

Date: 27 April 2020

To: Dr. Tarek Loubani

Project ID: 115775

Study Title: Non-invasive positive pressure ventilation mask to minimize mask leak and potential aerosolization leading to spread of virus such as COVID-19

Application Type: HSREB Initial Application

Review Type: Full Board

Meeting Date: 27/Apr/2020 13:00

Date Approval Issued: 27/Apr/2020 15:05

REB Approval Expiry Date: 27/Apr/2021

Dear Dr. Tarek Loubani

The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above mentioned study as described in the WREM application form, as of the HSREB Initial Approval Date noted above. This research study is to be conducted by the investigator noted above. All other required institutional approvals must also be obtained prior to the conduct of the study.

Documents Approved:

Document Name	Document Type	Document Date	Document Version
BiPAP Protocol April 7 2020 CLEAN	Protocol	07/Apr/2020	April 7 2020
DCT April 21 Clean	Other Data Collection Instruments	21/Apr/2020	April 21 2020
LOI April 17 2020 Clean	Written Consent/Assent	17/Apr/2020	April 17 2020

Documents Acknowledged:

Document Name	Document Type	Document Date	Document Version
REB Project Budget	Study budget	07/Apr/2020	April 7 2020

No deviations from, or changes to, the protocol or WREM application should be initiated without prior written approval of an appropriate amendment from Western HSREB, except when necessary to eliminate immediate hazard(s) to study participants or when the change(s) involves only administrative or logistical aspects of the trial.

REB members involved in the research project do not participate in the review, discussion or decision.

The Western University HSREB operates in compliance with, and is constituted in accordance with, the requirements of the TriCouncil Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2); the International Conference on Harmonisation Good Clinical Practice Consolidated Guideline (ICH GCP); Part C, Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations; Part 3 of the Medical Devices Regulations and the provisions of the Ontario Personal Health Information Protection Act (PHIPA 2004) and its applicable regulations. The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

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

Note: This correspondence includes an electronic signature (validation and approval via an online system that is compliant with all regulations).