Permission to Take Part in a Human Research Study

Title of Research Study: A Single Arm, Open-Label, Multi-Center, and Comparative Study of the ANNE™ Sleep System versus Polysomnography to Diagnose Obstructive Sleep Apnea: ANNE Program for the Non-Invasive Evaluation of Apnea in Sleep (APNEAs)

Name of Study Doctor/Researcher: Phyllis Zee MD PhD, Charles Davies MD PhD, Kuljeet Gill MD and Jennifer Cooksey MD

Supported By: This research is supported by Sibel Inc.

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 is suspected to have Obstructive Sleep Apnea (OSA) or has a Polysomnography Test (PSG) ordered by your doctor. We have developed a small wearable device that can monitor and evaluate your health, and we are studying how well it can find OSA compared to other kinds of 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 (SDB). Currently, doctors study how people with OSA sleep by having people take a test called a 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.

The small wearable device that will be used in this study is called the ANNE™ Sleep sensors. These 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 purpose of this research is to evaluate and compare the performance of the small wearable ANNE™ Sleep sensors and PSG study for finding out if a person has OSA. The wearable sensor 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, 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 approved for doctors to use to help see if their patients have OSA.

How long will the research last and what will I need to do?

We expect that you will be in this research study for 1 day. Patients that are suspected of having OSA or have a PSG ordered by their doctor may be asked to consider if they want to be in the study.

After you give your permission (also called consent), you will be scheduled to have a PSG study for 1 night at the sleep center and you will wear the wearable sensors for that night. You will be asked to complete a diary log when 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 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 a phone call with the research team member to provide study updates and ask any questions or concerns you may have after the 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. Adhesive stickers and Velcro straps used to attach the device to the skin are single use and will be thrown away after one use. Slight redness of the skin that disappears after two days may be reported after wearing and removing the adhesive stickers. This study involves the use of your private, personal information and there is a chance someone other than study team members may be able to identify you or see your information. The research team member has procedures in place to lower the chances of this happening. You may also experience increased sleepiness lasting no longer than 24 hours after participating in a PSG.

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?

There are no direct benefits for participating in this study. Possible benefits include an earlier or more reliable diagnosis of OSA for people in the future. If we find a result that is concerning, you or your physician will be notified.

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.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

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:

Permission to Take Part in a Human Research Study

Northwestern Memorial Hospital: 312-503-4409
Carle Foundation Hospital: 217-383-3440

Northwestern Lake Forest Hospital: 312-695-1800
Central DuPage Hospital: 630-232-0202

This research has been reviewed and approved by the Northwestern Institutional Review Board (IRB).

Northwestern IRB's contact information: 312-503-9338 or email IRB@northwestern.edu

You may contact the appropriate IRB 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 about 214 people will be in this research study.

What happens if I say "Yes, I want to be in this research"?

You will be invited to join the study by a member of the research team. You will give your permission (also called consent) to join the study to a member of the research team.

Once you give your consent to participate, the research staff will collect your information such as name, age, sex, race, home address, and medical history. Once you give your consent and meet the study entry qualifications, you will be considered enrolled.

The research staff will then ask you to schedule and participate in a PSG study with the wearable sensors for one night. Research staff may assist you in scheduling your PSG study if requested.

Polysomnography is a test conducted to study sleep and to diagnose a variety of sleep disorders. Some people refer to polysomnography (PSG) as a sleep study. The PSG takes place at a specialized sleep center. Your appointment will begin in the evening, about 2 hours before your usual bedtime.

You'll sleep overnight at the sleep center, where you'll stay in a private room. You can bring whatever is necessary for your bedtime routine, as well as your own pajamas.

A technician will administer the polysomnography by monitoring you as you sleep. The technician can see and hear inside your room. You'll be able to hear and talk to the technician during the night.

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

At least 24 hours prior to your PSG study, a research team member will call you to confirm your scheduled appointment. Once confirmed, a research team member will meet you at the sleep health center on the night of the PSG study. Your sleep technician will then set up all the PSG equipment for you. The wearable sensors will be placed on your body after the PSG equipment is applied by a member of the research team. Before your PSG starts, a research team member will ensure the sensors are working properly. If you agree, a research team member will take pictures of the wearable sensors placed on your body before or

after your PSG study. A research-dedicated phone will be used to take pictures. Your face or any personal information will not be in the photo. A research team member will then provide instructions to the sleep technician on how to use the wearable sensors.

