NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

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

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

Performance Site Principal Investigator: Natalie Kreitzer, MD

Performance Site: University of Cincinnati Medical Center, UC Gardner Neuroscience Institute, UC Health, LLC and UC Physicians Company, LLC associated offices and clinics.

Participant Name: _____

Telephone Number: _____

If applicable,
Legally Authorized Representative Name: _____

Telephone Number: _____

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 this form or do not understand something in it, 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.

If you are acting as a representative to give consent for another person to participate in this study, “you” throughout this consent form 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 are age 18 or older, had a recent stroke or transient ischemic attack (TIA) often called a “mini-stroke,” and are still in the hospital (initial hospitalization or rehabilitation stay).

You should not take part in this research if you have had any of the following: prior pneumothorax (punctured lung), massive nose bleeds, severe head trauma or head surgery in the last 6 months that could have caused a leak of the fluid around your brain, are currently using continuous positive airway pressure (CPAP, or its alternatives), are unable to use CPAP now, or are currently pregnant. The study team will talk to you to make sure that you are eligible.

WHY IS THIS RESEARCH BEING DONE?

After a stroke many patients have problems with physical function (such as arm or leg weakness), speaking (such as forming or findings words), or other functions of the brain. Patients who have had a stroke or TIA are also at elevated risk of future strokes and heart-related problems. We are looking for a way to improve recovery after stroke, reduce disability, and help reduce the risk of future strokes, heart attacks, and death.

Sleep apnea is a disorder that affects most patients – about 75 out of 100 – after stroke or TIA. In these cases, sleep apnea often goes unnoticed because the typical symptoms, snoring and daytime sleepiness, may not occur. Even though the effects of sleep apnea on the brain and body can be dramatic, people often don’t realize that they have sleep apnea. In sleep apnea, breathing stops or nearly stops, over and over again, while you sleep. This is caused by your throat narrowing or closing off many times per hour during sleep. This blocks air from flowing in and out of your lungs. With each breathing pause, your body’s oxygen levels can decrease. This may be particularly problematic after a stroke or TIA when the brain is trying to heal. The pauses in breathing from sleep apnea cause strain on many parts of your body, including your brain, heart, and blood vessels. Left untreated after stroke, sleep apnea has been linked to worse physical abilities, worse thinking, worse mood, and a higher risk of death and another stroke. Continuous positive airway pressure (CPAP) – if you use it while you sleep – can make your breathing normal again. The U.S. Food and Drug Administration (FDA) has approved CPAP for the treatment of obstructive sleep apnea.

We think CPAP treatment may improve outcomes after stroke. CPAP might improve your physical recovery, ability to speak, your thinking, and any other symptom you have from your stroke. It also may help prevent another stroke, or help prevent a heart attack or death. Although we have many reasons to think that CPAP might help you, no study has truly answered the question: does CPAP treatment have a good, bad, or no effect on stroke recovery or stroke prevention? This research study is designed to test whether people with recent stroke or TIA benefit from CPAP.

HOW LONG WILL YOU BE IN THE RESEARCH STUDY?

You will be in the research study for approximately 6 months.

The researchers may decide to take you out of this research study at any time. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

You may leave the study at any time. If you leave, there will be no penalty to you and your regular medical care will not be affected. If you decide to stop participating in the study, we do 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 Dr. Natalie Kreitzer.

Dr. Jeffrey Durmer, a sub-investigator on the study, is Chief Medical Officer for the company, FusionHealth, that provides the CPAP support for this study. He is also the Chief Medical Officer for Nox Medical, the company that makes the sleep apnea testing device used in the study. The University of Michigan (UM) and StrokeNet's CIRB have reviewed and approved Dr. Durmer's involvement in the study in accordance with UM's management and oversight. This disclosure is made in case this relationship affects your willingness to participate in the study.

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?

