Response to IRB #4

Date: 12/06/2020

1. While the purpose of this study is to assess the performance of the wearable sensor glove, the overall intent of this investigative medical device is not clear. The PI indicates several possible future applications of the glove, including its use by people with nerve damage, sensing loss, limb loss, or a prosthetic hand; as a diagnostic device to assist subjects with nerve damage, prosthetic usage, and the loss of feeling in a hand; or to noninvasively and rapidly assess physical measurements. Please explain the overall intent of the device.

2. The recruitment script calls for the recruiter to ask female potential subjects if they are pregnant. The board prefers the recruiter to inform potential subjects that women who are pregnant should decline to participate since the effect of pregnancy on physiological signals is unknown.

3. The informed consent document unnecessarily repeats information provided in the key information section. It also says in two places that "Subjects will be informed of the type of fabric material through the informed consent document." In both cases, this sentence should be removed.

4. What does this mean? For what intent/purpose:

"In this study, we will develop a wearable pediatric sensory transfer device that includes multiple noninvasive sensors to measure pressure, strain, and temperature."

**Protocol Methodology section:**

5. It says in one part that there is the risk of allergies? however, another part contradicts this. Which is it?

"E. There is a possibility that the patient is allergic to the material of the wearable sensor glove.

H. The wearable sensor glove will not pose any risk to the human skin in the hand"

6. The committee is not 100% sure on this; isn't their chance, even a tiny one, that this could happen. Please alter the language:

"E. The electronics are encapsulated in PDMS to waterproof the wearable sensor glove and prevent the wearable sensor glove from causing electrical shock if water is exposed to the system. So, there is no possibility of electrical shock."

7. You state "Thus, our device will be qualified for exemption from the FDA's device regulations under category 3(see 21 CFR 812.2(c)(3))" However, Your study is not Exempt from the IDE regulations. This is what exemption 3 is below from the CFR, you do not have a diagnostic and it is not just a glove, it contains sensors, which are not exempt and makes this a NS investigational medical device:

(3) A diagnostic device, if the sponsor complies with applicable requirements in Sec. 809.10(c) and if the testing: (i) Is noninvasive, (ii) Does not require an invasive sampling procedure that presents significant risk, (iii) Does not by design or intention introduce energy into a subject, and (iv) Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

Please delete that statement.

**Funding:**

8. The funding title explains what the real intent of this research is with the investigational medical device. This investigator should stick with this intent throughout this entire application:

"Shriners Hospitals for Children Wearable Pediatric Sensory Transfer Devices for Improved Neuromotor Control of Impaired Limbs."

**Subject Inclusion/Exclusion Criteria:**

9. This is not an adequate justification for exclusion of pregnant women and there needs to be a lit/research search performed on this or pregnant women may not be excluded. I know there is evidence that pregnancy does effect EEG/EMG signals, this might be a good starting point for the Investigator:

"D. This study does not include certain participants like pregnant women since we do not know how pregnancy would affect the physiological signals."

**Recruitment and Compensation:**

10. In the inclusion criteria it says "This pilot study aims to demonstrate how the newly developed wearable sensor glove measures physical parameters such as pressure, strain, and temperature in a non-invasive way. Thus, this study does not require specific individuals with certain characteristics as long as they are healthy adults between the ages of 18-40, they are not allergic to the fabric material of the glove, and they can speak and read English fluently as all instructions and documents will be provided in English." However, in the recruitment script, you say "The inclusion criteria is that you must be a healthy adult between the ages of 18 and 40, and you must be able to speak, read, and write English fluently." In one you state that subjects must write English fluently and in the other you do not. Please address this disparity

**Investigational medical device**

11. In part E of the investigational medical device section, the PI simply needs to put the title of the grant as this IS THE INTENT of the research and how it currently differs from current available devices that are approved for standard of care.

Intended use: Wearable Pediatric Sensory Transfer Devices for Improved Neuromotor Control of Impaired Limbs

12. Please revise your response to part F of the investigational medical device section. The intent of this device will absolutely affect the structure/function of the body. The Investigator states in his previous explanation of it affecting the function of the body: "The future version of this device would be a diagnostics device that assist subjects with nerve damage, prosthetic usage, and the loss of feeling in a hand are not able to detect.

13. What is this fabric made of? Please explain.

"biocompatible material Off-The-Shelf Glove - Fabric Glove (Patients are selected so that they are not allergic to the fabric material)."

14. In part I, Does the subject place their own hand in the glove or does the Investigator place the glove on the subject's hand?

"before the glove is placed on the subject. Once the subject's hand is placed inside the device."

15. If this is how the operator turns the glove on by using a magnet to trigger a magnetic switch, is the magnet used to turn the glove off or is it turned off completely by the tablet or smartphone? The committee feels there is a step that was left out as the Bluetooth is used to connect the device to the tablet/smartphone, not to manually turn the device on or off. We could be wrong but it needs to be described.

"ON: the operator will turn on the device by using a magnet to trigger a magnetic switch on the patch to activate the electronics. The operator will use a Bluetooth enabled tablet or smartphone to connect to the device to begin the data transfer.

OFF: the operator will turn off the wearable sensor glove using the Bluetooth enabled tablet or smartphone."

16. Explain in lay language what the output is?

"J. So, some features of the algorithm used to analyze the data are functions to get the average, range, minimum, maximum, and standard deviation. These mathematical numbers are used to characterize the sensors on the wearable sensor glove."

