

KEY INFORMATION FOR A PILOT STUDY TO CHARACTERIZE THE PERFORMANCE OF A WEARABLE SENSOR GLOVE

What Am I Being Asked to Do?

You are being asked to be a volunteer in this research study. This page will give you key information to help you decide if you would like to participate. Your participation is voluntary. As you read, please feel free to ask any questions you may have about the research to the Principal Investigator.

What is This Study About and What Procedures Will You be Asked to Follow?

This study will characterize the performance of a wearable sensor glove by measuring pressure, strain, and temperature parameters. All study activities will be conducted in Pettit Microelectronics Research Lab (MiRC 230) at Georgia Tech.

When you come to the Research Lab for a research session, we will ask you to sit in a chair, and you will remain seated while the wearable glove is in use. Next, your hands will be sanitized using hand sanitizer. Your right hand will be placed inside the fabric glove. During the research sessions, a tablet with a data acquisition system will wirelessly measure multiple signals transmitted from the wearable sensor glove such as pressure, strain, and temperature. You will be asked to perform a set of simple commands to characterize the functionality of the wearable sensor glove. These simple commands included tasks that are performed in everyday life such as but not limited to the following: using a computer mouse, clapping your hands, picking up a sealed bottle of cold water, etc.

The data recorded by the wearable sensor glove will be wirelessly transmitted and stored on a tablet for data analysis. Photos of your hand with the wearable sensor glove on it will be taken. 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.

Are There Any Risks or Discomforts You Might Experience by Being In this Study?

The wearable sensor glove is made from a comfortable fabric, so the material should not cause discomfort to the subject. Subjects will be informed of the type of fabric material through the informed consent document. There is a possibility that the patient is allergic to the material of the wearable sensor glove. However, as a safety precaution, the fabric material of the wearable sensor glove will be selected to avoid materials that can cause allergic reactions for the majority of people.

The wearable sensor glove will be made using a single sized glove that is designed to fit the size of most people's hands. The wearable sensor glove will be made from a flexible material that will conform the patient's hand. However, the patient might find some discomfort wearing a glove that is either too large or too small for their hand.

All sensors will be external to the fabric glove and will not come in contact with the subject's skin. The electronics to measure the different sensors will be located on the back of the hand. 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. The subject will only come in contact with the fabric component of the wearable sensor glove.

What Are the Reasons You Might Want to Volunteer for This Study?

You are not likely to benefit in any way from joining this study. We hope that this study will eventually be helpful in the development of sensor-enabled prosthetics.

Do You Have to Take Part in This Study?

It is fully your decision if you wish to be in this study or not. Your decision not to take part will involve no penalty. If you do participate, you may freely withdraw from the study at any time.

CONSENT DOCUMENT FOR ENROLLING ADULT PARTICIPANTS IN A RESEARCH STUDY

Georgia Institute of Technology

Project Title: A Pilot Study of Pressure, Strain, and Temperature Parameters Using a Wearable Sensor Glove

Investigators: *Woon-Hong Yeo, Ph.D.*

Protocol and Consent Title: *H17212*

You are being asked to be a volunteer in this research study. If any information contained in this consent form is not clear, please ask the study investigator (Dr. Woon-Hong Yeo) to explain any information that you do not fully understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision. This investigational measurement device has not been approved by the FDA for safety and efficacy, and it is being used for research purposes only.

Purpose:

This study aims to assess the function and reliability of a wearable sensor glove that can worn on the hand. You are being asked to participate in this study because you are a healthy adult between the ages of 18 and 40 years old. We expect to enroll 5 people in this study.

Exclusion/Inclusion Criteria:

INCLUSION:

- Can speak, read, and write English fluently

EXCLUSION:

- This study does not include certain participants like pregnant women, since we do not know how pregnancy would affect the physiological signals. During subject recruitment, we will verbally ask about pregnancy
- 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 can not read, write, and speak English fluently

Procedures:

If you decide to be in this research study, we will ask you to sign this consent form after you have had all your questions answered. You are welcome to scan the consent form or take a picture of the consent form for your records and the original copy will be stored safely by the Principal Investigator, Dr. Yeo, for record keeping. All study activities will be conducted in Pettit Microelectronics Research Labs at Georgia Tech.

When you come to the Research Lab (MiRC 230) for a research session, we will ask you to sit in a chair, and you will remain seated while the wearable glove is in use. Next, your hands will be sanitized using hand sanitizer. Your right hand will be placed inside the fabric glove.

During the research sessions, a tablet with a data acquisition system will wirelessly measure multiple signals from the glove such as pressure, strain, and temperature.

We will take still photos of you wearing the sensor glove to document the measurement sites and the time of the recorded signals. There will be one study session that will last for up to two hours on a given day. We will schedule the research sessions based on your availability.

