EARLY DETECTION OF COVID-19 INFECTION SYMPTOMS USING WEARABLE DEVICES

DESCRIPTION: You are invited to participate in a research study to gather information from wearable devices that are able to measure things such as step count, body movement, electrical changes in the skin related to stress (galvanic skin response \(<\text{GSR}\>\), skin temperature, your location (global positioning system \(<\text{GPS}\>\)), the amount of oxygen in your blood, your blood pressure, the quality of your sleep. We will be looking to see if this information will help us learn more about individual responses to health and illness.

Our purpose is to target COVID-19 positive participants or those at high risk because of known (such as people who have been in contact with somebody who tested positive, so are considered high risk to get infected as well). We are trying to establish if data collected from these type of devices (such as heart rate), can be used to predict the advent of an infectious disease (such as the COVID-19 one) before the actual symptoms start. We are asking about 1000 participants to be part of this study at Stanford University.

You will be asked to own and wear wearable device such as Fitbit or Apple watch and share with the study team the data collected by the device (such as the heart rate, physical activity level, etc.). The devices will be worn or used every day, for up to 24 hours per day, over the course of 24 months. Participants will be able to remove the devices for part of each day as needed and when they feel comfortable doing so.

DATA: The data will be collected from the wearable device(s) or company’s server and stored on secure Stanford University servers. In order to gain access to your physiological data, the study team will ask you to share an export data file (only for some devices). For other devices, we will ask you to share your device username and to reset your password to one provided by us for the duration of the study. This will allow us to retrieve your data remotely and allow you to continue to access your data during and after the study. Your username and new password will be stored in a secure online database and can only be accessed by study staff. Once you have finished the study, you can reset your password, restricting our access. Alternatively, if you prefer not to share your username, we can set up a temporary study username and password for you to use for the duration of the study.

Additionally, if you agree, we would like to collect medical record information from you. We will either ask your permission to access your electronic medical record and/or share these records with us.

Please note that you might also need to agree to a separate medical release form before sharing your records. This may vary by the clinic/hospital where you are receiving you medical care. If you are not sure, please ask your family doctor first.
Also, we will ask you to download a specific study-related app created by the Stanford Snyder’s lab, where you can easily link your wearable devices and share with the study team your daily health information. All the data collected in this app will be stored in a secure online database and can only be accessed by study staff.

DATA RELEASE: The data we collect for the study can and will be used for public use purposes. Any information that is shared publicly will be de-identified and no PHI (private health information, such as name, date of birth, address, etc.) will be shared. Identifiers might be removed from identifiable private information and/or identifiable specimens and, after such removal, the information and/or specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

TYPES OF DEVICES AND/OR APPS - this is a list of potential devices that the you may own and can be used in this study:

- Apple Watch (All Generations). Collecting: Heart rate, activity, sleep, steps, and calories burned. – For everyone, except people who are resident in the EU.
- Fitbit (including Alta HR, Charge 2, Charge 3, Blaze, Ionic, and Versa). Collecting: Heart rate, activity, sleep, steps, and calories burned.
- Oura Ring. Collecting: heart rate, activity, sleep, steps, and calories burned.
- Garmin (Forerunner, Edge). Collecting: heart rate, activity, sleep, steps, and calories burned.

TIME INVOLVEMENT: Your participation will take approximately 24 months and you will wear the device up to 24 hours a day for 24 months.

RISKS AND BENEFITS: The physical risks associated with this study are minimal: there could be a possible skin reaction to the bands supplied with the wearable devices. Additionally, there might be some loss of confidentiality for the data collected by the wearable devices. The benefits which may reasonably be expected to result from this study are device to quantify physiological data and also other interesting correlation data about eating habits, lifestyle changes in result of stress. We cannot and do not guarantee or promise that you will receive any benefits from this study.

PAYMENTS: You will receive no payment for your participation.

COST: There is no cost to you for participating in this study.

FUNDING: This study is being supported by Departmental funding.

PARTICIPANT’S RIGHTS: If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. The alternative is not to participate. You have the right to refuse to answer particular questions. The results of this research study may be presented at scientific or
professional meetings or published in scientific journals. Your decision whether or not to participate in this study will not affect your employment/medical care/grade in class.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. You will be responsible for any associated co-payments or deductibles as required by your insurance.

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

**EXPERIMENTAL SUBJECT’S BILL OF RIGHTS:** As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.
CONTACT INFORMATION:

Questions: If you have any questions, concerns or complaints about this research, its procedures, risks and benefits, contact the Protocol Director, Michael Snyder PhD at 650-723-4668.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at 650-723-2480 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Study Coordinator Contact: If you have questions or concerns about the study, please contact the research coordinator Alessandra Celli at 650-725-8491 or alessandra.celli@stanford.edu.