1.1

1.1 *Is this the initial submission or a response to REB recommendations?

- ○ Initial Submission
- ○ Response to REB recommendations

1.2 *Complete the Principal Investigator (PI) details:

*Prefix	*First Name	*Last Name
	Tarek	Loubani

Address

City

Province/State

Postcode/Zip

Telephone

*Email: tarek.loubani@lhsc.on.ca

Complete the additional PI details:

Western Academic Faculty/Department:

Please Select...

Hospital Department/Division:

Please Select...

1.3 *Are there any additional study team members (from Western and/or its affiliate institutions) who are working on this study?

- ○ Yes there are additional study team members
- ○ No other study team members involved

1.4

1.4 *Enter the complete study title:

Calibration and Validation of High Quality Low-Cost 3D Printed Pulse Oximeter

1.5

1.5 *What is the acronym or nickname/short title for the study? (NOTE: The acronym or nickname/short title will be used to identify the study and will be included in all notifications and REB submissions.)

Calibration and Validation of High Quality Low-Cost 3D Printed Pulse Oximeter

1.6

1.6 *Does this study involve the London hospitals (see HELP text if you are unsure)

- ○ No this study does not involve the London hospitals
- ◉ Yes this study involves the London hospitals
- ○ This study involves the London Hospitals but a ReDA submission has not been completed. NOTE: You cannot submit this application until the ReDA submission has been completed.

*What is the Lawson ReDA number associated with this study?

*As this study is taking place in the hospital, complete the Primary Institutional Representative details (NOTE: in the contacts directory search for Lawson Approvals):

Name	
Email	lawsonapproval@lawsonresearch.com

1.7

1.7 *What type of REB submission is this?

- ◉ Full Board
- ○ Delegated Level 2 - Prospective data collection
- ○ Delegated Level 1 - Retrospective study data and/or biological sample collection

1.8

1.8 *Are any of the investigator(s) based at any of the sites below or will the study utilize any patient data/biological specimens, staff resources or facilities within any of these sites? (Please indicate all applicable sites):

- [ ] No

LHSC Sites

- [ ] Adult Eating Disorder Service (Riverview)
- [ ] Byron Family Medical Centre
- [ ] Children's Hospital
- [ ] Fowler Kennedy Sports Medicine
- [ ] Kidney Care Centre (Westmount)
- [ ] London Regional Cancer Program (LRCP)
- [ ] Southwestern Ontario Regional Base Hospital Program
- [ ] Stroke Prevention & Atherosclerosis Research Centre
- [ ] University Hospital (UH)
- [ ] Victoria Family Medical Centre
- [ ] Victoria Hospital (VH)

St Joseph's Sites

- [ ] Mount Hope Centre for Long Term Care
- [ ] Parkwood Institute – Main Building
- [ ] Parkwood Institute Mental Health Care
- [ ] Southwest Centre for Forensic Mental Health Care
- [ ] St. Joseph's Family Medical and Dental Centre
- [ ] St. Joseph's Hospital

1.9

1.9 *Is this study directly related to a previously approved study at this institution (e.g., is this study a sub-study, extension, rollover, subsequent to a pilot study)?

- ○ Yes
- ○ No

1.10

1.10 *Is there a protocol/research plan for this study?

- ○ Yes
- ○ No

1.11

1.11 *Is this an Investigator-initiated study?

- ○ Yes
- ○ No

1.12

1.12 *Who is the Study Sponsor?

- ☐ Industry Sponsored
- ☐ External Non-Profit
- ☐ External PI
- ☐ Local PI
- ☐ Self

1.13

1.13 *Is this a student project?

- ☐ No
- ☐ Yes - Resident/Fellow
- ☐ Yes - MD
- ☐ Yes - Post-doctoral Fellow
- ☐ Yes - PhD
- ☐ Yes - Masters
- ☐ Yes - Undergraduate
- ☐ Yes - Other

1.14

1.14 *Has the study undergone a formal scientific or peer review (i.e., internal peer review or external review (e.g., CIHR, NSERC, NIH, etc))?

- ○ Yes
- ○ No

1.15

1.15 *Has the study been reviewed and approved by another REB in Canada?

