SleepSMART Sub-Study Eligibility Form
Subject ID:

Inclusion Criteria:	**Yes**	**No**
Sleep SMART participants who completed the Nox T3 sleep apnea testing and have sufficient data from that test	☐	☐
Ineligible for the CPAP run-in night as part of Sleep SMART. Specifically, a valid Nox T3 sleep apnea test report showed: a. REI <10 b. CAI ≥50% of the REI c. Or, both REI <10 and CAI ≥50% of the REI	☐	☐

Exclusion Criteria:	**Yes**	**No**
Current mechanical ventilation (can enroll later if this resolves) or tracheostomy	☐	☐
Anatomical or dermatologic anomaly that makes use of CPAP interface unfeasible	☐	☐
Severe bullous lung disease	☐	☐
History of prior spontaneous pneumothorax or current pneumothorax	☐	☐
Hypotension requiring current treatment with pressors (can enroll later if this resolves)	☐	☐
Other specific medical circumstances that conceivably, in the opinion of the site PI, could render the patient at risk of harm from use of CPAP	☐	☐
Massive epistaxis or previous history of massive epistaxis	☐	☐
Cranial surgery or head trauma within the past 6 months, with known or possible CSF leak or pneumocephalus	☐	☐
Recent hemicraniectomy or suboccipital craniectomy (i.e. those whose bone has not yet been replaced), or any other recent bone removal procedure for relief of intracranial pressure	☐	☐
Current receipt of oxygen supplementation >4 liters per minute	☐	☐
Current contact, droplet, or respiratory/airborne precautions	☐	☐

Name of Investigator: _____

Signature of Investigator: _____ Date: _____

NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Sleep for Stroke Management And Recovery Trial (Sleep SMART) validation substudy

Sponsor/Protocol Principal Investigator: Devin L. Brown, MD, MS; University of Michigan

Performance Site Principal Investigator: Steven Messé. MD

Performance Site: The Hospital of the University of Pennsylvania

Participant Name: _____

Telephone Number: _____

If applicable,
Legally Authorized Representative Name: _____

Telephone Number: _____

KEY INFORMATION

Purpose of the Study:	Test the usefulness of information from a continuous positive airway pressure (CPAP) device in identifying sleep apnea.
Length of the Study:	Typically one night.
Risks:	The most common risk is discomfort related to wearing the mask or using CPAP. See section titled "What are the Risks and Discomforts of the Research Study?" for additional risks related to the study.
Benefits of the Study:	The researcher and sponsor of this study do not promise that you will receive any benefits from this study.
Alternative procedures:	You can talk to your doctor about more detailed sleep testing and then, if appropriate, CPAP treatment.

INTRODUCTION

The study doctor wants to know if you would like to be part of a research study. This informed consent document contains important information about the research.

If you have any questions about or do not understand something in this document, you should ask the study doctor or study staff. You should also discuss your participation with anyone you choose in order to better understand this study and your options.

Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information.

You may choose either to take part or not to take part in this research study. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

If you are acting as a representative to give consent for another person to participate in this study, “you” throughout this consent document refers to that individual.

The obligation of a representative is to try to determine what the individual would do if competent, or if the subject's wishes cannot be determined, what the representative thinks is in the person's best interest. If possible, an attempt should be made to obtain permission from the individual. Some persons may resist participating in a research protocol that has been approved by their representatives. Under no circumstances may individuals be forced to participate.

