

Consent Form Mobile Sensing for Cardiovascular Health Study

You are invited to be in a research study. The research is about how mobile devices can be used to monitor cardiovascular health of their owners. You are invited to take part in this study because you expressed your interest by providing your email address or phone number through our website. Before you agree to be in the study, please read this form and ask any questions you have. **Your participation is completely voluntary. This means that whether you take part in this research is completely up to you.** Individuals who are located within China cannot participate in this study.

This study is being conducted by: Dr. Amirtahà Taebi from Department of Bioengineering at Lehigh University.

Background Information

The purpose of this study is: to establish a method for remotely and non-invasively collecting cardiovascular signals.

Procedures

If you agree to be in this study, this is we will ask you to do:

- Download and install the "Sensor Logger" app on your smartphone. You will be provided with an "App Instruction" document. Please follow the instructions in this document carefully.
- Use the code provided to you to enroll in this study in the app. Alternatively, scan the QR code that is provided to you, and it will automatically enroll you in this study.
- After enrolling in the study in the Sensor Logger app, you should fill out a short questionnaire (see the App Instruction document sent to you). Answering these questions will help us better analyze your cardiovascular data. So, please provide accurate responses to the best of your knowledge.
- Remove any clothing from your upper body.
- Lie down on your back facing upward (on a bed or floor) and start the recording on the app (see the App Instruction document sent to you).
- Place your smartphone on the mid-point between your nipples such that your smartphone's screen is facing upward and its top side is toward your head. See Figure 1.
- Breathe normally and avoid any additional body movements during the recording. Any body movements, including speaking, negatively affect the quality of the signals collected from your heart.
- After about 2 minutes (=120 seconds), pick up the phone and stop the recording.
- Enter a name for your recording in the comment box that appears on the screen, and answer a few questions.
- When asked if you want to upload your recordings to the cloud, select 'yes'.



Figure 1. Smartphone position on the chest, please remember to remove any upper body clothing before recording the data.

The researchers will collect the following data from you for the purposes of this research: age, sex, height, weight, race, ethnicity, cardiovascular history, family history of diseases, smoking habits, drinking habits, physical activity level, and education level. The following data will be also collected directly from your phone: your location, phone model and information, the orientation of your phone during data

recording (gravity), Sensor Logger app version, your phone's IMU (accelerometer and gyroscope) readings, and recording time and timezone. Your data collected for this research will be stored in our database. The part of the data that can be linked back to you, such as your location or phone device information, will be retained for three years after the completion of the study, and then will be destroyed permanently.

Risks and Benefits of being in the Study

The study involves the following foreseeable risks: The risks and discomforts associated with this study are minimal. Potential discomforts may include discomfort from placing a smartphone on the chest. Other risks include potential leakage of your data. We will do our best to protect your data during storage and when they are shared. However, there remains a possibility that someone could identify you. There is also the possibility that unauthorized people might access your data. In either case, we cannot reduce the risk to zero.

The benefits to participation: There are no direct benefits of this research to you. However, this study can advance our understanding of cardiovascular health and potentially improve methods for remote health monitoring.

You will not receive any direct benefit from sharing your data. However, sharing your data may contribute to research that could help others in the future.

Duration

Your participation in the study involves the following time commitment:

About 10-15 minutes. You may choose to participate in the study multiple times (for example, once a week for four weeks). Each follow-up session will take significantly less time than the initial enrollment session, since you will not be asked to repeat the same questions you responded at the time of initial enrollment. We expect that each subsequent session will take less than 5 minutes to complete.

Compensation

There is no compensation for participating in this study.

Confidentiality

We will collect your information through a mobile app, called Sensor Logger. This information will be stored in a restricted access cloud. The research team does their best to keep your information confidential to the degree permitted by technology. It is possible, although unlikely, that unauthorized individuals could access your online responses. However, this risk is similar to a person's everyday use of the internet.

We will do our best to protect your data during storage and when they are shared. However, there remains a possibility that someone could identify you. There is also the possibility that unauthorized people might access your identifier data. In either case, we cannot reduce the risk to zero.

We will not reveal your identity in any publications, presentations, reports about this research study, or when sharing your de-identified data. Data protection measures will be considered during transmission and storage. The data will be stripped of direct identifiers (such as your personal information) before the data processing. The coding key will be stored separately from the rest of the data to increase the confidentiality measures. The coding key will be retained for three years after the completion of the study, and will then be destroyed permanently.

