Response to IRB
Date: 10/23/2020

1. In part B of the Research Design and Methodology, you state the duration is 2 hours per study session, however, how many study sessions does a given individual go through? Please clarify.

An individual will go through 1 study session for a duration of 2 hours. This section of the proposal has been modified accordingly.

2. In part C of the Research Design and Methodology, please include all of the other data collection that will take place via the sensors and the glove, as well as the motions that subjects will perform.

The sensor glove will collect physical data through the interaction between the subject and surrounding environment. The sensor glove will record pressure, temperature, and strain. This section of the proposal has been modified accordingly.

3. In part E of the Research Design and Methodology, please list the risks of the device. Could subjects be potentially shocked? Could there be pinching from the glove's fit? Please list the risks.

There are no inherent risks from the use of the device. All sensors are on the outside of the wearable sensor glove. All electronics are on the outside of the wearable sensor glove. All electronics are encapsulated in PDMS to make them waterproof. This section of the proposal has been modified accordingly.

4. In part F of the Research Design and Methodology, please explain how the data will reviewed and analyzed. While we understand there may not be a set statistical plan, please explain how the data will be analyzed.

The data will be used to characterize the performance of the wearable sensor glove. The raw data from the sensors will be used to calibrate the performance of the wearable sensor glove. This section of the proposal has been modified accordingly.

5. In part C and D of the Subjects, Inclusion, and Exclusion Criteria, do subjects need to speak and understand English? If so, please include this.

Subjects do need to understand English as all documentation and instructions will be given in English. This section of the proposal has been modified accordingly.

6. In part F of the Subjects, Inclusion, and Exclusion Criteria section, please be aware that lack of availability is not sufficient reason to exclude a population. Please provide an alternative reason.

The inclusion and exclusion criteria have been modified accordingly.

7. In part A of the Recruitment & Compensation section, please include the word-of-mouth script in this section.

The word of mouth script has been added to the Recruitment and Compensation section.

8. In part B of the Data Management section, please address how often you will be checking the data for security and integrity purposes. For example, common schedules range from daily, weekly, to monthly. Please choose a schedule in which you will check the data.

The data collection will be check for security and integrity purposes every month. This section was modified accordingly.

9. In part J of the device section you mention a phone; is this part of the device?

No, a phone is not part of the device. This section of the IRB proposal has been clarified accordingly.

10. In part L of the device section, wouldn't another hazard be submergence into water? Please add this if applicable.

This hazard is not applicable. There is not water available for the subject to submerge the glove into it. This section was modified accordingly.

11. In the consent form, you state that subjects may be asked to pick up a glass of water; is there not a risk of sock if the water is spilt on the glove? Please include this in the risks section of the consent form.

There is not a risk of shock as there are multiple safety measures take to reduce possible risks. All sensors and electronics are on the outside of the glove, so that there is no possibility that the subject will be shocked by the electronics. Additionally, all of the electronics will be coated in an elastic membrane that makes it water impermeable. So, there is no possibility that water will be in contact with the electronics to cause shock. This section was modified accordingly.

12. The risks section of the consent form should be more robust and include actual risks of the glove.

The risks section of the consent form has been updated and the robustness of the consent form has been modified.

13. You state in the consent form that will be enrolling 5 people, however, in the application you state 10 people. Please address this disparity and make sure the application and documents are consistent.

The disparity between the consent form and the application has been modified for consistency.

14. The inclusion/exclusion section of the consent form should include language requirements.

The inclusion and exclusion section of the consent form has been modified to include a language requirement.

15. In the Use of Photographs, Audio, or Video Recordings section, please state what will happen to images at the end of the study.

Photographs, recordings, or other identifiable information about the subject will not be used in any future presentation or publication without the direct written consent of the subject. All other images and recordings taken during the study will adhere to the same standards that are placed on the subjects' data: it will be deleted after 3 years. The consent form has been modified accordingly.

16. Please upload a device brochure for the device being used in this study.

A device brochure for the device being used in this study has been included.

17. In the recruitment flyer, please include all if the inclusion/exclusion criteria, including language requirements.

The recruitment flyer has been modified to include the inclusion and exclusion criteria.

18. Is Dr. Hammond's Sensory Transfer system being used in this study? If so, is it another device? If so, it will need to be included in the device section.

No other devices are used in this study. This section of the proposal has been modified accordingly.