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Common Questions

1. 1. Registration Information

#	Question	Answer
1.1	Please confirm that you have reviewed the eligibility requirements for the Health Sciences Full Board application form.	Yes
1.2	Indicate the funding source	Self-funded|Other

	for this study.	
1.3	Please specify the name of the funding source selected above.	Summer Research Training Program for research assistant medical student
1.4	Is this a student project?	No
1.5	Is this a multi-site study?	No
1.6	If YES has been selected in question 1.5 above, name the lead site and project leader for the study. If the study is administered by a Coordinating or Contract Research Organization (CRO) provide the name and contact information.	
1.7	Are the investigator(s) based at any of the sites below or will the study utilize any patient data, staff resources or facilities within any of these sites? (Please indicate all applicable sites and read the associated notes found in the blue information icon above)	LHSC - Victoria Hospital|LHSC - University Hospital|St. Joseph's Health Care London
1.8	Lay Summary of the study (typically less than 5 lines).	Pulse oximetry is a vital tool in the rapid and non-invasive assessment of emergency patients, providing a continuous estimate of hemoglobin saturation in arterial blood. Unfortunately, the costs of these devices are prohibitive and reduce availability in smaller centres and poor countries, putting millions of patients in danger of easily treatable and preventable conditions. With current rapid prototyping technologies such as 3D printing, it is possible to create a very inexpensive pulse oximeter that meets or exceeds the gold standard. The goal of this study is to develop, validate and certify a pulse oximeter that measures hemoglobin, carboxyhemoglobin and methemoglobin. This pulse oximeter will be certified with Health Canada, and then released under the Open Hardware License (OHL), such that hospitals and ministries of health in rural and impoverished communities in Canada and internationally would have easy access to these devices.

2. 2. Background, Methodology and Analysis

#	Question	Answer
2.1	Has the study	No

	undergone a formal scientific or peer review (i.e. CIHR, NSERC, NIH)? If yes, please attach the approval letter (or relevant correspondence).	
2.2	Outline the study rationale including relevant background information and justification. Cite references where appropriate.	Pulse oximetry is a vital tool in the rapid and non-invasive assessment of emergency patients, providing a continuous estimate of hemoglobin saturation in arterial blood. Some pulse oximeters are even capable of monitoring carboxyhemoglobin and methemoglobin, though these capabilities dramatically increase costs. Unfortunately, the costs of both the simplified and extended devices are prohibitive and reduce availability in smaller centres and poor countries, putting millions of patients in danger of easily treatable and preventable conditions. The technologies involved in the manufacture of a pulse oximeter are widely known and have no active patents covering them. This includes carboxy- and met-hemoglobin monitoring. Despite this, no highquality device exists whose design and construction are both research-validated and open to the public for study, production and dissemination. With current rapid prototyping technologies such as 3D printing, it is possible to create a very inexpensive pulse oximeter that meets or exceeds the gold standard. Design considerations include: cost, availability of parts, ease of construction, quality, ease of maintenance, ease of use. Preliminary engineering work has been carried out for the pulse oximeter, with design specifications set and a prototype built. The prototype was the result of collaboration between an engineer and an emergency physician with extensive local and international emergency experience. The pulse oximeter device emits light in four wavelengths: 590nm, 610nm, 660nm, 940nm. These allow for the calculation of oxygenated hemoglobin (660nm and 940nm), carboxyhemoglobin (610nm) and methemoglobin (590nm). The current bill of materials for the prototype is included in Appendix A. A printed circuit board of the prototype is included in Appendix B. A photograph of a completed prototype is included in Appendix C. Software must be designed and written to translate the pulse oximeter's sensor signals into usable values, display them, and provide appropriate alarms when necessary. As per widely-understood and validated concepts, an R value is calculated (ratio of emitted to absorbed light). This value is compared to a look-up table created during an empirical calibration phase, which assigns R values to oxygen saturation values. The value is then displayed for the user along with a graphical display of the pulsatile wave to ensure the quality of the signal. An appropriate user interface must accompany this software to allow for the safe setting of limits and alarms. The goal of this two phase study is to develop, validate and certify a pulse oximeter that measures hemoglobin, carboxyhemoglobin and methemoglobin. Phase 1 consists of calibrating the experimental pulse oximeter and Phase 2 consists of validating it. This pulse oximeter will be certified with Health Canada, and then released under the Open Hardware License (OHL), such that hospitals and ministries of health in rural and impoverished communities in Canada and internationally would have easy access to these devices.
2.3	Study Objectives.	The purpose of this 2-Phase study is to calibrate a prototype pulse oximeter

