Permission to Take Part in a Human Research Study

Title of Research Study: Low Burden Wearable Sensor System for Diagnosing Obstructive Sleep Apnea Over Multiple Nights: Diagnostic Agreement with Home Sleep Testing

Name of Study Doctor/Researcher: Phyllis Zee MD, PhD

Supported By: This research is supported by Sibel Inc. and the National Institutes of Health

Financial Interest Disclosure: Dr. Steve Xu, an investigator on this study, is an inventor of the device being tested in this study and is a co-founder of the company Sibel Health and could benefit from the results of this study. In addition, Northwestern University owns the invention being tested in this study and may benefit financially from it in the future.

If your doctor is also the person responsible for this research study, please note that s/he is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Key Information:
The first few pages of this document include a summary of this study to help you decide whether to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?
We are asking you to take part in this research study because you are an adult who may have Obstructive Sleep Apnea (OSA). We have developed a small wearable device that can monitor and evaluate certain health measures, and we are studying how well this sensor can identify if a person has OSA compared to other kinds of sleep tests.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?
Obstructive sleep apnea (OSA) is a condition where breathing during sleep is reduced or temporarily stops multiple times leading to poor sleep. OSA is a form of what is called sleep disordered breathing (SBD). Currently, doctors study how people with OSA sleep by having people take a test called polysomnography (PSG). A PSG records your brain waves, the oxygen level in your blood, how fast your heart beats, and breathing during the study. Unfortunately, PSGs are expensive and only available for patients who have known OSA. Doctors use another

test called a Home Sleep Apnea Test (HST) for patients who might have OSA. HSTs are done at home and collect similar vital signs as PSGs. While HSTs are less expensive, both can be hard for both the doctor to detect OSA and for the patient to set up and complete the home testing.

The purpose of this research is to evaluate the performance of a small wearable sensor called the ANNE™ sensor compared to the HST study for finding out if a person has OSA. The ANNE sensors are still investigational and not yet approved by the U.S. Food and Drug Administration (FDA) for doctors to use to see if their patient has OSA.

The wearable sensor being used in this study measures how fast your heart beats, how fast you breathe, and the amount of oxygen in your blood. The sensor can also measure your blood pressure in a different way that is different than is usually done. The sensor uses what is called pulse arrival time, which is how fast your pulse travels from your heart to your finger. This may help give doctors a better way to determine times during sleep where breathing is temporarily reduced or stopped, and how severe OSA is, if present.

If this study is successful, the small wearable sensors may be developed for doctors to use to see if their patients have OSA in the future.

How long will the research last and what will I need to do?
Participating in this study will involve recording 4 nights of sleep data within an 8-week window after enrollment. If you agree to participate in this study (also called consent), a study team member will discuss with you detailed study procedures and you will inform them of the nights you are planning to record data. The study will take place in your home. You will have the option to pick-up/drop-off your study materials in person at Northwestern Feinberg School of Medicine or have it mailed to you.

A study kit containing all the wearable sensor equipment will be delivered to your home (or you can choose to pick it up in person). Once you receive the study kit you will have a 1-hour wearable sensor training session by phone with a member of the research team. This will help you understand how to use and wear the sensors. The HST study kit will be delivered to your home with instructions.

After the wearable sensor training session, your sleep will be measured during 4 separate study periods. For one night, you will wear the wearable sensors together (ANNE and HST). Then, you will wear the ANNE sensor alone for 3 nights. You will be asked to complete a diary whenever you wear the sensors. You will complete the log within 1 hour after you wake up. The diary is used to gather information about your daily sleep pattern. It has 15 questions and will take about 5-7 minutes to complete. You may skip any questions that make you feel uncomfortable. Lastly, you will have phone calls with the research team member to provide study updates and ask any questions or concerns you may have after each study test night.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research study"?**

Is there any way being in this study could be bad for me?
There are minimal risks associated with the small wearable sensor system. Slight redness of the skin that disappears after two days can be seen after wearing and removing the adhesive stickers that are used with the sensor system.

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Detailed Information:
ument includes detailed information about this study (in addition to the information listed above).