WHY HAVE YOU BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You are being asked to take part in this research study because you recently completed participation in Sleep SMART. Your participation ended because you did not have enough obstructive sleep apnea or had too much central sleep apnea to be eligible to continue.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research study is to see how well the information obtained from a sleep apnea treatment machine called CPAP can be used to identify sleep apnea. As part of Sleep SMART, you already had a Nox T3 sleep apnea test. We would like to compare these results with the results obtained from a CPAP machine. This CPAP machine automatically determines how much pressure it should deliver to keep your throat open. From a full night of use, we will be able to see how much pressure the machine determined you needed. The CPAP machine also sees how many times your

breathing decreased or stopped while you used it. We think these two pieces of information might be useful in identifying who has sleep apnea. If the information from a CPAP machine can accurately identify sleep apnea, we may be able to avoid formal sleep apnea tests, like the one you took. In the future, this would allow us to treat patients who have had a stroke with CPAP more quickly – without a separate night for a sleep apnea test. The U.S. Food and Drug Administration (FDA) has approved CPAP for the treatment of obstructive sleep apnea. You may not have obstructive sleep apnea, in which case you are unlikely to receive any benefit from CPAP use. However, by participating in this research, you could help other patients in the future who do have obstructive sleep apnea.

As described in the Sleep SMART consent form, the Nox T3 is not the best available method to diagnose sleep apnea. The best available method is a more complicated test that is often not tolerated well by hospitalized patients who have had a stroke or TIA. If the Nox T3 test shows you have sleep apnea, it is likely that a more complicated test would also show sleep apnea. However, if the Nox T3 shows you have little or no sleep apnea, you still may want to talk to your doctors about sleep apnea. It is still possible that you have it, but that we were not able to see it. If you have central sleep apnea, you should talk to your own doctors about it.

If you are not able to use the CPAP for at least 4 hours, or use of the CPAP seems to cause central sleep apnea, you should talk to your own doctor about whether you should have any further follow-up or whether other research opportunities may exist.

HOW LONG WILL YOU BE IN THE RESEARCH STUDY?

You will be in the research study for approximately one night.

The researcher may decide to take you off this research study at any time.

You may withdraw from the study at any time. If you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first so that stopping can be done safely. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful to you.

WHO IS CONDUCTING THE RESEARCH STUDY?

This study is funded by the National Institutes of Health.
This study is conducted by Devin L. Brown at the University of Michigan.
Medical supervision for the study is provided by Steven Messé, MD.

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?

About 120 people will take part in this study at 5-30 sites across the United States. A total of 10 people will take part in this study at The Hospital of the University of Pennsylvania.

WHAT IS INVOLVED IN THE RESEARCH STUDY?

You will have the following tests and procedures:

We will have you try out one or more CPAP masks and adjust the mask to make it more comfortable. You will practice taking it on and off. You will use CPAP for about 15-20 minutes before you go to bed to help you get used to it. You will then wear a mask and use the self-adjusting CPAP machine overnight. This type of CPAP machine automatically determines how much pressure it should deliver to keep your throat open. The machine adjusts to give you the smallest amount of pressure that you need. If you do not use it for at least 4 hours, we may ask you if you would like to try it again on a subsequent night(s). We will collect information from the CPAP machine about the pressure delivered, breathing pauses you may have had while using it, and air that may have leaked from the mask.

OTHER INFORMATION ABOUT STUDY PROCEDURES

You are not expected to need any time to recover from participating in this study.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Principal Investigator and study staff.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Principal Investigator or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Principal Investigator or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Ask questions as you think of them.
- Tell the Principal Investigator or research staff if you change your mind about staying in the study.

While participating in this research study, you should not take part in any other research project without approval from the Principal Investigator of each study. This is to protect you from possible injury arising.

WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?

Participation in this research involves the following risks:

Very common (may occur in between 1 out of 2 and 1 out of 10 people): Wearing the CPAP mask may be uncomfortable. Dry nose, dry mouth or throat, skin irritation from the mask, or initial difficulty falling asleep can all occur.

Common (may occur in between 1 out of 10 and 1 out of 100 people): More severe discomfort from the mask, dry eyes, nose stuffiness, nose bleeds, runny nose, stomach bloating, a feeling of claustrophobia.

Uncommon (may occur in between 1 out of 100 and 1 out of 1000 people): Skin breakdown, infection, or allergy related to the mask. CPAP can bring on pauses in breathing in some patients.

Very rare (may occur in less than 1 out of 10,000 people): A medical condition may exist that could increase risk for someone to use CPAP. For example, some lung diseases could increase risk that CPAP would cause a pneumothorax, in which air becomes trapped between the linings that cover the lungs. This would be a serious side effect, but its occurrence is extremely rare.

There may be unknown or unforeseen risks associated with study participation

WHAT ARE THE RISKS OF STOPPING YOUR CURRENT TREATMENT?

If you experience improvement in daytime sleepiness after using CPAP, this may go away after you stop using CPAP.

WHAT ARE THE REPRODUCTION RISKS?

CPAP is not known to pose a risk to you or your fetus. However, untreated sleep apnea could increase the risk of health-related issues for you, your pregnancy, or your newborn baby.

CPAP treatment may have negative effects on a fetus that are not currently known.

ARE THERE BENEFITS TO TAKING PART IN THE RESEARCH STUDY?

If you agree to take part in this research study, there may not be a direct benefit to you. We hope the information learned from this research study will benefit other patients with stroke or TIA in the future.

Potential benefits to you may include improvement in sleepiness or other symptoms of sleep apnea such as snoring – likely limited to the night of and day after CPAP use. If you do experience these benefits during the research, you could ask your doctors about whether you might need additional testing or treatment with CPAP outside this research study.

WHAT OTHER CHOICES FOR CARE ARE THERE?

You can talk to your doctor about getting more detailed testing of your sleep and then if appropriate, CPAP treatment.

WHAT IS THE CLINICAL TRIALS REGISTRY?

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

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.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

You may choose either to take part or not to take part in this research study. If you decide not to participate, you do not lose any benefits to which you would otherwise be entitled. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

You will be told of any important new information that is learned during the course of this research study, which might affect your health, welfare or your willingness to continue participation in this study.

Nothing in this consent document waives any legal rights you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Study center/sponsor employees and their family members do not have to be in this study. No one should influence or pressure you to be in this study. An employee's or his/her family member's decision to be in the study, or to leave the study early, will not affect the employee's job or job benefits.

WHAT IS A CERTIFICATE OF CONFIDENTIALITY?

To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this certificate, the researchers may not disclose information (for example by court order or subpoena) that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

Even with the Certificate of Confidentiality, if the investigator learns about abuse of a child or elderly person or that you intend to harm yourself or someone else, or about certain communicable diseases, they will report that to the proper authorities. If keeping information private would immediately put you or someone else in danger, the researchers would release information to protect you or another person.

AVAILABILITY OF INFORMATION

You will receive a copy of this signed and dated consent document.

You will be told about any new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

Any results from research related tests or assessments will not be used in your clinical care.

WHAT ARE YOUR COSTS TO BE IN THIS STUDY?

No additional costs will be charged to you or your insurance company related to your participation in this study.

WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?

You will receive $100 in compensation for the time you spend using CPAP overnight. Payments will be made to you with Greenphire ClinCard.

Greenphire ClinCard Reimbursement Program: Greenphire is a company working together with the University of Pennsylvania to manage your compensation. You will be issued a Greenphire ClinCard, which works like a debit card. When your participation is complete, funds will be approved and loaded onto your card. The funds will be available within one business day and can be used at your discretion. You will be issued one card

for the duration of your participation. In order for Greenphire to be able to reimburse you via the ClinCard, Greenphire needs to collect certain information about you from your study doctor, including your name, address, and date of birth.

All information about you is stored in a secure fashion and is deleted from Greenphire's system once the study has been completed. Your information will not be shared with any third parties (including the study sponsor) and will be kept completely confidential.

By signing this consent form, you consent to providing all the before mentioned personal information that is needed to set up payments. You agree that the information you provide is used by Greenphire to perform reimbursement payments to you.

By registering with ClinCard system and using the ClinCard, you consent to participate in the ClinCard program.

Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year.

