

RECOMMENDATIONS FORM
HEALTH SCIENCE RESEARCH ETHICS BOARD
Full Board Review | Dr. Joseph Gilbert, HSREB Chair**Ethics Officer: Vikki Tran**

DO NOT begin any study related activities until you receive final notification of approval from the Office of Research Ethics (ORE). If this study involves Lawson, you must also ensure you have received Lawson's Institutional Approval (IA).

SUBMISSION DETAILS

Review Date	April 19, 2016
REB ID*	107952
Study Title	Calibration and Validation of High Quality Low-Cost 3D Printed Pulse Oximeter
Principal Investigator	Dr. T. Loubani

*This number must be quoted on all modifications, revisions and correspondence.

SUBMISSION STATUS

The proposed study submission has been reviewed and the following decision has been reached:

TABLED - SIGNIFICANT CONCERNS HAVE BEEN IDENTIFIED

This submission has been reviewed by the REB and has been tabled (REB deferred its decision) to a subsequent meeting as the research proposal does not have sufficient information for the REB to arrive at a determination. Please see REB Recommendations below and address each.

REB RECOMENDATIONS

In a separate document (1) respond to each REB Recommendation (DO NOT refer to other documents. Provide an answer.), and (2) submit all revised documents (if applicable). If a separate response letter is not submitted the file will be sent back until this is done.

General

1. This study has been tabled as the Board has major concerns with the risks to healthy participants due to the cannulation of the radial artery (not described) and dropping the blood oxygen down to 70%. Please comment on whether there will be a full ICU monitoring system in place, how the participant will be protected and whether the study is done during the normal shift of the ED physician. Additionally, please comment on whether there has been agreement with the ER to carry out this study and who will monitor the participant to let the physician know if something happens
2. Please comment on any potential financial conflict of interest

Western Protocol

3. Section 1.4 indicates that this is not a student project but 1.3 indicates that funding is from a Summer Research Training Program for a research assistant medical student. Please clarify and comment on who will pay for human and material resources beyond the student

4. Section 2.3: Section 2.2 indicates that the software needed to make the prototype still needs to be designed and written. Please comment on who, where, what testing, whether this is open or closed source code and the maintenance for this
5. Section 2.6: Please indicate whether patients with pneumonia will be excluded
6. Section 4.4 and 4.7: Please submit these to the REB once received. Please note that ethics approval will be withheld until the NCT# is received
7. Section 6.7: Please note that first patient contact should be made within the circle of care
8. Section 6.7: There are recruitment emails that are submitted to the REB for review. Please include this in this section and revise the confidentiality section accordingly
9. Section 7.17, 7.20: This contradicts section 7.1 and 7.2 which indicates that no personal identifiers are being collected. Please clarify

Letter of Information (phase 1)

10. Page 1: Please explain arterial catheter in lay terms
11. Page 1: “Two cubic centimetres of blood will be drawn for...” Please quantify this using ml or tsp/Tbsp
12. The device is called “high quality”. Please re-word this as this is coercive
13. Please explain external catheter, calibration and validation in lay terms
14. Please include information as to how blood pressure and heart rate will be monitored during the testing
15. Please indicate whether the participant can withdraw their data if they withdraw consent
16. Please include information on what will occur if there is a research related injury
17. Please include the risks of the arterial line ex. pain, thrombosis, hemorrhage etc.

Letter of Information (phase 2)

18. Please indicate whether the participant can withdraw their data if they withdraw consent
19. The device is called “high quality”. Please re-word this as this is coercive

HOW TO RE-SUBMIT TO THE REB**STEP 1: Create a “Response to REB Recommendations” Document**

In a separate document respond to the each REB Recommendation. Clearly answer each item within your Response document. Do not refer to other documents.

STEP 1 is mandatory for all REB Submissions

STEP 2: Revise Western Protocol

The REB may recommend that the Western Protocol be revised. In order to revise the Western Protocol, you must download a Word copy from ROMEO.

- Log in to ROMEO (<https://grant3.vm.its.uwo.ca/Romeo.Researcher/>)
- Locate the study | Role: PI/Project Team Member – Applications (Submitted – Requiring My Attention)
- Click ‘Edit’
- Click ‘Export to Word’, save to your computer
- Make changes to the Western Protocol using Tracked Changes (<https://support.office.com/en-gb/article/Track-changes-while-you-edit-024158a3-7e62-4f05-8bb7-dc3ecf0295c4?ui=en-US&rs=en-GB&ad=GB>)

- Create a 'Clean' Copy of the Western Protocol (<https://support.office.com/en-in/article/Accept-tracked-changes-4838d24c-d5d1-4c6c-8e39-78b44bd2b4cc>)

STEP 3: Revise Study Documents

The REB may recommend that certain documents (Letter of Information/Consent, Advertisements, Instruments, etc.) be revised. These revised documents must be provided to the REB along with your Response document. Tracked and Clean copies of each revised document are required. Tracked and Clean copies of each revised document are required.

- How to make a 'Tracked' version (<https://support.office.com/en-gb/article/Track-changes-while-you-edit-024158a3-7e62-4f05-8bb7-dc3ecf0295c4?ui=en-US&rs=en-GB&ad=GB>)
- How to make a 'Clean' version (<https://support.office.com/en-in/article/Accept-tracked-changes-4838d24c-d5d1-4c6c-8e39-78b44bd2b4cc>)

STEP 4: Re-submit via ROMEO

Before re-submitting to ROMEO, ensure that:

1. Tracked and Clean copies of all documents have been created
2. Version dates (dd/mm/yyyy) and Page numbers (x of y) have been updated in document headers/footers
3. Document file names are unique
4. Document file names do not contain special characters (/ , - ? ! @ #)

When you are ready to re-submit:

- Log in to ROMEO (<https://grant3.vm.its.uwo.ca/Romeo.Researcher/>)
- Locate the study | Role: PI/Project Team Member – Applications (Submitted – Requiring My Attention)
- Click 'Edit'
- Click the 'Attachments' Tab, complete all fields, Click 'Add Attachment'
- Once all attachments have been added, click 'Submit'

Only the PI may 'Submit' to the REB