A total of 15,010 patients are expected to enroll in this study and be screened for sleep apnea across about 110-150 sites in the United States. About 3,000 are expected to participate in the second part of the study, in which sleep apnea treatment is tested.

WHAT IS INVOLVED IN THE RESEARCH STUDY?

Brief overview:
In this study, we will first test you for sleep apnea. If you have enough obstructive sleep apnea to participate, you will try using CPAP for one night. If you use it successfully, you will then be assigned to one of two treatment groups for 6 months. One group receives CPAP and the other does not. If you are in the CPAP group, we will provide support to help you use CPAP, including a sleep coach and the supplies you need.

The details
Your medical records will be reviewed to collect information about your stroke, stroke care, and risk factors for stroke. We will ask you questions about your current and recent health.

There are two main parts of this study. The first part (one or two nights) applies to everyone and is to determine whether you are eligible to continue to participate in the second part (six months).

PART 1 (usually one or two nights): We will test you for sleep apnea with a device called the Nox T3 portable respiratory sleep monitor. The monitor records your breathing, blood oxygen, pulse, heart rhythm, and movements during the night. It also records sound to capture your snoring, but could also capture conversations you have while the device is on.

You will wear a soft oxygen sensor over your finger, small tubes at your nose, bands around your chest and around your abdomen (both over your night clothes). Tape may be put on your face to hold the tubing in place.

The small box that makes the recordings will be attached to your gown or shirt. You will wear another on your wrist.

You will wear the Nox T3 for one night. If the recording does not function correctly, we may ask you to try again on one or more nights.

The Nox T3 will also record a simple form of electrocardiogram (EKG) to check your heart rhythm. This will require that we put small electrode patches on the skin of your chest.

The information from the Nox T3 is downloaded and processed by a company called FusionHealth. This company specializes in sleep medicine. The information is processed by computer software and reviewed by a technologist. It will not be reviewed by a doctor. The EKG information will not be reviewed to assess for heart rhythm problems.

We will tell you if your test results indicate that you have:
(1) little or no significant sleep apnea,
(2) obstructive sleep apnea, or
(3) a different type of sleep apnea, called central sleep apnea, in which the brain fails to signal the body to breathe sufficiently.

If you have enough obstructive sleep apnea to participate, you may continue on with the research study.

If you do not have enough obstructive sleep apnea, your participation in the study is over.

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 qualify for the study, detailed results of the test will be provided to you and your current team of doctors after you complete the research study, about six months after you enrolled if you finish part 2.

Sleep apnea is typically treated by nightly use of a machine that provides CPAP. The machine is connected to a mask that you wear over your nose, over your nose and your mouth, under your nose, or at your nostrils. We will try to find the mask type that is most comfortable and effective for each person. The machine supplies pressurized air through the mask so it reaches your throat. The pressurized air holds your throat open while you sleep. If you have enough obstructive sleep apnea to participate, you will try using CPAP for one night. A sleep study in a sleep laboratory is often done to determine what CPAP setting a patient needs to breathe well. In this type of sleep study, CPAP settings are gradually increased until a pressure is shown to work.

As a sleep study in a sleep laboratory often is not practical or appealing just after stroke, we will use a special, self-adjusting CPAP machine to determine what pressure works best for you continuously, in real time. You will wear a mask and use the self-adjusting CPAP machine for one night in the hospital. This is the CPAP “test night.” 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. We think that this machine is just about as effective as a study in a sleep laboratory.

This CPAP “test night” will help us make sure that CPAP does not cause you to have new central sleep apnea. The CPAP “test night” also will help us make sure you can easily use the CPAP.

If you are able to use the CPAP for at least 4 hours during the CPAP “test night” and the CPAP does not bring on central sleep apnea, you may continue with the research study. If you do not use CPAP for at least 4 hours during the “test night,” but you are interested in trying again, you may be eligible for a second test night(s).

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, your participation in the study is over. If this happens, you should talk to your own doctor about whether you should have any further follow-up or whether other research opportunities may exist.

