Consent Form A (Screening and Diagnosis)

Consent Form To Participate In A Research Study

Study Title: Diagnosis and treatment of sleep apnea in shelter residents

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Funding Source: CIHR

Introduction:
You are being asked to take part in a research study. Please read the information about the study presented in this form. The form includes details on study's risks and benefits that you should know before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish including your friends, family, and family doctor. Participation in this study is voluntary and your choice will not affect or compromise the regular care you would receive.

Background/Purpose:
Sleep quality is important for physical and mental health. Compared to the general population, shelter residents have poor sleep quality, sleep less, report more snoring, have more sleeplessness, and are more tired during the day. Poor sleep quality can contribute to low quality of life, poor mental health, increased anxiety, inability to work, and lack of motivation.

Sleep apnea is a common sleep disorder characterized by frequent interruptions of breathing during sleep. Unfortunately, there is no study on the commonness of sleep apnea in shelter residents. Untreated sleep apnea reduces quality of life, increases the risk of high blood pressure, and can reduce the ability to work and stay safe for shelter residents.

The purpose of this study is to see how many shelter residents have sleep apnea. We will use two portable devices which are attached to interested residents during their sleep. The study will recruit

400 participants during the study and it is expected that it will take 5 years to complete this study. You are being invited to participate in this study because you are living in a shelter.

Study Visit and Procedure:
You will be asked to complete a set of tasks at multiple visits. These are described below (You can find out the summary of visits and tasks in Figure 3):

Questionnaires
To assess your sleep and the risk factors of sleep apnea, we need you fill a set of online questionnaires. These questionnaires asks questions in different areas such as personal information (gender, sexual orientation, education, etc.), medication history, mental and physical health, sleep status, daily tiredness, etc. A research assistant will help you to complete these questionnaires. The questionnaires take approximately one and a half hours to finish. Health-ITUES questionnaire should be completed in the morning and after the night study.

Smartphone application
This application will assess the risk of sleep apnea during the wakefulness. It asks you to say some vowels loudly and clearly. The application asks for your height, weight, age, and neck circumference. Then, it asks you to complete a video task which includes repeating "see", "saa", and "soo" vowels for 15 seconds. The research assistant will help you finish a video-speech task using a smartphone application.

If you wish to participate in the at-shelter diagnostic phase (using polysomnography devices), you will be asked to follow the next two procedures.

Measurements procedure
The research assistant will help you measure your weight with the scales, height, neck, waist and hip circumferences with the measuring tape, and then your blood pressure using blood pressure measuring device.

Recording procedure
One device will be set-up to record your sleep data. This will occur at the shelter. The Prodigy (portable sleep assessment device) will be tested. This device screen your sleep during night and record physiological information during sleep. In the morning, a research assistant will come to disconnect the selected device and measure your blood pressure again and help you fill Health-ITUES questionnaire.

