Document: Consent Form

Study: Preventing the Development of Chronic Pain: Treating PTSD at Acute Pain Onset

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RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

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Protocol Title: Preventing the Development of Chronic Pain: Treating PTSD at Acute Pain Onset

Sponsor(s): Department of Defense

Name of Participant: _____

Key Information:

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected.

The purposes of this study are to 1) determine whether we can reduce your trauma-related stress symptoms using either Stellate Ganglion Block (SGB) treatment or Cognitive Processing Therapy (CPT); and 2) whether doing so can help you fully recover from the pain you reported when you visited the Emergency Department or Primary Care and Preventative Medicine. SGB treatment is a procedure involving an injection of local anesthetic into the side of the neck around the nerve that is part of the sympathetic nervous system, which controls our body's response to stressful situations and blocks pain. CPT is a talk therapy that can help you identify and challenge unhelpful trauma-related beliefs about yourself, others, and the world.

If you are eligible and agree to participate in this study, your participation may last up to 6 months after this initial interview. You may be asked to: 1) participate in 10 sessions of Cognitive Processing Therapy within a 5-day period; or 2) have two Stellate Ganglion Block injections within a 2-week period; or 3) continue with

usual care. You will be assigned randomly (by chance, like flipping a coin) to receive either CPT or SGB or receive only your usual care. During visits, you will be asked to complete interviews, self-report surveys that ask about demographic information, mental health symptoms, trauma-related thoughts, and pain symptoms. CPT sessions and your responses to questionnaires will be conducted entirely remotely via Microsoft Teams. For a detailed description of study procedures, please see the "What are the activities you will be doing if you participate in this study?" section of this consent form.

There are risks to you for participating in this study. CPT has been shown to be both effective and safe. If you have the CPT treatment, there is a risk of feeling temporarily distressed (upset or anxious) during sessions. CPT is a commonly used treatment for traumatic-related symptoms that is well-supported by research. Any increased distress is temporary and tends to decrease over the course of treatment. For a detailed list of risks, you should know about, please see the "What are the risks and discomforts of participating in this study?" section of this consent form.

SGB treatment has been shown to be effective and safe. If you have the SGB treatment, you may feel a warmth or tingling sensation in your arm or face following the injections. The injection site may be painful and may become bruised. When the anesthetic begins to affect the nerve bundle, you may feel a lump in their throat or experience voice hoarseness (raspy voice). For a detailed list of risks, you should know about, please see the "What are the risks and discomforts of participating in this study?" section of this consent form.

Although unlikely, there is a risk of loss of confidentiality if your medical information or identity is obtained by someone other than the investigators. To prevent this risk, all study staff will work very hard to ensure that all data is stored securely so that only members of the study staff will have access to data that could identify you. No data that could identify you will ever be revealed to any outside parties without your consent. Your identity will not be revealed on any report, publication, or at scientific meetings.

You may benefit from taking part in this study. Based on past research, you may experience reduced trauma-related stress symptoms if you are assigned to the CPT or SGB treatments.

You have the option to not participate in this study and may discontinue at any time. Your only other option to participating in this study is to not participate.

Detailed Information: Please review the rest of this document for details about the above topics and additional information you should know before making a decision about whether or not you will participate in this study.

Why are you being invited to participate in this study?

You are being asked to participate in this study because you presented to the Rush Emergency Department or a Primary Care and Preventative Medicine office with an acute pain complaint, and you reported a trauma symptom.

How many participants will take part in this study?

Approximately 345 participants are expected to take part in this study at Rush University Medical Center.

What are the activities you will be doing if you participate in this study?

If you provide your consent to be in this study by signing this informed consent form, you will have an intake

assessment during which you will be asked about various physical and mental health symptoms and substance use. This session will consist of interviews and questionnaires.

After the intake assessment, you will be randomly assigned (by chance, like flipping a coin) to receive Cognitive Processing Therapy, or Stellate Ganglion Block, or usual care.