Risks or Discomforts:

The wearable sensor glove is made from a comfortable fabric, so the material should not cause discomfort to the subject. Subjects will be informed of the type of fabric material through the informed consent document. There is a possibility that the patient is allergic to the material of the wearable sensor glove. However, as a safety precaution, the fabric material of the wearable sensor glove will be selected to avoid materials that can cause allergic reactions for the majority of people.

The wearable sensor glove will be made using a single sized glove that is designed to fit the size of most people's hands. The wearable sensor glove will be made from a flexible material that will conform the patient's hand. However, the patient might find some discomfort wearing a glove that is either too large or too small for their hand.

All sensors will be external to the fabric glove and will not come in contact with the subject's skin. The electronics to measure the different sensors will be located on the back of the hand. 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. The subject will only come in contact with the fabric component of the wearable sensor glove.

Benefits:

You will not receive any direct benefits from your participation in the study. Your participation in this study may help others in the future with musculoskeletal disorders, nerve damage, individuals who have lost their sense of feeling in their hand, and those who use a prosthetic on their arm.

Compensation to You:

You will not receive any compensation for participating in this study.

Storing and Sharing your Information:

Your participation in this study is gratefully acknowledged. The data collected during this study will be identified by a code, and the list linking the code to your contact information will be stored on a secured USB. The PI will store the USB in a safety deposit box in the investigator's research office. It is possible that your information/data will be enormously valuable for other research purposes. By signing below, you consent for your de-identified information/data to be stored by the researcher and to be shared with other researchers in future studies. If you agree to allow such future sharing and use, your identity will be completely separated from your information/data. Future researchers will not have a way to identify you. Study data will be identified by numbers (subject 1, subject 2, ...). The linking the code to a subject will be stored on a secured USB which will be secured in a PI's safety box.

Use of Photographs, Audio, or Video Recordings:

Photos will only include your hand wearing the wearable sensor glove. We will only collect data for research purposes. The physiological data and photos collected will be saved on a password protected laptop or tablet. Your study data will be identified by numbers. You should know that research data may be reviewed or copied by Georgia Institute of Technology. We will not use any photographs, recordings, or other identifiable information about you in any future presentation or publication without your consent. All photographs, audio, or video recordings will adhere to the same data protocol as your data: it will be stored safely, non-descriptively on a flash drive for 3 years, and then all digital data will be deleted.

Confidentiality:

We will comply with any applicable laws and regulations regarding confidentiality. To protect your privacy, your records will be kept under a code number rather than by name. Your records will be kept in locked files and unless you give specific consent otherwise, only study staff will be allowed to look at them. Your name and any other fact that might point to you will not appear when results of this study are presented or published. To make sure that this research is being carried out in the proper way, the Georgia Institute of Technology IRB may review study. 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.

Costs to You:

Participants in this study will not have any costs associated with their participation in this study.

Questions about the Study:

If you have any questions about the study, please contact the Principal Investigator, Dr. Woon-Hong Yeo, at his cellphone (206-715-0287) or email (whyeo@gatech.edu).

In Case of Injury/Harm:

If you are injured as a result of participating in this study, please contact the Principal Investigator, Dr. Woon-Hong Yeo, at his cellphone (206-715-0287) or email (whyeo@gatech.edu). Neither the Principal Investigator nor the Georgia Institute of Technology has made provision for payment of the costs associated with any injury resulting from the participation in this study.

Conflict of Interest:

Dr. Yeo is an inventor of technologies used to develop soft, wearable electronics for health monitoring. He has a role in Huxley Medical that licenses this/these technologies or makes or sells these products. This study could affect Dr. Yeo's financial status. This has been disclosed to and is managed by the Georgia Institute of Technology Office of Research Integrity Assurance.

Questions about Your Rights as a Research Participant:

Your participation in this study is voluntary. You do not have to be in this study if you do not want to be.

You have the right to change your mind and leave the study at any time without giving any reason and without penalty.

Any new information that may make you change your mind about being in this study will be given to you.

You may keep this copy of the consent form for your own records.
You do not waive any of your legal rights by signing this consent form.

If you have any questions about your rights as a research participant, you may contact Ms. Kelly Winn at the Georgia Institute of Technology Office of Research Integrity Assurance, at (404) 385-2175.

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study.

Participant Name (printed)

Participant Signature

Date/Time

Signature of Person Obtaining Consent

Date/Time

Consent to Store and Share your Information:

“I agree that my de-identified information/data may be stored and shared for future, unspecified research.”

SIGNATURE _____

“I do not allow my de-identified information/data to be stored and shared for future, unspecified research. These may only be used for this specific study.”

SIGNATURE _____