You will complete the sleep diary and usability survey which will be provided to you by an email link or by paper form provided in your kit. A research team member will then meet you at the sleep center to collect the study kit. The research coordinator will contact you and will confirm your participation is complete. Finally, a gift card will be sent to your home.

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:

- Prior to your sleep study, complete a survey about your demographics, medical history, and sleep.
- Have 1 phone call lasting no longer than 10 minutes with a research team member at least 24 hours before your PSG night to confirm your scheduled PSG and go over any questions or concerns
- Schedule and participate in a PSG study while wearing the ANNE sensors for one night
- Complete the sleep diary within 1 hour of waking
- Complete a usability survey at the end of the study

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:
Northwestern Memorial Hospital: 312-503-4409
Carle Foundation Hospital: 217-383-3440

Northwestern Lake Forest Hospital: 312-695-1800
Central DuPage Hospital: 630-232-0202

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 redness or discomfort for some time. Wearing a sensor on your chest and your finger may be visible to others during nighttime wear.

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

You may feel sleepier if you did not sleep much after completing your PSG study. You should feel better within 24 hours.

Every research study involves some risk to your private information. Pictures of your finger and chest will be taken for publication and research purposes. You can decline to have your photo taken. 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.

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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 costs to you.

Will being in this study help me in any way?

There are no direct benefits for participating in this study. If we find a result that is concerning, you or your physician will be notified. If you take part in this study, we hope to learn something that can help adults in the future.

What happens to the information collected for the research?

The study team members, Northwestern Memorial Hospital (NMH), Carle Foundation Hospital, Northwestern Lake Forest Hospital, Northwestern Medical Group (NMG), or Central DuPage Hospital (CDH), may use your information and share it with:

- The Institutional Review Boards (the committee that is in charge of protecting the rights of all adults and children who take part in research studies).
- Your other providers and their team member directly involved in your care.
- The Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA), or other government offices.
- HealthCore will support data analyses, statistical analyses, and monitoring to ensure the study is being conducted properly.

These are the only people to which we will give your information. We cannot guarantee that those listed above will not share it with others without your permission.

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, 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.

What else do I need to know?

If you agree to take part in this research study, you will receive a $150 gift card for your time and effort for completing the study. 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, or certain health information indicating or relating to a condition as well diaries and questionnaires
- Records about study medication or drugs
- Records about study devices

The following clinical providers may give the researchers information about you: Northwestern Memorial Hospital, Carle Foundation Hospital, Northwestern Lake Forest Hospital, Northwestern Medical Group, and Central DuPage Hospital.

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of the locations listed above and there clinical partners (or affiliates): the 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 [except that such information may be viewed by the Study sponsor and its partners or contractors at the study doctor's office.

The following entities may receive your health information:

- Authorized members of the Northwestern Memorial Hospital, Carle Foundation Hospital, Northwestern Lake Forest Hospital, Northwestern Medical Group, and Central DuPage Hospital's workforce who may need to see your information, such as administrative team members from the Office for Research, Office for Research Integrity and members of their respective Institutional Review Board.
- Your participation in this clinical trial may be tracked in an electronic database and may be seen by researchers running other trials that you are enrolled in and by your doctors.
- Northwestern Memorial Hospital 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.
- HealthCore will act as a study monitor and auditor to make sure that the study is being done properly,
- 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.

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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 your respective institution:

Northwestern Memorial Hospital
Phyllis Zee MD PhD
Chief of Sleep Medicine
Northwestern Memorial Hospital
Professor of Neurology
Northwestern University Feinberg School of Medicine
P: 312-503-4409
Email: p-zee@northwestern.edu
676 N St Clair St Arkes Pavilion, Ste 7-701, Chicago, IL 60611

Charles Davies MD PhD
Program Lead, Sleep Medicine
Carle Foundation Hospital
Clinical Research Associate Professor
Carle Illinois College of Medicine
P: 217-383-3440
Email: Charles.Davies@carle.com
602 W University Ave, Urbana, IL 61801

Central DuPage Hospital (CDH).
Kuljeet Gill MD
25 N Winfield Rd Ste 204, Winfield, IL 60190-1295
Email: KellyGill@northwestern.edu
P: 630-232-0202

Northwestern Lake Forest Hospital
Jennifer Cooksey, MD
676 N St Clair St, Ste 7-701, Chicago, IL 60611
Email: jessica.cooksey@northwestern.edu
P: 312-695-1800

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. Unless you revoke your consent, it will not expire.

Permission to Take Part in a Human Research Study

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