If you are assigned to Cognitive Processing Therapy (CPT): CPT is a talk therapy that can help you identify and challenge unhelpful trauma-related beliefs about yourself, others, and the world. Doing so will help you develop more balanced views and behave in more adaptive ways that can be helpful in your recovery. You will participate in 10 sessions, which will occur twice per day for 5 consecutive (in a row) days. On each treatment day, you will participate in a morning session, then complete brief assignments, and then participate in an afternoon session. These sessions will occur remotely by Microsoft Teams.

If you are assigned to the Stellate Ganglion Block (SGB): You will be brought to the Rush Pain Center procedure room by a medical assistant who will attach heart, blood pressure, and breathing monitors. You will then be allowed to get used to the room and relax for 10 minutes. You will be moved to a supine position (i.e., laying down) and an intravenous (IV, into the vein) catheter will be placed in your arm. A nasal cannula will be placed in your nose and oxygen will be delivered at a rate of 2 L/min. The anesthesiologists will discuss the procedure with you. In consultation with you, the anesthesiologist may recommend that you undergo mild sedation during the procedure. If you choose to receive sedation, the anesthesiologist will administer a small dose of propofol (up to 50mg) into the IV catheter. Effects of propofol are mild, and at this dose, will allow you to be aware of your surroundings and be able to respond to verbal prompts from the staff. Effects will occur within 20-60 second of the injection. The anesthesiologist may elect to give you a second injection if the procedure is not completed within 2 to 10 minutes. With this level of propofol sedation, no additional aids (e.g., oxygen mask) are needed to maintain normal breathing.

An ultrasound system will be used to view the anatomy of your neck and needle position. For the SGB procedure, the area of the injection site on your neck will be prepared and localized with 1% lidocaine (anesthetic) and a sensor will be placed on your neck. After, 7 mL of 0.5% ropivacaine (anesthetic) will be injected into the site of the stellate ganglion in your neck. The spread of the injection will be monitored.

Below are images of the procedure and injection site:

If you are assigned to Usual Care: You will not receive any active intervention. You will complete a number of interview and questionnaire assessments.

Will your information be used for research in the future?
Information collected from you for this study may be used for future research or shared with other researchers. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, you will not be asked for additional consent.

What are the risks and discomforts of participating in this study?

There are risks to you for participating in this study.

If you receive CPT.
One potential risk is that you may experience some distress when sharing personal information during the interviews and during sessions. Any distress from CPT is expected to reduce over time. All sessions will take place during regular business hours and clinical staff will be available to assist in the case of distress or a crisis. We will also obtain the contact information of a trusted individual who resides no more than a 20-minute drive from you, if available. Should you experience increased distress during any of the visits, we will first contact your trusted individual to complete a wellness check before we would reach out to 911/emergency services for a formal wellness check. If you experience an emergency or a life-threatening medical situation during a telephone/video assessment or treatment session, call 911 or go to your nearest emergency room immediately.

If you receive SGB treatment.

The risks of propofol sedation include the potential for an allergic reaction. If you are allergic to eggs or egg product please tell the anesthesiologist.

Side effects, risks, and/or discomforts from the propofol injection for minimal sedation for the SGB block procedure include:
More common
- Blurred vision
- confusion
- dizziness, faintness, or lightheadedness when getting up suddenly from a lying or sitting position
- fast, slow, irregular, or pounding heartbeat or pulse
- headache
- nervousness
- pounding in the ears
- problems with movement
- sweating
- unusual tiredness or weakness

Less common
- Bluish lips or skin
- chest pain or discomfort
- difficulty breathing
- lightheadedness, dizziness, or fainting

