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SUBJECT INFORMATION AND CONSENT FORM

Title of Study:

Mobile Health: Audio-based Interfacing to Clinical Sensors - Calibration and Validation of an Audio Pulse Oximeter Sensor (AudioOx) Using Direct Blood Gas Measurement

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When we say "you" in this consent form, we mean you or your child.
When we say "we" in this consent form, we mean the doctors and researchers involved in this study. They are listed at the top of this page.

1. INTRODUCTION

You are invited to participate in this study because you are going to have a type of blood sample testing as part of your routine clinical care. We are investigating the use of a non-invasive low-cost monitor for measuring oxygen levels in the blood.

2. YOUR PARTICIPATION IS VOLUNTARY

Your participation is entirely voluntary, so it is up to you to decide whether or not to participate. 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 do decide to participate, you will be asked to sign this form. Even after you have done this, you are free to withdraw from the study at any time, and you do not have to give any reasons for your decision.

If you choose not to be involved or withdraw from the study, you do not have to tell us why. The medical care that you will be receiving will not be any different or less than the care you would normally receive. Please take time to read this information and ask any questions that may help you to understand the study before you decide whether or not to be in the study.

3. BACKGROUND

Pulse oximetry is a non-invasive method to assess blood oxygen saturation level (SpO_2) and heart rate (HR). A pulse oximeter sensor consists of light-emitting diodes applied to an area of the body with good local blood flow (i.e. fingertip or ear lobe). Red and infrared light is shone through the blood-perfused tissue under the sensor, and received by an opposing photodiode. Information from the photodiode is relayed to a signal-processing unit or monitor, for calculation of oxygen saturation from the relative photo-absorbance of red and infra-red light.

For over 20 years, pulse oximeters have been successfully utilized for assessing a patient's need for oxygen in health care settings and have become the de facto standard monitoring device in the developed world. However, pulse oximeters are rare in developing countries because they are expensive and require a reliable source of electricity.

We plan to make pulse oximetry available to resource poor countries by designing a low-cost, battery-powered pulse oximeter device consisting of a low cost pulse oximeter sensor connected to a cell phone. The use of cell phones as patient monitors is appealing as they are widely available in many developing countries. Utilizing battery power, cell phones do not rely on a continuous source of electricity. Furthermore, a cell phone has the efficiency, integrated display and processing power required to analyze and store the raw data derived from the pulse oximeter sensors. Data from the pulse oximeter can be transmitted to referral centers for diagnostic and advisory purposes where cellular and networking services permit.

Proprietary oximeter sensors and modules are expensive. To reduce cost, we hope to develop an audio pulse oximeter sensor (AudioOx), a simple oximeter sensor that interfaces via the audio jack of any standard cell phone. By utilizing

the audio jack for transmission of data from the sensor to phone, we can ensure that cell phone types most common in various areas of the world are universally supported. Preliminary laboratory tests have shown that oximetry data from the AudioOx has sufficient signal strength and resolution for extraction of heart rate and oxygen saturation.

Health Canada has not approved the sale or use of AudioOx as a clinical monitor, although they have approved its use in this clinical study.

4. WHY IS THIS STUDY BEING DONE?

The development of any new pulse oximeter equipment requires calibration and evaluation for accuracy. The best and most accurate measurements of oxygen levels in the blood come from blood samples analyzed by special laboratory equipment. We would like to use these measurements as references to calibrate the AudioOx, and evaluate its accuracy.

There is no standard calibration tool for pulse oximeters. To paraphrase the current ISO Pulse Oximetry international standard document: "There is today no accepted method of verifying the correct calibration of a pulse oximeter probe/pulse oximeter monitor combination other than testing on human beings. This is due to the complexity of the optical intricacies of the interaction of light and human tissue upon which pulse oximetry depends".

Oxygen saturation data collected as part of your care can be used to calibrate and evaluate the accuracy of the audio oximetry data. In line with ISO testing requirements, we will use measurements from blood gas analysis as well as secondary pulse oximeters for reference measurements of both SpO_2 .

Drs. Ansermino, Petersen and Dumont have a patent on the AudioOx and are trying to bring it to market.