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More detailed information about the risks of this study can be found under **"Detailed Risks: Is there any way being in this study could be bad for me?"**

Will being in this study help me in any way?
Possible benefits include an earlier or more reliable diagnosis of OSA for patients like you in the future. If you take part in this study, we hope to learn something that can help adults in the future with your condition.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You decide whether to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled, and it will not affect your clinical care.

Your alternative to participating in this research study is to have an HST test as prescribed by your doctor.

Whom can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, contact the research team or the study doctor at (312) 503-6568. If you are experiencing problems with the sleep testing materials at home, a member of the research team will provide you with a contact number that you can reach out to during evenings/weekends.

This research has been reviewed and approved by the Northwestern University Institutional Review Board (IRB). You may talk to them at 312-503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?
We expect up to 100 people will be in this portion of the research study.

What happens if I say "Yes, I want to be in this research"?
You will be asked for your permission to join the study by a member of the research team member. You will give your permission (also called consent) to join the study to a member of the research team.

The research team member will set-up a time to call you to discuss this consent form. Once you give your consent to participate, the research staff will conduct a screening questionnaire to

confirm you qualify for the study and also collect your information such as name, age, sex, race, home address, and medical history.

We will arrange for a study kit containing our ANNE wearable sensors, adhesives, Velcro straps, WatchPAT, diary, and survey to be sent to your home or to be available for you to pick-up at Northwestern University Feinberg School of Medicine at 303 E. Superior Street, Chicago, IL 60611.

The ANNE kit will include:

- Wearable **study sensors**
    a. The ANNE Sleep consists of 2 sensors, a chest unit worn on your chest and a limb unit that wraps around your finger.
- **Study electronic devices** (Tablet or smart phone with sensor application pre-loaded).
- **Wireless charger and charger adaptors** for the study devices
- **Adhesives** to secure the chest and finger sensors (silicone based)
- **Printed instructions** for the ANNE device

The HST study kit will be sent to your home. Instructions on how to use the HST will be provided by the research team. The kit will include:

- An **HST device**. This device will be a WatchPAT system that will keep track of your body position (information such as whether you're lying on your back, side, or stomach). It will also store all the information from your HST

The HST kit will include:

- **WatchPAT**: The WatchPAT, like the rectangular device, is a finger clip, however it includes a small chest sticker and does not require a chest strap or nasal cannula.
- An **RESBP sensor** is an accessory of the WatchPAT home care device for use with patients suspected to have sleep related breathing disorders. The integrated sensor monitors the snoring level, which aids in the evaluation of the severity of sleep related breathing disorders, and the body position which aids in the evaluation of the type of sleep related breathing disorders. The sensor also provides raw chest movement signal data to measure the subjects breathing during the night.

You will have a video phone call or Zoom session with the research team member when the study kits arrive to your home. Either the call or the Zoom session will last about 1 hour. You will review all the equipment in the study kits with the team member. You will have a training session with them to learn how to apply the wearable sensors and how to complete the diary and survey. The research team member will make sure you or additional people you chose to include will be in the video chat.

The research staff will then ask you to do the following tasks:

(1) Wear the ANNE and HST sensors for 1 night
(2) Wear the ANNE sensors alone for 3 nights

(3) Return the sensors via a pre-paid shipping label/box or in person drop-off at 303 E. Superior Street, Chicago, IL 60611

The research staff will also confirm with you on which nights you would like to complete the testing. The nights do not have to be grouped together. The ANNE and HST night does need to be completed first, however. After you have completed the first night, you will have a phone call lasting no longer than 10 minutes with the research team member to confirm home testing was successful and answer any issues if needed. The research team may reach out to you after your subsequent nights of testing to have additional phone calls lasting no longer than 10 minutes to confirm home testing was successful and answer any questions if needed.

The diary and survey will be available to complete from a link sent to your email. If you prefer paper copies, the study team will provide them. You will complete these within 1 hour after you wake up and it will take approximately 5-10 minutes to complete. You may skip any questions that make you feel uncomfortable.

You will be advised to not drink alcohol or take sleep medication on all testing nights. If you drink alcohol or take sleep medication, you will be asked to note it in the diary.

Once all tests are completed, you will complete the final survey which will be provided to you by an email link. A paper copy may be requested if desired. The research coordinator will contact you after they receive the kit. A gift card will be sent to your home once all materials have been returned and surveys confirmed completed.

