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.**

There are many possible uses for this technology in the future and the above description details all possible use cases. However, to be more specific, the most directly applicable intent of this investigative medical device would be to improve the neuromotor control of impaired limbs.

**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.**

The recruitment script has been modified accordingly. Please see attached document.

**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.**

The informed consent document has been modified accordingly.

**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."**

The wearable pediatric sensory transfer device is the wearable sensor glove detailed in other sections of the proposal. The wearable sensor glove is used to transfer sensory information from the hand. The wearable sensor glove has sensors on the outside of the glove. These sensors measure pressure, strain, and temperature between the subject’s hand and the surrounding environment. The intent of this investigative medical device, wearable sensor glove, would be to improve the neuromotor control of impaired limbs.

**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"**

There is a possibility that the subject is allergic is to the material of the wearable sensor glove. The subject will be informed of the material of the wearable sensor glove during the informed consent state of recruitment. The subject will know in advance if they are allergic to the glove material and they will not participate in the study if they are allergic to the glove material.

**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:**

**Original:**

**"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."**

Modified:

"E. The electronics are encapsulated in PDMS. This material prevents water from contacting the electronics and battery on the wearable sensor glove. The wearable sensor glove is made from a non-conductive and insulating material. Therefore, these protective methods prevent the wearable sensor glove from causing electrical shock to the subject if water is exposed to the system. Therefore, it is very unlikely for the subject to be exposed to an 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.**

**Modified:**

There is a possibility that the patient is allergic to the material of the wearable sensor glove. The fabric component of the sensor glove will be made from an off the shelf fabric glove, and the participant will wear the wearable sensor glove just as one would put a normal glove on their hand. The device will be made from a wearable fabric as seen in the following referenced papers: [1] and [2]. The fabric of the glove is the only material that comes in contact with the subject. [1] Franc Sensors (Basel, Switzerland) vol. 19,2 296. 13 Jan. 2019, doi:10.3390/s19020296 [2] Hughes, J., Spielberg, A., Chounlakone, M., Chang, G., Matusik, W. and Rus, D. (2020), A Simple, Inexpensive, Wearable Glove with Hybrid ResistivePressure Sensors for Computational Sensing, Proprioception, and Task Identification. Adv. Intell. Syst., 2: 2000002. doi:10.1002/aisy.202000002

**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."**

This intent will be used throughout the remainder of the application for simplicity purposes.

**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."**

This is not a clinical study. Therefore, does the exclusion of pregnant women require justification?

**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**

The recruitment script has been modified to the following:

Recruitment will be done through the use of flyers placed on bulletin boards at the Woodruff School of Mechanical Engineering at the Georgia Institute of Technology and through word-of-mouth. A copy of the flyer is attached to the application for reference. The word-of-mouth script would be the following: Recruiter: "Hello! I hope you are having a nice day. Are you interested in participating in a study?" Potential Subject: "Sure! What is the study about?" Recruiter: "We are conducting a pilot research study of a wearable sensor glove that will be used in the future to improve neuromotor control in impaired limbs. 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." Potential Subject: "Oh, great! What is the eligibility criteria?" Recruiter: "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 and read English fluently. Do you meet these criteria?" Potential Subject: "Yes, I do." Recruiter: "However, this study does not include certain participants like pregnant women, since we do not know how pregnancy would affect the physiological signals. If you are pregnant, please remove yourself from this study." Potential Subject: "No I am not pregnant." Recruiter: "Great. Are you allergic to nylon, as this is the fabric material that constitutes the fabric glove?" Potential Subject: "No, I am not allergic to nylon." Recruiter: "Awesome. If you are interested in participating, please contact the Principal Investigator, Woon-Hong Yeo, Ph.D., Assistant Professor, whyeo@gatech.edu or sites.google.com/view/yeogroup. Thank you for your time!"

**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**

Part E of the investigational medical device section should be modified to the following:

The intent of this research is that the wearable pediatric sensory transfer devices are for the improved neuromotor control of impaired limbs. The wearable pediatric sensory transfer device addresses an unmet need. The treatment to improve neuromotor control in impaired limbs is either surgery, therapy, or nerve stimulation. Currently, there is not a wearable device that helps improve the 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.**

Part F of the investigational device section should be modified to the following:

During this preliminary pilot study to characterize the performance of the wearable sensor glove, the wearable device does not affect the structure or any function of the body of man or other animals. In the future, when the intent of the investigation medical device is fully realized, it will be used to improve the neuromotor control of impaired limbs.