Rare
- Anxiety
- bleeding gums

- burning, crawling, itching, numbness, prickling, "pins and needles", or tingling feelings
- changes in vision
- chills
- cloudy urine
- cough
- coughing up blood
- delirium or hallucinations
- difficult urination
- difficulty swallowing
- dry eyes, mouth, nose, or throat
- excessive muscle tone
- eye pain
- fever
- flushing or redness of the face
- general feeling of illness
- hives, itching, skin rash
- inability to move the eyes
- increased blinking or spasms of the eyelid
- increased menstrual flow or vaginal bleeding
- increased watering of the mouth
- irritability
- joint pain or swelling
- loss of appetite
- mood or mental changes
- muscle aches, cramps, or pains
- muscle spasms or twitching
- muscle stiffness, tension, or tightness
- nausea or vomiting
- nosebleeds
- pain in the arms or legs
- prolonged bleeding from cuts
- puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue
- red or dark brown urine
- red or black, tarry stools
- restlessness
- shaking
- sleepiness or unusual drowsiness
- sore throat
- sticking out of tongue
- tightness in the chest
- trembling
- trouble sleeping
- trouble speaking
- uncontrolled twisting movements of the neck, trunk, arms, or legs
- unusual facial expressions

Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, the anesthesiologist may be able to tell you about ways to prevent or reduce some of these side effects. Check with the anesthesiologist if any of the following side effects continue or are bothersome or if you have any questions about them: Bleeding, blistering, burning, coldness, discoloration of skin, feeling of pressure, hives, infection, inflammation, itching, lumps, numbness, pain, rash, redness, scarring, soreness, stinging, swelling, tenderness, tingling, ulceration, or warmth at the injection site.

For the SGB procedure, you may feel a warmth or tingling sensation in your arm or face following the injection. The injection site may be painful and may become bruised. When the anesthetic begins to affect the nerve bundle, you may feel a lump in their throat or experience voice hoarseness. Subjects who experience hoarseness will be advised not to eat or drink for six hours after the block. Subjects may also develop nasal congestion, especially on the side of the injection, or may even develop a headache. Side effects should disappear within 4 to 6 hours. Horner's syndrome revealed by a decreased pupil size, a drooping eyelid and decreased sweating on the side of their face on which the block was placed, may occur. Prior studies suggest that Horner's syndrome will occur in approximately 70% of subjects and will resolve within 4 to 6 hours of the block.

In addition, the IV catheter that is placed in your arm may cause a bruise. Occasionally, an infection develops at the IV site.

You will be instructed not to drive and/or operate heavy machinery for 24 hours after the procedure. You may experience hoarseness which should disappear within 4-6 hours. You will be instructed not eat food or drink for four hours after the procedure or until your ability to swallow as normal has returned.

Side effects, risks, and/or discomforts from the ropivacaine injection as part of the SGB treatment may include:

<u>Common side effects of SGB (>10%):</u>
- Hypotension (low blood pressure)
- Bradycardia (slow heart rate)
- Nausea
- Vomiting
- Back pain

<u>Less common side effects of SGB (1 to 10%):</u>
- Chest pain
- Hypertension (high blood pressure)
- Tachycardia (fast heart rate)
- Headache
- Pain
- Paresthesia (abnormal sensation such as tingling, numbness, prickling, burning, chilling)
- Dizziness
- Chills
- Hypoesthesia (numbness)
- Anxiety
- Pruritus (itching)
- Hypokalemia (low potassium)
- Oliguria (low urine output)
- Inability to fully urinate
- Urinary tract infection
- Anemia