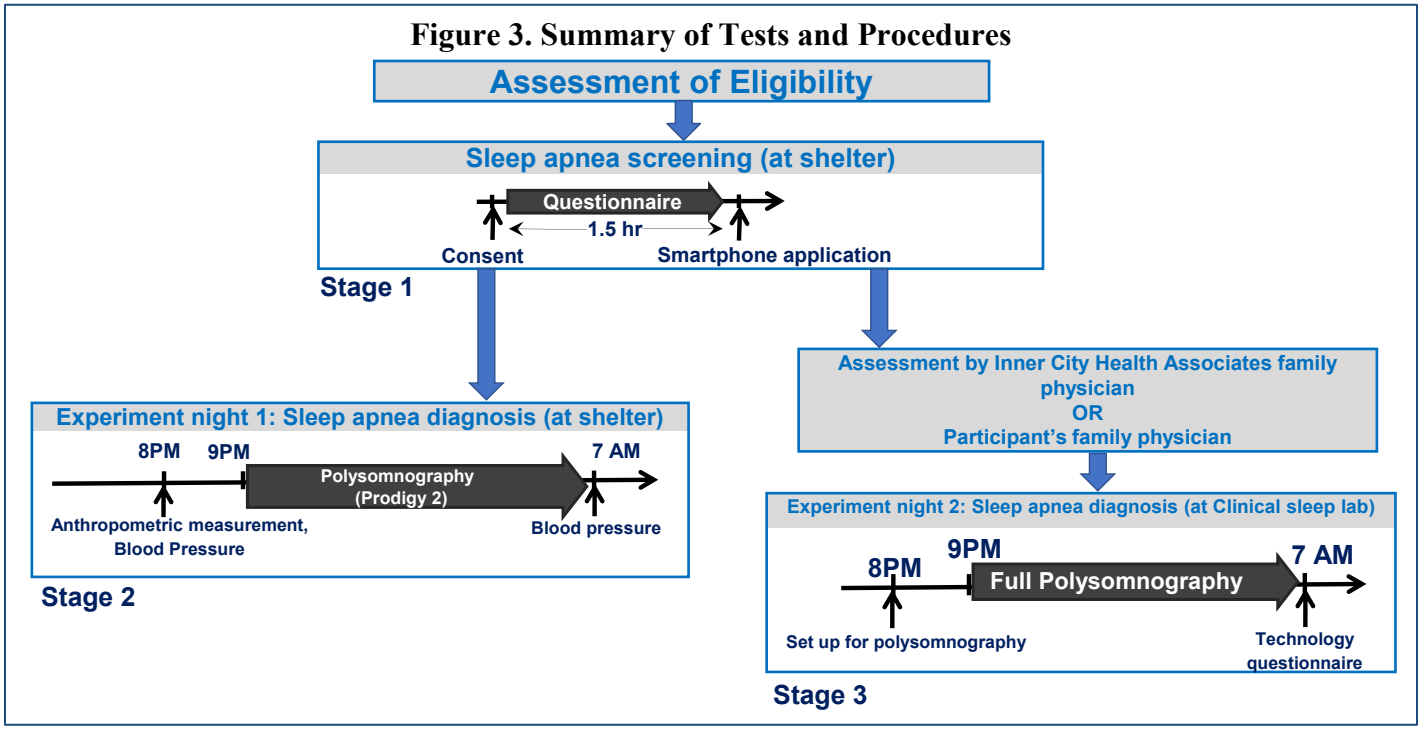
Referral procedure
Your data will then be analyzed, and if you are diagnosed to have a high risk of sleep apnea or snoring, you will be notified and referred to a family physician (at shelter) from Inner City Health Associates (ICHA). If you have your own family physician, the research assistant will provide you with the referral form and you need to bring it to your physician. The referral form can be either emailed to you or brought to your place by the research assistant.
If you still want to continue participating in the study at that time, the family physician will refer you to the hospital for a clinical sleep study and fax the filled out referral. Afterwards, you are asked to stay one night at clinical sleep laboratory to complete a gold standard sleep apnea

diagnosis using advanced polysomnography devices. After that stage, if you are diagnosed with obstructive sleep apnea, you will be offered to participate in the treatment phase of the study at the UHN Centre for Sleep Health and Research.

Prodigy (Portable Sleep Monitoring Device)
The overnight sleep monitoring can be performed using a portable device called the Prodigy from Cerebra Health Company (Figure 1). This device records movement of chest and abdomen, breathing rate, heart rate, level of oxygen in the blood, and brain activity using electrodes that are attached to the skin.

Figure 1. Prodigy sleep system setup

Figure 3. Summary of Tests and Procedures



Remote (Online Visits) – Depending on current restrictions caused by the COVID-19 pandemic, some tasks and visits may be done virtually with the research assistant speaking to you online through MS Teams. This will be discussed with you on a case-by-case basis if remote visits are needed.

Risks:
Taking part in this study has risks. Some of these risks are known to us, which are listed below. There is also a possibility of risks that we do not know about and have not seen in humans to date. Please call the study team if you have any side effects even if you do not think it has anything to do with this study. The risks we know of are:

Risks of portable polysomnography (the Prodigy) - You may experience slight skin irritation from the medical tapes that attach the electrodes to your skin. In case of unusual skin irritation, please inform the researcher to stop the recording.

Risks of the questionnaires – The questionnaires may include some sensitive questions about your personal life and your mental health. If any of these questions bother you, please inform the research assistant.

Risks of the disclosing personal health information – The referral form, which contains the result of the questionnaires and the estimation of your sleep status, might be sent to you through email, and the emails are not guaranteed to be secured.

Benefits:
You may not receive direct benefit from being in this study. Information learned from this study may help shelter residents with undiagnosed sleep apnea in the future.

Reminders and Responsibilities:
It is important to remember the following things during this study:

- Ask the study team about anything that worries you.
- Tell your study team if you change your mind about being in this study.

