VALIDATING ALGORITHMS FROM WEARABLES DATA TO PREDICT ONSET AND PROGRESSION OF RESPIRATORY INFECTION INCLUDING COVID-19 - FITBIT

SUMMARY OF THE STUDY

• We are asking you to consider being in this research study, and your participation is completely voluntary.

• The purpose of this study is to understand if wearable devices can be used to track infectious diseases like COVID-19. Your participation will take 3-5 hours over a period of 2 years total. We will ask you to download our mobile app and share your wearables data. The app may send you an alert and ask you to report symptoms or circumstances back to us. If some participants wish, they can undergo additional optional sampling where they will be asked to collect nasal swabs samples and blood samples from a finger prick.

• The risks of participating in this study are minimal and may include: a possible loss of confidentiality; skin reaction to the bands supplied with the wearable devices; pain and/or inflammation at the site of the finger prick.

• We cannot and do not guarantee or promise that you will receive any benefits from this study.

• The alternative is not to participate in the study.

PURPOSE OF RESEARCH

You are invited to participate in a research 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 like the Fitbit smartwatch, can be used to predict the onset of an infectious disease such as COVID-19 before the symptoms start. Depending on your device, we will collect data such as steps, distance, calories burned, and active minutes), heart rate,

location, nutrition, sleep, weight, heart rate variability (HRV), Fitbit cardio fitness score, off-wrist time, and sedentary time.

In a previous study, we developed an algorithm that can correlate changes in physiological parameters (such as heart rate) with onset of infectious disease(s). We hope that this algorithm can be used to help detect the onset of sickness or disease, even before any symptoms start. The purpose of this study is to test this algorithm. We will do this by sending participants an alert when we detect a change in their physiological parameter(s). After receiving the alert, participants will be asked to report circumstances back to the research team. This will help us to understand whether the algorithm is detecting the onset of infection(s), or if there is another reason for the physiological change (eg heart rate change because of watching a scary movie, stress, medications).

Please note that the study device (algorithm used with wearable device data and MyPHD app) is not FDA approved for the use under this study.

We are asking about 500 participants to be part of this study at Stanford University.

Active participation will take approximately 3-5 hours total over the course of up to 2 years.

WHO CAN BE ENROLLED IN THE STUDY?

To be eligible for this study, you must:

- Be 18 - 70 years of age;
- Live in USA
- Do not have any known cardiac conditions (e.g. coronary artery disease or history of myocardial infarction, brady- or tachyarrhythmias, valvular disease, cardiomyopathy, etc) or cardiac devices (e.g. implanted cardiac monitor, pacemakers, defibrillators, etc).
- Not be pregnant.

- Are at high risk of exposure to COVID-19 because of contact with positive individuals (e.g. healthcare workers, frontline workers, student attending on-campus classes, etc.)

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. If you decide not to participate it will not have any negative effect on you or your medical care. You can decide to participate now but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

WHAT WILL YOU ASK ME TO DO?

Taking part in the study will involve:
1- Downloading an app, MyPHD, developed by the Snyder lab at Stanford University, that will allow us to collect the data from the wearable device;
2- Telling us about your symptoms and circumstances using the app when asked;
3- If some participants wish, they will be asked to provide additional optional sampling to collect at home (see below description for optional sampling).

Reporting symptoms but not collecting samples:

- When you receive an alert on the app, we will ask you to report your symptoms and circumstances via the app for the next several days to weeks, when prompted.

Optional Sampling– reporting symptoms and collecting samples:

- We will mail you a kit to collect samples at home
- We may ask you to take a baseline sample when you enroll
- When you receive an alert on the app, we will ask you to
  - report your symptoms and circumstances via the app for the next several days to weeks, when prompted.
  - take a microsample (a drop of blood from a finger prick) and nasal swabs sample at home several times over the next several weeks, when prompted.

We will ask everyone to report their health status at least once per month using the app.

We will ask you to continuously wear the Fitbit device and share the data collected by the device with the study team. The devices will be worn or used every day, for up to 24 hours per day, up to 24 months. You will be able to remove the devices for part of each day as needed and when you feel comfortable doing so.

The study-related app, MyPHD, that we will ask you to download will give us access to your Fitbit wearable device data remotely. You will receive instructions via email on how to properly install the app and how to sync it to your Fitbit smartwatch that we will provide, so it can securely collect your data.

