Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: Stellate Ganglion Block for the Treatment of COVID-19-Induced Olfactory Dysfunction: A Prospective Pilot Study

Principal Investigator: Nyssa Farrell

Research Team Contact: **Nyssa Farrell, MD**
314-362-5000

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you experience chronic COVID-19-induced olfactory (smell) dysfunction and other long COVID symptoms.

The purpose of this research study is to evaluate the effectiveness and safety of a Stellate Ganglion Block (SGB) in improving olfactory dysfunction in patients with chronic COVID-19-induced olfactory impairment. The stellate ganglion is a collection of nerves found on each side of your voice box. The stellate ganglion block (SGB) involves an ultrasound-guided injection of a local anesthetic to inhibit the stellate ganglion.

The SGB consists of lidocaine and mepivacaine injections which are approved by the U.S. Food and Drug Administration to cause numbness or loss of feeling around nerves for patients having certain medical procedures. Lidocaine and mepivacaine are used as local anesthetic. They prevent pain by blocking the signals at the nerve endings in the skin. These medicines does not cause unconsciousness as general anesthetics do when used for surgery**.**

WHAT WILL HAPPEN DURING THIS STUDY?

Visit 1 and 2 will take place at the medical center. The study team will provide you with directions to the visit location.

Visit 1:
In preparation to receive the Stellate Ganglion Block (SGB), you will be asked to not eat or drink anything 8 hours prior to Visit 1. If needed, you can take morning medications with a small sip of water. At the initial visit, you will be asked to complete a few questionnaires about your smell and taste dysfunction. The questionnaires will take about 15 minutes to complete and you are free to skip any questions that you would prefer not to answer. Then you will be prepared to receive the first Stellate Ganglion Block (SGB). The study doctor will use a handheld wand for ultrasound guidance to locate

the area in your neck to inject the medications lidocaine and mepivacaine. The setup and injection will take about 10 minutes followed by a 10-minute post-injection observation period. You and your vital signs (heart rate and breathing) will be monitored throughout the procedure and after the procedure.

Visit 2 (5-10 days after 1st SGB):
In preparation to receive the second Stellate Ganglion Block (SGB), you will be asked to not eat or drink anything 8 hours prior to Visit 2. If needed, you can take morning medications with a small sip of water. Prior to undergoing a SGB on the opposite side of your neck to your initial SGB, you will be asked to describe any adverse events experienced after the first SGB, and again to fill out the same questionnaires about your smell and taste. The setup and injection will take about 10 minutes followed by a 10-minute post-injection observation period. You and your vital signs (heart rate and breathing) will be monitored throughout the procedure and after the procedure.

Visit 3 (1 month after 2nd SGB):
The final visit will occur virtually and you will be asked to complete the same questionnaires about your smell and taste. You will also be asked to describe any adverse events experienced since the second SGB and to provide your opinion about potential future studies using the Stellate Ganglion Block.

Will you save my research information to use in future research studies?

We would like to use the data we are obtaining in this study for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding COVID-19 induced olfactory dysfunction, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your data you give up any property rights you may have in the data.

We will share your data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your data for future research you should contact the research team member identified at the top of this document. The data will no longer be used for research purposes. However, if some research with your data has already been completed, the information from that research may still be used. Also, if the data has been shared with other researchers it might not be possible to withdraw the data to the extent it has been shared.

Please place your initials in the blank next to Yes or No for the question below:

My data may be stored and used for future research as described above.

_____ Yes **_____ No**
Initials **Initials**

Unless you agree to future use as described above, your private information, including data, collected as part of this study will not be used or distributed for future research studies, even if identifiers are removed.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 20 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for approximately 1 month.

There are a total of 3 visits:

- Visit 1 requires a visit to the medical center and will last approximately 1-2 hours
- Visit 2 requires a visit to the medical center and will last approximately 1-2 hour
- Visit 3 is a virtual visit and will last approximately 10-20 minutes

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Lidocaine/mepivacaine:
Side effects that you should report to the doctor as soon as possible:

- allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue
- breathing problems
- changes in vision
- chest pain
- feeling faint or lightheaded, falls
- headache
- seizures
- slow, irregular heartbeat

- trembling or shaking
- unusually weak or tired
- confusion
- ringing in your ears
- Horner syndrome - constricted pupil (miosis), drooping of the upper eyelid (ptosis), absence of sweating of the face (anhidrosis), and sinking of the eyeball into the bony cavity that protects the eye (enophthalmos).

  If you experience Horner Syndrome or any side effect listed above following the injection, the post-injection observation period will last up to 2 hours. You and your vital signs (heart rate and breathing) will be monitored throughout the observation period.

Side effects that are expected, common, usually lasting up to 24 hours and usually do not require medical attention (report to your doctor and study team if they continue or are bothersome):

- anxiety or nervousness
- backache
- feelings of cold, heat, or numb
- irritation at site where injected
- nausea, vomiting
- hoarseness
- mild shortness of breath
- dysphagia (difficulty swallowing)
- globus (feeling of something stuck in the throat)
- congestion- nasal
- temporary weakness in the arm
- blurry vision
- droopy eye lid
- eye redness
- neck pain or pain at injection site

Breach of Confidentiality
One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because of the information learned as a result of this study.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could receive the same study treatment without being in the research.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

The University and the research team are not receiving payment from other agencies, organizations, or companies to conduct this research study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at 314-362-5000 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those listed below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures.

- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will password protect all electronic files containing your data and use a double lock method when storing physical hard copy research records containing your data. Only the study team members will have access to your identifiable data.

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.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
    - **If you revoke your authorization:**
      - The research team may only use and share information already collected for the study.
      - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
      - You will not be allowed to continue to participate in the study.

Can we contact you by email and/ or text?

We would like to contact you by email and/or text for the purposes listed below. Some of these messages may contain health information that identifies you.

- Questionnaire completion

Only the research team will have access to your email and/or text communications. We will only communicate in this method to send you the information listed above. If you have any questions, wish us to stop sending these messages or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email and/or text.

- Text messaging is not a secure communication method.
- There is always a risk that the message could be intercepted or sent to the wrong email address and/or phone number. To avoid this, we will send a test message to ensure we have the correct email address and/or telephone number.
- [For email] When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer or cell phone with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any messages sent or received on any electronic devices used for work or through a work server.
- If you lose your phone, others may be able to access the messages that we send.

Do you agree to allow us to send your health information via email?

_____ Yes **_____ No**
Initials **Initials**

Do you agree to allow us to send your health information via text?

_____ Yes **_____ No**
Initials **Initials**

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research Study.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because in our judgment it would not be safe for you to continue.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: **Nyssa Farrell, MD at 314-362-5000.** If you experience a research-related injury, please contact: **Nyssa Farrell, MD at 314-362-5000.**

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 08/23/23.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)