17. Please include the algorithm is this statement:

"K. The fabrication of the wearable sensor glove can be broken down into three distinct components: off-the-shelf fabric glove, soft electronic sensors, and circuit electronics."

18. "Off-the-shelf fabric glove" needs to be replaced on the label with whatever the glove is made out of:

"This is an investigational device; limited by Federal (or United States) law to investigational use." -Substances: This device is composed of thin metals (Au, Cu, Pd, and Ag), commercial chip components, flexible PCB substrate, biocompatible polymers, and an off-the-shelf fabric glove. The entire electronics are completely enclosed by a biocompatible polymer(silicone elastomer). -Hazards, precautions, and adverse effects: There is a choking hazard if the device is or any components are swallowed. When handling the device, do not add excessive loads to the wearable sensor glove, which may break the electronic circuit or sensors. Do not submerge the wearable sensor glove in water as the water might affect the integrity of the device. There are no adverse effects by using this device."

19. Please remove "There are no adverse effects by using this device as this device is being tested for safety" from "L. Caution: "This is an investigational device; limited by Federal (or United States) law to investigational use." -Substances: This device is composed of thin metals (Au, Cu, Pd, and Ag), commercial chip components, flexible PCB substrate, biocompatible polymers, and an off-the-shelf fabric glove. The entire electronics are completely enclosed by a biocompatible polymer(silicone elastomer). -Hazards, precautions, and adverse effects: There is a choking hazard if the device is or any components are swallowed. When handling the device, do not add excessive loads to the wearable sensor glove, which may break the electronic circuit or sensors. Do not submerge the wearable sensor glove in water as the water might affect the integrity of the device. There are no adverse effects by using this device."

**Informed consent**

20. Who is "they?"

"Dr. Yeo will ask whether any information in the informed consent form is not clear. They are allowed to take home an unsigned copy of this consent form to think about or discuss with family or friends their participation in this study before making their decision."

21. In part B of the informed consent section, "you state More importantly, voluntary participation and withdrawal information will be given with the following example: 'Your participation in this study is voluntary. You may decide to not participate in this study. Your decision not to take part will involve no penalty or loss of benefits to which you are otherwise entitled. If you do participate, you may freely withdraw from the study at any time. Your decision to with draw will involve no penalty or loss of benefits to which you are otherwise entitled." However, this is simply a regurgitation of template language. Please include language that is more substantial.

**Recruitment flyer**

22. Please inform possible subjects in lay language what the real intent of the research and glove is? This could perhaps resut in a better response rate

"Study Description on recruitment flyer:

We are conducting a research study of a wearable sensor glove that can take measurements from the applied forces and conditions on the hand. Participants will wear the wearable sensor glove for up to 2 hours for a single study session. The wearable glove will be worn by the participant on their right hand. The wearable sensor glove will be worn while the participant is seated in a research lab and measurements will be taken by the wearable sensor glove and sent to a nearby computer/tablet while the participant completes a set of simple tasks. This study will contribute to the knowledge about the functionality and utility of the wearable sensor glove."

Real Intent suggestion: "Would you like to participate in a research study in which we are trying to develop a wearable glove that will be used with children to possibly improve their control of impaired limbs?"

23. Again, there is this mention of being able to write English fluently on the recruitment flyer when it was not mentioned in the actual inclusion criteria on the application:

"Eligibility Criteria: INCLUSION: Can speak, read, and write English fluently"

Please address these disparities.

24. The reason you state pregnant women cannot participate in the flyer is not consistent with the reason you posited in the application:

"EXCLUSION:This study does not include certain participants like pregnant women, since we do not know how pregnancy would affect the physiological signals."

25. The entire Exclusion section on this flyer needs modification:

"This study does not include minors as the device is sized to fit adults.

This study does not include participants who are in EU countries.

The subject is not allergic to the fabric material that constitutes the fabric glove.

Individuals who cannot read, write, and speak English fluently"

suggestion:

-state there are no minors

-Remove the EU disclosure. This is performed in person on GT campus, there are no EU located participants and no reason to include this information at all.

-Please state what the fabric is made of so subjects know if they are allergic to it.

-are subjects actually excluded if they cannot write English fluidly? Be sure to address this disparity as mentioned earlier.

26. At the bottom of the recruitment flyer, please make clearer and decipherable what the contact information is.

27. How does the question relate to the development of a pediatric glove on the Final Questionnaire:

"What do you think are the potential benefits of wearing this device at home /office?"

**Proposal:**

28. Why is Frank Hammond listed as PI and how is he related to this research and why is he not listed on the application?

"Principal Investigators: Frank L. Hammond III, Ph.D. - Georgia Institute of Technology, Atlanta, GA."

29.For the word of mouth script, please refer to the requested changes for the flyer, as they are the same and should be implemented the similarly.

**Consent form**

30. The KEY INFORMATION section contains too much procedural information and scientific jargon. Slim it down and make it brief for the lay individual to decide if they want to participate or not.

31. There is a spelling error in the key information section:

"Therefore, there is no risk in cSo, there is no possibility of electrical shock."

32. the entire Inclusion/exclusion section of the consent needs to be addressed, please see previous comments about this and applying them similarly to consent form.

33. Items that are in the Key Information section should NOT be repeated in the main consent. Please remove from the main consent things that were already stated in the key information section.

34. In the benefits section of the consent form, please list the actual intent of the device.

35. The language in the consent form needs simplifying, especially with the procedures. All the scientific jargon explanations are not needed. Please reduce the reading level of the consent form.