		and to conduct an equivalence test to determine if the prototype is equivalent to the gold standard pulse oximeter. The primary objectives are 1) to compare arterial blood sample oxygen saturation measurements to the device's R value to create an empirical calibration curve as per the FDA document “Pulse Oximeters - Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff”, section 4.1.1 (http://www.fda.gov/RegulatoryInformation/Guidances/ucm341718.htm#s4); 2) to determine if the experimental pulse oximeter measurements correspond with the gold-standard pulse oximeter measurements; and 3) to determine if the prototype pulse oximeter is equivalent to the gold standard pulse oximeter.
2.4	Describe the study design and methodology. Please be specific (e.g. Randomized, cohort, double blind).	This randomized controlled trial consists of 2 Phases. Phase 1 will include 50 healthy, non-smoking adults (greater than 18 years of age) to calibrate the experimental, 3D printed pulse oximiter. Participants will be recruited through e-mail advertisements and posters between May – August 2016. In Phase 2 we will conduct an equivalence study with 350 adult (greater than 18 years of age) emergency department (ED) patients and community volunteers visiting either Victoria or University Hospital at London Health Sciences Centre (LHSC). Investigators will approach patients at the invitation of a member in the circle of care to discuss the study. Recruitment will occur between October 2016 and January 2017. After going through the LOI and gaining documented written consent, the patient will be enrolled. All study procedures will be conducted in the ED (Victoria and University Hospital) at LHSC by the PI.
2.5	Indicate the inclusion criteria.	This study has 2 Phases. In Phase 1, healthy, non-smoking adult volunteers greater than 18 years of age are invited to participate. In Phase 2, all adult (>18) non-critical patients and healthy community volunteers visiting the ED at VH and UH are eligible to participate.
2.6	Indicate the exclusion criteria.	Potential participants will be excluded based on the following criteria: Phase 1: greater than 70 years of age, current smokers, previous history of cardiac disease (e.g., atrial fibrillation, myocardial infarction, congestive heart failure), history of moderate or severe asthma, history of seizures, history of stroke or transient ischemic attack, and pregnant women will be excluded._ Patients with any active pulmonary disease such as pneumonia will be excluded. Individuals who are unwilling to participate or are less than 18 years old will be excluded, as will those who are unable to consent. Phase 2, critical patients will be excluded from participating. Individuals who are unwilling to participate or are less than 18 years old will be excluded, as will those who are unable to consent.
2.7	Document the usual standard of care at the trial site(s) for this population (including diagnostic testing, frequency of follow up visits).	A gold-standard pulse oximeter will be placed on another finger of the participant's hand and continuously monitored as per the institution's procedural sedation protocols. Participant samples will be tested with a CO-oximeter to ensure that background carboxyhemoglobin (COHb) is less than 2%.
2.8	Document the study procedures and any	All study procedures will be conducted in the emergency department (VH and UH) at LHSC with an emergency-trained physician (EP) present at all times

