

CONSENT TO TAKE PART IN RESEARCH

Study title: Monitoring Stress Response with Wearable Electronics

Principal Investigator: XXXXX

You are being asked to take part in a research study. Taking part in research is voluntary.

Your decision whether or not to take part will have no effect on the quality of your academic standing or health care services. Please ask questions if there is anything about this study that you do not understand. We are looking for people who are relatively healthy to participate.

What is the purpose of this study?

The purpose of the study is to validate that a set of wearable, non-invasive sensors are capable of measuring and recording the physiological stress response.

Will you benefit from taking part in this study?

You will not personally benefit from being in this research study. We hope to gather information that may help reduce physical and mental stress for people in the future.

What does this study involve?

This study is interested in capturing your physiological response to stressors by measuring your body's response to mild stressors – such as public speaking, mental arithmetic, responding to an unexpected noise, and placing your foot in cold water. You will be asked to wear three different sensors to measure your cardiac, respiratory, and sweat response while conducting a series of tests known to induce the stress response.

What are the options if you do not want to take part in this study?

If you elect to partake in the study, we will ask you to complete the full series of stress tests. If you are uncomfortable at any time during the experiment, you have the option to cancel the experiment. Just let us know.

If you take part in this study, what activities will be done only for research purposes?

You will be asked to wear ECG (electrocardiogram) electrodes to measure cardiac activity, a chest strap to measure respiration, and GSR (galvanic skin response) sensors to measure your sweat response. You will then be asked to do the following:

- 1) Sit in a resting position while data is collected to establish a resting baseline – 10 minutes
- 2) Receive instructions for the next task – 4 minutes

- 3) Prepare to deliver a speech to laboratory staff – 4 minutes
- 4) Deliver a speech – 4 minutes
- 5) Rest for 5 minutes
- 6) Receive instructions for the next task – 4 minutes
- 7) Solve math problems in your head while seated - 4 minutes
- 8) Rest for 5 minutes
- 9) Receive instructions for the next task – 4 minutes
- 10) Solve math problems in your head while standing - 4 minutes
- 11) Rest for 5 minutes
- 12) Receive instructions for the next task – 4 minutes
- 13) Sit quietly with your eyes shut / randomly exposed to a startling noise (gong) – 4 minutes
- 14) Rest for 5 minutes
- 15) Receive instructions for the next task – 4 minutes
- 16) Place foot in ice cold water – 4 minutes
- 17) Recovery period – 10 minutes

This will required a total of approximately 80 minutes. If you are not available for the entire 80 minutes please let the researcher know how much time you have to participate. The researcher will then choose a subset of the above tasks for you to do that will only last as long as you have available.

Please note that the sensors are being used for research only. Although the sensors are designed to pick up and relay information about your cardiac system and skin response to stress, the researchers are not trained medical professionals and are unable to interpret or determine that this information has any meaning for you regarding your health. If you like, you may see your data after you've completed the testing.

What are the risks involved with being enrolled in this study?

Psychological Risks:

You will be exposed to stressors that invoke the physiological stress response. The risks involved with these experiments are minor because the stressors themselves are quite common place in student life (conducting mental arithmetic, public speaking, etc). Researchers will inform you about each stress test before it is administered.

Physical Risks:

Placement of ECG electrodes on a person's chest must be done in a manner that protects your personal privacy and comfort level. We estimate the likelihood of these physical risks and the seriousness of their impact to be moderate. To mitigate this risk, both male and female researchers

will be present throughout the experiment. You will be instructed on how to position the ECG electrodes and respiration monitor, and you will then place them on your own body.

Risk of electrical shock is always a concern when connecting ECG electrodes across the heart. The likelihood of such an event is deemed to be extremely low and the seriousness of such an event is high. The ECG electrodes have current limiting features to minimize any risk of electrical shock. All experimental sensor designs will be powered off of a floating, 3.3V battery and completely isolated from power mains.

Other important items you should know:

- **Leaving the study:** You may choose to stop taking part in this study at any time.
- **Number of people in this study:** We expect XX people to enroll in this study here.
- **Funding:** XXXXXXXXXX provides funding to XXXXX for this research.
- **Product Development:** If the results of this research are used to develop a product sold for a profit, you will not share in the profit.

How will your privacy be protected?

The information collected as data for this study includes:

Cardiovascular data (heart rate and other cardiovascular measures)

Respiration data (breathing rate, inhalation time, exhalation time)

Electrodermal activity (galvanic skin response)

Data collected for this study will be maintained indefinitely.

We are careful to protect the identities of the people in this study. We also keep the information collected for this study secure and confidential. All data collected in this study will be de-identified from its participants. All electronic data will be stored on password protected computers by the research staff; all hardcopies of data will be locked in a file cabinet in the PI's office.

The information collected for this study will be used only for purposes of research as stated earlier in this form.

Who may use or see your health information?

By signing this form, you allow the research team to use your health information and give it to others involved in the research. The research team includes the study director plus others working on this study at XXXXX.

The information collected for this study may be used by researchers or officials of the

following institutions.

◆ XXXXX

◆ XXXXX

◆ XXXXX

During this study, information that identifies you may be given to some organizations that may not have a legal duty to protect it. These organizations may also use and disclose your information for other purposes.

Your permission to use your health information for this study will not end until the study is completed. During this study, you and others who take part in the study may not have access to the study data. You may ask for study data once the study is over.

It is possible for a court or government official to order the release of study data including information about you.

What if you decide not to give permission to use and share your personal health information?

If you do not allow use of your health information for this study, you may not take part in this study. If you choose to stop taking part in this study, you may cancel permission for the use of your health information. You should let the researcher know if you want to cancel your permission. The study team will assist you in putting your wishes in writing. Information collected for the study before your permission is cancelled will continue to be used in the research.

Will you be paid to take part in this study?

Yes. Participants will receive \$X-\$XX for taking part in the stress response study. The exact payment will depend on how many of the stressors have time to engage with (\$X for each stressor you agree to be engaged – oral presentation, mental arithmetic, startle response, cold water response)

Whom should you call with questions about this study?

If you have questions about this study or concerns about a research related injury, you can call the research director for this study: XXXXX at XXX-XXX-XXXX during normal business hours.

If you have questions, concerns, complaints, or suggestions about human research at XXXXX, you may call the Office of XXXXX at XXX-XXX-XXXX during normal business hours.

CONSENT

I have read the above information about *Monitoring Stress Response with Wearable Electronics*

and have been given time to ask questions. I agree to take part in this study and I have been given a copy of this signed consent form.

Participant's Signature and Date /

PRINTED NAME

Researcher or Designee Signature and Date

PRINTED NAME