CHILDREN'S & WOMEN'S HEALTH CENTRE OF BRITISH COLUMBIA

Department of Anesthesia
British Columbia's Children's Hospital
4480 Oak Street
Vancouver
V6H 3V4
Tel 604 875 2711
Fax 604 875 3221

SUBJECT INFORMATION AND CONSENT FORM

Title of Study:

Screening for Sleep Apnea in Children Using a Mobile Device

Principal Investigator

Dr. Mark Ansermino, Dept. of Anesthesia, Tel: 604-875-2711

Co-Investigators

Dr. Walter Karlen, Dept. of Electrical/Comp Engineering, Tel: 604-827-3534
Dr. Guy Dumont, Dept. of Electrical/Comp Engineering, Tel: 604-822-2336
Dr. David F. Wensley, Dept. of Critical Care, Tel: 604-875-2744
Joanne Lim, Dept. of Anesthesia, Tel: 604-875-2711

If you are a parent or legal guardian of a child who may take part in this study, permission from you and the assent (agreement) of your child may be required. When we say "you" or "your" in this consent form, we mean you and/or your child; "we" means the doctors and other staff.

1. INVITATION

You are invited to participate in this study because you are undergoing an overnight sleep study called polysomnography at BC Children's Hospital.

2. YOUR PARTICIPATION IS VOLUNTARY

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services to which you are entitled or are presently receiving.

Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study, why the research is being done, what will happen to you during the study and the possible benefits, risks and discomforts.

If you wish to participate in this study, you will be asked to sign this form.

Please take time to read the following information carefully and to discuss it with your family, friends, and doctor before you decide.

3. WHO IS CONDUCTING THE STUDY?

The study is being conducted by the Pediatric Anesthesia Research Team (PART – www.part.cfri.ca). The study is sponsored by the Canadian Institutes of Health Research (CIHR) and the Natural Sciences and Engineering Research Council of Canada (NSERC).

4. BACKGROUND

The diagnosis of sleep apnea in children presents a challenging problem. The high frequency of sleep apnea poses a serious threat to the healthy growth and development of many children. The lack of oxygen during sleep can lead to daytime sleepiness, growth failure, heart failure, behavioural problems and developmental delay. Polysomnography (PSG) is the standard test for the diagnosis of sleep apnea. This test requires a comprehensive sleep laboratory and the inconvenience of an overnight stay.

Pulse oximetry (a non-invasive device with sensors that measures the amount of oxygen in blood) is part of the standard PSG. However, we believe that with improved engineering design it has the potential to provide a standalone sleep apnea screening and testing device. Our goal will be to improve the ability of pulse oximetry to be used as a screening tool with the additional information extracted from the recorded signal (especially the respiratory [breathing] information).

We have developed the Phone Oximeter (www.phoneoximeter.org), a pulse oximeter interfaced to a mobile device (iPod Touch or netbook computer). The Phone Oximeter used for screening of sleep apnea would offer several advantages over PSG: this portable device could be used at home, will cause less sleep disturbance, allowing for a more natural sleep pattern, and provide the ability to monitor patients over multiple nights, while evaluating the response to medication and other medical interventions. In addition, the ability of the Phone Oximeter to wirelessly communicate information (no delay in interpretation of

results or response to critical events) offers a distinct advantage over traditional pulse oximeters.

5. WHAT IS THE PURPOSE OF THE STUDY?
We wish to record and evaluate overnight pulse oximetry data for identifying sleep apnea with the Phone Oximeter. We are hopeful that doctors can use this to more easily diagnose sleep apnea in the future.

6. WHO CAN PARTICIPATE IN THE STUDY?
You may be eligible to participate in this study if you are between 1 month – 18 years old, and having an overnight PSG study.

7. WHO SHOULD NOT PARTICIPATE IN THE STUDY?
You cannot participate if you have abnormal heart rate, or abnormal hemoglobin (protein in blood that carries oxygen).

8. WHAT DOES THE STUDY INVOLVE?
Overview of the Study
The study is taking place in the Medical Day Unit sleep labs of British Columbia Children's Hospital. We will recruit 140 subjects.

There are no extra tests, medications or treatments required. The only difference between the usual overnight PSG sleep study and this study would be the addition of a second pulse oximetry finger sensor. The finger sensor does not hurt and is similar to a bandaid.

If You Decide to Join This Study: Specific Procedures
If you agree to take part in this study, the procedures you can expect will include the following:
In addition to the usual sensors for PSG, the Sleep Technician will apply an additional sensor to your finger which is then connected to the Phone Oximeter. The Sleep Technician will make sure all sensors are well connected and working. You will then go to sleep as usual. We will record the data coming from the additional finger sensor with the Phone Oximeter. At the end of the night, the Phone Oximeter will be stopped together with the rest of the sensors.