Part 1 is routinely performed during your stroke or rehabilitation hospitalization. At a few hospitals, admission to a research unit, sleep laboratory, or other unit may be possible to complete these components. If this occurs, it will not be charged to you or your insurance company. Similarly, at some hospitals, these components may be completed in your home. These options are not available at all hospitals or for all participants.

PART 2 (6 months): You will be “randomized” into one of the study groups described below. Randomization means that you are put into a group completely by chance. It is like flipping a coin, you have a 50/50 chance.

You will be randomly assigned to have either usual medical care, for stroke and TIA patients, plus CPAP (one group), or the same usual medical care without CPAP (another group), for the next 6 months.

You will have an equal chance of being in either specific group. By having some participants use CPAP and some not use it, we will be able to figure out whether recovery or prevention of another stroke is better one way or the other.

If you receive CPAP, we will give you the CPAP device to bring home with all of the equipment you need and show you how to use it. The CPAP device is called the “AirSense 10 Autoset” or “AirSense 11 Autoset”. It is a device that continually adjusts the air pressure needed to keep your airway open. The amount of pressure you need can change depending on your body position, sleep stage, nose congestion, medications, and other factors This CPAP device personalizes your treatment. We ask that you use it every night, for the whole night, while you sleep. You should also use it if you take a nap during the day. If you are hospitalized or take a trip during the next 6 months, you should take the machine with you.

Available to you free of charge is a website and smartphone app called myAir, where you can track your own CPAP progress. The tool provides personalized support through emails. You can also select to receive these messages through texting. Many patients who use CPAP find myAir to be extremely helpful and some even find it to be fun. People who use myAir tend to succeed better in using their CPAP. The app allows you to track your usage hours, mask seal, and effectiveness of the CPAP. The app provides a nightly score based on these factors, and you can earn “badges” for your performance. Please visit this website: myair.resmed.com to learn more about it. This service is provided by ResMed, the company that manufactures the CPAP devices used in Sleep SMART. Their standard privacy rules apply (see their website for more details

A team of health care professionals including a sleep coach at a company called FusionHealth, near Atlanta, Georgia will provide support to help you use CPAP regularly. The CPAP machine is equipped with wireless cellular service. This is used to provide information about your CPAP use to the professionals at FusionHealth, and to some research study team members. The cellular service usually works very well.

Should it fail, you may be asked to return data cards within the CPAP device by mail monthly. New cards will be mailed back. You may also be provided the option to drive your CPAP device to a local shop (e.g. Starbucks) and plug it in there, where cellular coverage is likely to be better.

Your sleep coach at FusionHealth will monitor your CPAP use and contact you by phone to provide support. FusionHealth may discuss your sleep apnea test results with you but will not share the results report. They may also contact someone close to you whose information you provide, such as a caregiver, to help you with your CPAP use.

If you go to an inpatient rehabilitation facility or nursing home following your hospitalization, FusionHealth may contact you, someone close to you, or a provider or nurse at the facility to help you with your CPAP.

We also encourage you to phone your sleep coach at 470-655-6688 for support. A study team member may offer to store this number in your cell phone. That way, when your sleep coach calls you, you will recognize the number. We ask that you call your sleep coach at FusionHealth before your hospital discharge just to make an initial contact. We hope that contact with the sleep coach will be very helpful to you. If you complete a call with your sleep coach during the first 7 days of discharge from your current hospitalization, Sleep SMART will email you a $10 Amazon gift card as a thank you (if you provide an email address).

FusionHealth can provide alternative masks if needed; send you other equipment by mail; give you good suggestions; give you a different type of PAP machine called bilevel PAP, if CPAP is not working well for you; and help with many of the challenges some people encounter with CPAP. They also want to get to know you and hear how you are

doing with CPAP. This means you don't need to have a problem first in order to answer their call or reach out to them. The cost of your sleep coach's services is covered by the study.

