

STANFORD UNIVERSITY Research Consent Form

Protocol Director: Snyder, Michael

IRB Use Only

Approval Date:

Expiration Date:

Protocol Title: Validating algorithms from wearables data to predict onset and progression of respiratory infection including COVID-19- FITBIT

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of this study to evaluate the use of algorithms from wearables data to predict onset and progression of respiratory infection. We are trying to establish if data collected from wearable devices can be used to predict the onset of an infectious disease such as COVID-19 before the symptoms start.

All data will be stored securely on RedCap or Stanford Medicine Box. Data from your blood microsamples and nasal swabs samples will be considered in the context of the study participant population to determine if different types of biological responses exist, and if so, how we might predict the response of an individual.

You will also be asked to complete a survey about your symptoms, share if you have a COVID-19 test and the results of the test, as well as other medical information that are relevant to infectious diseases.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study.

Signing the form is not a condition for receiving any medical care outside the study.

Participant ID:



STUDY

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If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Dr. Michael Snyder (mpsnyder@stanford.edu).

What Personal Information Will Be Obtained, Used or Disclosed?

Data collected during the study consists of, but is not limited to, your name, date of birth, phone number, email address, postal address, gender, ethnicity, other demographic information, medical record number, answers to questionnaires, wearable device serial number (if available), test results and other diagnosis, treatment, or physiologic information from your medical record. If you are in Arm A, to do COVID-19 testing LetsGetChecked will collect your name, email address, address, phone number, date of birth, sex, ethnicity, COVID-19 symptoms and other health conditions.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director Dr. Michael Snyder
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S;
- Department of Health and Human Services;
- The Food and Drug Administration (FDA);

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- The National Institute of Health (NIH);
- LetsGetChecked;
- The local health officer where you reside.

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on December 31, 2030 or when the research project ends, whichever is earlier.

PLEASE PRINT A COPY OF THIS FORM TO KEEP FOR YOUR RECORDS.

[the below italic part will all be ON RED CAP]:

I've read the attached document and I AGREE with the terms of the study.

I've read the attached document and I DO NOT AGREE with the terms of the study.

Please enter your signature _____

Participant ID:



STUDY