Confidentiality:
Personal Health Information
The study doctor and the study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could identify you and includes:

- Name
- Date of birth (Year and Month)
- New or existing medical records that includes types, dates and results of medical tests or procedures.

The following people may come to the hospital or be given remote access to an electronic portal (via the internet) to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study is following proper laws and guidelines. When using the electronic portal, we will share your medical record number using a secure method, so that your records are included as part of their review.

- Representatives of the University Health Network (UHN) including the UHN Research Ethics Board.

These individuals have completed privacy training and signed confidentiality agreements and/or are required by law to keep your information confidential. Whether on-site or remotely, UHN makes all efforts to ensure that your information is shared in a way that is secure and private (encrypted). However, any electronic communication carries some risk of third parties gaining unauthorized access to information.
Your study doctor will keep any personal health information about you in a secure and confidential location for 10 years.

Research Information in Shared Clinical Records:
If you participate in this study, information about you from this research project may be stored in your hospital file and in the UHN computer system. The UHN shares the patient information stored on its computers with other hospitals and health care providers in Ontario so they can access the information if it is needed for your clinical care. The study team can tell you what information about you will be stored electronically and may be shared outside of the UHN. If you have any concerns about this, or have any questions, please contact the UHN Privacy Office at 416-340-4800, x6937 (or by email at privacy@uhn.ca).

Study Information That Does Not Identify You:
The study information will be shared with the sleep physicians who are part of the research team. You will be identified with a study number only and any information about you that is sent out will have a number and will not show any information that directly identifies you. No names or identifying information will be used in any publication or presentations.

Voluntary Participation:
Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You may withdraw from the study at any time if you feel any discomfort during the study. We will give you new information that is learned during the study that might affect your decision to stay in the study.

Withdrawal from the Study:
The Researchers can take you off the study early if you pose any harm or safety concern to the research team.
If you decide to leave the study, you have the right to request withdrawal of information collected about you. Let your study team know.

Costs and Reimbursement:
You will not have to pay for any of the procedures or interventions involved with this study. For completion of all the questionnaires and the smartphone application task, you will receive $50. If you wish to participate in the at-shelter diagnostic using polysomnography devices, you will also receive $75 in compensation. Also, after completion of the referral to the sleep physician and participation in the in-laboratory diagnostic, you will receive another $75. Hence the total reimbursement for finishing all tasks of this study will be $200.

Rights as a Participant:
If you are harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost. By signing this form, you do not give up any of your legal rights against the investigators, the collaborating company, or involved institutions for compensation, nor does this form relieve the investigators, the collaborating company, or involved institutions of their legal and professional responsibilities.

Incidental Findings:
During the course of the study, there is a possibility that we might unintentionally come to know of new information about your health condition from (such as depression, asthma, etc.) that are conducted as part of the study. These are called "incidental findings". You will be asked to indicate whether you wish to be re-identified and notified in the event of an important incidental finding that is related to you.

Conflict of Interest:
Researchers have an interest in completing this study. Their interests should not influence your decision to participate in this study.

Questions about the Study:
If you have any questions, concerns or would like to speak to the study team for any reason, please call Azadeh Yadollahi (Principal Investigator) at (416) 597 3422 ext. 7936 or Maria Theresa N. Del Mundo (Research Associate) at (416) 597-3422 x7840 or Behrad TaghiBeyglou (Research student) at (416) 597 3422 ext 7652 or (437) 992-6530 (in case of an emergent issue or unavailability of the previous numbers).

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (UHN REB) or the Research Ethics office number at 416-581-7849. The REB is a group of people who oversee the ethical conduct of research studies. The UHN REB is not part of the study team. Everything that you discuss will be kept confidential.
You will be given a signed copy of this consent form.

Consent:
This study has been explained to me and any questions I had have been answered.
I know that I may leave the study at any time. I agree to the use of my information as described in this form. I agree to take part in this study.

Please select the stages of the study you wish to participate in:

Yes	No	
☐	☐	Questionnaires and smartphone application (Stage 1)
☐	☐	Measurements and full night at-shelter sleep test (Stage 2)
☐	☐	Full night in-clinic sleep test (Stage 3)

Print Study Participant's Name	Signature	Date

My signature means that I have explained the study to the participant named above. I have answered all questions.

Print Name of Person Obtaining Consent	Signature	Date

The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.

Print Name of Witness	Signature	Date

Relationship to Participant