FusionHealth experts include sleep doctors and staff with a great deal of experience helping patients manage CPAP. Your CPAP support team is able to talk with you on the phone or over a video connection, using the internet, if you prefer. They are able to stay in touch with you by text, phone, or email, if you give them permission. You should be aware though that text and email are not necessarily secure (private) ways to share private health information. Your sleep coach may offer to have you text a picture of your face to help your coach select the mask that best fits your face. If you elect to do this, your photo may be stored in FusionHealth's secure electronic system.

FusionHealth may ask you if it is ok for them to record a telephone call with your sleep coach. If you agree to have the call recorded, they will use the call for quality control and training purposes. If you prefer for the call not to be recorded, you can decline the recording. They will not record a call with you without your permission.

If FusionHealth finds that they are not able to help you with your CPAP, they may contact the researchers at the hospital where you enrolled in Sleep SMART. The researchers may refer you to local sleep experts who might be able to assist you with your device. The cost of any clinical care provided by a local sleep expert would not be covered or reimbursed by Sleep SMART.

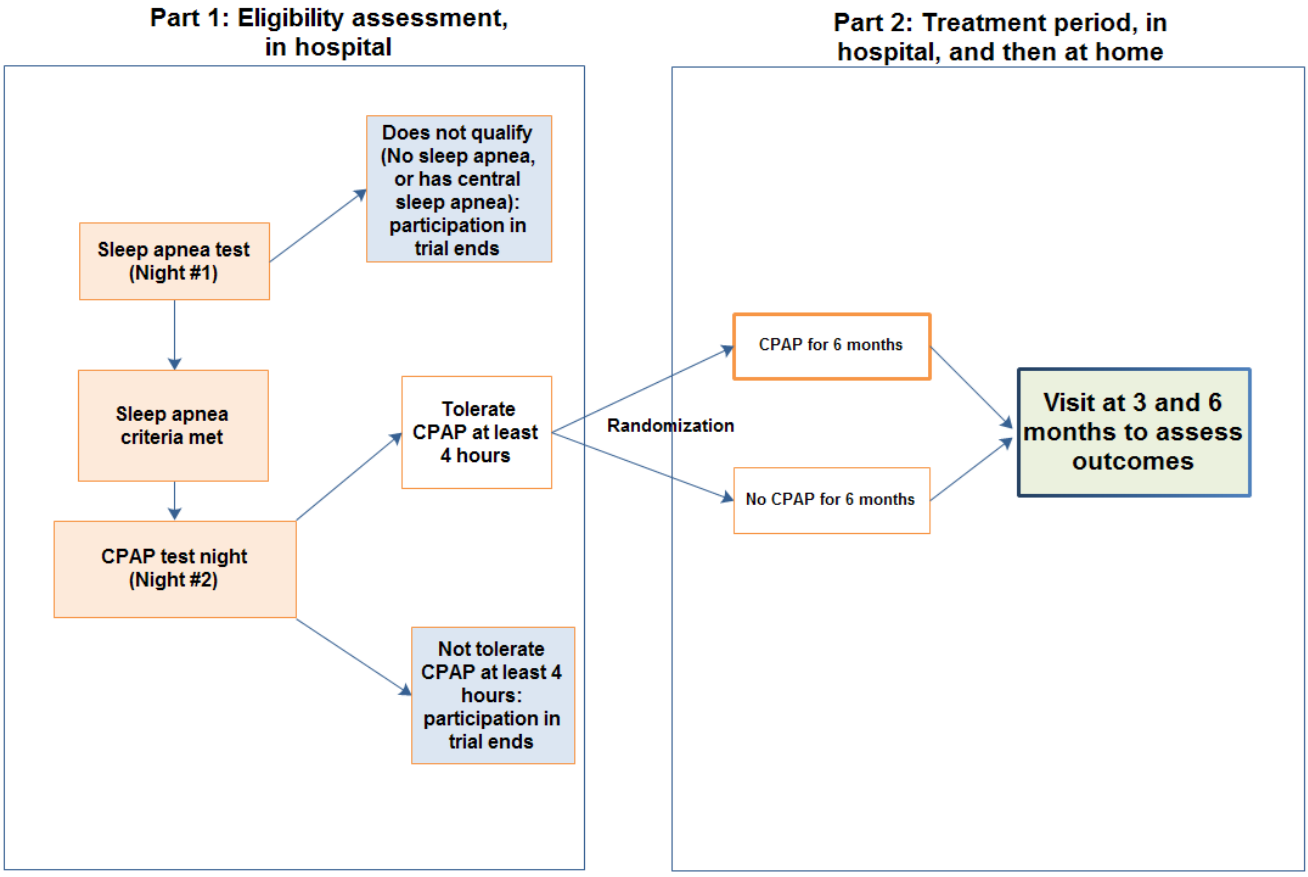
If you are treated by a local sleep expert, we would like to obtain information about your use of the new treatment device. We may ask you to mail data cards from the device back to FusionHealth. Or it may be possible for FusionHealth to equip the device with an electronic transmitter so the information is sent to FusionHealth automatically.

