove the instructions and unused options: in cash; or by direct deposit via electronic funds transfer (EFT) (additional language: in which funds are deposited into your bank account or pre-paid debit card. Compensation for participation in research is considered taxable income. If you receive $600 or more in any one calendar year, the VA is required to*

*report this information to the Internal Revenue Service. Form 1099 (Miscellaneous Income) will be issued to you OR Payments will generate Internal Revenue Service Form 1099 regardless of reimbursement amount); by gift card]*. [*Included for use of EFT, otherwise remove:* The funds will be coming from the VA's Austin Financial Services Center.] Your social security number will be obtained to allocate payment.

| Activity | Baseline Assessments | Completion of Phase I | Completion of Phase II |
|---|---|---|---|
| Required Study Procedures | $25 | $100 | $75 |
| Optional PPR Assessment | $25 | $25 | $25 |

**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:

[LSI name(s)] at [phone number(s)] or [SC name] at [phone number].

AFTER HOURS:

[LSI name(s)] at [phone number(s)] or the local VA [number/MH number] and have the operator page [XXinsert LSI nameXX] or Call the [VA name] [psychiatrist/MH specialist] on call at [phone number].

**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 entitled. The investigator may continue to review the data already collected for the study but cannot collect further information except from public records. You will continue to receive the same standard of care whether you decide to continue taking part in the

research study. Refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress within the VA.

**RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION**

Your participation in the study may also be discontinued at any time without your consent by the investigator, Institutional Review Board, or other regulatory governmental agencies, the study doctor, or the sponsor. This could happen if you become pregnant, experience a study-related injury, to protect your health or safety, if you do not follow study procedures, no longer meet study requirements, or if the study is cancelled. You will be notified of your termination and will be transferred to the appropriate care.

**WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?**

You may contact [the investigator], at [XXXX] with any questions, complaints, and concerns about the research or related matters. If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

**WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?**

Sometimes during the course of a research study, new information becomes available about the SGB 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, your research doctor will arrange for your medical care to continue. If you decide to continue in the study, you might be asked to sign an updated informed consent form. Your research doctor 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.

The research team will be conducting quarterly data checks to ensure participants safety. If we find out participants are experiencing worse symptoms due to the study, we will communicate these safety concerns with you.



**FOR VA CENTRAL IRB USE ONLY**

**PI/SC Approval Date: 05/06/2025**
*Per PI Amend 14*

**LSI Approval Date: N/A**

**LSI Verification Date: N/A**

Participant Name: _____ Date: _____

Title of Study: Efficacy and Safety of Stellate Ganglion Block for Post-traumatic Stress Disorder in Veterans

Principal Investigator: _____ VA Facility: _____

Principal Investigators for Multisite Study: [redacted]

**AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY**

The site coordinator 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. 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. *(Include if applicable:* A copy of this signed consent will also be put in your medical record.*)*

| **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 |



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Participant Name: _____ Date: _____

Title of Study: Efficacy and Safety of Stellate Ganglion Block for Post-traumatic Stress Disorder in Veterans

Principal Investigator: _____ VA Facility: _____

Principal Investigators for Multisite Study: [redacted]

**CONSENT TO PARTICIPATE IN OPTIONAL PPR ASSESSMENT**

Please write your **INITIALS** on the appropriate line:

Psychophysiological Assessment (optional):

I agree to attend three on-site psychophysiological assessments during the study:

1. At the time of randomization, prior to the Phase I Day 0,
2. During the Phase I Week 8 visit window,
3. During the Phase II Week 8 visit window.

_____ Will participate _____ Will NOT participate