**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)."**

The wearable sensor glove is made from an off-the-shelf glove. The fabric of the glove is made from nylon 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."**

Part I of the investigational device section should be modified to the following:

This device is an off-the-shelf glove with an elastic wrist band, such that it does not require any adhesives or tape to be used to mount the wearable sensor glove to the hand of the subject. The subject's hands will be disinfected with hand sanitizer before the glove is placed on the subject. The subject will place the glove on their hand. Once the subject's hand is placed inside the device, the operator will turn on the device by using a magnet to trigger a magnetic switch on the patch to activate the electronics. Using a magnet is the only method to turn on the wearable sensor glove. The magnet is not used to turn off the wearable sensor glove. The operator will use a Bluetooth enabled tablet or smartphone to connect to the device to begin the data transfer. The operator will instruct the subject to perform a set of simple commands to characterize the wearable sensor glove. When the subject is finished performing the set of commands given by the operator, the operator will turn off the wearable sensor glove. The operator turns off the wearable sensor glove using the Bluetooth enabled tablet or smartphone. The operator will then ask the subject to remove the glove and place it on the table. The subject will remove the glove from their hand as one would normally remove a glove off of their hand. There are no specific instructions for one to remove the glove from their hand as the glove component of the wearable sensor glove is an ordinary, off-the-shelf glove. The subject's hands will be sanitized using hand sanitizer and a sanitizer spray will be sprayed to the outside and the inside of the glove for the next subject to use.

**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."**

Part I of the investigational device section is modified to the following to clarify the confusion:

This device is an off-the-shelf glove with an elastic wrist band, such that it does not require any adhesives or tape to be used to mount the wearable sensor glove to the hand of the subject. The subject's hands will be disinfected with hand sanitizer before the glove is placed on the subject. The subject will place the glove on their hand. Once the subject's hand is placed inside the device, the operator will turn on the device by using a magnet to trigger a magnetic switch on the patch to activate the electronics. Using a magnet is the only method to turn on the wearable sensor glove. The magnet is not used to turn off the wearable sensor glove. The operator will use a Bluetooth enabled tablet or smartphone to connect to the device to begin the data transfer. The operator will instruct the subject to perform a set of simple commands to characterize the wearable sensor glove. When the subject is finished performing the set of commands given by the operator, the operator will turn off the wearable sensor glove. The operator turns off the wearable sensor glove using the Bluetooth enabled tablet or smartphone. The operator will then ask the subject to remove the glove and place it on the table. The subject will remove the glove from their hand as one would normally remove a glove off of their hand. There are no specific instructions for one to remove the glove from their hand as the glove component of the wearable sensor glove is an ordinary, off-the-shelf glove. The subject's hands will be sanitized using hand sanitizer and a sanitizer spray will be sprayed to the outside and the inside of the glove for the next subject to use.

**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."**

The output of these algorithms is used to characterize the sensors on the wearable sensor glove. For example, the maximum and minimum forces detected by the pressure sensor are used to define the limits of the pressure sensor. Additionally, the maximum and minimum temperature detected by the temperature sensors detect the limits of the temperature sensor.

**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."**

Part K of the investigational device section should be modified to the following:

The fabrication of the wearable sensor glove can be broken down into four distinct components: off-the-shelf fabric glove, soft electronic sensors, circuit electronics, and data analysis algorithms. The fabric glove will be an off-the-shelf glove worn on the right hand of the subject. This fabric nylon glove is ultra-soft, breathable, and washable. The fabric glove is the only component of the wearable sensor glove that will come in contact will the skin of the subject. The fabric glove will have an elastic band to secure the glove the subject's hand. A new, novel approach will be used to fabricate the soft electronic sensors by combining the conventional micro-fabrication techniques with materials transfer printing and integration. This method will be used to fabricate sensors to measure pressure, temperature, and strain. These wearable sensors will be mounted to the outside of the fabric glove and they will not come in contact with the subject's skin. The circuit electronics will be used using off-the-shelf commercial ICs that are placed on a flexible PCB, printed circuit board, that will be mounted to the backside of the fabric glove. Low-temperature curing solder will be used to bind the ICs to the flexible PCB. The final step would be to encapsulate the flexible PCB is a silicone to make the system waterproof. The data analysis algorithms are used to characterize the sensors on the wearable sensor glove.

**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."**

Part L of the investigational device section should be modified to the following:

-Device: "Wearable Sensor Glove", manufactured by Yeo Research Group at the Institute for Electronics and Nanotechnology at Georgia Tech.

-Functions: This device includes an array of non-invasive sensors, powering, and data telemetry units.

-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 a nylon 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.

**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."**

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-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.

