Mass General Brigham

Research Consent Form
Certificate of Confidentiality Template
Version Date: March 2026

Subject Name:

MRN or DOB:

Subject Identification

Protocol Title: Combination tonsillectomy and hypoglossal nerve stimulation for OSA patients with lateral pharyngeal collapse.

Principal Investigator: Daniel Vena, PhD

Site Principal Investigator: Phillip Huyett, MD

Description of Subject Population: Adults with obstructive sleep apnea

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

We are asking you to be in a research study. This form will tell you what you should expect if you agree to be in the study. You will find more information about each of the following points later in this form.

It is your decision whether or not to join the study. We are asking you to be in this study because you have obstructive sleep apnea and are a candidate for treatment with hypoglossal nerve stimulation, with or without tonsillectomy. We are doing research to learn whether adding tonsillectomy to hypoglossal nerve stimulation improves sleep apnea outcomes in patients with a specific pattern of airway collapse. If you agree, you will be randomly assigned to receive hypoglossal nerve stimulation (otherwise known as HGNS) with or without tonsillectomy and will complete several sleep studies and questionnaires to measure treatment response. You will be in the study for approximately 6 months if you decide to stay for the whole study.

The main risks of being in the study are those related to surgery and anesthesia, including pain, bleeding, infection, and discomfort, as well as inconvenience or sleep disruption from home or

laboratory sleep studies. For a detailed explanation of all associated risks, refer to the "Risks" section provided later in this document.

You will not benefit from taking part in this research study. If you take part in this study, your participation may help people in the future. The alternative to taking part in this study is to decide not to participate and receive your usual or normal care you would receive outside of the study.

You will be paid up to $525 by check for taking part in this research study. You will find more information about the payment amount for each visit and a plan if you do not complete all study visits later in this form.

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Daniel Vena, PhD is the person in charge of this research study. You can call him/her at **617-852-0719; Mon-Fri 24/7**. You can also call our licensed physician **Phillip Huyett, MD at 617-573-3793, Mon-Fri; 9AM-5PM** with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call **Natalie Lawrence at (617) 525-8888, Mon-Fri; 9AM-5PM.**

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB. You can call them at 857-282-1900.

You can talk to them about:

- A complaint, problem, or concern
- Ask questions, offer input, or obtain information
- Your rights as a research participant

Detailed Information

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.

Why is this research study being done?

We are doing this research to learn whether removing the tonsils along with hypoglossal nerve stimulation (HGNS) helps treat obstructive sleep apnea better than HGNS alone in some patients.

HGNS is a device that is approved by the U.S. Food and Drug Administration (FDA) to treat obstructive sleep apnea. Tonsillectomy is a standard surgical procedure. Both treatments are part of usual medical care. This study looks at whether using them together improves sleep apnea in patients with a certain type of airway blockage.

Dr. Daniel Vena, the Principal Investigator on this study, and Dr. Phillip Huyett, an investigator on this study, have a financial interest in Inspire Medical Systems, the manufacturer of the Hypoglossal nerve stimulator. In accordance with Mass General Brigham's conflict of interest policies, the MGB Office for Interactions with Industry has reviewed Dr. Vena's and Dr. Huyett's financial interest in the company and determined that the interest creates no significant risk to the welfare of participants in this study or to the integrity of the research. If you want more information about this, please contact the MGB Office for Interactions with Industry at 857-282-2024 or PHSOIIRESEARCH@MGB.ORG.

Who will take part in this research?

We are asking you to take part in this research study because you have obstructive sleep apnea and are being treated with hypoglossal nerve stimulation, with or without tonsil removal.

About **72 people** will take part in this research study. All participants will be enrolled at Mass General Brigham.

This research study is being paid for by the **National Institutes of Health (NIH)**.

What will happen in this research study?

If you choose to take part in this study, you will receive care that is part of standard treatment for obstructive sleep apnea, along with some extra research tests. The study will last about **6 months**.

Before surgery (Baseline)

- You will review and sign this consent form.
- You may complete questionnaires about your sleep and daytime symptoms (about 15–20 minutes).
- You will complete a **routine sleep study** to measure your sleep apnea (done either at home or in the sleep lab).

Assignment to a study group

- You will be **randomly assigned** (by chance, like flipping a coin) to one of two groups:
    - Hypoglossal nerve stimulation (HGNS) **with tonsil removal**, or
    - Hypoglossal nerve stimulation **without tonsil removal**
- Neither you nor the study team can choose your group.

Surgery

- All participants will have **HGNS surgery**, which is standard medical care.
- Some participants will also have their **tonsils removed** during the same surgery.
- These procedures are done at Mass General Brigham.
- Surgery and recovery follow usual clinical care.

After surgery

- About **4 weeks after surgery**, your HGNS device will be turned on and adjusted.
- Over the next several weeks, your doctor will adjust the device to find the best settings.
- You may also be asked to keep a brief log of pain medications you take during your recovery.

Follow-up testing

- After about **1 month of using HGNS**, you will:
    - Complete another **routine sleep study** (done either at home or in the sleep lab).
    - Complete questionnaires about your sleep and symptoms
- Some participants will be asked to complete **extra sleep studies** with the HGNS device turned on or off to help understand how the treatments work.

Physiology Overnight Sleep Study (Optional)

Some participants may be asked to take part in one overnight physiology sleep study in a sleep research laboratory. This study helps us understand how breathing and the airway behave during sleep.

This study includes:

- A standard sleep study, which measures brain activity, breathing, oxygen levels, and heart rate
- A mask worn over the nose and mouth to measure airflow during sleep
- Short, controlled changes in air pressure during sleep to see how easily the airway closes, with the HGNS device turned on and off

The study is done overnight and usually lasts about 10–12 hours.

You may feel some mild discomfortfrom the air pressure changes, and your sleep may be disturbed. The pressure changes are brief and are stopped if they cause discomfort or wake you up.

If enough information cannot be collected (for example, if you do not sleep well or the signals are unclear), you may be asked to repeat the study. You will be compensated for each completed study night. Taking part in this sleep study is optional and not required to be in the main study.

Mass General Brigham safety system
Mass General Brigham has an electronic system that lets your study doctors know if you are admitted to a Mass General Brigham hospital or visit a Mass General Brigham emergency department. This helps the study team know about possible problems or side effects while you are in the study.

Additionally, a notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs)

Stopping early

- You may leave the study at any time.
- The study doctor may also stop your participation if it is best for your health or if the study is stopped.
- If you leave early, you will continue to receive your regular medical care.

Sharing research data

- Information collected for this study may be shared with other researchers outside Mass General Brigham.

- Your information will be **coded** and will not include your name or other details that directly identify you.

How may we use and share your samples and health information for other research?

The samples and information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to you. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

You will receive the results of tests that are important for your medical care from your treating doctor, just as you would outside of a research study. These results may be used to guide your treatment.

In general, you will **not receive individual results from the research study** that are not part of your routine medical care. Some of the information collected is for research purposes only and is used to better understand sleep apnea and treatment response. These research results are not meant to guide your personal medical care.

If the study sponsor provides general information about the overall results of the research, we may share that information with you. Results from this study may also be published or presented, but your name and other identifying information will not be included.

What are the risks and possible discomforts from being in this research study?

The research parts of this study involve extra sleep studies, questionnaires, and (for some people) an optional overnight physiology sleep study. These research procedures have some risks and discomforts.

Sleep studies (home or sleep lab):
You may feel discomfort from wearing sensors or equipment during sleep. The equipment may bother you or disturb your sleep. Some people feel tired the next day.

Optional physiology sleep study:
If you take part in the optional sleep lab study, air pressure may be briefly lowered for a few breaths, which may feel unusual or wake you up. These changes are short and are stopped if they cause discomfort. Your sleep may be interrupted during the night.

Questionnaires:
Some questions about sleep and daily functioning may feel personal or uncomfortable to answer. You may skip any questions you do not want to answer.

Privacy and confidentiality risks:
There is a small risk that your private information could be seen by someone who is not part of the study. Steps are taken to protect your information, such as using coded data and secure computer systems.

You should understand that the risks listed above are related to the **research tests only**. Risks related to your medical care, including surgery or medical treatment, will be explained to you separately by your medical team as part of routine care.

What other treatments or procedures are available for your condition?

You do not have to take part in this research study to be treated for obstructive sleep apnea.

Other treatments or procedures that may be available to treat obstructive sleep apnea include:

- **Continuous positive airway pressure (CPAP)** therapy
- **Oral appliance therapy** (a mouthpiece worn during sleep)
- **Surgery** to the throat, jaw, or airway
- **Weight loss and lifestyle changes**
- **No treatment**, if you choose

Your doctor can talk with you about these and other treatment options and help you decide what is best for you.

Can you still get medical care within Mass General Brigham if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Mass General Brigham now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

Yes. You will be paid for completing certain research procedures in this study. Payment is based on which study activities you complete.

- You will receive $150 for completing the baseline and follow-up study procedures, including sleep studies and questionnaires.
- You will receive $75 for each additional sleep study done for research purposes.
- If you take part in the optional overnight physiology sleep study, you will receive an additional $175.

You may receive up to $525 total if you complete all research procedures. You will also be reimbursed for reasonable parking and transportation costs related to study visits, up to a total of $100.

If you do not complete the entire study, you will be paid only for the research procedures you complete. If a sleep study needs to be repeated because the data were not usable, you will not be paid extra for the repeat study.

You may be asked to provide your Social Security number to be paid for taking part in this study. Money received from participating in research is considered taxable income according to federal tax law. If your total payments from Mass General Brigham are over $2000 per year, Mass General Brigham will report these payments to the Internal Revenue Service. If this happens, you will receive a 1099 form from Mass General Brigham. If you have questions about this, please contact the person in charge of this study**.**

We may use your samples and information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples or information are used for this purpose.

What will you have to pay for if you take part in this research study?

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

For this study:

- The research-related sleep studies and questionnaires done only for research purposes will be paid for by study funds.
- Medical care that is part of your usual treatment for sleep apnea (such as clinic visits, surgery, anesthesia, device care, or hospital stays) will be billed to you or your health insurer as it would be if you were not in the study.
- You may be responsible for co-pays, deductibles, or other costs required by your insurance for routine care.

If you have questions about possible costs, please ask the study team. We can also help connect you with Patient Financial Services to review coverage and expected costs.

What happens if you are injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Mass General Brigham to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why:

- Mass General Brigham researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Mass General Brigham ethics board or an ethics board outside Mass General Brigham that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Mass General Brigham who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)

- Other: Researchers within or outside Mass General Brigham, for use in other research as allowed by law.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any legal action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay, including as described in this form. For example, you may give them permission, as you are doing in this form, to release information to insurers, medical providers or other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Certain information from the research may be put into your medical record and will not be covered by the Certificate. This may include records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record.

Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate.

Even with these measures to protect your privacy, once your identifiable information is shared outside Mass General Brigham, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research may be published in a medical book or journal or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Optional Physiology Sleep Study

You may be asked to take part in an optional overnight physiology sleep study as described earlier in this form. This study is **not required** for participation in the main research study.

Your decision about whether or not to take part in this optional study will **not affect your participation in the main study or your medical care**.

Please indicate your choice below:

☐ **YES**, I agree to take part in the optional overnight physiology sleep study.

☐ **NO**, I do NOT agree to take part in the optional overnight physiology sleep study.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

I give my consent to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

_____
Print Name

_____ _____ _____
Subject Signature Date Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.

- I have answered all questions about this research study to the best of my ability.

Print Name

Signature of Study Doctor or Person Obtaining Consent

Date

Time (optional)

Consent Form Version Date: 04/29/2026