Sunnybrook
HEALTH SCIENCES CENTRE

INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Full Study Title: The Ontario Sleep Health Study

Principal Investigator: Dr. Andrew Lim, Department of Neurology, 416-480-6100 ext. 2461

Sponsor: This study is being funded by the Canadian Institutes of Health Research, and the Heart and Stroke Foundation of Ontario

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INFORMED CONSENT

You are being asked to consider participating in a research study. A 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, provides information about the study procedures, 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. If you wish, someone may be available to verbally translate this form into your preferred language. You may take as much time as you wish to decide whether or not to participate. Feel free to discuss it with your friends and family, or your family doctor. The study staff will tell you if there are any study timelines for making your decision. Please ask the study staff or one of the investigator(s) 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 consider participating in this study because you are a participant of the Ontario Health Study (OHS) who agreed to be re-contacted regarding additional OHS-associated studies.

Sleep is critical to human health. Adults spend a third of their lives asleep, but insufficient sleep and disrupted sleep are common and have a major impact on health. Circadian rhythms – near 24-hour biological rhythms governed by an internal 'biological clock' – also influence health. Disrupted circadian rhythms, as experienced by millions of Ontarians with shift-work or jet lag, can lead to accidents, lost productivity, and many common diseases. However, there is still much we do not understand about the genes influencing our sleep and biological rhythms, and the impact of sleep and circadian rhythms on the health and wellbeing of Ontarians.

WHY IS THIS STUDY BEING DONE?

The overall goal of the Ontario Sleep Health Study is to better understand the impact of sleep and circadian disruption on the health and well-being of Ontarians, and to better understand the impact of our genes on our sleep and circadian rhythms.

WHAT WILL HAPPEN DURING THE STUDY?

This study will take place in your home. We will mail you equipment which you will use yourself to measure your own sleep and biological rhythms over a 10-day period. You will then mail this back to the study centre using a postage-paid envelope. The study will involve:

1) Wearing a wristwatch like accelerometer (Figure 1 below) 24-hours a day for 10 consecutive days, except when swimming. This tells us when you are sleeping, and how well you are sleeping. It is not a tracking device, nor does it record heart rate – it simply measures the amount you are moving at any given time.
2) Wearing a device to measure your breathing in your sleep for 1 night. This "ApneaLink" device consists of soft nasal prongs to measure breathing, a sensor to wear around your finger to measure blood oxygen, and a band around your chest to measure breathing movements (Figure 2 below).
3) Completing a written or online questionnaire about your sleep habits, biological rhythms, and daily functioning
4) Completing an online questionnaire about memory and concentration.
5) Providing some basic demographic information, including your OHIP number, to allow us to connect data from this study to health information and blood samples that you have already provided to the Ontario Health Study, as well as to information contained in current and future public health databases.

These data will be linked to health information, measurements, and blood samples that you have already provided to the Ontario Health Study or may provide to the Ontario Health Study in the future, as well as to public health records databases, to enable us to study the links between genetics, sleep and circadian rhythms, and health outcomes. At the end of the Ontario Sleep Health Study, all data collected as part of this study will be made available to the Ontario Health Study and incorporated into the Ontario Health Study database.

Figure 1: Actiwatch Accelerometer

Figure 2: ApneaLink Sleep Breathing Monitor

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that about 2,000 people in the province of Ontario will participate in this study. The length of this study for participants is 10 days. The entire study is expected to take about four years to complete and the results should be known in five years.

WHAT ARE THE RESPONSIBILITIES OF THE STUDY PARTICIPANTS?

If you decide to participate in this study, you will be asked to do the following, all of which will happen in your home. We will mail you equipment which you will use yourself to measure your own sleep and biological rhythms over a 2-week period. You will not need to come to the study centre.

1) Wear a wristwatch like accelerometer (Figure 1 above) 24-hours a day for 10 consecutive days, except when swimming. This tells us when you are sleeping, and how well you are sleeping. It is not a tracking device, nor does it record heart rate – it simply measures the amount you are moving at any given time.

2) Wear a device to measure your breathing in your sleep for 1 night. This "ApneaLink" device consists of soft nasal prongs to measure breathing, a sensor to wear around your finger to measure blood oxygen, and a band around your chest to measure breathing movements (Figure 2 above).
3) Start using these devices on the first day that you receive them; this is important because
   a) the on-board memory of the wristwatch accelerometer will run out in 14 days and if there is a delay in starting the recording, we will not be able to get a full 10 days of recording
   b) delaying the ApneaLink recording may cause the batteries to lose their charge, which may cause the test to fail during the night.
4) Complete a written or online questionnaire about your sleep habits, biological rhythms, and daily functioning.
5) Complete an online questionnaire about memory and concentration.
6) Provide some basic demographic information, including your OHIP number, to allow us to connect data from this study to health information and blood samples that you have already provided to the Ontario Health Study, as well as to information contained in current and future public health databases.
7) Mail the study equipment and questionnaire back to the study centre using the provided pre-addressed postage-paid envelope.