**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."**

Part B of the informed consent section should be modified to the following:

Participants will be recruited from Georgia Tech through the use of flyers and website advertisements. Informed consent will be physically obtained by Dr. Yeo in the physiology research lab (MiRC 230) in the Pettit building. A written informed consent form including all necessary information will be given to participants of the study, and Dr. Yeo will explain everything in the study and consent form before asking for the participant's agreement. Dr. Yeo will ask whether any information in the informed consent form is not clear. Participants 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. More importantly, voluntary participation and withdrawal information will be given to potential subjects through the following statements: "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 withdraw will involve no penalty or loss of benefits to which you are otherwise entitled." Researchers will determine if subjects have been provided sufficient information by asking the subjects if they have any questions and if they fully understand what they (subjects) are being asked to do. Researchers will determine whether subjects comprehend what they are being asked to do by asking them to regurgitate it back to the researchers. Finally, researchers will determine whether the subject’s participation is truly voluntary by going over the research proposal, making sure the subjects fully understand their research study, and asking them to sign the written informed consent form.

**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.**

Part B of the informed consent section should be modified to the following:

Participants will be recruited from Georgia Tech through the use of flyers and website advertisements. Informed consent will be physically obtained by Dr. Yeo in the physiology research lab (MiRC 230) in the Pettit building. A written informed consent form including all necessary information will be given to participants of the study, and Dr. Yeo will explain everything in the study and consent form before asking for the participant's agreement. Dr. Yeo will ask whether any information in the informed consent form is not clear. Participants 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. More importantly, voluntary participation and withdrawal information will be given to potential subjects through the following statements: "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 withdraw will involve no penalty or loss of benefits to which you are otherwise entitled." Researchers will determine if subjects have been provided sufficient information by asking the subjects if they have any questions and if they fully understand what they (subjects) are being asked to do. Researchers will determine whether subjects comprehend what they are being asked to do by asking them to regurgitate it back to the researchers. Finally, researchers will determine whether the subject’s participation is truly voluntary by going over the research proposal, making sure the subjects fully understand their research study, and asking them to sign the written informed consent form.

**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?"**

The recruitment flyer has been modified accordingly.

**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.**

The recruitment flyer has been modified accordingly.

**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."**

The recruitment flyer has been modified accordingly.

**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.**

The recruitment flyer has been modified accordingly.

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

The recruitment flyer has been modified accordingly.

**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?"**

This question provides an idea to the researchers if the device was cumbersome to use. If the device was cumbersome to use, adults would not want to wear this device at home or in the office. Additionally, this feedback might provide some more edge cases for the researchers to study to understand the benefits of a wearable sensor glove.

**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."**

Dr. Hammond is the other Principal Investigator on this research proposal. This research proposal is a joint venture between two labs: Dr. Hammond and Dr. Yeo. At this stage of the research proposal, Dr. Yeo is working on one part of the research proposal, whereas Dr. Hammond is working on the other part. The two aspects of the research proposal are independent of one another. Therefore, Dr. Yeo’s prototype will require an IRB to test his part of the research proposal and Dr. Hammond will require an IRB to test his part. The two parts of the research proposal are completely independent of each other at this time. Therefore, Dr. Hammond is not listed as a Principal Investigator for this IRB proposal.

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.

The recruitment script has been modified to the following:

Recruitment will be done through the use of flyers placed on bulletin boards at the Woodruff School of Mechanical Engineering at the Georgia Institute of Technology and through word-of-mouth. A copy of the flyer is attached to the application for reference. The word-of-mouth script would be the following: Recruiter: "Hello! I hope you are having a nice day. Are you interested in participating in a study?" Potential Subject: "Sure! What is the study about?" Recruiter: "We are conducting a pilot research study of a wearable sensor glove that will be used in the future to improve neuromotor control in impaired limbs. 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." Potential Subject: "Oh, great! What is the eligibility criteria?" Recruiter: "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 and read English fluently. Do you meet these criteria?" Potential Subject: "Yes, I do." Recruiter: "However, this study does not include certain participants like pregnant women, since we do not know how pregnancy would affect the physiological signals. If you are pregnant, please remove yourself from this study." Potential Subject: "No I am not pregnant." Recruiter: "Great. Are you allergic to nylon, as this is the fabric material that constitutes the fabric glove?" Potential Subject: "No, I am not allergic to nylon." Recruiter: "Awesome. If you are interested in participating, please contact the Principal Investigator, Woon-Hong Yeo, Ph.D., Assistant Professor, whyeo@gatech.edu or sites.google.com/view/yeogroup. Thank you for your time!"

**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.**

The informed consent form was been modified according.

**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."**

This spelling mistake has been fixed and the consent form was been modified accordingly.

**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.**

This section of the consent form has been modified accordingly.

**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.**

This informed consent form was been modified accordingly.

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

This section has been modified accordingly.

**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.**

The consent form has been modified accordingly.