Please note that Sensor Logger is a third-party application. During installation or use, the app may request permission to access various features of your phone that are not required for this study. You can find a full list of different types of data the app can record in the following link:

<https://github.com/tszheichoi/awesome-sensor-logger/blob/main/UNITS.md>. For our purposes, we only need access to your phone's accelerometer, gyroscope, gravity sensor, and location while you record

data. We do not need access to other sensors or data sources such as the microphone, camera, or health data (e.g., heart rate). You may safely deny permission for the app to access these unnecessary features. Please be aware that a risk posed by the app is that your data could be compromised by data breach or misuse by the app developers—who are not affiliated with our research team.

If you wish to delete your data at any time, follow these steps from the app developer: “To request the deletion of your data from Sensor Logger Cloud, please send an email to sensorlogger@tszheichoi.com. In the email, include relevant information that will help to identify your account. Once Sensor Logger verifies your request, they will permanently delete your identifiable data from our system and notify you via email. Please note that this process may take some time. For any other inquiries about data deletion, contact sensorlogger@tszheichoi.com.”

Information Sharing

If you agree to take part in this study, data will be collected from you. We would like to make your data available for other research studies that may be done in the future. Before your data are shared for other research studies, they will be de-identified. This means that any information that could identify you will be removed. Future research may be about topics similar to this study. However, research could also be about unrelated topics. These studies may be done by researchers at Lehigh University or other institutions, including commercial entities. Our goal is to make more research possible. We plan to keep your de-identified data indefinitely.

We will protect the confidentiality of your information to the extent possible. Your data will be coded to protect your identity before they are shared with other researchers. Dr. Amirtaha Taebi at Lehigh University will have a code key that can be used to link to your identifying information. The code key will be securely stored. Your deidentified data will be shared in a way where anybody around the world can access them. Researchers cannot easily link your identifying information to the data.

It is unlikely, but possible, that others (such as Lehigh University, or state or federal officials) may require us to share the information you give us to ensure the research was conducted safely and appropriately. We will only share your information if law or policy requires us to do so. If the researchers learn that you are abusing, neglecting, going to engage in self-harm, or intend to harm another, state law requires the researchers report this behavior or intention to the authorities.

Voluntary Nature of the Study

Participation in this study is entirely voluntary:

If you decide not to participate there will be no penalty, and you will not lose benefits to which you are otherwise entitled. Your decision whether to participate will not affect your current or future relations with Lehigh University. If you decide to participate, you are free to not answer any question or stop being the study at any time without affecting those relationships.

European Union’s General Data Protection Regulation (GDPR) Compliance

The relevant “Legal Basis” for the collection and/or processing of your personal data for research purposes is your consent to participate in this research study, as demonstrated by your consent. This consent form also serves as the “Privacy Notice” for the purposes of the GDPR.

Your consent to participate in this study and provide your personal data is voluntary. You have the right to withdraw your consent at any time and to have your personal data deleted, except in cases where there is a legal obligation for the researchers to maintain this data. Data may also be maintained by the researchers if it has been fully anonymized, and there no longer exists any means of reidentifying individual participants. You also have the right to obtain a copy of any personal data collected by the researchers as part of this study. You may exercise your right to withdraw consent for the use of your personal data by contacting the Principal Investigator at +1 (610) 758-4096, amirtaha@lehigh.edu.

Contacts and Questions

The Institutional Review Board (IRB) for the protection of human research participants at Lehigh University has reviewed and approved this study. If you have questions about the research study itself, please contact the Principal Investigator at +1 (610) 758-4096, amirtaha@lehigh.edu. If you have questions about your rights or would simply like to speak with someone other than the research team about the questions or concerns, please contact the IRB at (610) 758-2871 or inirb@lehigh.edu. All reports or correspondence will be kept confidential.

Statement of Consent

I have read the above information. I have had the opportunity to ask questions and have my questions answered. By downloading the Sensor Logger app, clicking the enroll button in the “Mobile Sensing for Cardiovascular Health Study” in the app, and recording and uploading my signals to the cloud, I consent to participate in the study and agree that my data can be used in scientific research, including scientific publications and presentations. Participating in this study means I agree to sharing my data.