CONSENT TO PARTICIPATE IN RESEARCH

IGI FAST Study: An integrated approach to safely reintroduce onsite work during the COVID-19 pandemic

Key Information

- You are being invited to participate in a research study. Participation in research is completely voluntary.
- The specific purpose of this study is to model and evaluate the efficacy of asymptomatic testing and automated contact tracing to prevent the spread of COVID-19 within the campus population.
- The study will take a total of 2.5 hours over the course of 6 months, and you will be asked to give saliva samples at campus kiosks every other week which will be tested in a COVID-19 diagnostics lab. These tests are not FDA approved so if they return a positive or inconclusive result, you will be directed to confirmatory testing at University Health Services or your own primary care physician.
- The clinical validity of this test has not yet been shown so we cannot fully ensure the accuracy of any results, positive or negative.
- Results will be reported to participants by encrypted email and, in the case of positive or inconclusive results, by phone.
- Risks and/or discomforts may include breach of confidentiality.
- There is no direct benefit to you. The results from the study may benefit the UC Berkeley campus by mitigating spread of COVID-19.

Introduction and Purpose

The IGI FAST (Free Asymptomatic Saliva Test) Study is an investigation into preventative measures being taken to protect on-campus employees during the COVID-19 pandemic. The study's Principal Investigators are Professor Jennifer Doudna, PhD (Executive Director, Innovative Genomics Institute) and Dr. Guy Nicolette, MD (Assistant Vice Chancellor for University Health Services), and the study coordinator is Alexander Ehrenberg (PhD Student, Dept. of Integrative Biology).

The purpose of this study is to model and evaluate the efficacy of asymptomatic testing to prevent the spread of COVID-19 within the campus population. You are being invited to participate in this study because you have been approved for on-campus work at UC Berkeley between June 2020 and January 2021.

The saliva-based test for COVID-19 we refer to here will use an OMNIgene kit (OM-505) for saliva sampling. This device is not FDA-approved for clinical use. The test done in the lab is derived from an FDA-authorized test currently used in the same diagnostics lab. As such, this test is experimental, and results require confirmation by an FDA-approved clinical test.

Procedures

If you agree to participate in this study, you will be given access to regular (every two weeks) saliva-based COVID-19 testing using an experimental test focused exclusively on asymptomatic individuals. If at any point in the study you experience symptoms of COVID-19, please visit https://uhs.berkeley.edu/coronavirus-covid-19-information for guidance. You should not return for asymptomatic testing until you test negative and your symptoms resolve.

You will schedule visits to testing kiosks spread throughout the UC Berkeley campus using an online scheduling application. During the online scheduling you will be asked several brief questions to get information on how much time you are spending on campus, where you are working on campus, whether or not you have ever been diagnosed with COVID-19, and your use of a mobile contact tracing application, if any. At the testing kiosk you will need to present your ID and confirmation email. At the kiosk, you will spit into a tube while being watched by kiosk personnel. You will then return the tube to the personnel. This sample will be brought to the IGI SARS-CoV-2 diagnostics lab for testing.

The procedure at the testing site will take 5-10 minutes each visit. In total, for the duration of this study, you can expect to spend a total of roughly 2.5 hours for the asymptomatic testing. You can choose to end participation in this study at any time and will not be penalized for missing appointments. If you are concerned about being able to perform the procedure due to disability or other physical limitations, please contact the study coordinator at igi-fast@berkeley.edu as soon as possible.

The diagnostic test used in this study, SARS-CoV-2 detection from an OMNIgene saliva collection kit, is not currently approved by the FDA and is investigational. If your sample tests positive for SARS-CoV-2, the virus that causes COVID-19, or is inconclusive, you will be called and sent an encrypted email by a clinician who will recommend that you to self-isolate and guide you to make an appointment with the UHS Tang Center or your own primary care physician for confirmatory testing. To aid with this confirmatory testing, study investigators may share information (name, date of birth, university identifier numbers, date of test, result of test) connected to a positive or inconclusive result. This confirmatory testing is important because the saliva-based test has not been fully approved by the FDA for diagnosis of COVID-19. The confirmatory testing is not a part of this research study and only exists to inform clinical decisions about your care. If your saliva sample tests negative, you will receive an encrypted email that will mention the limitations of it as a research result. Your sample may also be rejected by the lab if the sample cannot be tested due to quality issues. In this case, a study coordinator will send you an encrypted email and offer you the option to get retested before your next appointment.

Study time: Your study participation will take a total of 2.5 hours over the course of 6 months.

Study location: All study procedures will take place online and at tent kiosks throughout the UC Berkeley campus.

