Western Research

Date: 21 April 2020

To: Dr. Tarek Loubani

Project ID: 115775

Study Title: Reduced-aerosolizing BiPAP for patients in environment at risk of COVID-19

Application Type: HSREB Initial Application

Review Type: Full Board

Dear Dr. Tarek Loubani,

The Western University Health Sciences Research Ethics Board (HSREB) has reviewed the application for the study named above and determined that it may be approved upon the receipt of satisfactory responses to the items outlined below.

List of requests and recommendations:

Review Form Comments
Thank you for your report to the Board. If possible, the Board would like further follow up with the same type of leak data along with any adverse events by 1pm on Monday April 27th for our next HSREB meeting. Thank you for your cooperation. 1. Q1.4 Please ensure that MCs actual role is reflected in this application. If the role is to facilitate REB approval remotely for a limited period as she is now in Calgary, this should be reflected in WREM, which is ultimately what is approved. 2. a) Q1.10/2.21 While it is understood that Dr. Loubani has not monetary conflict of interest, the Board nonetheless recognizes a conceptual COI and recommends he recuse himself from the analysis or at the very least has third party input performed on the analysis. b) Please clarify how and at what timepoints (via export of continuous machine data? As per personal communication with P. Jones) leak/physical seal of mask will be measured. 3. Q2.10 As per preliminary recommendations, there are procedures in this RCT that are not routine and these need to be reflected in WREM. There are most certainly procedures to be carried out that are not usual care as this is a RCT with an experimental device. Randomization, how will efficacy of ventilation support be measured (only chart review data?), how will aerosolization be measured (Q2.24 mentions more frequent assessment of the seal)? Are participants enrolled in the study for the entirety of their BiPap usage or for how long? Please ensure an explanation of everything the participant will experience is included in WREM. 4. Q2.16 The LibreOffice database would be a technology to acknowledge here. Please explain it's use in WREM. 5. Q3.7 Please insert your registration #NCT04344925 into WREM. 6. Please confirm ongoing institutional approval of not seeking an ITA. The development, manufacture, and testing of the device is would not seem to be being conducted within a single corporate entity. Glia and Dr. Loubani may be one and the same but LHSC and Glia and LHSC and General Dynamics along with other partners are NOT the same. 7. Q11.3/11.5 It would seem that there still needs to be some acknowledgement of medical risks in both WREM and LOI as discussed in response document. 8. Please update with the DSMB members who have no conflict as proposed on April 17th via correspondence. 9. Q12.11 Please describe the consent process taking into account all of the possible scenarios. Again, the response document does this but it is not reflected in WREM. More detail is also needed. If consented by SDM and they regain capacity, how and when are they re-consented? If the participant or SDM is approached for delayed consent, what are the practicalities of this? What if a participant dies? What happens to their data/approach of SDM? Is there any use of telephone/verbal SDM consent? As per conditional approval, deferred consent (when required) must be obtained within 48 hours. SDMs must be emailed a copy of the LOI when relying on their verbal consent. Verbal consent for study participation must be appropriately documented in the clinical and study record. This needs to be reflected in WREM. 10. Q12.13 Please upload most up to date (April 17th evening 20:53hrs) LOI/C to WREM. 11. Q12.20 It would not really be appropriate for an SDM to sign in cases of a language barrier. This doesn't mean that the participant lacks capacity to consent – merely that they need a translator. Please explain. Also, it seems like you WILL encounter these populations and so this answer needs to be changed from "none". Even if there is delayed consent because of a communication difficulty and emergent issue, consent still needs to be obtained and address these potential challenges unless there are exclusion criteria to the contrary. 12. Q14.3 How will funds be administered if not held at a local institution?

IMPORTANT RESUBMISSION NOTES:

- Ensure that you change Q1.1 from "Initial Submission" to "Response to REB Recommendations". Consult the "Help" tab in WREM for a guidance document on submitting responses.

- In a separate document, include each REB question/recommendation and your specific response to each. DO NOT refer to other documents.
- Submit all revised documents (e.g. instruments, LOI etc.) in TRACKED and CLEAN copies. The TRACKED copies must only be uploaded when prompted (i.e., in the section called "Resubmission Information").
- When uploading the revised CLEAN copies, you MUST delete the old versions. Deleting the old versions will archive them and NOT permanently delete them.
- Ensure there is a version date (dd/mm/yyyy) in the footer of each revised document. This version date must be consistent with the version date entered when uploading the document.
- Please note that if a response is not received within 6-months of recommendations, this application will be considered stalled and be withdrawn.

If the above instructions are not followed, the file will be sent back until this is done. Please note that once we receive your response, further questions generated by your response may be asked.

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).

Please submit your response through WREM at your earliest convenience.

Please do not hesitate to contact us if you have any questions.

Sincerely,

Nicola Geoghegan-Morphet, Ethics Officer on behalf of Dr. Joseph Gilbert, HSREB Chair