Dear reviewers,

Thank you for providing feedback regarding our Health Canada study application. We have listed your concerns below and have addressed them individually. We have provided tracked and untracked updated documents.

1. *The protocol makes reference to the randomized control trial; however, by reviewing the information in the protocol there is no randomization in the study design. Confirm the type of study design that will be conducted and revise the protocol, as required. Provide redlined and clean copies of the revised protocol.*

   We agree that the study should not be classified as a randomized control study. Thank you for clarifying. The study participants are included in both the experimental arm (experimental oximeter) and control arm (control oximeter) simultaneously.

2. *There is a discrepancy in the duration of the study in the protocol and the screening deficiency response letter. Revise the protocol to include the correct timeframe. Provide redlined and clean copies of the revised protocol.*

   We have updated our timeline accordingly. We plan on initiating the study in June of 2018 and completing it by December of 2019.

3. *In the screening deficiency response letter there is a timeframe for the treatment and follow-up schedules; however, these are not included in the study procedures of the protocol. Confirm if there is any follow up for this study. If so, the protocol should be revised. Provide redlined and clean copies of the revised protocol.*

   No treatment or follow-up are scheduled for the patients involved in this study. The protocol has been updated accordingly:

   - Study Duration: Jun 1, 2018 – December 31, 2019
   - Recruitment: June 1, 2018 – August 30, 2018
   - Phase 1 trial (Calibration): Sept 1, 2018 – April 30, 2019
   - Phase 2 trial (Validation): May 1, 2019 – December 31, 2019

4. *The protocol makes reference to the low-cost 3D printed pulse oximeter, which is an investigational device. Confirm where the device is manufactured and by whom, what materials are used in its manufacture, and if the device has been granted any authorization in Canada.*

   We have included this information in a separate section entitled 'Experimental Oximeter' and have included a Bill of Materials. This device is manufactured by the research team in London, Ontario under the supervision of Glia Inc. (Corporation #924742-4; HC Company ID #141507). A Bill of Materials is included in the revised proposal. The device has not been granted any special authorization in Canada.

5. *Confirm which control pulse oximeter(s) will be used. Provide the name(s), manufacturer(s), and Canadian medical device licence number(s).*

   We have confirmed this in the Protocol section of the application: (GE Carescape B850 Patient Monitor; General Electric; license 119340)