Informed Consent Form for Participation in a Research Study

Study Title: Remote sleep assessment in adults at risk for dementia using the ANNE Vital Sign System

Protocol number: 5366

Study Doctor:

Dr. Andrew Lim, Associate Professor, Division of Neurology, Sunnybrook Health Sciences Centre, 416-480-6100 x2461

Dr. Mark Boulos, Staff Neurologist, Division of Neurology, Sunnybrook Health Sciences Centre, 416-480-4473

Funders: Centre for Aging and Brain Health Innovation Advancement and the Canadian Consortium on Neurodegeneration in Aging

Sponsor: Sunnybrook Research Institute

INTRODUCTION

You are being invited to participate in a clinical trial (a type of study that involves research). You are invited to participate in this trial because you are a participant in The Canadian Consortium on Neurodegeneration in Aging (CCNA) Canadian Therapeutic Platform Trial for Multidomain Interventions to Prevent Dementia (CTU) or an affiliated study. This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

The study staff will tell you about the study timelines for making your decision. Between now and the completion of your baseline visit, you will be given the opportunity to read the consent form and consider consenting to participate in the study.

Taking part in this study is voluntary. You have the option to not participate at all or you may choose to leave the study at any time. Whatever you choose, it will not affect the usual medical care that you receive outside the study.

IS THERE A CONFLICT OF INTEREST?

There are no conflicts of interest to declare related to this study.

WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?

Sleep apnea is characterized by temporary pauses or stops to your breathing. Currently, sleep apnea is diagnosed using an in-lab sleep study, which involves spending a night in a sleep laboratory hooked up to wires on the head, chest, and legs. However, this is not feasible for many older adults. To overcome this barrier, we will utilize an investigational vital signs monitor – the Advanced NeoNatal Epidermal (ANNE) Vital Sign System (Sibel Health, Evanston, IL, USA).

The ANNE Vital Sign System is a wireless system that measures heart and lung signals. In addition, the sensors measure acceleration, oxygen levels, and temperature. The research participant is not an intended operator but can self-apply the sensors under direction of a qualified healthcare professional.

Health Canada, the regulatory body that oversees the use of investigational devices in Canada, has not approved the sale or use of the ANNE Vital Sign System. An Investigational Testing Authorization (ITA) is pending submission and review and only upon approval will Health Canada allow the ANNE Vital Sign System to be used in this study. This study will only be active with an approved ITA.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to test the hypothesis that sleep apnea is associated with accelerated cognitive decline in older adults at risk for dementia. We will measure sleep apnea at baseline and 12 months later and relate this to cognitive function at the same time points. Data from this study may identify sleep apnea as a treatment target to decrease the risk of dementia.

WHAT OTHER CHOICES ARE THERE?

You do not have to take part in this study.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that about 750 people will take part in this study, recruited from sites across Canada with data collection happening at Sunnybrook Research Institute in Ontario.

Recruitment for this study should take place over 2 years with results known by approximately April 2025.

WHAT WILL HAPPEN DURING THIS STUDY?

You have been referred by a participating CTU site to participate in this study. We have been given your contact information (name, phone, email address) by the participating CTU site after your verbal interest in this study. You have been given a copy of this consent form either by email or by regular mail, and will engage in a phone/video call to discuss the key elements of this form.

During the phone/video call, you will be given the opportunity to verbally agree to participate. Upon agreement, study staff will prepare shipment of the ANNE Vital Sign System to you. Two copies of the consent form will be signed and dated by study staff and included in the package. At this time, study staff will also request from the CTU referring site your study ID (PSCID).

After you receive the shipment, a second phone/video call will be scheduled to once again discuss the key elements of this consent form and allow time for questions. Should you need more time to review the consent form, a third phone/video call will be scheduled within 3 days of the second. If you agree to participation, you will sign both copies of the consent form, retain 1 for your records and return the other at the end of your session. At this time, study staff will instruct you on the proper application and use of the ANNE Vital Sign System. You will be asked to wear the ANNE Vital Sign System sensors for 24 hours before removing it yourself at home and shipping the device back to the study centre using a pre-paid, pre-addressed package. You will also be asked to complete a short study questionnaire. You will return the device after your baseline recording and a new device will be mailed back to you to repeat this procedure 12 months later.

The ANNE Vital Sign System data is downloaded by study staff via Bluetooth locally to an iOS device. SRI staff will process the data then upload to the Longitudinal Online Research and Imaging System120 (LORIS). LORIS is a web-based database that is physically located at McGill University in Montreal. It will store data that does not contain any direct identifiers of yourself. You will be assigned a unique coded study identification number. The database can only be accessed by people who are involved in research.

Please talk to the research team if there is information that you do not feel comfortable sharing.

Study data may be sent to and received from investigators at other academic institutions for the research purposes explained in this protocol. Additionally, some study data may be shared with the device manufacturers to facilitate analyses in support of the academic aims above. Any study data about participants that is sent outside of the participating institution will have a code and will not contain identifiable information, and will be transferred through secure methods.

Study data may be accessed for future analysis.

You will be provided with a questionnaire at the conclusion of your ANNE Vital Sign System

recording. The purpose of the questionnaire is to understand the patient experience with the sensors. Each questionnaire will take about 10 minutes to complete.

The information you provide is for research purposes only. Some of the questions are personal. You can choose not to answer questions if you wish.

Even though you may have provided information on a questionnaire, these responses will not be reviewed by your health care team or study team - if you wish them to know this information please bring it to their attention.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

If you choose to participate in this study, you will be expected to:

- Wear the ANNE Vital Sign System for 24 hours at baseline and at 12 months, and;
- Allow us to access the results of your Montreal Cognitive Assessment (MoCA) as part of your CTU participation;
- Complete a short questionnaire about use of the ANNE Vital Sign System
- Forgo wearing nail polish, showering, bathing, or otherwise participating in an activity where the sensors may get wet, during the time you are wearing the sensors.

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

Your participation in this study will last for 12 months with measurements collected at baseline and 12 months.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the study doctor or study staff.

Information that was recorded before you withdrew will be used by the researchers for the purposes of the study, but no information will be collected after you withdraw your permission. If you would like information that was recorded before you withdrew not to be used by the researchers, you may submit a verbal or written request to the study staff and your data will not be used.

The study doctor may stop your participation in the study early, and without your consent, for reasons such as:

- You are unable to complete all required study procedures
- The study doctor no longer feels this is the best option for you
- The Sponsor decides to stop the study
- The Regulatory Authority/ies (for example, Health Canada) or research ethics board withdraw permission for this study to continue

If you are removed from this study, the study doctor will discuss the reasons with you.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

There are minimal known risks associated with the use of the ANNE Vital Sign System. ANNE Vital Sign System may cause mild discomfort, skin irritation, redness, itching, rash, or contact dermatitis in some individuals. You may be asked to shave a small (approximately 3”x2” section) of your chest, but this is optional and you may decline to do this and still participate. The ANNE Vital Sign System will not be used on individuals with known allergies or hypersensitivities to hydrogel adhesives or nickel, or implantable cardiac devices. The battery used in the sensors may present a risk of fire, explosion, or chemical burn if mistreated. The ANNE Vital Sign System will only be used if there are no signs that the silicone shell or any other device components are damaged. In the event that you experience excessive heat, discomfort, or any of the above risks or harms from the device, remove immediately and contact the study doctor. Contact information for the study doctor can be found on page 7 of this document.

Participants must report any adverse events to study staff up to seven (7) days following removal of the ANNE Vital Sign System sensors. Contact information for reporting adverse events can be found on page 7 of this document in the section titled “WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?”.

In the unlikely event that you experience a possible adverse event, the individual you contact to report the adverse event will 1) advise you to seek care with your local health care provider; 2) liase with the local health care provider, with your consent, to support the provision of necessary health care; and 3) collect information on, record, and report as necessary to the research ethics board and Health Canada details of the possible adverse event.

Research data may indicate a risk of having sleep apnea. The ANNE Vital Sign System has been validated against standard overnight sleep studies in a study of 225 individuals, however data collected as part of this study are for research purposes only and may not constitute a diagnosis of sleep apnea. In these cases, participants will be called via telephone by study staff to be a) notified that they have a high probability of having sleep apnea and if accompanied by severe sleepiness should refrain from driving, b) encouraged to contact their family physician for clinical evaluation where an official diagnosis of sleep apnea may or may not be made, and c) asked to notify study staff if they obtain treatment, unless treatment is obtained after their month 12 visit.

You will be told about any new information that might reasonably affect your willingness to continue to participate in this study as soon as the information becomes available to the study staff. This may include new information about the risks and benefits of being a participant in this study.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

There are no benefits to you for taking part in this study.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the study doctors and study staff will only collect the information they need for this study.

Records identifying you will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) medical/clinical study records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines:

- Representatives of the Sunnybrook Research Institute, Sunnybrook Health Sciences Centre or the Sunnybrook Research Ethics Board, because they oversee the ethical conduct of research studies at Sunnybrook
- This institution and affiliated sites, to oversee the conduct of research
- Health Canada (because they oversee the use of investigational devices in Canada)

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Your name, address, email, or other information that may directly identify you will not be used. The records received by these organizations may contain your participant code, initials, sex, and date of birth.

The following organizations may also receive study data:

- Site research groups affiliated with this study for the research purposes explained in this consent form.
- Sibel Group (Evanston, IL, USA), the device manufacturer, to facilitate analyses in support of the research purposes explained in this consent form.

Information sent to Sibel Group or between site research groups will be de-identified and encrypted so that it is only accessible by the intended recipient. Data sent to Sibel Group is in a file format (.shrd) that can only be opened by Sibel Group's own software. No personal health information will be disclosed.

Communication via e-mail is not absolutely secure. We do not recommend that you communicate sensitive personal information via e-mail.

In addition to the data that will be collected for this study, the researchers will also be collecting the following personal health information:

- Date of birth
- Sex
- Handedness
- History of sleep apnea and current treatment

This additional data is being collected to identify whether age or sex influences the association between the ANNE Vital Sign System and cognition.

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be used in analyses and will be published/presented to the scientific community at meetings and in journals.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

Data downloaded from the ANNE Vital Sign System sensors by research staff to the associated ANNE iOS apps resides on the Apple servers and no assurance can be made about its

confidentiality or that it will only be used for research purposes.

WILL FAMILY DOCTORS/HEALTH CARE PROVIDERS KNOW WHO IS PARTICIPATING IN THIS STUDY?

Your family doctor/health care provider will not be informed by the study team that you are taking part in the study. You can choose to let your family doctor/health care provider know, if you like.

WHAT IS THE COST TO PARTICIPANTS?

Participation in this study will not involve any additional costs to you or your private health care insurance.

WHAT HAPPENS IF I HAVE A RESEARCH RELATED INJURY?

If you become sick or injured as a direct result of your participation in this study, your medical care will be provided. Financial compensation for such things as lost wages, disability or discomfort due to this type of injury is not routinely available.

By signing this consent form, you do not give up any of your legal rights.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

Participants are not being paid to take part in this study.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please contact the research team.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form you do not give up any of your legal rights against the study doctor or involved institutions for compensation, nor does this form relieve the study doctor or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in this study.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to your study doctor, or the doctor who is in charge of the study at this institution. That person is:

Dr. Andrew Lim 416-680-6100 x2641

Name	Telephone
If unavailable, you can contact:	
Dr. Mark Boulos	416-680-4473
Name	Telephone

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. That person is the **Chair of the Sunnybrook Research Ethics Board at (416) 480-6100 ext. 88144.**

DOCUMENTATION OF INFORMED CONSENT

You will be given a copy of this informed consent form after it has been signed and dated by you and the study staff.

Full Study Title: Remote sleep assessment in adults at risk for dementia using the ANNE Vital Sign System

Name of Participant: _____

Participant/Substitute decision-maker

By signing this form, I confirm that:

- This research study has been fully explained to me and all of my questions answered to my satisfaction
- I understand the requirements of participating in this research study
- I have been informed of the risks and benefits, if any, of participating in this research study
- I have been informed of any alternatives to participating in this research study
- I have been informed of the rights of research participants
- I have read each page of this form
- I authorize access to my personal health information, medical record and research study data as explained in this form
- I have agreed, or agree to allow the person I am responsible for, to participate in this research study

_____	_____	_____
Name of participant/Substitute decision-maker (print)	Signature	Date

ASSISTANCE DECLARATION

Was the participant assisted during the consent process? ☐ Yes ☐ No

☐ The consent form was read to the participant/substitute decision-maker, and the person signing below attests that the study was accurately explained to, and apparently understood by, the participant/substitute decision-maker.

☐ The person signing below acted as a translator for the participant/substitute decision-maker during the consent process. He/she attests that they have accurately translated the information for the participant/substitute decision-maker,

and believe that that participant/substitute decision-maker has understood the information translated.

_____	_____	_____
Name of Person Assisting (Print)	Signature	Date

Person obtaining consent

By signing this form, I confirm that:

- This study and its purpose has been explained to the participant named above
- All questions asked by the participant have been answered
- I will give a copy of this signed and dated document to the participant

_____	_____	_____
Name of Person obtaining consent (print)	Signature	Date