In order to use the provided Fitbit device, you will have to create an account on the Fitbit website and agree with the Fitbit's Privacy Policy and Terms of Service, which are separate from this research consent form. Fitbit's Privacy Policy describes how Fitbit collects, uses, shares, and protects your data. Fitbit may also have access to device identifiers so they may be able to identify that you are a participant in this research. For more information about the information that Fitbit may have access to, refer to Fitbit's Privacy Policy. By agreeing to the Fitbit's Privacy Policy and Terms of Service, you give Fitbit the right to use Fitbit information so they can provide, improve, and develop their services. In addition, it is important to read Fitbit's Terms of Service because it includes information about your legal rights when using Fitbit's products that may differ from your rights as a participant in this study. You can always exercise your right to access your personal information and to understand how Fitbit collects, uses, and discloses the information to other third parties by logging into your Fitbit account and using your account settings.

Stanford will have access to data about your activity (including steps distance, calories burned, and active minutes), heart rate, location, nutrition, sleep, weight, heart rate variability (HRV), Fitbit cardio fitness score, off wrist time, and sedentary time.

We will analyze data from your wearable device with the symptoms and circumstances you report to us. We will also gather your health information by asking you directly or by looking at your electronic medical record if you agree (see section below). You have the right to refuse to answer particular questions. If you are participating in other Stanford research study(ies), we will ask for your permission to obtain and analyze research data collected from that research study if that study allows for the sharing of your research data.

YOUR MEDICAL INFORMATION

If you agree, we would like to collect medical history and medical information regarding COVID-19 infection and/or other infectious diseases including test results and diagnoses. We will either ask your permission to access your electronic medical record and/or ask you to 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 your medical care. If you are not sure whether or not you want to give this study permission to access your medical records, please talk to your physician about it first.

ALERTING:

When our algorithm detects a change in your heart rate or other physiological parameters, you will receive an alert via a push notification from the study app. You will be asked to report circumstances back to us. This will help us to track if you are getting sick, or whether there might be other reasons for the change in the physiological parameter. Some examples of other reasons for change in physiological parameters are: watching a scary movie, high level of stress, change in medication, intense and prolonged physical activity, etc. Please note that this alert is for research purposes only. We can't promise to monitor or notify you about medically significant issues, but it is possible that in some cases we might contact you if we believe there is something worth following up.

OPTIONAL SAMPLING

If you wish to provide additional optional samples, you will receive by mail a kit containing all the supplies together with the instructions for you to follow to collect blood microsamples and nasal swabs samples. You can collect the samples at home and safely store them in your fridge using the bags we will give you. We expect you to mail the samples back on a weekly basis. We will give you the shipping materials and shipping instructions.

We would like to collect samples at the following times. We will send you reminders via the app:

- Soon after you enroll you will collect one microsample
- When you receive an alert (within 24 hours) you will collect one microsample and one nasal swabs sample. We will provide you with instructions on how to collect the samples.
- 3 days, 1 week, 2 weeks and 4 weeks after the alert you will collect a microsample and nasal swabs sample (4 times total over the course of 4 weeks)
- 12 weeks after the alert you will collect one microsample.

If you report any symptoms you will be asked to restart this timeline schedule. For example, if you develop a sore throat on day 10 after the alert, we will ask you to collect samples on that day, then 3 days, 1 week, 2 weeks and 4 weeks after that. We will send you reminders via the app.

Preferably the microsamples should be collected in the morning after fasting for 10 hours. Every time you collect microsamples, please complete a short online survey to tell us the day and time of samples collection and the barcode number of the microsampling device. All the data collected in this study will be stored in a secure online database and can only be accessed by study staff.

WHAT TEST WILL YOU DO ON MY SAMPLES?

We will perform a series of test, including but not limited to:

- C-reactive protein (CRP), a protein that indicates the level of inflammation in your body;
- Testing for several different types of respiratory infections including COVID-19, that can indicate if you have an active infection; this test will be

prescribed by a licensed health care provided through a company called LetsGetChecked (see below for more details).
- Antibodies for COVID-19 or other infections, that can indicate you might have been exposed to the COVID-19 virus or other virus in the past.

Any of your samples used in research may result in new products, tests or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the Investigators, Stanford University and/or others. However, donors of samples do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries.

DATA RELEASE:

The data we collect for the study may be used for research use purposes, for example making the algorithms publicly available, or sharing research data in databases that can be accessed by the public. Any information that is shared publicly will be de-identified and no personal identifiers (such as name, date of birth, address, etc.) will be shared.