- ○ Yes
- ○ No

1.16

1.16 *Has the study been rejected by any other REB?

- ○ Yes
- ○ No

1.17

1.17 *Is this a US Food and Drug Administration (FDA) monitored study and/or a study funded or supported by the US governmental agency?

- ○ Yes
- ◉ No

1.18

1.18 *Is this a multi-centre study?

- ○ Yes
- ○ No

1.21

1.21 *Is there and external third party (Coordinating or Contract Research Organization) overseeing the study?

- ○ Yes
- ○ No

1.22

1.22 *Indicate how the results will be communicated to participants and other stakeholders (e.g.; advocacy groups, scientific community).

***To Participants:**

- ☐ Debriefing Script
- ☐ Group debriefing
- ☐ End of study letter
- ☐ Publication(s)
- ☐ Other
- ☐ No Plan

***To Other Stakeholders:**

- ☐ Presentation(s)
- ☐ Publication
- ☐ Other
- ☐ No plan

1.23

1.23 *Provide a brief lay/non-scientific summary of the study (max 250 words)

2.4

2.4 *Will you collect biological specimens in this study?

- ○ Yes
- ○ No

2.5

2.5 *What are the study hypotheses or research question(s) or purpose of this study?

2.6

2.6 *What is the rationale for this study (why is it being done)? In your response ensure to include relevant background information from previous studies that have been done. Cite references where appropriate and add as a separate attachment (do not include within your response).

Upload any references used above (if applicable):

2.7

2.7 *Provide a summary of the study design AND methodology (it would also be helpful to submit a flow diagram if available):

Upload a flow diagram (if applicable):

2.8

2.8 *Will this study include the following population(s): (select all that apply):

- ☐ Patients
- ☐ People who are unable to consent
- ☐ Healthy Volunteers
- ☐ Caregivers/Study Partner
- ☐ Cognitively impaired individuals
- ☐ Students
- ☐ Adult individuals temporarily unable to provide consent (i.e. unconscious)
- ☐ Staff/Health care providers
- ☐ Pregnant Women
- ☐ People with mental health issues
- ☐ Elderly people
- ☐ People institutionalized
- ☐ People with palliative disease
- ☐ Prisoners/persons in detention
- ☐ People in long-term care
- ☐ People in poverty
- ☐ Minors
- ☐ People in medical emergencies
- ☐ Other

2.13

2.13 *Does this study include a non-patient group (e.g., caregiver, student, employee, etc.)?

- ○ Yes
- ○ No

2.14

2.14 *Is this a collaborative community-based project?

- ○ Yes
- ○ No

2.15

2.15 *Indicate your data collection tools/forms by selecting the relevant option(s) below:

- ☐ Paper Survey(s)/Questionnaire(s)
- ☐ Online Survey(s)/Questionnaire(s)
- ☐ Interview Guide(s)
- ☐ Focus Group Guide(s)
- ☐ Non-Participant Observation Guide(s)
- ☐ Participant Observation Guide(s)
- ☐ Other (e.g., visual stimuli, participant diary, data collection forms, etc.)

2.16

2.16 *How will the data collection tool(s)/form(s), completed by the participant, be administered (e.g. in person, paper, electronic)?

2.17

2.17 If you are directing participants to a website or electronic materials, provide the web address (as applicable):

2.18

2.18 *Are there any associated sub-studies or companion studies?

- ○ Yes
- ○ No

2.20

2.20 *What is the local sample size?

2.21

2.21 *Describe how study data will be analyzed. If there is a description of how study data will be analyzed in a protocol/research plan, please indicate the page number.

2.22

2.22 *Provide the inclusion criteria:

2.23

2.23 *Provide the exclusion criteria.

2.24

2.24 *What is/are the primary objective(s) of the study and briefly describe how it/they will be measured. NOTE: For qualitative research studies-If this is not applicable indicate "NA"

2.25

2.25 What is/are the secondary objective(s) (if applicable) of the study and briefly describe how it/they will be measured.

2.26

2.26 *Does this study include any use of deliberate deception or withholding of key information that may influence a participant's performance or response?

- Yes
- No

2.27

2.27 *Will study participants be subject to restrictions (lifestyle) during the study?