5. WHO CAN PARTICIPATE IN THE STUDY?

In order to participate in the study, you must be having an arterial blood sample taken for routine care in the operating room (OR) or catheterization laboratory (CathLab), or be admitted to either the Neonatal Intensive Care Unit (NICU) or Pediatric Intensive Care Unit (PICU). You must also be receiving (or have already received), as part of your hospital care, a small, thin plastic tube into an artery in the arm or leg, from which small blood samples will be taken and analyzed.

6. WHO SHOULD NOT PARTICIPATE IN THE STUDY?

Children who weigh less than 1kg should not participate. Because they are so small, it is difficult to find places to put the sensors on their skin. Patients who

are receiving high doses certain medicines known as vasoconstrictors should also not participate.

7. WHAT DOES THE STUDY INVOLVE?

The study is taking place in the operating rooms and catheterization laboratory of British Columbia Children's Hospital, as well as in the neonatal and pediatric intensive care units. We will recruit approximately 200 children.

If you are assessed as being suitable for being in the study and you choose to participate, you will have one, two or three additional sensors placed on one hand, arm or leg. These sensors will sit on top of the skin, and shine a small red light onto the skin. As part of your routine care at the hospital, you will have at least one small blood sample taken. We will record the results of these blood tests, so the study will not require you to have any additional blood samples taken. The sensors will remain in place for a few minutes before and after each blood measurement that is performed as part of routine care.

8. WHAT ARE THE POSSIBLE HARMS AND SIDE EFFECTS OF PARTICIPATING?

Similar pulse oximetry sensors that measure the oxygen level in the blood are used routinely in all hospitals. These sensors are hypoallergenic, and do not pose any risk to your health.

The placement of an arterial line, or small, thin tube placed in the artery of the arm or leg, is a routine method of monitoring changes in blood pressure, or taking small blood samples to test the level of dissolved gases in the blood. These study procedures will only be performed if you have an arterial catheter as required for your routine care. No extra blood samples will be taken.

9. WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

There are no direct benefits to your participation in this study. The information we obtain from the study will be used to improve pulse oximeter sensors that will be used for others in the future. There is no financial reimbursement for participation.

10. WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?

Your participation in this research is entirely voluntary. You may withdraw from this study at any time. If you decide to enter in the study and withdraw at any time in the future, there will be no penalty or loss of benefits to which you are otherwise entitled, and your future medical care will not be affected.

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. By law, this data cannot be destroyed.

11. WHAT ARE MY LEGAL RIGHTS?

Signing this consent form in no way limits your legal rights against the sponsor, investigators or anyone else.

12. CAN I BE ASKED TO LEAVE THE STUDY?

The study doctor(s)/investigators may decide to discontinue the study at any time, or withdraw you from the study at any time, if they feel that it is in your best interests.

13. WHAT WILL THE STUDY COST ME?

There will be no additional financial cost to you for your participation in the study. You will not be charged for any research procedure. You will not receive any remuneration/reimbursement for participation.

14. WILL MY PARTICIPATION IN THIS STUDY BE KEPT CONFIDENTIAL?

Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent to the disclosure.

Research records and medical records identifying you may be inspected, in the presence of an Investigator or his or her designate, by representatives of the UBC Research Ethics Boards, for the purpose of monitoring the research. However, records which identify you by name or initials will be kept in a locked cabinet and will not be allowed to leave the Investigators' offices. Copies of relevant data, which identify you only by code number, may be required by regulatory agencies. However, you will not be identified by name, initials, or date of birth as part of this study data.

15. 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.

16. WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT MY RIGHTS AS A SUBJECT DURING THE STUDY?

If you have any concerns about your treatment rights as a research subject, please contact the Research Subject Information Line at the University of British

Columbia Office of Research Services at 604-822-8598 (Toll Free Number 1-877-822-8598) or if long distance, email to RSIL@ors.ubc.ca.

17. CONSENT TO PARTICIPATE

I have read or have had read to me all of the above. I have had enough time to consider entry to the study. All of my questions have been answered to my satisfaction. I understand that my participation is entirely voluntary and that I may refuse to participate, or I may withdraw from the study at any time.

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

I acknowledge having received a signed and dated copy of this consent form for my own records.

Name of Subject: _____

Printed name of subject	Signature	Date
Printed name of subject's parent / Legally acceptable representative	Signature	Date
Printed name of principal investigator/ Designated representative	Signature	Date