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible for the following:

- Have an initial phone call with a member of the research team to go over the consent and screening questionnaire
- Complete a 1-hour sensor training session with a research team member over the phone
- Have up to 4 phone calls lasting no longer than 10 minutes each with a research team member to discuss study updates and go over any questions or concerns during your participation in the study (one call after each night of recorded sleep)
- Wear the ANNE sensors and HST together for one night
- Wear the ANNE sensors alone for three nights
- Complete a sleep diary on nights you wear the sensors
- Complete a final survey after the last night of recorded data
- Return all sensors and accessories to the research team member via pre-paid mail package or in-person at the end of the study at 303 E. Superior Street, Chicago, IL 60611.

What happens if I say "Yes", but I change my mind later?
You do not have to be in this study if you do not want to. This will have no impact on your medical care. If you join the study and then change your mind, you can leave this study.

If you decide to leave the study, contact the researcher or research team member at (312) 503-6568.

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Detailed Risks: Is there any way being in this study could be bad for me?
You may have some side effects or discomfort while in this research. If you have any side effects, you should tell the study doctor or research team member as soon as possible. They will monitor you closely.

Sensor and adhesive: Removal of the sensor and adhesive may hurt (like removing a band-aid) and cause temporary skin irritation, redness or discomfort. Wearing a sensor on your chest and your finger may be visible to others during nighttime wear. The devices will be placed on skin epidermis without conductive gel, thereby minimizing the risk of any allergic reaction, however, it may be possible. The adhesives have passed both biocompatibility, skin sensitization and cytotoxicity testing.

Survey/Diary: If you are uncomfortable with any questions, they may be skipped.

Loss of confidentiality: Every research study involves some risk to your private information. It is possible that other people could find out you were in the study or see your study information. We will take every step to keep this from happening. Your data will be stored in a secure online system.

See the section below titled: **"What happens to the information collected for the research?".**

Will it cost me anything to participate in this research study?
Taking part in this research study will not lead to any extra costs to you.

Will being in this study help me in any way?
We cannot promise any benefits to you or others from your taking part in this research. The ANNE sensor being studied will not be used to diagnosis or treat your condition, but may help in doing so with other patients in the future.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB, other representatives of this institution including Northwestern Memorial Hospital (NMH), Northwestern University (NU), Northwestern Medical Group (NMG), Northwestern Memorial Lake Forest Hospital, Central DuPage Hospital (CDH), Anthem, Inc., Sibel, Inc., and the National Institutes of Health (NIH).

Data Sharing
De-identified data from this study may be shared with the research community at large to advance science and health, and with the sponsor of this study, the National Institutes of Health and Sibel Inc. for commercial purposes, and with Anthem, Inc. and its subsidiaries. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

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What else do I need to know?

If you agree to take part in this research study, you will receive a $100 gift card for your time and effort for completing all 4 nights with corresponding surveys. If you complete one night with the HST and ANNE and one night with ANNE only, you will receive $50 in gift cards for your time and effort for completing these 2 nights with corresponding surveys. A detailed description of how to use and activate the card and when fees apply is included with the card.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removing you from the study include not wearing the sensors enough or if you do not follow the study procedures.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Demographic data including name, birthdate, address and phone number
- Results of physical examinations
- Medical history
- Lab tests, diaries, questionnaires, or certain health information indicating or relating to a sleep condition
- Records about sleep medication or drugs
- Records about sleep study devices

During this study, you may be coming to a Northwestern Memorial HealthCare/Northwestern Medicine entity for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB) and Northwestern Memorial HealthCare/Northwestern Medicine entities and its current and future affiliates.

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy

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[except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Memorial HealthCare, and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Memorial HealthCare, for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- Sibel, Inc. and the National Institutes of Health (NIH), who are sponsoring the study, and those organizations' contractors and partners, including Anthem, Inc.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Phyllis Zee
Institution: Northwestern University
Department: Sleep Medicine
Address: Abbott Hall Suite 520
710 N Lake Shore Drive
Chicago Illinois 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

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Unless you revoke your consent, it will not expire.

Signature Block for Capable Adult:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent