



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

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SUBJECT INFORMATION AND CONSENT FORM

Development and Evaluation of iPleth for Uganda (in vivo evaluation)

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BACKGROUND

You are invited to participate in this research study because you are a staff anesthesiologist, a trainee anesthesiologist, anesthesia technician, nurse, engineer or lay user.

In poorer parts of the world, most preventable anaesthesia morbidity and mortality is related to airway and respiratory problems leading to lack of oxygen (hypoxia). Hypoxia is difficult to detect clinically until the blood turns blue. A pulse oximeter gives an early warning of hypoxia by monitoring the percentage of hemoglobin in the blood that is oxygenated. An early, rapid and effective response to early signs of hypoxia, detected and displayed by a pulse oximeter, can rescue the patient from the permanent effects of lack of oxygen, such as brain damage or death.

Many technological advances in healthcare, such as pulse oximetry, have not been widely adopted in many developing countries. Anesthesia death rates in developing nations are 100 to 1,000 times higher than in the developed world. In these countries, pulse oximetry is seen as a luxury, rather than a necessity. The relatively high initial cost of pulse oximetry has been a significant barrier to global adoption. The availability of an inexpensive and robust device would be a significant boost to wider adoption.

A pulse oximeter that uses a cell phone to analyze the information received from a sensor placed on the finger will be evaluated. We will determine if a standard iPodTouch/iPhone can be used to intelligently analyze and creatively communicate information from the sensor and if the software interface can minimize the need for training and provide education on the use of the device. A successful implementation should enhance the delivery of information from a pulse oximeter and allow the user to monitor, supervise and intervene during anesthesia.

It is our intent to optimize these aspects of our prototype through this usability study. iPleth is a software application that is being developed by our research team to provide on the job training in the use of the device and enhanced expert advice.

WHAT IS THE PURPOSE OF THE STUDY?

To evaluate the usability of the iPleth interface pulse oximeter prototype in the hands of expert anesthesiologists/trainees, anesthesia technicians, nurses and lay medical users to determine areas for improvement for the interface.

We will recruit 50 subjects for this study.

WHO CAN PARTICIPATE IN THE STUDY?

Consenting anesthesiologists, anesthesia residents, anesthesia technicians, nurses, engineers and lay users may participate in this study.

WHO CANNOT PARTICIPATE IN THIS STUDY?

Subjects that do not consent or who are unable to consent cannot participate in this study.

WHAT DOES THE STUDY INVOLVE?

As a subject in this study, we ask you to use iPleth on a patient subject to examine its usability.

You will be given instruction on how to “think aloud” (we will audio record your speech).

When the test period is completed, you will be asked to fill out a short questionnaire, for your feedback and comments on the interface.

Audio Recordings

All digital audio recordings will be kept safely on password protected computers in a locked cabinet in a locked office. Only the Investigators and designated representatives will have access to the recordings. The recordings will be given unique code numbers and no identifiable information will be used. The recordings will be stored on site for 5 years and then destroyed. There are no plans for secondary use of the audio recordings.

WHAT ARE YOUR RESPONSIBILITIES?

In addition to your usual clinical duties, you are responsible for interacting with the iPleth interface and “thinking aloud” to provide insight into your use of the application.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

The results of this study will determine the usability of iPleth, including possible areas for improvement. This will lead to future versions of iPleth being more widely used by clinicians.

WHAT HAPPENS IF YOU DECIDE TO WITHDRAW CONSENT TO PARTICIPATE?

Your participation in this research is entirely voluntary. You may withdraw from this study at any time without providing any reasons. 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.

If you choose to enter the study and then decide to withdraw at a later time, all data collected in the study will be retained for analysis.

WHAT ARE YOUR LEGAL RIGHTS?

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

WHAT WILL THE STUDY COST?

There will be no cost to you for your participation in the study.

WHAT ARE THE RISKS INVOLVED IN PARTICIPATING?

There are no foreseeable risks in participating in this research study.

WILL YOUR 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. However, research records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of Health Canada and the UBC Research Ethics Boards for the purpose of monitoring the research. However, no records which identify you by name or initials will be allowed to leave the Investigator's offices.

Your rights to privacy are also protected by the *Freedom of Information and Protection of Privacy Act of British Columbia*. This Act lays down rules for the collection, protection, and retention of your personal information by public bodies, such as the University of British Columbia and its affiliated teaching hospitals. Further details about this Act are available upon request.

The fact of your participation in this study cannot be kept strictly confidential as you will be observed in the study. However, we will not provide a list of participants or non-participants to anyone not involved in running this study. In particular, we will not provide such a list to anyone who has supervisory responsibilities. In reporting results from this study, we will not identify you.

WHO TO CONTACT IF YOU HAVE QUESTIONS ABOUT THE STUDY DURING YOUR PARTICIPATION?

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

WHO DO YOU CONTACT IF YOU HAVE ANY QUESTIONS OR CONCERNS ABOUT YOUR RIGHTS AS A SUBJECT DURING THE STUDY?

If you have any concerns about your rights and/or experiences as a research subject, please contact the Research Subject Information Line at the University of British Columbia Office Research Services, at 604-822-8598 or if long distance e-mail to RSIL@ors.ubc.ca.

CONSENT TO PARTICIPATE

I have read 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 may withdraw from the study at any time.

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

I do not waive any of my legal rights by signing this consent form.

Printed name of subject	Signature	Date
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Printed name of principal investigator/ designated representative	Signature	Date
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