WHAT COMPENSATION IS AVAILABLE IN CASE OF INJURY?

Your hospital or physician's office will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. You will be responsible for any associated co-payments or deductibles as required by your insurance. If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs.

You do not waive any liability rights for personal injury by signing this form.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator. The researcher's name and phone number are listed in the consent form.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE AND CONFIDENTIAL?

Your identity will be kept as confidential as possible as required by law. Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier outside of NIH StrokeNet. Your research records may be disclosed outside of The Hospital of the University of Pennsylvania, but in this case, you will be identified by a unique code number. This information will be kept in a secure location and access limited to research study personnel. The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed**.**

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

Authorization to Use Your Health Information for Research Purposes

A federal regulation known as the Privacy Rule gives you certain rights concerning the privacy of your health information. Researchers covered by this regulation are required to get your authorization (permission) to use and disclose (share with others) any health information that could identify you. You should have received a Notice of Privacy Practices when you received health care services here. If not, let us know and a copy will be given to you.

If you sign this informed consent document, you are giving permission for the use and disclosure of your health information for purposes of this research study. You do not have to give this permission. Your health care outside of the study, payment for your health care, and your health care benefits will not be affected if you choose not to sign this document. However, if you do not sign this document, you will not be able to participate in the study.

Who Will Use and Disclose My Health Information? The study doctor and research staff (the study team) may use your health information to conduct, review, and determine the results of the study. The study team may also use your information to prepare reports or publications about the study. However, your name will not appear in any report or publication without your permission.

What Health Information will be Used and Disclosed? The study team will record your medical history, the treatment you receive, and the results of examinations and tests done during the study on study forms. The study team will send the completed study forms to the study sponsor. Representatives from the groups identified below may need to look at your medical records to make

sure that the information on the study forms is correct or that the study was conducted properly. Your medical records may include other health information about you and may include documents that directly identify you. Reviews like that will take place at the study center or where the medical records are stored and can take place after the study is over.

Who Will Receive My Health Information? Your study information or medical records (as described above) or both may be shared with the following people or groups:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services.
- The funder of this research, National Institute of Health.
- The representative of companies/Institutions working on the study on behalf of the Sponsor may have access to, inspect and review your information during and after the study for verification of clinical and scientific research procedures and/or data.
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study.
- Other collaborating institutions.
- The results of imaging studies may be disclosed to outside institutions, not directly involved in this research study, as part of a collaborative imaging project. Your name and other identifying information will not be disclosed.
- Department of Health and Human Services (DHHS) agencies.
- The StrokeNet Central Institutional Review Board and any other committees responsible for overseeing the research.
- StrokeNet Central Institutional Review Board Human Research Protection Program staff.
- The StrokeNet National Data Management Center (NDMC), housed in the Data Coordination Unit (DCU) in the Department of Public Health Sciences at the Medical University of South Carolina (MUSC).
- Study team members at the University of Michigan

Will My Information be Protected by the Privacy Rule After it is Disclosed to Others? The Hospital of the University of Pennsylvania is required by the Privacy Rule to protect your health information. After your information is shared with others, such as the study sponsor, it may no longer be protected by the Privacy Rule. The people who receive this information could use it in ways not discussed in this form and could disclose it to others. The sponsor will use and disclose your information only for research or regulatory purposes or to prepare research publications. In addition to using it for this study, the sponsor may reanalyze the study data at a later date or combine your information with information from other studies for research purposes not directly related to this

study. The goal of any such research would be to learn more about drugs, devices or diseases or to help design better studies in the future. When using your information in these ways, the sponsor may share it with regulatory authorities, other researchers, its business partners, or companies it hires to provide research-related services.

What Happens if I Leave the Study Early? If you stop participating in the study early for any reason, the study team will tell the sponsor why. If the study team asks you to come to any more study visits and you agree, the study team will send the sponsor information from those visits as well. All information collected about you may continue to be used and disclosed.