At certain times during the trial, we may also have another opportunity to support you with a "chatbot" service. A chatbot is a software program that is designed to interact with you as a person would. The chatbot is not a medical provider. If it is available, and you would like to participate in this opportunity, you will start the process by texting a couple pieces of information to the chatbot, "Tess". Tess can provide emotional wellness support, reminders about Sleep SMART appointments, CPAP support, or just have conversations with you. All of your communication with Tess will be by text message. If your cell phone plan charges for texts, charges may apply.

All participants in part 2, including those assigned to CPAP and those not, will come in for study visits around 3 months and 6 months after the randomization. Study visits will take place University of Cincinnati Medical Center, UC Gardner Neuroscience Institute, UC Health, LLC and UC Physicians Company, LLC associated offices and clinics. These follow-up assessments will allow the study team to check on you and are very important to help determine whether CPAP is helpful for stroke patients.

The research team will contact you, or someone close to you whose information you provided, to schedule these visits. At these visits, we will check on you and assess your recovery. This assessment will focus on your brain and nervous system function. This will include a “neurological examination” such as the one you had when you were first seen in the hospital. We will also check your memory, thinking, mood, quality of life, and overall status using questionnaires. We will also check your blood pressure and may assess your walking speed. We will also ask you about any hospitalizations or new symptoms you may have had. If you were seen in an emergency room or a hospital, we will try to collect your medical records from those institutions.

These 3- and 6-month visits are very important. If you cannot return for either of these visits, a researcher may try to go to your home to conduct the visit. If that is not possible, the researchers may try to make some of the assessments by telephone. To schedule the visits, the study team may try to contact you by telephone, email, or text, if you give them permission. You may incur fees through text messaging depending on your text messaging plan. If a researcher cannot contact you, he or she may try to reach you through an alternate contact, such as a close relative or friend, if you have supplied this information. In between visits to the medical center where you enrolled in the study, we may also call you periodically to check on how you are doing. This diagram provides an overview of the design of the study:



This research does not require you to stop any current treatment, or usual care after stroke or TIA.

After your participation in the research study ends, you may keep the CPAP device (AirSense 10 or 11) and related equipment if you were in the CPAP group. Depending on your individual circumstances, it may be reasonable to continue or stop the use of the CPAP after your participation in the study is over. You should discuss this decision with your doctor. However, if you keep using any equipment from the study, you should do so under the supervision of a provider who has experience with treatment of sleep apnea. If you continue to use the equipment after the study is over, you will be responsible for any cost related to maintenance or supplies for this continued use.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Principal Investigator and study staff.
- If you are randomized to use CPAP, make your best effort to use it whenever you sleep: all night, every night, and during any daytime naps.