· Muscle cramps
· Dyspnea (shortness of breath)
· Rhinitis (stuffy nose)
· Fever

Rare side effects of SGB (<1%):
· Agitation (irritation)
· Amnesia
· Angioedema (swelling under skin)
· Asthenia (weakness)
· Atrial fibrillation (irregular heartbeat)
· Auditory disturbance
· Blepharoptosis (droopy eye)
· Bronchospasm (difficulty breathing)
· Cardiac arrhythmia (irregular heartbeat)
· Change in vision
· Coma
· Confusion
· Cough
· Deep vein thrombosis (blood clot in deep vein)
· Drowsiness
· Dyskinesia (involuntary muscle movements)
· Electrocardiogram (ECG) abnormality
· Emotional lability (rapid changes in mood)
· Extrasystoles (extra, abnormal heartbeats)
· Fecal incontinence (inability to control bowel movements)
· Hallucination
· Horner's syndrome that resolves within a few hours
· Hypersensitivity reaction (allergic reaction)
· Hypokinesia (slowed or reduced muscle movement)
· Hypomagnesemia (low level of serum magnesium)
· Hypothermia (low body temperature)
· Hypotonia (decreased muscle tone)
· Insomnia (having trouble sleeping)
· Jaundice (yellow tint to skin and eyes)
· Malaise (general discomfort)
· Myalgia (muscle pain)
· Myocardial infarction (heart attack)
· Nervousness
· Neuropathy (nerve numbness or weakness)
· Nightmares
· Orthostatic hypotension (form of low blood pressure)
· Pain at injection site
· Paresis (partial paralysis)
· Phlebitis (inflammation of veins)
· Pulmonary embolism (blood clot in lung)
· Seizure
· Skin rash
· ST segment changes on ECG (change in waves measured on ECG)

· Stupor (state of near unconsciousness)
· Syncope (fainting/temporary loss of consciousness)
· Tenesmus (continuous feeling of needing to evacuate bowel)
· Tinnitus (ringing in ears)
· Tremor (shaking)
· Urinary incontinence (involuntary leakage of urine)
· Urticaria (hives)
· Vertigo (dizziness)

While SGB treatment is a safe procedure, there may be pregnancy/fetal risks for women of childbearing age/potential. Therefore, if this applies, you may be asked to discuss the procedure with the study doctor to make sure that the procedure will be safe regarding your specific risks.

There is a risk of loss of confidentiality. To minimize risk of loss of confidentiality, all participants will be assigned a participant study number that will be used to identify them. Only study team members will have access to the study data.

There may be other risks that may happen that we cannot predict.

What if there is new information that may affect your decision to participate in this study?

During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent form in order to continue participating in this study.

Can you leave or be removed from this study?

You have the right to leave a study at any time without penalty. For your safety, however, you should consider the study doctor's advice about how to leave this study. If you leave this study before the final study visit, the study doctor may ask you to complete the final steps. You are able to ask that your study-related information be removed from the study at any time. However, it may not be possible to withdraw or delete your information in cases when it has already been shared with other researchers. The removal of any study-related data does not include any information that may be stored on the secure Rush network server. Upon leaving the study, you will be given appropriate referrals to Rush University Medical Center or other community resources as needed. If you become actively suicidal with intent, the study clinician will refer you to a higher level of care (i.e., psychiatric, medical, or emergency services). You will no longer be able to continue in this course of CPT but may be able to enroll at a later time after reaching stability per eligibility requirements.

The researchers and Sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You do not follow the instructions;
- The study is canceled for any reason.

What about confidentiality of your medical information?

This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold or refuse your treatment, payment, enrollment, or eligibility for benefits if you do not sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study.

By signing this document, you voluntarily authorize (give permission to) Dr. John Burns, his study team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information that identifies you for the study described in this document.

During the study, Dr. Burns and his study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained as a result of this study. Some of this information will come from your medical record. The health information that Rush may use or disclose for this research includes:

- Name
- Dates related to study visits and length of study participation
- Email address
- Telephone number
- Medical Record Number or Health Plan beneficiary number, if applicable
- Responses to self-report assessments
- Audio and video recordings of sessions and copies of session materials

The study team will use this information about you to complete this research. Dr. Burns and his study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of this study. The persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used or disclosed to:

- De-identified video recordings will be sent to approved external collaborators for analysis
- Scientific databases in de-identified form
- Monitoring agencies such as the Food and Drug Administration (FDA), The Department of Defense, and the Rush Institutional Review Board (IRB).