Identifiers might be removed from samples and data and the de-identified samples and data could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. Research using private information and/or specimens is an important way to try to understand human disease. You are being given this information because the investigators want to save private information and/or specimens for future research.

Your information and specimens will be stored with a code number that is linked to your name and other identifiers.

Fitbit will have access to the information you entered to create your account, and the information as covered in the Fitbit Privacy Policy and Terms of Service.

Stanford will protect your data in accordance with this consent and authorization form. In addition, if you agree to create a Fitbit account and provide information to Fitbit, your Fitbit data collected as part of this study will be shared with the

researchers with your permission via the MyPHD app. It is important for you to read Fitbit's Privacy Policy which describes how Fitbit collects, protects, uses, and shares your information.

Upon your request, we can provide you a visual representation of some data collected from the wearable devices combined with your self-reported data about sickness and symptoms. You are welcome to express interest by emailing us at covid19_fitbit_study@stanford.edu. Please note that this representation of data is a summary of the data collected over a certain period of time with no interpretation of results, and it must be considered for research use only.

If you wish to provide us with additional optional samples, we may inform you of any research results we learn from your samples. Results from the nasal swabs regarding active COVID-19 infection (meaning you have the virus at the time of the sampling) will be available to you from the LetsGetChecked website. You will need to create an account on their website by entering your name, email address, address, phone number, date of birth, sex, ethnicity, COVID-19 symptoms and other health conditions. You will need to agree to their Terms of Use and Privacy Policy when you set up your account, which is separate from this consent form and this research study. You should receive the COVID-19 results within 2-3 days from the day you collect and ship the samples. There is no cost for you for this test, including the shipment.

Please note that we are obligated to share positive coronavirus test results with the public health department of the county in which you live. The COVID-19 results will then be transferred from the LetsGetChecked company to the Stanford research team using a secure file transfer protocol, a HIPAA compliant system which will ensure a high level of security.

On the microsamples, we might perform COVID-19 and other infections antibodies test. This test helps to determine if a person may have been infected with the virus that causes COVID-19. The test looks for the presence of antibodies, which are specific proteins made in response to infections. Antibodies are detected in the blood of people who are tested after infection; they show an immune response to the infection. Microsampling to test the presence of other infection disease

antibodies will be for research only and you will not receive the results from the test.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Collect samples as instructed.
- Complete surveys about your symptoms and circumstances when prompted.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about participating in the study.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time.

If you withdraw from the study, we will continue using data collected from you, your health information and samples unless you tell us not to. It is possible that some samples and data may not be able to be withdrawn after the study has started.

The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

· Failure to follow the instructions of the Protocol Director and study staff.
· Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

There could be a possible skin reaction to the bands supplied with the wearable devices. The finger prick may cause discomfort, pain and/or inflammation at the site of the finger prick.

Although we will make every effort to keep your information confidential, there is a theoretical risk of a privacy breach as there is for every research study.

POTENTIAL BENEFITS

Reasonably expected benefits include:

- Contribution to understanding and tracking COVID-19 infection.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

ALTERNATIVES

The alternative is not to participate in the study.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

You will be told of any important new information that is learned during the course of this research study which might affect your condition or your willingness to continue participation in this study.

CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even de-identified information might be re-identified.

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.

FINANCIAL CONSIDERATIONS

You will not be paid to participate in this research study.

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

The National Institute of Health (NIH) is providing financial support and/or material for this study.

COMPENSATION for Research-Related Injury

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.

CONTACT INFORMATION

Questions, Concerns, or Complaints: if you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should contact the research coordinator Arshdeep Chauhan at arshdeep.chauhan@stanford.edu. You should also contact the protocol director Michael Snyder at mpsnyder@stanford.edu at any time if you feel you have been hurt by being a part of this study.

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)-723-5244 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.

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.

CERTIFICATE OF CONFIDENTIALITY:

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

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

[will all be ON REDCAP]:

Are you participating in any other research studies? Yes _____No_____
If yes, please list them: _____

Are you willing to be re-contacted for future studies? Yes__ No____

Do you agree to share your information from your medical record?

o *Yes, I agree to share medical records*
o *No, I do not agree to share medical records*

[Only if you are participating in other Stanford research study(ies)]
Do you agree in giving us access to research data collected from other Stanford research study?

Yes____ No_____

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.

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

Please enter your signature. _____