- If you have trouble using CPAP, contact FusionHealth for assistance.
- 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 help protect you from possible injury arising from involvement with two different research studies at the same time.

Overall, two of the most important responsibilities to consider, if you are thinking about participating in Sleep SMART, are these: First, if you are assigned to use CPAP, you should be ready to give it your very best effort. Some people find CPAP easy, whereas others find that it takes a while to get used to sleeping with it. No participant can be sure CPAP will work for them, but if you participate in Sleep SMART, you should be ready to give it a good try and work with the study team trying to help you succeed. Second, regardless of whether you receive no CPAP; receive CPAP and use it; or receive CPAP and find you cannot use it well, you should be prepared to return at 3 months and 6 months for the follow-up visits. Sleep SMART depends on volunteers like you who make every effort within reason to complete these critical study assessments.

WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?

Risk of the Nox T3 portable respiratory sleep monitor and CPAP Device

- Very common (may occur in between 1 out of 2 and 1 out of 10 people): Wearing the devices may be uncomfortable. Dry nose, dry mouth or throat, skin irritation from the mask, or initial difficulty falling asleep can all occur, especially in the beginning while getting used to using CPAP or finding the mask model that works best for you.

- 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. (If this occurs during the “test night,” you will not be eligible for the second phase of the study.)

- 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.

Untreated, sleep apnea can be life threatening. Excessive daytime sleepiness can cause people to fall asleep at inappropriate times, such as while driving. You should always avoid driving or operating dangerous machinery when you are sleepy.

Electrocardiogram (EKG) Risk
You may experience mild irritation, slight redness and itching at the site on your skin where the electrodes for the EKG sensors are placed. The electrodes may hurt when being removed from your skin.

There may be unknown or unforeseen risks associated with study participation.

There is a risk of loss of confidentiality of your information. . Although every reasonable effort has been taken, confidentiality during Internet communication procedures cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study

You will read more about the protection of your information later in this form. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this study.

WHAT ARE THE REPRODUCTIVE RISKS?

CPAP is not known to pose a risk to you or your fetus should you become pregnant during the course of this study. 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.

If you become pregnant during the course of your participation in this study, you should let your doctor and the research team know immediately. Whether or not you are in the CPAP group, you will continue to be followed in the study. However, the study team will offer to help you find a sleep medicine doctor to address whether your sleep apnea needs attention, for clinical reasons. Treatment cannot come from the study while you are pregnant.

ARE THERE BENEFITS TO TAKING PART IN THE RESEARCH STUDY?

You may not receive any personal benefits from being in this study.

We hope the information learned from this research study will benefit other patients with stroke and TIA in the future.

You will receive information about whether you may have sleep apnea from the sleep apnea test. You will get the specific results of your sleep apnea test when you finish the study.

If the chatbot is available, you may also receive benefits from emotional wellness support provided by the chatbot (who will interact with you by text).

WHAT OTHER CHOICES FOR CARE ARE THERE?

The alternative to participating in this research trial would be to receive standard of care medical treatment, similar to that which will be received by all subjects in the trial. This most often would not involve testing or treatment for sleep apnea. You can talk with your doctors about whether testing and treatment for sleep apnea may be appropriate for you, outside of this research study. Evaluation and treatment outside the Sleep SMART study would likely require visits to a sleep disorders center. Typically, you would have overnight testing, called polysomnography, usually in a sleep laboratory. This provides more detailed testing of sleep and breathing during sleep than the Nox T3 device used in the current study. Treatment most often would involve sleeping with some form of positive airway pressure (PAP), as in Sleep SMART. PAP is often started in a sleep laboratory so that it can be adjusted manually, in real time, to your needs.. Usually, you would visit a durable medical equipment (DME) company to obtain the device, mask, and other supplies. Treatment outside Sleep SMART usually would not include remote support by FusionHealth, or an equivalent service, to help you at home with your PAP use. Instead you would likely travel to a sleep disorders clinic for follow-up visits, and the clinicians there or staff at the DME company would assist you.