Benefits

COVID-19 does not present with symptoms in many individuals and features a varied incubation period where individuals may still be infectious. Asymptomatic surveillance testing can be used to prevent the spread of COVID-19 between asymptomatic individuals. By receiving asymptomatic testing in this study, you will have the benefit of preventing the spread of COVID-19 from yourself to others. As a whole, this study protects the campus community by minimizing the spread of COVID-19 between asymptomatic individuals.

Risks/Discomforts

Saliva sampling is not associated with any physical risks. You will be asked to avoid food or drink for 30 minutes prior to your appointments which may involve mild discomfort. Some individuals may

experience social or cultural discomfort with individuals watching them spit. We will maximize, to the best of our ability, your privacy during sample collection. Additionally, there may be stigma associated with a diagnosis of COVID-19. This can be minimized by only disclosing your personal results to individuals you feel responsible to.

- **Breach of confidentiality:** As with all research, there is a chance that confidentiality could be compromised; however, we are taking precautions to minimize this risk.

Confidentiality

Your study data will be handled as confidentially as possible. If results of this study are published or presented, individual names and other personally identifiable information will not be used.

To minimize the risks to confidentiality, we will not store any identifiable information regarding your test results outside of the database ran by the licensed clinical lab, unless you give us specific permission. Any identifiable information entered into the scheduling system or at the time of enrollment are kept on an encrypted server that will not be distributed to anyone other than the diagnostic testing lab; University Health Services; clinicians you direct us to; local, state, and federal public health agencies such as the California Department of Public Health; the Food and Drug Administration (FDA) and other government agencies involved in keeping research safe for people; other studies you give us specific permission to share your data with; and University of California staff who have oversight over the diagnostic lab or the testing kiosks.

When the research is completed, your data and samples may be saved for future research. Your data will be retained indefinitely by the diagnostics lab in a HIPAA-compliant database for legal requirements of their licensure. Your samples will be retained indefinitely by the diagnostics lab.

Clinically relevant results, including individual results, will be disclosed to you if the diagnostics lab finds that your saliva sample is positive or negative for SARS-CoV-2 or is inconclusive. These results are for research purposes only and will not become part of your medical health record. Positive or inconclusive results may be disclosed to University Health Services or primary care clinicians you direct us to.

Your personal information may be released if required by law. Authorized representatives from the following organizations may review your research data for purposes such as monitoring or managing the conduct of this study:

- University of California
- Food and Drug Administration (FDA) and other government agencies involved in keeping research safe for people.

Identifiers might be removed from the identifiable private information or identifiable biospecimens. After such removal, the information or biospecimens could be used for future research studies or distributed to other investigators for future research studies without additional informed consent from the subject or the legally authorized representative.

Saliva samples collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

This research study will not include whole genome DNA or RNA sequencing.

Clinically relevant research results, including individual research results, will be disclosed to subjects.

Alternatives

Your other choices may include:

- Getting no asymptomatic testing
- Getting standard testing outside of this study.
- Participating in another study providing asymptomatic testing.

Compensation/Payment

You will not be paid for participation in this study, nor will you or your insurance carriers be asked to pay to participate in this study.

Costs of Study Participation

You will not be charged for any of the study activities.

Rights

Participation in research is completely voluntary. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled. You will not be penalized for missing appointments. If you want to withdraw from the study, please contact igi-fast@berkeley.edu.

If you withdraw from the research, the data collected about you up to the point of withdrawal will remain part of the study and may not be removed from the study database per FDA regulations.

Questions

If you have any questions or concerns about this study, you may contact the study coordinator, Alexander Ehrenberg, at igi-fast@berkeley.edu.

If you have any questions or concerns about your rights and treatment as a research subject, you may contact the office of UC Berkeley's Committee for the Protection of Human Subjects, at 510-642-7461 or subjects@berkeley.edu.

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CONSENT

You will be emailed a copy of this consent form and Medical Research Subject's Bill of Rights, which will also be available on this webpage.

Please read each sentence below and think about your choice. After reading each sentence, select either the "yes", "no", or "not applicable" (for #5 only) box. No matter what you decide, it will not affect your ability to return to campus.

1. My saliva samples and associated data may be used to detect SARS-CoV-2 infection. I consent to be contacted with my results. These results are for research purposes only and will not become part of my medical health record; however, they may be securely communicated to University Health Services or primary care clinicians you direct us to if the result is of clinical or public health concern.
2. I consent for data I enter into this consent form, the study enrollment form, or this study's scheduling system to be used for this research study on COVID-19.