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Participant Information and Consent Form

Preliminary validation of novel non-invasive physiologic sensors – a volunteer study

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1. Invitation

You are invited to participate in this study because you are an adult age 19 and older, and you are a non-smoker with no history of heart disease, breathing disorder or neurological problems.

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.

This consent form describes the procedures that are being carried out for research purposes. Please review the consent document carefully when deciding whether or not you wish to be part of the research and sign this consent only if you accept being a research participant.

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 this study?

The study is being conducted by researchers in the Pediatric Anesthesia Research Team (PART) and the Electrical & Computer Engineering in Medicine (ECEM) group at UBC.

No investigator is receiving any financial compensation from any outside funding agency for conducting or being involved with any part of the study. It is possible that the investigators may benefit from commercialization of the sensors they will be testing. You are welcome to request any details, from the Principal Investigator-Dr Mark Ansermino, concerning the teams current industry sponsored research or the potential commercialization opportunities for the sensors being tested. The University of British Columbia and the investigators have spun off a company (LionsGate Technologies- LGT) that is commercializing previous sensors developed by the team. The University and the investigators do have an equity stake in LGT. .

4. Background

Non-invasive methods to measure the amount of oxygen in your blood (SpO2), blood pressure, airflow (from breathing), electrical signals from the heart (ECG), electrical signals from the brain (EEG), temperature and other parameters are increasingly available as over the counter devices purchased for use at home. The Electrical and Computer Engineering in

Medicine (ECEM) group at the University of British Columbia, Vancouver, Canada, is developing a suite of low-cost non-invasive sensors that can be made available for use at home and in low resource settings where traditional health services may be limited or absent. These sensors will be connected to a cell phone running mobile health (mHealth) applications. This will allow us to use the processing and display capabilities of cell phones.

For example, pulse oximetry is a non-invasive device with a sensor (similar to a bandaid) that measures the amount of oxygen in your blood (SpO2) and your heart rate (HR). A pulse oximeter sensor is placed on an area of the body with good blood flow (such as the fingertip or the nostril). Light from the sensor is shone through the tissue and this information is used to calculate the SpO2.

For over 20 years, pulse oximeters have been used to assess a patient's needs for oxygen in health care settings and are the standard monitoring device in the developed world. Pulse oximeters, however, are rare in developing countries because they are expensive and require electricity.

The ECEM and PART aim to make pulse oximetry and other physiological monitoring 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 a good idea, as they are widely available in many developing countries. Cell phones do not need a continuous source of electricity because they can use their battery power. This is important, as most poor countries cannot provide the power supply needed for standard patient monitoring. A cell phone can also analyze and store the raw data it gets from the pulse oximeter sensors. When cell service allows, data from the pulse oximeter on the cell phone can be moved to different locations for advice and diagnosis.

Oximeter sensors and modules are expensive. To reduce cost, we hope to develop simple sensors (ie. AudioOx) that can be plugged into the audio jack of any standard cell phone. By using 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 audio pulse oximeter (AudioOx), audio spirometer (for measuring airflow in breathing), audio blood pressure, audio NIRS and audio temperature data from the sensor phone system can produce information that is useful to healthcare providers.

5. What is the purpose of the study?

In the developing stages, vital sign monitors require testing to make sure the sensors are functional and accurate. The only way to test these sensors is to compare them to other currently available sensors.

The objective of this research is to evaluate these new non-invasive sensors. To do this we will:

i. Place multiple sensors on healthy participants (adult volunteers).
ii. Observe these participants in a closely supervised medical environment.
iii. Request participants go through a range of physiological manoeuvres.
iv. Compare data collected from the prototype sensors to commercially available reference sensors.

6. Who can participate in this study?

You may be able to participate in this study if*:*

- You are 19 years or older
- You have no medical history of respiratory, cardiovascular and/or neurological problems

7. Who should not participate in this study?

You will not be eligible to participate in this study if:

- You are a smoker, or are otherwise exposed to high levels of carbon monoxide
- You have open cuts or wounds on your body that will interfere with placement of the sensors we are testing

8. What does the study involve?

Overall design of the study
This will be a non-invasive observational study of healthy adult volunteer participants. The total duration of the study will be no more than ninety minutes. The study will be conducted with medical supervision, in the clinical care facilities at BC Children's Hospital. In order to evaluate and validate the sensors, we will gather a range of physiological data from participants, and have them complete a series of maneuvers during the study.