While you participate in the study you will have access to your medical record, but Dr. Burns is not required to release to you study information that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. Any study information in your medical record will be kept indefinitely. Your identity will not be revealed in any report, publication, or at scientific meetings. As part of this study, all study visits will be recorded. All audio and video recordings collected for research will be uploaded to the secure Rush University Medical Center server within one business day and will be deleted from the recording device immediately upon upload. Transcriptions of interview recordings will be stored on the secure server as well and will only be accessed by members of the study staff. Electronic copies of CPT worksheets will be stored in a secure folder and will be accessed only by you and members of the study staff. After your final visit, the worksheets stored in this folder will be deleted and copies will be uploaded to the secure Rush University Medical Center server.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed below.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. John Burns at 1645 W. Jackson Blvd, Suite 400, Chicago, IL 60612 or phone 312-942-0379. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or

disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety of this research study. It will expire upon completion of the study or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. All information and data collected in the study will be stored on the RUMC secure server or in a secure, locked cabinet in the Department of Psychiatry and Behavioral Sciences. Only members of the study staff will have access to identifiable data. No identifiable data will ever be disclosed to outside parties. De-identified data may be reported in aggregate (with other participants' data) for internal clinical use, publications, or other presentations. In order to conduct the study, the study investigators will use and may share personal health information. This includes information already in your medical record, as well as information created or collected during the study. Any data shared will have all identifying information removed and will be assigned a unique study code. When identifying data cannot be removed (as in the case with audio and video files), they will be provided with a unique study code and stored in a separate and secure network location.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

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.

Certificate of Confidentiality

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) If there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research participants;
(4) for the purpose of auditing or program evaluation by the government or funding agency

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. Please contact the investigator for more information on how to provide this consent.

If you disclose actual or suspected abuse, neglect, or exploitation of a child, or disabled or elderly adult, the researcher or any member of the study staff must, and will, report this to Child Protective Services (such as the Department of Family and Human Services), Adult Protective Services, and/or the nearest law enforcement agency.

What are the costs to participate in this study?

All costs for the required study surveys and costs associated with clinic time and supplies will be paid by the Department of Defense.

Will you be paid for your participation in this study?

You will be compensated up to $300 for your time and effort to participate in all of the assessment and therapy sessions. You will be compensated with Amazon gift cards. This compensation will be allocated according to this schedule: $100 for completion of the initial baseline session; $50 upon completion of the Day 14 assessments; $50 upon completion of Day 28 assessments; $100 upon completion of Day 112 assessments. We will email these gift cards after each of the time points just described. If you do not have access to internet email, we will mail the gift cards to you.

Will you be reimbursed for travel costs related to your participation in this study?

If you must use a rideshare service or taxi to attend your Stellate Ganglion Block appointments at the Rush Pain Center, costs for these rides within 20 miles of Rush in any direction will be reimbursed.

What if you are injured as a result of your participation in this study?

If you get ill or injured from being in the study, Rush University Medical Center will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Burns at telephone number 312-942-0379.

You should let any health care provider who treats you know that you are in this study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact your study doctor.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

Who can you contact for more information about this study?

Questions are encouraged. If you have further questions about this study, you may call Dr. Burns at 312-942

0379 or email at john_burns@rush.edu.

Who can you contact if you have concerns about your rights as a study participant?

Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?

Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Burns in writing at the address on the first page. Dr. Burns may still use your information that was collected prior to your written notice.

Attachment: Study Consent Form.docx

SIGNATURE BY THE PARTICIPANT:

Please type your full legal name (participant) in the box below:

Please enter today's date below (mm/dd/yyyy)

Please select one of the options below:

By clicking on this text box, you are **CONSENTING TO PARTICIPATE** in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily by the study staff. You do not waive any of your legal rights by signing this consent form.

☐ I **agree** to participate

By clicking here, you **DO NOT AGREE** to participate

☐ I **do not agree** to participate

We would like to share the taped video recordings of intake and follow-up assessments and CPT sessions with external collaborators for the purpose of data analysis. Please mark your response:

☐ I **agree** to have my video shared with your collaborators for analysis

☐ I **do not agree** to have my video shared with your collaborators for analysis