	study specific testing that will be done.	(PI) between May 2016 and January 2017. Phase 1 (Calibration; approximately 50 participants): Upon obtaining informed consent, participants will be positioned supine in a hospital bed. Participants will be cannulated with an indwelling arterial catheter for frequent sampling of arterial blood. The experimental pulse oximeter will be placed on the participant's finger and continuously monitored. A gold-standard pulse oximeter will be placed on a separate finger on the participant's same hand and continuously monitored as per the institution's procedural sedation protocols. Participant samples will be tested with a CO-oximeter to ensure that background carboxyhemoglobin (COHb) is less than 2%. Two blood samples will be taken with the participant on room air. The participant will then be fitted with 100% oxygen by non-rebreather mask. Under careful monitoring by the EP, oxygen saturation level will be decreased with gas mixtures of progressively decreasing oxygen and increasing nitrogen. Measurements will be recorded until the participant has unstable vitals (e.g., hypotension, tachycardia), is symptomatic or a pulse saturation of 70% is achieved. Oxygen levels will be immediately restored. Arterial blood samples will be drawn and oxygen saturation will be measured when the gas mixture and R value readings have stabilized. 2 cubic centimetres of blood will be drawn for every 5% drop in blood oxygen saturation from 100% to 70% or earlier if the participant experiences unstable vitals or is symptomatic. Phase 1 of the study will take approximately 60 minutes to complete. This study design is routine for all pulse oximeters, and is as recommended by the FDA guidance document “Pulse Oximeters - Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff”, section 4.1.1 (http://www.fda.gov/RegulatoryInformation/Guidances/ucm341718.htm#s4) Phase 2 (validation; approximately 350 community volunteers and ED patients): Study volunteers from the community or patients who have attended the ED for care are eligible to participate. Investigators will approach patients at the invitation of a member in the circle of care to discuss the study. Recruitment will occur between October 2016 and January 2017. After going through the LOI and gaining documented written consent, the volunteer/patient will be enrolled. The experimental and control pulse oximeters will be placed on two different fingers on the same hand. Participants will not be cannulated in Phase 2. Patients will then have one measurement taken with the experimental pulse oximeter and another measurement taken with a gold standard pulse oximeter. Measurements of oxygen saturation will be recorded to establish equivalence of the two oximeters. Part two of the study takes 5 minutes to complete, is completely non-invasive, and will not interfere with regular clinical care. There will be no interference with a patient's normal care during this phase.
2.9	Will any participant(s) be withdrawn from or denied usual therapy, or be subjected to other restrictions for any condition in order to participate in the study?	No
2.10	If YES has been selected in question 2.9	

	above, please explain.	
2.11	Describe the primary and secondary outcomes of this study and how they will be measured.	The purpose of this study is to calibrate an experimental pulse oximeter and to conduct an equivalence test to determine if the prototype is equivalent to the gold standard pulse oximeter. The prototype first must be calibrated. The primary outcome of calibration is to measure arterial blood sample oxygen saturation levels and compare these measurements to the prototype's R value (measured as the ratio of emitted to absorbed light) to create an empirical calibration curve. Once the curve has been determined, the prototype pulse oximeter will be compared to the gold standard pulse oximeter to establish equivalence. The primary outcome to establish equivalence is to compare the experimental pulse oximeter measurements to the gold-standard pulse oximeter measurements.
2.12	What is the local sample size?	400
2.13	What is the total sample size?	400
2.14	Is the sample size justified in the sponsor or other study protocol?	No
2.15	If YES in question 2.14 above, indicate the protocol page number. If NO, provide sample size justification.	According to FDA recommendations, 15 participants is the minimum number required for calibration studies. In order to ensure the experimental pulse oximeter is adequately calibrated, we have determine a sample of 50 participants is sufficient for Phase 1. In Phase 2, to maintain a power of 0.80 with an alpha of 0.05, the sample size was calculated at 350 participants to establish equivalence. **Phase 1 sample size** The phase 1 (calibration) sample size was determined by considering the FDA and ISO recommendations for calibration studies on healthy volunteers. While 15 is the minimum number required (See FDA document attached), we expect a sample size of 30 patients. To allow for unexpected variability, we have requested a sample size of 50 from the REB, though this number might be reduced after a interim analysis at 25-30 patients. **Phase 3 Sample Size** The phase 3 sample size was calculated in the following way: Consider a clinical trial comparing two groups, a standard therapy (s) and a novel therapy (n). In each group, a proportion of subjects responds to the treatment: Ps and Pn. If the intention of the study is to show that the two groups are equivalent, the usual formulation of the null hypothesis (Ps=Pn) encounters logical difficulty. A statistical test may fail to reject this null hypothesis, but this will not mean that the two treatments are equivalent. Blackwelder (Controlled Clinical Trials 1982; 3: 345-353) proposes a

		solution. If a difference between the two treatments, call it D, is specified that *practically* represents equivalence, then the null hypothesis can be restated to include the specified difference. In other words, that: Ps is greater than or equal to Pn + D. Rejection of this hypothesis implies that the difference between the standard and novel treatments is less than or equal to D, indicating equivalence. The sample size needed to reject this hypothesis at alpha = 0.05 and beta = 0.20 (power of 80%) is: $(Z_{0.95} + Z_{0.80})^2 [Ps(1-Ps) + Pn(1-Pn)] / (Ps-Pn-D)^2$ We made the following assumptions: 1) "response rate" being the proportion of correct readings, assuming a 4% variance is .96 in both the "gold standard" and "new pulse ox" groups. 2) A practical difference (accepted clinical difference between the novel and standard device) of also 4%. With these numbers, we require 296 patients/volunteers in both groups. Equivalence is hard to prove and has the highest sample size needed. We rounded this number up to 350 to account for unexpected variability or difficulties. If we desired a non-inferiority study, those numbers go down significantly to 13/group. If there is truly no difference between the standard and experimental treatment, then 26 patients are required to be 80% sure that the lower limit of a one-sided 95% confidence interval (or equivalently a 90% two-sided confidence interval) will be above the non-inferiority limit of -4. However, because of the very short amount of time required for each participant and no risk, we elected to run an equivalence trial. **Reference** Julious SA. Sample sizes for clinical trials with Normal data. *Statist. Med.* 2004; **23**:1921-1986.
2.16	Describe the method(s) for data analysis.	Data will be entered directly into a study-specific LibreOffice database (The Document Foundation, Berlin, Germany). No personal identifiers are being collected in this study. Standard descriptive statistics will be summarized using means and standard deviations and differences in proportions will be assessed by the Pearson chi-squared statistic where appropriate. All data analyses will be performed using R (R Foundation, Vienna, Austria). Phase 1: to validate the experimental pulse oximeter, readings from the arterial blood sample will be plotted against the R value from the prototype to establish a best-fit curve. Phase 2: two one sided tests will be employed to determine if the experimental pulse oximeter is equivalent to the gold standard. The confidence interval around the mean difference between the prototype and

		gold standard will be compared to predetermined acceptance criterion.
2.17	Is an interim analysis planned?	No
2.18	If YES to question 2.17 above, please describe.	
2.19	How will the results of this study be made public?	Peer reviewed publication|Presentation
2.20	If report to participants or other is selected above, please explain.	
2.21	Does this study include any use of deliberate deception or withholding of key information that may influence a participant's performance or response?	No
2.22	If YES in question 2.21 above, describe this process and provide justification for the planned deception or partial disclosure. Also describe how and when the participants will be debriefed. Please include the debriefing letter of information and consent.	
2.23	Are biological specimens to be taken or analyzed for the purposes of this research protocol?	Yes
2.24	Are any biological specimens being taken for future genetic testing or other unspecified testing or studies?	No

2.25	The subsequent use of tissue or biomaterials (except blood) originally collected for diagnostic purposes must be approved by the Department of Pathology Tissue Use Committee prior to submission to the HSREB and a copy of their approval appended to this form. If the Tissue Committee approval is not available at the time of submission to the HSREB, ethics approval will be withheld until a copy of Tissue Committee approval is received.	Not applicable

3. 3. Drugs and Natural Products

#	Question	Answer
3.1	Does the study involve drugs or natural products? If NO, please proceed to the Clinic Trials tab.	No
3.2	Is Drug 1 an investigational drug?	
3.3	Drug 1 - Generic Name	
3.4	Drug 1 - Brand Name	
3.5	Drug 1 - Dose	
3.6	Drug 1 - Frequency	
3.7	Drug 1 - Route	
3.8	Drug 1 - Duration	
3.9	Is Drug 2 an investigational drug?	
3.10	Drug 2 - Generic Name	
3.11	Drug 2 - Brand Name	

3.12	Drug 2 - Dose	
3.13	Drug 2 - Frequency	
3.14	Dose 2 - Route	
3.15	Drug 2 - Duration	
3.16	Is Drug 3 an investigational drug?	
3.17	Drug 3 - Generic Name	
3.18	Drug 3 - Brand Name	
3.19	Drug 3 - Dose	
3.20	Drug 3 - Frequency	
3.21	Drug 3 - Route	
3.22	Drug 3 - Duration	
3.23	Is Drug 4 an investigational drug?	
3.24	Drug 4 - Generic Name	
3.25	Drug 4 - Brand Name	
3.26	Drug 4 - Dose	
3.27	Drug 4 - Frequency	
3.28	Drug 4 - Route	
3.29	Drug 4 - Duration	
3.30	Is Drug 5 an investigational drug?	
3.31	Drug 5 - Generic Name	
3.32	Drug 5 - Brand Name	
3.33	Drug 5 - Dose	
3.34	Drug 5 - Frequency	
3.35	Drug 5 - Route	

3.36	Drug 5 - Duration	
3.37	Is Drug 6 an investigational drug?	
3.38	Drug 6 - Generic Name	
3.39	Drug 6 - Brand Name	
3.40	Drug 6 - Dose	
3.41	Drug 6 - Frequency	
3.42	Drug 6 - Route	
3.43	Drug 6 - Duration	
3.44	Is Drug 7 an investigational drug?	
3.45	Drug 7 - Generic Name	
3.46	Drug 7 - Brand Name	
3.47	Drug 7 - Dose	
3.48	Drug 7 - Frequency	
3.49	Drug 7 - Route	
3.50	Drug 7 - Duration	
3.51	Is Drug 8 an investigational drug?	
3.52	Drug 8 - Generic Name	
3.53	Drug 8 - Brand Name	
3.54	Drug 8 - Dose	
3.55	Drug 8 - Frequency	
3.56	Drug 8 - Route	
3.57	Drug 8 - Duration	
3.58	Is Drug 9 an investigational drug?	

3.59	Drug 9 - Generic Name	
3.60	Drug 9 - Brand Name	
3.61	Drug 9 - Dose	
3.62	Drug 9 - Frequency	
3.63	Drug 9 - Frequency	
3.64	Drug 9 - Route	
3.65	Drug 9 - Duration	
3.66	Is Drug 10 an investigational drug?	
3.67	Drug 10 - Generic Name	
3.68	Drug 10 - Brand Name	
3.69	Drug 10 - Dose	
3.70	Drug 10 - Frequency	
3.71	Drug 10 - Route	
3.72	Drug 10 - Duration	

4. 4. Clinical Trials

#	Question	Answer
4.1	Is this a clinical trial? If this is NOT a clinical trial, please select NO and proceed to the Risks and Benefits section.	Yes
4.2	Proposed type of clinical trial:	
4.3	Does this trial involve a drug, device or natural health product used for an indication outside the Health Canada Notice of Compliance (NOC) or Drug Identification Number (DIN) application or Medical Device	Yes - Device

	License?	
4.4	If YES to question 4.3 above, have you received a No Objection Letter (NOL) or comparable document from Health Canada?	Not yet submitted - sole Canadian site therefore require Health Sciences REB approval prior to submission to Health Canada
4.5	Is this a US Food and Drug Administration monitored study?	No
4.6	Has this study been or will this study be registered on a publicly accessible clinical trial registry?	Yes
4.7	If YES is specified in question 4.6 above, please indicate the registry name and registration number.	Will be registered at clinicaltrials.gov
4.8	Is there a data safety monitoring board (DSMB)? If YES, please note that you must submit the Data Safety Monitoring Committee report(s) to the Office of Research Ethics using Form 2-F-014.	No
4.9	If there is a DSMB, is it independent of the sponsor?	
4.10	If NO in question 4.9 above, please provide justification.	
4.11	Has the drug or other therapy been evaluated in previous human trials?	Not applicable
4.12	If NO in question 4.11 above, please describe any animal studies that have led to this study. (Cite references where applicable)	
4.13	Will this trial use a placebo or active comparator?	Yes
4.14	If YES in question 4.13 above, please describe the placebo or	Pulse oximetry is a vital tool in the rapid and non-invasive assessment of emergency patients, providing a continuous estimate of hemoglobin

	active comparator and justify its inclusion. Also, please describe how the risks to participants will be minimized.	saturation in arterial blood. In addition to the prototype pulse oximeter being evaluated, a gold-standard pulse oximeter will be placed on another finger on the same hand of the participant and continuously monitor blood saturation levels as per the institution's procedural sedation protocols. The use of the gold standard as a comparator will allow us to monitor blood saturation levels concurrently with the prototype. Additionally, the use of the gold standard as a comparator poses no risk to the participant.

5. 5. Risks and Benefits

#	Question	Answer
5.1	Describe any direct benefits to the study participants.	There are no known benefits to the study participants.
5.2	Describe the potential benefits to society.	Developing and validating a high-quality, low-priced pulse oximeter whose design is freely available will impact emergency rooms in both the developed and developing worlds. In the developed world, a sub-$25 pulse oximeter that measures hemoglobin, carboxyhemoglobin and methemoglobin will make it possible for physicians to provide better care for patients without the pitfalls of traditional pulse oximeters that do not measure carboxy- and met-hemoglobin. In the developing world, these low-cost pulse oximeters will allow ministries of health and hospitals to forgo rationing of these devices and provide them to hospitals and clinics, multiplying the availability dramatically.
5.3	List and describe the potential risks/harms/inconveniences of the study, including risks from radiation exposure. This information must be included in the informed consent documentation.	During the study protocol in Phase 1, participants will be cannulated with an indwelling arterial catheter for frequent sampling of arterial blood. Participants may feel discomfort during the catheter insertion process. The participant will also be fitted with a non-rebreather mask as part of the Phase 1 study protocol in order to reduce the oxygen saturation level with gas mixtures of progressively decreasing oxygen and increasing nitrogen. Participants may experience low blood pressure, tachycardia or chest pain. Phase 1 is estimated to take 60 minutes to complete. In Phase 2 of the study, participants will wear both the experimental and gold standard pulse oximeter. There are no additional risks associated with wearing two pulse oximeters for the five minute duration of the study. Phase 2 is estimated to take 5 minutes to complete.
5.4	For the study risks listed above, describe the monitoring to be undertaken during and following the study conclusion.	The entirety of the study protocol will be conducted within the emergency department at LHSC, on a hospital bed, with an emergency trained physician monitoring at all times. In Phase 1 the arterial catheter will be inserted by an experienced emergency physician. Should an adverse event occur, the participant will be monitored one-on-one by the physician and treated according to best medical practice. Arterial oxygen saturation will be continuously monitored as per the institution's procedural sedation protocols.
5.5	If a research participant is/or becomes pregnant, breastfeeds	No

	a child or fathers a child while in the study, does their participation in the study pose a possible risk to the fetus or child?	
5.6	If YES is selected in question 5.5 above, please discuss these risks and indicate what monitoring will be undertaken during the study and following the study conclusion?	
5.7	If a research participant fathers a child while in the study, will access to the health records of the "pregnant" partner and/or her child be required and/or will the woman or child be monitored by this study during and/or after the pregnancy?	No

6. 6. Recruitment and Informed Consent

#	Question	Answer
6.1	Describe the method(s) for recruiting participants.	Investigators will receive referrals from other Healthcare providers|Advertising (i.e. poster or email or web-based). Please submit a copy of all advertisements.
6.2	If OTHER or DATABASE OF PEOPLE is selected in question 6.1 above, please specify here.	
6.3	Will personal health information (PHI) be used to identify potential participants?	No
6.4	If PHI will be used, please describe the screening and consent process regarding PHI.	
6.5	How will potential participants be contacted? Please provide a copy of all telephone scripts and correspondence documents in the attachments tab.	Phase 1: By poster or via email Phase 2: In Person in the Emergency Department. First patient contact will be within the circle of care
6.6	If OTHER is selected in question 6.5 above, please specify in this box.	

6.7	Describe the process for obtaining informed consent. Please attach a copy of the Information Letter/Consent Form, Audio/Video Recording Consent Form, and the content of any telephone script and/or any other material that will be used in the informed consent process.	Participants will be provided with the LOI and informed consent document. The investigator will verbally describe the study to the participant. The participant will be made aware of the purpose of the study, what their participation in the study entails, assured there is no deception in the protocol, be made aware of the risks of participating, and be assured that they may end their participation in the study at any time without consequence. The investigator will provide ample time to read the LOI and actively solicit any questions or concerns. Documented written consent will be obtained before enrolling the participant. For Phase 2, patients will have first contact within the circle of care for participation.
6.8	Indicate if the research will involve any of the following:	Healthy volunteers|Patients|Employees or students of UWO or the institution where the study is being carried out
6.9	Will minors or persons not able to consent for themselves be included in the study?	No
6.10	If YES is selected in question 6.9 above, describe the consent process and indicate who will be asked to consent on their behalf and discuss what safeguards will be employed to ensure the rights of the research participant are protected.	
6.11	When the inability to provide an informed consent is expected to be temporary, describe what procedures will be used to regularly assess capacity and to obtain consent if the individual later becomes capable of providing consent. Alternatively, if diminished capacity is anticipated for the study population, describe the procedure used to assess capacity and obtain ongoing consent.	N/A
6.12	List any anticipated communication difficulties:	None
6.13	Describe the procedures to address any communication difficulties (if applicable):	
6.14	Indicate what compensation, if any, will be provided to participants and include a justification for compensation.	Participants will not be compensated for taking part in this study.