Will My Authorization Ever Expire? This Authorization does not have an expiration date. The study team may need to correct or provide missing information about you even after your study participation is over and a review of your medical records may also take place after the study is over.

May I Take Back My Authorization? You have the right to take back (revoke) your Authorization at any time by writing to the person in charge of this research study whose information is listed on the front of this document. If you revoke your Authorization, the study team will not collect any new health information about you. However, they can continue to use and disclose any already-collected information if that is necessary for the reliability of the study. The sponsor can also still keep and use any information that it has already received. If you revoke your Authorization, you can no longer continue to participate in the study.

May I Look At My Study Information? You have a right to see and make copies of your medical records. However, to ensure the reliability of the study, you will need to wait to see your study records until the study is completed.

Future Use

Information that could identify you will be removed from the study data. After removal, the study data could be used for future research studies. The study data could also be given to another researcher for future research studies. This may be done without getting additional permission from you.

Will access to my medical record be limited during the study?

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make medical or billing decision about you (e.g., if included in your official medical record).

Please indicate below whether you want us to notify your primary care physician or your specialist of your participation in this study. Please initial your selection below.

____I **want** the researcher to inform my primary care physician/specialist of my participation in this study.
____I **do not want** the researcher to inform my primary care physician/specialist of my participation in this study.
____I do not have a primary care physician/specialist.
____The researcher is my primary care physician/specialist.

Who Can Answer Your Questions?

If you have questions, concerns, complaints and or suggestions about this research study or to report a research-related injury, please contact the Principal Investigator: Steven Messé, 215-349-5990.

You can also call the StrokeNet CIRB at 513-558-5259, Monday-Friday 8AM--5PM EST if you:

- Think the research has hurt you.
- Have general questions about giving consent or your rights as a research participant in this research study.
- Have questions, concerns, complaints and/or suggestions about the research, cannot reach the research team or you want to talk to someone else.

To report complaints or concerns to an independent agency in an anonymous and confidential manner, please call the Research Compliance Hotline at 1-800-889-1547.

Investigator Information:

Devin L. Brown MD, MS; University of Michigan
Principal Investigator Name

The Hospital of the University of Pennsylvania
Local Site Name

Steven Messé, MD 215-349-5990
Local Principal Investigator Name Telephone Number 24 hr Emergency Contact

I have read or someone has read to me, this Informed Consent Document which describes the purpose and nature of this research. I have had time to review this information and have been encouraged to ask questions. If I do not participate or if I discontinue my participation, I will not lose any benefits or any legal rights. My participation in this research is completely voluntary. I have received (or will receive) a copy of this signed and dated document for my records and future reference. I have been given the information about the use and disclosure of my health information for this research study.

I give my consent to participate.

_____
Signature of participant Date

_____
Print Name

OR

_____
Signature of legally authorized representative Date

_____ _____
Print Name Relationship to Participant

Person Obtaining Consent

I attest that the requirements for informed consent for the medical research project described in this document have been satisfied – that the participant has been provided with the Experimental Subject's Bill of Rights, if appropriate, that I have discussed the research project with the participant and explained to him or her in non-technical terms all of the information contained in this informed consent document, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered.

_____
Signature of Person Obtaining Consent Date

_____
Print name

The following witness line is to be signed only if the consent is provided as a summary document and accompanied by a short form foreign language consent.

_____

Witness Date

_____

Print name

WITNESS STATEMENT:

The participant was unable to read or sign this consent document because of the following reason:

___ The participant is illiterate
___ The participant is visually impaired
___ The participant is physically unable to sign the consent document. Please describe:

_____

Other (please specify):

_____

_____

I confirm that I was present as a witness for the consent process for this study. I confirm that the participant named above was read the information in the consent document and that the participant has agreed to take part in the research study.

_____ _____

(Date) (Printed Name of Witness)

_____

(Signature of Witness)

_____ _____

(Date) (Printed Name of Individual Obtaining Consent)

_____