

Date: 19 May 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 Amendment Form

Review Type: Delegated

Full Board Reporting Date: 02June2020

Date Approval Issued: 19/May/2020 14:10

REB Approval Expiry Date: 27/Apr/2021

Dear Dr. Tarek Loubani,

The Western University Health Sciences Research Ethics Board (HSREB) has reviewed and approved the WREM application form for the amendment, as of the date noted above.

Documents Approved:

Document Name	Document Type	Document Date	Document Version
BiPAP Protcol Version April 22 2020	Protocol	22/Apr/2020	April 22nd 2020

Documents Acknowledged:

Document Name	Document Type	Document Date	Document Version
Health Canada Authorization	NOL/NOA/ITA	11/May/2020	May 11 2020

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).