

Response to IRB #3  
Date: 10/30/2020

**1. The required Good Clinical Practice CITI training has not been completed by Carl Demolder. Please have this study team member complete this required CITI training as soon as possible.**

This study member has already completed the "Good Clinical Practice" CITI training. The certification of completion has been added that study team member's profile.

**2. Please remove current response to question A of the Investigational Medical Device section and replace with your responses to the following questions:**

- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;**
- Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;**
- Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or**
- Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.**

This section has been modified and updated accordingly.

**3. Please revise your response to question I of the Investigational Medical Device section to also state how the glove and sensors are taken off, and turned off, and disinfected.**

This section has been modified and updated accordingly.

**4. Please revise your response to question J of the Investigational Medical Device section to also state how the device is powered.**

This section has been modified and updated accordingly.

**5. Please revise your response to question J of the Investigational Medical Device section to also state how the algorithm and medical device app work (your response to question D of the same section has "algorithm" and "device app" checked).**

This section has been modified and updated accordingly.

**6. Please remove the following statement from your response to question L of the Investigational Medical Device section as you cannot state that the device is "safe."  
--- "The wearable sensor glove is safe to touch and wear on the skin."**

This section has been modified and updated accordingly.

**7. Please revise the hazards section of your response to question L of the Investigational Medical Device section to only state that there is a choking hazard if the device is or any components are swallowed.**

This section has been modified and updated accordingly.

**8. Please revise your response to question L of the Investigational Medical Device section so that the hazards, precautions, and adverse effects are combined into one section. This section should only discuss the choking hazard, excessive loading, and precautions that should be taken to prevent device failure (do not submerge device in water).**

This section has been modified and updated accordingly.

**9. Please revise your selection in question P of the Investigational Medical Device section to change from "Class I General Controls" to "Class II General Controls and Special Controls With Exemptions."**

This section has been modified and updated accordingly.

**10. Please make the following revision to the Confidentiality section in the consent form:**

**--- Current: To make sure that this research is being carried out in the proper way, the Georgia Institute of Technology IRB may review study**

**--- Change to : The Georgia Institute of Technology IRB, the Office of Human Research Protections and/or the Food and Drug Administration may look over study records during required reviews.**

The consent form has been modified and updated accordingly.

**11. Please remove the following statement from the Confidentiality section in the consent form and move to the end of the Procedures section in the consent form:**

**--- Additionally, you will be asked to complete a questionnaire at the end of the study to evaluate your experience, assess the device's comfort level, and provide valuable feedback.**

This consent form has been modified and updated accordingly.