- Yes
- No

2.28

2.28 *Describe the circumstances under which a participant may be withdrawn from the study.

3.1

3.1 *Is this a clinical trial?

- Yes
- No

11.1

11.1 *Describe any direct benefits to the study participants.

11.2

11.2 *What is the overall anticipated public and scientific benefits of the study?

11.3

11.3 *List and describe the known risks/harms/inconveniences of any tests, procedures or other protocol-mandated activities that are conducted for research purposes only (including approximate rates of occurrence, severity and reversibility). This information must be included in the informed consent documentation.

11.5

11.5 *For the study risks listed above, describe the monitoring to be undertaken during and following the study conclusion.

11.6

11.6 *Are there any reproductive risks associated with participation in the study?

- ○ Yes
- ○ No

11.7

11.7 *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 and/or child be monitored by this study during and/or after the pregnancy?

- Yes
- No

11.8

11.8 *Does participation in this study affect alternatives for future care or eligibility for future research?

- Yes
- No

11.9

11.9 *Is there a data and safety monitoring board (DSMB) or committee (DSMC)?

- Yes
- No

11.10

11.10 *Are there any plans to perform an interim analysis?

- Yes
- No

11.11

11.11 If you are using imaging or sample testing in your study procedures, how would incidental findings be disclosed to participants (if applicable)?

12.1

12.1 *Will Personal Information (PI) and/or Personal Health Information (PHI) be used to identify potential participants (pre-screening)?

- Yes
- No

12.2

12.2 *Is a waiver of the requirement to obtain informed consent being requested for this study?

- Yes
- No

13.1

13.1 *(For patient orientated research studies.) Do you plan now or in the future to link your study data to the large healthcare databases held at the Institute for Clinical Evaluative Sciences (ICES)? For example, this would allow you to follow patients passively life-long, determine their healthcare costs, assess how similar your patients are compared to Ontario citizens, and help identify control groups.

- Yes
- No
- N/A

13.2

13.2 *Are you collecting personal identifiers for this study?

- Yes
- No

13.5

13.5 *Where will information be collected as part of this study be stored (applies to both paper copy and electronic copy)? (select all that apply)

- ☐ University or Hospital network drive
- ☐ University or Hospital local hard-drive
- ☐ Office/Lab of PI or Research team member on Institutional Property
- ☐ Laptop
- ☐ Memory Stick
- ☐ Cloud Storage
- ☐ Off-site
- ☐ Other

13.6

13.6 *Indicate the measures in place to protect the confidentiality and security of any study data including Personal Information (PI) or Personal Health Information (PHI) that is accessed, collected and used (select all that apply):

- ☐ Access to medical records and/or study data will be limited to authorized personnel
- ☐ Access to electronic data will be password protected and encrypted
- ☐ Electronic data will be stored on a Western, hospital or other institutional server with firewalls and other security and back-up measures in place
- ☐ Study data stored on external hard drive, laptop(s) and/or mobile device(s) will be encrypted
- ☐ Paper copies of study data will be stored in locked filing cabinets in a secure location
- ☐ A master linking log with identifiers will be stored separately from the study data
- ☐ Other

13.9

13.9 *Please specify the study data custodian (who is responsible for maintaining the study data).

13.11

13.11 *Will you be sending/sharing data off-site for this study?

- ○ Yes
- ○ No

13.15

13.15 *Will you link the locally collected data with any other datasets, databases or registries (e.g., health registries, Statistics Canada)?

- ○ Yes
- ○ No

13.16

13.16 *Is the purpose of this study to establish a registry/database?

- ○ Yes
- ○ No

14.1

14.1 *Is this study funded?

- ○ Yes
- ◉ No

15.1

15.1 *Are translated participant materials (e.g., consent or assent forms, recruitment materials, and/or participant materials such as diaries or questionnaires, etc.) included in this study and require HSREB approval?

- ○ Yes
- ○ No

16.1

16.1 *Will the PI or Co-Investigator(s) or anyone connected to them through their interpersonal relationship (including their partners, family members, or their former or current professional associates) receive any personal financial benefit in connection with this study?

