Sunnybrook
HEALTH SCIENCES CENTRE

Informed Consent Form for Participation in a Research Study

Study Title: Cross-sectional investigation of sleep apnea and cognition in older adults using the ANNE Vital Sign System

Protocol number: 5140

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Funders: Alzheimer's Society of Canada

INFORMED CONSENT

You are being invited to participate in a clinical trial (a type of study that involves research). A clinical trial or research study is a way of gathering information on a treatment, procedure, or medical device or to answer a question about something that is not well understood.

This form explains the purpose of this research study, the tests and procedures involved, possible risks and benefits, and the rights of participants.

Please read this form carefully and ask any questions you may have. You may have this form and all information concerning the study explained to you. Feel free to discuss it with your friends and family, or your family doctor. Please ask the study staff or one of the investigators to clarify anything you do not understand or would like to know more about. Make sure all your questions are answered to your satisfaction before deciding whether to participate in this research study.

Participating in this study is your choice (voluntary). You have the right to choose not to participate, or to stop participating in this study at any time.

INTRODUCTION

You are being asked to participate in this study because you are enrolled in a study led by Dr. Rabin at Sunnybrook Health Sciences Centre (titled: Investigating Risk and Protective Factors for Dementia in A Multi-Ethnic Cohort) or because you are a healthy individual from the community. The purpose of this study is to find out whether sleep quality is related to early changes in memory and other thinking abilities.

Sleep quality will be assessed with a new state-of-the art non-intrusive device called the ANNE Vital Sign System (see below). You will be asked to wear the ANNE Vital Sign System on your chest and index finger for 24 hours. This device is small, lightweight, and well-tolerated.

You will also be asked to complete several tasks that assess your memory and other thinking skills. Some of the tasks may be completed on a computer and some may be completed on paper.

We will examine relationships between your sleep quality, as measured by the ANNE Vital Sign System, and your performance on the memory/thinking tasks.

WHY IS THIS STUDY BEING DONE?

Sleep is critical to human health. Adults spend a third of their lives asleep. Insufficient sleep and disrupted sleep are common and have a major impact on health. For example, there is research suggesting that poor sleep quality increases the risk of cognitive impairment and dementia. Unfortunately, studies in older adults linking objectively measured sleep quality with performance on tests of memory and other thinking abilities are lacking.

To address this issue, a new generation of wearable devices has become available that enable quantification of sleep in one's own home with minimal discomfort. The Advanced NeoNatal Epidermal (ANNE) Vital Sign System (Sibel Group, Niles, IL, USA) was originally created for the purposes of providing real-time vital signs (heart and lung signals) monitoring in children. The characteristics that make it ideal for use with children also make it ideal for use in detecting/measuring sleep quality in adults.

The ANNE Vital Sign System consists of two water-resistant sensors – a chest sensor (ANNE Chest) and a finger sensor (ANNE Limb). The chest sensor is a 7.2x3.9x0.9cm, 17g silicone-encased sensor that contains an accelerometer and gyroscope (these measure movement), thermometer, and surface electrodes from which ECG (heart signals), respiratory movements (breathing), and temperature can be measured. The finger sensor is a 9.6x2.9x1.9cm, 18g silicone-encased sensor that wraps around the finger and allows for measurement of your oxygen levels and temperature.

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.

As described above, the purpose of this study is to determine whether sleep quality, as measured by the ANNE Vital Sign System, is related to early changes in memory and other thinking abilities in adults. We are interested in studying the earliest possible changes in memory and thinking because interventions applied as soon as possible have the best chance of being effective. If there is a strong relationship between sleep quality and performance on memory and thinking tasks, these findings would suggest that poor sleep quality should be targeted as a strategy to improve cognition in older adults.

WHAT WILL HAPPEN DURING THIS STUDY?

This study involves one visit during which you will be asked to complete a series of cognitive tasks to assess your memory and other thinking abilities. After you have completed the tasks, you will be shown how to use the ANNE Vital Sign System and then asked to take it home with you. You will be asked to wear the ANNE Vital Sign System for 24 hours, including 1 night of sleep. After you have used the ANNE Vital Sign System, you will be asked to return it, either by mail or in person, to our study staff at Sunnybrook Health Sciences Centre.

The study involves collecting information about your sleep from the ANNE Vital Sign System and your cognition from the memory/thinking assessment. This information will be entered into an electronic database. The information will be securely stored and will be maintained by the principal investigator of this study. The database can only be accessed by people who are involved in this research.

The components of the study are described in greater detail below:

Cognitive testing:

Cognitive (thinking and memory) testing will occur in-person. It is preferred that this testing is done in the morning. You will be given several tasks that assess attention, processing speed, memory, language, visuospatial processing, and executive function. Some of the tasks may be completed on a computer and some may be audio recorded for scoring purposes. This testing will take approximately 1 hour to complete.

You may take breaks during the testing to avoid tiring, and you may return for an additional appointment if needed.

If you wear reading glasses or hearing aids, please bring them with you to this visit.

ANNE device:

After cognitive testing, you will be shown how to use the ANNE Vital Sign System. You will be shown how to affix and remove the sensors to your chest and dominant index finger according to the manufacturer recommendations. You will be given the ANNE Vital Sign System to take home and asked to wear the sensors for a 24-hour period, including 1 night of sleep. You will also be provided with ANNE hydrogel adhesive and a clinical waterproof 3M Tegaderm dressing.

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 300 people will take part in this study. Enrollment into this study may overlap with enrollment in another study at Sunnybrook Health Sciences Centre led by Dr. Rabin. If both studies are approved and active, you will be given the option to participate in both studies. If you are enrolled in both studies and you have completed the cognitive testing in the

other study, you will not be asked to undergo cognitive testing in this study, as the tests overlap.

This study is expected to take approximately 10 years to complete.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

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

- Complete tests to assess your memory and thinking
- Wear the ANNE Vital Sign System for 24 hours continuously, including 1 night of sleep
- Return the ANNE Vital Sign System to the study staff at Sunnybrook (either in person or via mail)

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

Your participation in this study will involve one in-person visit, lasting no more than 1.5 hours. You will also be required to wear the ANNE Vital Sign System for a 24 hour period, including 1 night of sleep.

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 principal investigator 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 the 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 principal investigator 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
- You do not follow the study directions
- The principal investigator believes it is best for you to stop being in the study.
- 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 staff will discuss the reasons with you.

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

ANNE Vital Sign System:

There are minimal known risks associated with the use of the ANNE Vital Sign System. The ANNE Vital Sign System may cause mild discomfort, skin irritation, redness, itching, rash, or

contact dermatitis in some individuals. 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 and tablet 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. If you experience excessive heat, discomfort, or any of the above risks or harms from the device during use, you should remove the ANNE Vital Sign System. Additionally, the procedure involving the ANNE Vital Sign System may involve unforeseeable risks that are not listed here.

Participants must report any adverse events to study staff up to seven (7) days following removal of the ANNE Vital Sign System sensors.

Cognitive Tasks:

The battery of cognitive tasks will take approximately 1 hour to complete and may be tiring. You can request a break any time if you feel you need one.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

You will not benefit from participating in this study. We hope that the information learned from this study will contribute to our understanding of the relationship between sleep quality and cognition.

We will not be communicating results from the study to you. If in the course of participating in this study you become concerned that you may have a sleep-related health issue, we suggest that you contact your family doctor.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

You have the right to have any information about you and your health that is collected, used or disclosed for this study to be handled in a confidential manner.

If you decide to participate in this study, the investigator(s) and study staff will look at your personal health information and collect only the information they need for this study. “Personal health information” is health information about you that could identify you because it includes information such as your

- Name, address, telephone number, and date of birth, or health card number (see below).

You have the right to access, review and request changes to your personal health information.

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:

- The research ethics board who oversees the ethical conduct of this study in Ontario.
- *Representatives of Sunnybrook Health Sciences Centre and Sunnybrook Research Institute*, who oversee the conduct of research at this location.
- 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. Representatives of Clinical Trials Ontario, a not-for-profit organization, may see study data that is sent to the research ethics board for this study. 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:

- Sibel Group (Niles, 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.

Any study data about you that is sent outside of the hospital will have a code and will not contain your name or address, or any information that directly identifies you. Study data that is sent outside of the hospital will be used for the research purposes explained in this consent form.

The investigator(s), study staff and the other people listed above will keep the information they see or receive about you confidential, to the extent permitted by applicable laws. Even though the risk of identifying you from the study data is very small, it can never be eliminated. Any information sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries dealing with protection may not be as strict as in Canada. However, any information will be transferred in compliance with all relevant Canadian privacy laws.

De-identified study data will be analyzed using CrowdEEG, an online password-protected EEG annotation tool developed in collaboration with the University of Waterloo to facilitate analysis of the study data by our research staff. The data will be hosted by University of Waterloo servers but only research staff affiliated with our study will have access to them.

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.

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: Dr. Jennifer Rabin, Sunnybrook Research Institute, 416-480-6100 ext. 83737 or by email: jennifer.rabin@sri.utoronto.ca.

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

Data collected using the ANNE 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.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

You will not be paid to participate in this study. However, we will cover the cost of parking for each in-person study visit. Snack vouchers will also be provided for all in-person visits.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You have the right to ask questions and to receive answers throughout this 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.

If you have any questions about this study you may contact the person in charge of this study (Principal Investigator) Dr. Jennifer Rabin, Sunnybrook Research Institute, 416-480-6100 ext. 83737, jennifer.rabin@sri.utoronto.ca

The Sunnybrook Research Ethics Board has reviewed this study. If you have questions about your rights as a research participant or any ethical issues related to this study that you wish to discuss with someone not directly involved with the study, you may call the **Chair of the Sunnybrook Research Ethics Board at (416) 480-6100 ext. 88144.**

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: Cross-sectional investigation of sleep apnea and cognition in older adults using the ANNE Vital Sign System

Name of Participant: _____

Participant/Substitute decision-maker

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

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 to participate in this study or agree to allow the person I am responsible for to participate in this study
- This informed consent document may be placed in my medical records.
- I may be contacted by Dr. Jennifer Rabin's lab in the future for any possible added procedures to the study.

☐ I agree to be contacted about future research studies at Sunnybrook Health Sciences Centre led by Dr. Rabin.

☐ I agree to have my data from this study linked to data from another research study (study title: Investigating risks and protective factors for dementia in a multi-ethnic cohort) in which Dr. Rabin is the Principal Investigator.

_____	_____	_____
Name of participant (print)	Signature	Date

Person obtaining consent

By signing this form, I confirm that:

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

Name of person obtaining consent (print)	Signature	Date

Statement of Investigator
I acknowledge my responsibility for the care and wellbeing of the above participant, to respect the rights and wishes of the participant as described in this informed consent document, and to conduct this study according to all applicable laws, regulations and guidelines relating to the ethical and legal conduct of research.

Name of investigator (print)	Signature	Date