If You Decide to Join This Study: Specific Procedures
We will place a number of sensors on your body:

Examples of the types of sensors that this might include may include are:

Shining and measuring light through your skin, measurement of pressure in your arteries (e.g by placing a cuff around your arm or wrist), measuring the very small voltages produced by your body (e.g. ECG), measuring your temperature, measuring your movements or the movements produced by your heart beating or the volume or concentrations of gases you breath.

Specific maneuvers may be required for each sensor to induce physiological changes.

1. Exercise or movement (such as leg raises or cycling on a stationary bicycle).
2. A cold pressor test (immersion of your hand in ice cold water for 60 seconds)
3. Breathing of a low oxygen gas mixture through a mask.

9. What are my responsibilities?

You will be responsible for following the investigators' instructions throughout the length of the study.

10. What are the possible harms and discomforts?

There is minimal risk associated with the application of the sensors we are testing. Mild skin irritation may occur from a sensor or the tape that secures it. However this normally clears within a few hours. Hypoallergenic tape will be used to secure other sensors, when it is required. The inflation of the blood pressure cuff may cause brief periods of discomfort and mild skin irritation. The portion of the blood pressure cuff that fits around your arm is not different from that used by your doctor.

We may ask you to stick your hand in a bucket of ice water. This may cause your heart rate to increase and causes some discomfort, however you can stop the test at any time by removing your hand from the ice water.

We may ask you to some simple exercises (leg raises or similar), in order to raise your heart rate by no more than 30% above your resting rate.

You may be asked to breathe a low oxygen concentration (this would be comparable to being at an altitude of less than 4000m (12% at sea level) and similar to what many high performance athletes are exposed to on a daily basis as part of their altitude training regime. Some subjects may find it uncomfortable when they are breathing the low oxygen gas mixture to simulate altitude. The subjects may feel that they are breathing heavily, or feel light-headed. They may begin to feel some symptoms such as headache, poor appetite, dizziness, or nausea. They may become slightly confused, or notice poor coordination. There will be a physician present at all times to monitor the subjects, to answer any questions and to carry out testing procedures.

If you feel any discomfort, or have any concerns, you will be attended to immediately. You will be able to discontinue the study at any time. You will be very carefully monitored during the full course of the study. Oxygen and emergency drugs will be immediately available should they be required.. The study will be conducted in a suite with emergency resuscitation equipment at BC Children's Hospital.

11. What are the potential benefits of participating?

There are no direct benefits to you. We expect that you will be interested in how these sensors work and how these measurements can give an indication of the health status of your body. .

Out goal is to use the information gathered during the validation of these sensors to create low-cost vital sign monitors that can be used to improve healthcare for patients all over the world.

12. 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 enrolment in the study will be retained for analysis.

13. 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 investigators may withdraw you from the study.

14. How 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 her/his designate by representative, and the UBC Clinical 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 participant 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 participant 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.

Studies involving humans now routinely collect information on race and ethnic origin as well as other characteristics of individuals because these characteristics may influence how people respond to different medications. Providing information on your race or ethnic origin is voluntary.

15. What happens if something goes wrong?

In the event you become injured or unexpectedly ill while participating in this study, necessary medical treatment will be available at no additional cost to you. An emergency action plan for the laboratory is in place. The study will be conducted in an appropriately equipped medical facility, and the study doctor present is a medically trained doctor. If you become injured or unexpectedly ill as a consequence of participation in the study due to study procedures, your medical condition will be evaluated and medical care will be provided by one of the investigators or you will be referred for appropriate treatment.

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

16. 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 receive any payment for participation.

17. 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, or if you experience any adverse effects, you can contact Dr Mark Ansermino at 604-875-2711.

18. 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).

19. Signatures

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Participant Consent

My signature on this consent form means:

- I have read and understood the information in this consent form.
- I have had enough time to think about the information provided.
- I have been able to ask for advice if needed.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I understand that there are no direct benefits to me from this study.

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

_____	_____	_____	_____
Signature of Person Obtaining Consent	Printed name	Study Role	Date

Please indicate if you agree to be contacted by the researchers for participation in future studies:

If you check "Yes", you may be invited to participate in this study again

☐ Yes ☐ No