- ○ Yes
- ○ No

16.2

16.2 *Will the PI or Co-Investigator(s) or anyone connected to them through their interpersonal relationships (including their family members, friends, or their former or current professional associates) receive any personal (financial or otherwise) benefits including patent or intellectual property rights, royalty income, employment, share ownership, stock options, etc?

- Yes
- No

16.3

16.3 *Is the PI or Co-Investigator(s) aware of any other community relationships, academic interests, financial partnerships, or economic interests (e.g., spin-off companies in which researchers have stakes or private contract research outside of the academic realm) or any other incentives that may compromise their integrity, independence or ethical duties in the conduct of the research?

- Yes
- No

16.4

16.4 * Is the PI to Co-Investigator(s) aware of any institutional conflicts of interest (financial or non-financial) that may have an impact on the research?

- Yes
- No

16.5

16.5 * Does the PI or Co-Investigator(s) or anyone connected to them through their interpersonal relationships (including their family members, friends, or their former or current professional associates) have any proprietary interest in the product under study or in any entity that is sponsoring or otherwise supporting the conduct of the study?

- Yes
- No

16.6

16.6 *Will or does the PI or Co-Investigator(s) or anyone connected to them through their interpersonal relationships (including their family members, friends, or their former or current professional associates) have any association or connection with an entity that is sponsoring or otherwise interested in the outcome of the study? (e.g., consultant, advisor, board member, employee, director, etc.)

- Yes
- No

16.8

16.8 * Are there any other real, potential or perceived conflict of interest to declare to the REB?

- ○ Yes
- ○ No

19.1

19.1 *Principal Investigator Signature:

- I attest that, to the best of my knowledge, the information in this application is complete, current and accurate;
- I attest that I am appropriately qualified to conduct this study, and that I am a member in good standing with my respective regulatory authority.
- As the PI:
  - I assume full responsibility for the scientific and ethical conduct of the study at this institution
  - I agree to conduct this study in compliance with TCPS2 (2nd edition of Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans); AND with the provisions of the Freedom of Information Protection of Privacy Act (FIPPA), and its applicable Regulations; AND with all other applicable laws, regulations or guidelines;
  - I attest that I have sufficient space, time and resources to conduct this study;
  - I attest that the study Co-Investigator listed in this application (if applicable) is appropriately qualified to assume my responsibilities in the event that I am unable to do so;
  - I certify that all Co-investigators, researchers and other personnel (research team) involved in this project at this institution are appropriately qualified and experienced, and have undergone appropriate training (e.g., having done their TCPS2 Core tutorial training) to fulfill their role in this project;
- I acknowledge that I am responsible for promptly reporting any of the following to the REB:
  - modifications or amendments, such as changes in PI, changes in Co-investigator (if applicable), specific required changes to the consent form, etc.;
  - all local reportable events that meet the REB reporting criteria, including but not limited to local unexpected, serious adverse events (SAEs), privacy breaches, protocol deviations and any new information that may adversely affect the safety of the participants or significantly affect the conduct of the study;
  - progress report (renewal/ continuing review form), annually or as often as requested by the REB;
  - completion or termination (e.g., End of Study Form)
- I certify that REB approval and all external and local institutional approvals will be obtained before the study will commence;
- I certify that the research team will adhere to the protocol and consent form as approved by the REB unless to eliminate an immediate safety hazard to participants and in accordance with any conditions placed on the REB approval;
- I certify that all information provided in this application represents an accurate description of the conduct of the study.

Privacy and Security Acknowledgement:

- On behalf of all members of my research team, as the PI, I am aware of my obligations in maintaining the importance of maintaining the confidentiality of personal information and the privacy of individuals with respect to that information;
- I will ensure that the personal information is used only as necessary, to fulfill the specific study objectives and related study questions described in the application approved by the REB. This includes all conditions and restrictions imposed by the REB and the institution in which the study is being conducted, governing the use, security, disclosure, return or disposal of the study participants' personal information;
- I agree to take any further steps required by the REB or the institution to ensure that the confidentiality and security of the personal information is maintained in accordance with the Freedom of Information Protection of Privacy Act (FIPPA), its accompanying regulations, and the Tri-Council Policy Statement.