WHAT IS THE CLINICAL TRIALS REGISTRY?

A description of this clinical trial will be available on 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 website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT ARE 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.

Nothing in this consent form 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 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. The decision of an employee or his/her family member to be in the study, to decline participation, or to leave the study early will not affect the employee's job or job benefits.

AVAILABILITY OF INFORMATION

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

WHAT ARE YOUR COSTS TO BE IN THE STUDY?

The study will pay for items or services that are provided only because you are in the research study, such as the sleep apnea test mentioned above (the Nox T3) and the 6 months of CPAP if you are in the CPAP group. You and your insurance company will not be charged for the support you receive from FusionHealth, Tess the chatbot, or use of the myAir app/website If you get a bill you think is wrong, call the researchers' number listed below.

You or your health plan will pay for all the things that you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services
- If you are in the CPAP group and you are having problems using your machine even with the help of FusionHealth, we may get a local Sleep Medicine doctor to help you. Insurance may be billed for this.
- MRI if performed for new stroke symptoms as part of routine clinical care

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed below or call your health plan's medical reviewer.

WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?

You will be given $25 after the completion of the study enrollment interview/sleep apnea test. If you qualify for the CPAP test night, you will also receive $25 after that. You will receive $75 after you complete the 3-month visit, and $75 after you complete the 6-month visit. These amounts – a total of $200 if you complete all phases of the research study – are intended to help compensate you for your time, any inconvenience, and travel. Payments will be made to you using a prepaid debit card. The money will be loaded onto your card within one business day of your participation. Details of the debit card system are explained on an additional information sheet. If you are in the CPAP group, you will also be eligible for a $10 gift card if you complete the FusionHealth care team call within 7 days of your hospital discharge.

If you receive payments for being a part of this research study, you may be asked to complete an Internal Revenue Service (IRS) form. The amount you receive may count as income and may affect your income taxes. Your social security number will be required to complete the IRS form.

WHAT COMPENSATION IS AVAILABLE IN CASE OF INJURY?

If you think you have suffered a research related injury, you should promptly notify the Principal Investigator. Your hospital or physician's office will offer care for research-related injuries, including first-aid, emergency treatment and follow-up care as needed. Be aware that your health care payer/insurer might not cover the costs of study-related injuries or illnesses. However, the medical facility at which you enrolled in this research generally will cover such costs. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

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 and FusionHealth, the company that will help some participants with CPAP. If you agree to have a telephone call with FusionHealth recorded, they will store the audio file on a secure server. The recording will not be shared outside of the Sleep SMART/FusionHealth team. They will destroy the recording at the end of the study. You can decide what information you want or do not want to share with Tess the chatbot. The chatbot system maintains strict confidentiality standards that will be described to you before you accept the services, but are also available here: www.x2ai.com/privacy. The CPAP device will communicate through cellular modem with the myAir app/website to make information about your CPAP use available to you Your research records may be disclosed outside of The University of Cincinnati Medical Center, UC Gardner

Neuroscience Institute, UC Health, LLC and UC Physicians Company, LLC associated offices and clinics and FusionHealth, but in this case, you will be identified by a study identification number. Identifiable 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. As FusionHealth may need to contact you to help you manage your CPAP, they will have your name and contact information. They will keep your name and contact information separate from your other data and maintain very strict confidentiality standards to help protect your privacy.

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.

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.