9. WHAT ARE MY RESPONSIBILITIES?
There are no further responsibilities other than allowing an additional finger sensor to be attached for the overnight period.

10. WHAT ARE THE POSSIBLE HARMS AND DISCOMFORTS
The risks and side-effects of the standard or usual treatment of overnight PSG will be explained to you as part of your standard care. There are no additional risks with placement of another finger sensor.

11. WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING?
No one knows whether or not you will benefit from this study. There may or may not be direct benefits to you from taking part in this study. We hope that the information learned from this study can be used in the future to benefit other people with similar problems.

12. WHAT ARE THE ALTERNATIVES TO THE STUDY TREATMENT?
If you choose not to participate in this study or to withdraw at a later date, the following treatment options may be available to you: usual overnight PSG. You can discuss these options with your doctor before deciding whether or not to participate in this research project.

13. WHAT IF NEW INFORMATION BECOMES AVAILABLE THAT MAY AFFECT MY DECISION TO PARTICIPATE?
If you choose to enter this study and at a later date a more effective treatment becomes available, it will be discussed with you. You will also be advised of any new information that becomes available that may affect your willingness to remain in this study.

14. WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?
You may withdraw from this study at any time without giving reasons.
If you choose to enter the study and then decide to withdraw at a later time, all data collected about you during your enrollment in the study will be retained for analysis.

15. CAN I BE ASKED TO LEAVE THE STUDY?
If you are not able to follow the requirements of the study or for any other reason, the study doctor may withdraw you from the study and will arrange for your care to continue. On receiving new information about the test, your research doctor might consider it to be in your best interests to withdraw you from the study without your consent if they judge that it would be better for your health.

16. WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?
Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the

Investigator or his or her designate by representative, and the UBC C&W Research Ethics Board for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a subject in this study. Only this number will be used on any research-related information collected about you during the course of this study, so that your identity [i.e. your name or any other information that could identify you] as a subject in this study will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected and also give you the right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor.

17. AFTER THE STUDY IS FINISHED

The Phone Oximeter is a research tool and is not yet available for sale. Study results and publication(s) may be available at the conclusion of the study. Please check the PART website (http://www.part.cfri.ca) for information regarding this study and for contact information on accessing the results.

18. WHAT HAPPENS IF SOMETHING GOES WRONG?

Signing this consent form in no way limits your or the subject's legal rights against the investigators or anyone else, and you do not release the study doctors or participating institutions from their legal and professional responsibilities.

19. WHAT WILL THE STUDY COST ME?

There will be no additional cost to you for your participation in the study. You will not be charged for any research procedure. You will not be paid for participation.

20. WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY DURING MY PARTICIPATION?

If you have any questions or desire further information about this study before or during your participation, you can contact Dr. Ansermino at 604-875-2711.

21. WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT MY RIGHTS AS A SUBJECT?

If you have any concerns or complaints about your rights as a research subject and/or your experiences while participating in this study, contact the Research Subject Information Line in the University of British Columbia Office of Research Services by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598).

22. SUBJECT CONSENT TO PARTICIPATE
Study title: **Screening for Sleep Apnea in Children Using a Mobile Device**

Subject Consent

My signature on this consent form means:

- I have read and understood the subject information and consent form.
- I have had the opportunity to ask questions and have had satisfactory responses to my questions.
- I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time without changing in any way the quality of care that I receive.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.

The parent(s)/guardian(s)/substitute decision-maker (legally authorized representative) and the investigator are satisfied that the information contained in this consent form was explained to the child/subject to the extent that he/she is able to understand it, that all questions have been answered, and that the child/subject assents to participating in the research.

I will receive a signed copy of this consent form for my own records.

I consent to participate in this study.

Subject's Signature	Printed name	Date
Parent/Guardian Signature	Printed name	Date

Signature of Person Obtaining Consent	Printed name	Study Role	Date

If this consent process has been done in a language other than that on this written form, with the assistance of an interpreter/translator, indicate:

Language: _____

Was the subject assisted during the consent process in one of ways listed below?

☐ Yes ☐ No

If yes, please check the relevant box and complete the signature space below:

☐ The consent form was read to the subject, and the person signing below attests that the study was accurately explained to, and apparently understood by, the subject (please check if subject is unable to read).

☐ The person signing below acted as an interpreter/translator for the subject, during the consent process (please check if an interpreter/translator assisted during the consent process).

_____	_____	_____
Signature of Person Assisting in the Consent Discussion	Printed Name	Date

23. SUBJECT'S ASSENT TO PARTICIPATE

I have had the opportunity to read this consent form, to ask questions about my participation in this research, and to discuss my participation with my parents/guardians. All my questions have been answered. I understand that I may withdraw from this research at any time, and that this will not interfere with the availability to me of other health care. I have received a copy of this consent form. I assent to participate in this study.

_____

Printed name of subject Signature Date