7. 7. Confidentiality and Data Security

#	Question	Answer

7.1	Are you collecting personal identifiers for this study?	No
7.2	Identify any personal identifiers collected for this study. Select all that apply.	None
7.3	Explain and justify the use of this identifier - Full name:	
7.4	Explain and justify the use of this identifier - Initials:	
7.5	Explain and justify the use of this identifier - Health card number:	
7.6	Explain and justify the use of this identifier - Address:	
7.7	Explain and justify the use of this identifier - Full postal code:	
7.8	Explain and justify the use of this identifier - Partial postal code:	
7.9	Explain and justify the use of this identifier - Telephone number:	
7.10	Explain and justify the use of this identifier - Email:	
7.11	Explain and justify the use of this identifier - Family Physician:	
7.12	Explain and justify the use of this identifier - Date of birth:	
7.13	Explain and justify the use of this identifier - Partial date of birth:	
7.14	Explain and justify the use of this identifier - Hospital number:	
7.15	Explain and justify the use of this identifier - Other:	
7.16	Where will information collected as	University or Hospital network drive (specify below)|Memory

	part of this study be stored? (select all that apply)	stick
7.17	If required, please specify further information below.	All data collected will be maintained on the LHSC “P” Drive in a password protected folder. Investigators will only look at or analyse data on LHSC computers. Data will only be passed between investigators on encrypted memory sticks or through the LHSC secure FTP sites. Hard copies will be stored in a locked filing cabinet and destroyed once the data has been electronically recorded. While no identifying data will be collected, blood sample data~~Data~~ will be coded with unique serial numbers to facilitate data entry and validation. The serial number will in no way identify the patient.
7.18	If identifiable participant information is stored on a hard drive or portable device, the device must be encrypted. Describe the encryption being used.	The Division of Emergency Medicine uses 256-bit encryption technology for data security. Access to the data requires an electronic signature and valid username and password; all users must be authorized by the principal investigator.
7.19	How will you record study data?	Data Collection Form
7.20	Describe the coding system to protect identifiable information or explain why the data must remain identifiable.	While no identifying data will be collected, blood sample data~~Data~~ will be coded with unique serial numbers to track data entry and validation. After the relevant information is collected from the participant and recorded in a secure password protected database and data validation is complete, the original data collection form will be destroyed.
7.21	How will you store and protect the master list, signed original letters of information and consent documents or other data with identifiers?	Paper file (Required Protection: Locked cabinet in locked institutional office)|Electronic file (local) (Required Protection: Password protected computer on a secure network behind institutional firewalls - specify location)
7.22	If any options are selected above, please provide the specific details here.	All data collected will be maintained on the LHSC “P” Drive in a password protected folder. Investigators will only look at or analyse data on LHSC computers. Data will only be passed between investigators on encrypted memory sticks or through secure FTP sites. Hard copies will be stored in a locked filing cabinet and destroyed once the data has been electronically recorded. Data will be coded with unique identifiers and the master list containing any identifiers will be stored separately from the collected data.
7.23	How will you store and protect data without identifiers?	Data will be coded with unique identifiers and the master list containing any identifiers will be stored separately from the collected data with only the unique identifier to link the master list to the participant information.
7.24	If you plan to de-identify the study data, please describe the method of de-	