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

There are no medical risks to you from participating in this study. However, you may experience side effects from participating in this study. Some side effects are known and are listed below, but there may be other side effects that are not expected. If you decide to take part in this study, you should contact the study coordinator at 416-480-5143 or ontariosleephealthstudy@sunnybrook.ca about any side effects or study-related injuries that you experience.

- There may be some minor discomfort from wearing the wristwatch-like accelerometer.
- There may be some minor disturbance of your usual sleep on the night that you are wearing the ApneaLink device.
- You may learn something about your sleep that you were unaware of, such as your probability of having a sleep disorder, which could cause some anxiety or discomfort
- 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.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

You may or may not benefit directly from participating in this study. The physical measurements collected by the Ontario Sleep Health Study are only for research purposes. This means that the physical measurements are not diagnostic and are not designed to replace routine clinical care. Participating in the Ontario Sleep health Study does not replace a visit to your doctor or healthcare professional. At the end of your participation in this study, we will mail you a summary of the results of the home sleep testing.

Although you may or may not benefit directly from participating in this study, your participation will further our understanding of the genes influencing sleep and circadian rhythms, and the impact of disrupted sleep and circadian rhythms on the health and well-being of Ontarians. This research could contribute to the potential development of new treatments to combat the adverse effects of sleep and

circadian disruption. This research may also inform the design of school, work, or other schedules to minimize the effects of sleep and circadian disruption.

CAN PARTICIPATION IN THIS STUDY END EARLY?

You can choose to end your participation at any time without having to provide a reason. However, if you choose to end your participation before completing the study, you will still be asked to send the study equipment back to the study centre using the postage-paid envelope provided. If you choose to withdraw, your choice will not have any effect on your current or future medical treatment or health care. If you withdraw voluntarily from the study, you are encouraged to contact the study coordinator Giselle Kraus at 416-480-5143 or ontariosleephealthstudy@sunnybrook.ca. If you withdraw your consent, the information that was/were collected before you left the study will still be used. No new information about you will be collected and no further testing will be done without your permission.

WHAT ARE THE COSTS OF PARTICIPATING IN THIS STUDY?

Participation in this study will not involve additional costs you. You will not need to come to the study centre. All study procedures will happen in your home. We will mail you equipment which you will use yourself to measure your own sleep and circadian rhythms over a 10-day period.

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, 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 THE STUDY PARTICIPANTS PAID TO PARTICIPATE IN THIS STUDY?

You will not be paid to participate in this study. However, if you decide to participate in this study, at the end of your participation in the study, you will be provided with a $10 gift card.

HOW WILL MY 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 investigators and study staff will look at the health information and genetic information you have already provided or agreed to provide to the Ontario Health Study and collect only the information they need for this study.

They may also look at personal health information contained in public health record databases 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
- Date of birth

- New and existing medical records, or
- The types, dates and results of various tests and procedures

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

The following people may come to the hospital to look at your personal health information to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines:

- Representatives of the Sunnybrook Research Institute, Sunnybrook Health Sciences Centre of the Sunnybrook Research Ethics Board, because they oversee the ethical conduct of research studies at Sunnybrook

Access to your personal health information and any information you have provided to the Ontario Health Study will take place under the supervision of the Principal Investigator of this study and the Principal Investigator of the Ontario Health Study.

"Study data" is health information about you that is collected for the study but does not directly identify you. 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 the hospital will be used for the research purposes explained in this consent form. At the end of the Ontario Sleep Health Study, all study data collected in this study will be shared with the Ontario Health Study and incorporated into the Ontario Health Study database.

The investigators, 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 risk of identifying you from the study data is very small, it can never be completely eliminated. The Principal Investigator will keep any personal health information about you in a secure and confidential location for 10 years and then destroy it according to Sunnybrook policy.

When the results of this study are published, your identity will not be disclosed. You have the right to be informed of the results of this study once the entire study is complete.

DO THE INVESTIGATORS HAVE ANY CONFLICTS OF INTEREST?

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

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You have the right to receive all information that could help you make a decision about participating in this study. You also have the right to ask questions about this study and your rights as a research participant, and to have them answered to your satisfaction, before you make any decision. You also have the right to ask questions and to receive answers throughout this study.

If you have any questions about this study you may contact the study coordinator Giselle Kraus at 416-480-5143 or ontariosleephealthstudy@sunnybrook.ca.

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 **Dr. Brian Murray, Chair of the Sunnybrook Research Ethics Board at (416) 480-6100 x4276.**

DOCUMENTATION OF INFORMED CONSENT

Please sign both copies of this form. Keep one for yourself, and return one to the study centre in the same envelope as the study equipment.

Full Study Title: The Ontario Sleep Health Study

Name of Participant: _____

Participant/Substitute decision-maker

By signing this form, I confirm that:

- I have read the information provided to me. 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 understand that at the end of my participation in this study, I will receive a summary of the results of the actigraphy and home sleep breathing measurements
- I authorize access to my personal health information, medical record and research study data as explained in this form, including all demographic and health information I have provided or may in the future provide to the Ontario Health Study, data including genetic data I have consented to be generated from biospecimens I have provided or may in the future provide to the Ontario Health Study, as well as information about me found in both current and future health-related databases
- I have agreed to participate in this research study

_____	_____	_____
Name of participant (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