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 form, 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 form. However, if you do not sign this form, 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. FusionHealth will also use health information collected during the study to monitor your CPAP treatment and share this information with you and the study team. 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. You authorize the release of your medical records from the current hospitalization and all hospitalizations during your 6 months of participation. This allows the study team to see if you had an event of interest (e.g., a stroke or heart attack) during the follow-up time period. Information about your health and medical services may be obtained from the Medicare program, if you are a member, and the Uniform Data System for Medical Rehabilitation. 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 sponsor of this research, the National Institutes 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 its Human Research Protection Program staff, and any other committees responsible for overseeing the research.
- StrokeNet National Coordinating Center at the University of Cincinnati.
- StrokeNet National Data Management Center at the Medical University of South Carolina.
- The principal investigators and event assessors at the University of Michigan.
- FusionHealth, the company providing services to the trial to help manage information for the sleep apnea tests and provide care management related to the CPAP.
- If you enroll in myAir, you will provide your personal information, and your CPAP device will transmit data about your CPAP use to this application/website – a service provided by ResMed, the manufacturer of the CPAP device.
- The researchers may need to use the information to create a databank of information about your condition or its treatment. It may be used in the future to perform research related to stroke, sleep apnea, or another topic.
- We may submit information about you that we collect from this research to an existing data repository. A data repository is a large database where many patients' data have been contributed. All identifiable information is removed before the information is sent to the repository so that your information would not be recognized as yours. This includes your name, address, telephone number, etc.

Will My Information be Protected by the Privacy Rule After it is Disclosed to Others? University of Cincinnati Medical Center, UC Gardner Neuroscience Institute, UC Health, LLC and UC Physicians Company, LLC associated offices and clinics 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 form. 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 the 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 summaries of your research test results until the study is completed.

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, or suggestions about this research study or to report a research-related injury, please contact the Principal Investigator at your site: Natalie Kreitzer, MD (304) 687-7813.

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, or suggestions about the research; cannot reach the research team; or 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.

Permission to make contact to schedule visits:

We would like to contact you after your hospitalization for routine purposes including to schedule your 3- and 6-month follow-up appointments. If you check "yes" below, you are agreeing to allow us to contact you by telephone (including leaving voicemails), text, or email. Please check no or yes to each.

Telephone (including voicemail):	☐ No	☐ Yes: Phone number: _____
Other phone/voicemail:	☐ No	☐ Yes: Phone number: _____
Texting:	☐ No	☐ Yes: Phone number: _____
Email:	☐ No	☐ Yes: Email address: _____

Alternative contact for scheduling, helping to reach you, or helping with CPAP:

Name: _____ Phone number: _____

Relationship: _____

Name: _____ Phone number: _____

Relationship: _____

Contact Person:

We would also like to find out some information about you from one of your relatives or friends. This person will be asked questions about your memory and thinking prior to your current illness. If you check “yes” below, you are agreeing to allow us to interview a specific friend or relative of yours, and you will provide the name of this person and contact information if necessary (check one).

☐ No ☐ Yes Name of person: _____

Contact information: _____

Investigator Information:

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

University of Cincinnati Medical Center, UC Gardner Neuroscience Institute, UC Health, LLC and UC Physicians Company, LLC associated offices and clinics.
Local Site Name

Natalie Kreitzer, MD (304) 687-7813
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 form 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.

_____ _____
Name of Participant (PRINT) Telephone Number

_____ _____
Signature of Participant (18 or older with capacity to consent) Date

OR

_____ _____
Name of Legally Authorized Representative (PRINT) Telephone Number

_____ _____
Signature of Legally Authorized Representative Date

_____
Relationship or Authority of Legally Authorized Representative to Participant

Person Obtaining Consent

I attest that the requirements for informed consent for the medical research project described in this form 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 form, 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.

_____

Name of Person Obtaining Consent (PRINT)

_____ _____

Signature of Person Obtaining Consent Date

WITNESS STATEMENT (if required):

The participant or LAR is unable to read or sign this consent form because of the following reason(s):
___ The participant or LAR is non-English speaking.
___ The participant or LAR is illiterate.
___ The participant or LAR is visually impaired.
___ The participant or LAR is physically unable to sign the consent form. 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.

_____

Name of Impartial Witness (PRINT)

(may be interpreter if participant/LAR is non-English speaking)

_____ _____

Signature of Impartial Witness Date