	identification.	
7.25	How long will you keep the study data?	Computer and electronic records will be encrypted and secured in a locked filing cabinet at LHSC where the research data will be stored for 15 years and then destroyed according to current practice, which includes placing the records in locked, confidential shredding bins. The bins are then collected by an outsourced company and the contents are shredded.
7.26	How will you destroy the study data after this period? (If applicable)	Computer and electronic records will be encrypted and secured in a locked filing cabinet at LHSC where the research data will be stored for 15 years and then destroyed according to current practice, which includes placing the records in locked, confidential shredding bins. The bins are then collected by an outsourced company and the contents are shredded. All study files will be appropriately deleted and all memory sticks cleared.
7.27	Does this study require you to send data outside of the institution where it is collected? This includes data taken off-site for analysis. Please note that Western/Robarts are considered off-site locations for hospital/Lawson based studies, and vice-versa.	No
7.28	Where will the data be sent?	
7.29	Does the data to be transferred include personal identifiers? If yes, a data transfer agreement may be necessary.	No
7.30	List the personal identifiers that will be included with the data sent off-site.	
7.31	How will the data be transmitted?	
7.32	Please specify any additional details on data transmission below.	
7.33	Will you link the locally collected data with any other data sets?	No
7.34	If YES is selected in question 7.33 above, identify the dataset	
7.35	If YES is selected in question 7.33 above, explain how the linkage will occur.	

7.36	If YES is selected in question 7.33 above, provide a list of data items contained in the dataset.	
7.37	Will the study data be entered into a database for future use?	No
7.38	If YES is selected in question 7.37 above, please specify where it will be stored, who the custodian will be, who will have access to the database and what security measures will be in place.	
7.39	Please list agencies/groups/persons outside of your local research team who will have access to the identifiable data and indicate why access is required.	None

8. 8. Conflict of Interest

#	Question	Answer
8.1	Will any investigators, members of the research teams, and/or their partners or immediate family members function as advisors, employees, officers, directors or consultants for a study-related sponsor or funding source?	No
8.2	Will any investigators, members of the research team, and/or their partners or immediate family members have a direct or indirect financial interest (including patents or stocks) in the drug, device or technology employed in this research study?	No
8.3	Will any investigators, members of the research team, and/or their partners or immediate family members receive any personal benefit (apart from fees for service) as a result of, or connects to this study?	No
8.4	If YES is selected in any of the above, please describe the nature of the conflict of interest and how all conflict(s) of interest will be managed.	

9. 9. Industry Sponsored Protocols

#	Question	Answer
9.1	Is this an industry sponsored protocol?	No
9.2	Billing Information - Company Institution:	
9.3	Contact Person:	
9.4	Email of Contact Person:	

9.5	Street Address:	
9.6	City:	
9.7	Country:	
9.8	Province/State:	
9.9	Phone Number:	
9.10	Fax:	
9.11	Contract and/or protocol reference number required:	
9.12	Additional Sponsor Reference or contact information:	
9.13	Do you wish to apply for a REB Administration Fee Adjustment/Waiver?	
9.14	Do you agree to the Conditions for Industry Funded Research Investigators?	
9.15	Do you agree to provide supporting documents? (These can be added in the attachments section)	

10. 10. Confirmation of Responsibility

#	Question	Answer
10.1	I assume full responsibility for the scientific and ethical conduct of the study as described in this REB application and submitted protocol.	Yes
10.2	I agree to conduct this study in compliance with the Tri-Council Policy Statement (TCPS2), Ethical Conduct in Research Involving Humans and any other relevant regulations and guidelines.	Yes
10.3	I certify that all researchers and other personnel involved in this project at this institution are appropriately qualified and experienced or will undergo appropriate training to fulfill their role in this project.	Yes
10.4	I certify that any and all conflicts of interest have been declared.	Yes
10.5	I have obtained all necessary resource utilization signatures, and all costs associated with the use of these resources have been declared.	Yes
10.6	On behalf of my research team, I recognize the importance of maintaining the confidentiality of all personal information, including personal health information, and the privacy of individuals with respect to that information. I will ensure that the personal information is used	Yes

	only as necessary, to fulfill the specific research objectives and related research questions described in this application and approved by the REB. This includes all conditions and restrictions imposed by the REB govern	
10.7	I will adhere to the Protocol and Informed Consent document as approved by the Health Sciences REB.	Yes
10.8	Have you exported a copy of this submission to Word using the "Export to Word" button? Note that you will be unable to submit future revisions if this is not done.	Yes

Attachments

Description	File Name	Version Date
	107952 Loubani (post).pdf	22/04/2016
Source code for oximeter, taken from https://github.com/GliaX/oximeter	oximeter_codeino.txt	04/05/2016

//<![CDATA[
Sys.Application.initialize();
//]]>