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

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PARTICIPANT INFORMATION AND CONSENT FORM

Title of Study:

Monitoring at Home Before and After Adenotonsillectomy

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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 scheduled for a tonsillectomy or adenoidectomy operation 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).

4. BACKGROUND
While adenotonsillectomy is a very safe procedure, recent research has highlighted that in rare cases children can have breathing problems after the operation. These breathing problems can be made worse in certain cases by using strong medicines like morphine after the operation.

A pulse oximeter is a device that uses a sensor placed on your finger or toe to painlessly measure the amount of oxygen in your blood, in addition to other important information. We have developed the Phone Oximeter (www.phoneoximeter.org), a pulse oximeter interfaced to a mobile device (iPod Touch or netbook computer). We have already shown that we can use this device to predict which patients have Obstructive Sleep Apnoea (blocked breathing during sleep) with a good level of accuracy.

5. WHAT IS THE PURPOSE OF THE STUDY?
We wish to record and evaluate overnight monitoring (from the Phone Oximeter) for three nights before your surgery and three days directly after your surgery with the Phone Oximeter. We are hopeful that we can use this data to help design a mobile device application to predict which children could develop breathing problems after their operation. The Phone Oximeter could also be used at home after adenotonsillectomy as a warning device in case a child develops difficulty breathing in the nights after surgery.

6. WHO CAN PARTICIPATE IN THE STUDY?
You may be eligible to participate in this study if you are between 3 months – 17 years old, and having tonsillectomy, adenoidectomy or both.

7. WHO SHOULD NOT PARTICIPATE IN THE STUDY?

You cannot participate if you have abnormal heart rhythm, or a known abnormal hemoglobin (protein in blood that carries oxygen).

8. WHAT DOES THE STUDY INVOLVE?

Overview of the Study

If you wish to participate in the study a researcher will come over to the clinic to explain the study and to show you how to use the Phone Oximeter. You will be shown how to attach a sticky sensor (like a band aid) around your big toe. A sock should be placed over the sensor. The sensor is attached via a long wire to a tablet computer device. A bracelet which measures movement will be also worn overnight. You will wear the sensor and bracelet every night for 3 nights in a row after your clinic visit. You can return the equipment to the hospital when the 3 nights of recordings are complete (or we can arrange a pick-up). We can also arrange postage if you live outside Vancouver.

The next set of recordings will be over the first three consecutive nights after surgery. If you are admitted to the ward or to the Intensive Care Unit for the first night after surgery, we will arrange to do the recordings there. Equipment can be returned to the hospital in a similar way as following the 1st set of recordings.

We will have a total of 40 participants.

9. WHAT ARE MY RESPONSIBILITIES?

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:

Training in using the Phone Oximeter and overnight activity bracelet.
Set up of equipment for 3 consecutive nights on 2 separate occasions.
A small amount of data entry before and after each recorded sleep.
Recharging the Phone oximeter tablet each day after recording.
Arranging return of equipment to the hospital.

10. WHAT ARE THE POSSIBLE HARMS AND DISCOMFORTS

There is a possible risk of your child not sleeping as well as usual due to unfamiliar equipment attached to the toe and wrist. Similar studies have been completed previously at home, and most children will sleep as usual. The data collected will only be used for research and will not affect the treatment received.

11. WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING?

There 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 children who are scheduled for the same operation and make the procedure even safer for them.

12. WHAT ARE THE ALTERNATIVES TO THE STUDY TREATMENT?
You can opt out of home monitoring and have the usual standard of care.

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, you have the right to request the withdrawal of your information collected during the study. This request will be respected to the extent possible. Please note however that there may be exceptions where the data will not be able to be withdrawn for example where the data is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data, please let your study doctor know. If your participation in this study includes enrolling in any optional studies, or long term follow-up, you will be asked whether you wish to withdraw from these as well.

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.

The application on the Phone Oximeter is protected by username and password. The application is protected by encryption to protect it in case someone accessed the data stored on the Phone Oximeter. The data collected during surgery and the period after surgery will be stored in a locked filing cabinet in a locked office in a secure building.

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 participant'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 PARTICIPANT?

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

22. PARTICIPANT CONSENT TO PARTICIPATE

Study title: **Monitoring at Home Before and After Adenotonsillectomy**

Participant Consent

My signature on this consent form means:

- I have read and understood the participant 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/ participant to the extent that he/she is able to understand it, that all questions have been answered, and that the child/ participant 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.

_____	_____	_____
Participant's Signature	Printed name	Date
_____	_____	_____
Parent/Guardian Signature	Printed name	Date
_____	_____	_____ _____

Signature of Person Obtaining Consent	Printed name	Study Role	Date