UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	COVID SAFE 2.0 Screening Program
Protocol Number:	850592
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Research Study Summary for Potential Subjects

You are being invited to participate in a research study led by Drs. Rinad Beidas, Scott Sherrill-Mix, and Arupa Ganguly at the University of Pennsylvania. Your participation is voluntary, and you should only participate if you completely understand what the study requires and the risks of participation. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 573-2540 for assistance.

The research study is being conducted to evaluate the implementation of a COVID-19 screening program. The program will use point of care testing, which means using saliva-based self-collection to administer point of care screening for COVID-19 in your laboratory setting. We will not be collecting any samples as part of this study. You will run the test yourself in your laboratory and then you will dispose of it according to best laboratory practice.

The self-administered saliva-based screening test was developed by researchers at the University of Pennsylvania. If you receive a positive result on the saliva-based screening test, you will be asked if you received a confirmatory test using a Clinical Laboratory Improvement Amendments (CLIA) approved test for COVID-19. Results from this point of care testing and any follow-up confirmatory testing will all be self-reported by you. No results will be entered into your medical chart, as we will not have any access to your medical record.

If you agree to join the study, you will be asked to complete the following research procedures:

- Watch a brief video on how to do point of care testing, which will involve self-collecting a saliva sample and then running an assay test in your laboratory
- Self-collect a saliva sample and then run an assay test using the equipment available to you at your laboratory. You can use point of care testing as much or as little as you want – but no more than daily for up to four weeks

- Complete online surveys once a week about your use and results of the test as well as your experience using the point of care testing (these surveys will take about 15 minutes to complete each week)

Once your participation is completed, you may also be contacted about engaging in a brief 30-minute interview with the research team about your perspective of this point of care testing. You can schedule this interview at a time most convenient to you. You do not have to agree to participate in this interview in order to participate in this point of care testing.

Participants may benefit from regular screening for COVID-19. Regular screening may help to identify COVID-19 cases earlier and prevent its spread. You may not get any benefit from being in this research study. The most common risks of participating in the study include inconvenience, mild discomfort or anxiety from testing procedures, and minimal risk of breach of confidentiality. Participation in the study is voluntary and you may choose to not participate.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. You are free to decline or stop participation at any time during or after the initial consenting process.

Why am I being asked to volunteer?

You are being invited to participate in a research study because you are a Penn faculty, staff, or trainee who works in person on campus at a Perelman School of Medicine laboratory.

This research is designed to evaluate the implementation of a COVID-19 screening program. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled and your employment status will not be impacted in any way. You may also decide to discuss the study with your family, friends, or family doctor. Being in a research study is different from being a patient.

If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

The purpose of the study is to evaluate the implementation of a COVID-19 screening program.

How long will I be in the study?

Your study participation will last up to four weeks.

What am I being asked to do?

If you are eligible and decide to participate, we will ask you to:

1. Watch a brief training video on how to self-collect a saliva sample and administer the test.

2. Self-collect a saliva sample and administer the point of care testing as often as you want (but no more than once a day for up to four weeks). You will be instructed to not eat or drink for 30 minutes prior to collecting your saliva and to collect saliva in an isolated room. You will be instructed to collect saliva into a 1.5mL collection tube containing inactivation buffer (TCEP and EDTA) using a small funnel and inactivate at 95°C for 10 minutes. You will then transfer 6ul of saliva into 2 PCR tubes containing amplification master mix and primers, put tubes in a heat block at 65°C for 45 minutes and assess fluorescence using a simple battery-powered fluorescence viewer. This viewer will be located in the same area where you pick up your saliva collection test kits. Once you assess your sample, you will be instructed to dispose of the saliva sample safely and in accordance with best laboratory practices. No saliva samples will be collected by the research team at any time as part of this study.
3. Complete online surveys once a week for up to four weeks. You will answer questions about your use and results of the test, various aspects of the point of care testing and implementation of the screening program. These surveys will take about 15 minutes to complete and will be available via REDCap, a web-based application for collecting and managing survey data that can be completed via computer or mobile device.

Your information will be labeled with a code number. Personal information will be secured as described in the information protection section. None of your information will be entered into your medical record.

What are the possible risks or discomforts?

There is a minimal risk of breach of confidentiality and privacy. The research team will take precautions to make sure your privacy is maintained. We will use commercial-grade encryption to protect your information. Your personal information will only be used by study team members who have been trained to use secure protocols to maintain the privacy of your data. Whenever possible, data will be de-identified to protect your privacy.

Risks and side effects related to this study include the possibility that answering certain questions in the surveys may make you feel slightly uncomfortable or you may become fatigued from the number of questions. The risks of self-collecting a saliva sample for testing may include inconvenience, false positives or false negatives, and testing may induce feelings of fear or anxiety, some discomfort, and may result in missing days of work. If you feel like you may have been infected with COVID-19 or are experiencing symptoms, please seek out testing regardless of the saliva-based test results. We expect the risk of picking up and dropping off test kits to be no more than the risk of returning to work..

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

Anticipated Benefits to Participants: Participants may benefit from regular screening for COVID-19. This may help to identify COVID-19 cases earlier than would be identified following other guidelines. You may not get any benefit from being in this research study.

Anticipated Benefits to Society: It is expected that participation in the study will help protect the Penn community and decrease the rate of COVID-19 transmission among others on campus. These findings may help to manage the ongoing COVID-19 epidemic and to better prepare institutions for responding to future epidemics.

What other choices do I have if I do not participate?

Individuals who choose not to participate in this study can follow established protocols for COVID-19 monitoring, testing, and containment. Participants should regularly review the most recent guidelines of their department, as policies are expected to be updated frequently as the ongoing epidemic evolves.

Will I be paid for being in this study?

Each time you complete a weekly survey, you will be entered into a lottery to receive one of four $100 e-gift cards.

Will I have to pay for anything?

All costs of saliva collection test kits and assay tests will be covered by the study.

Will I receive the results of research testing?

Only you will be able to view your assay test results because you will be administering the test yourself. You will be asked the result of the test through the online surveys.

What happens if I am injured from being in the study?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. The study is expected to last about up to two months.

This study may also be stopped at any time by your physician, the study Sponsor, or the principal investigator without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor, the study Principal Investigator, has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care. The investigators do not anticipate any risks to participants who leave the study early although incomplete data will limit the potential benefits from more frequent monitoring and limit the potential benefits to the participant and society.

How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records.

The Penn Medicine Academic Computing Services (PMACS) will be the hub for the hardware and database infrastructure that will support the project and is where the REDCap web portal is based. The PMACS is a joint effort of the University of Pennsylvania's Abramson Cancer Center, the Cardiovascular Institute, the Department of Pathology, and the Leonard Davis Institute. The PMACS provides a secure computing environment for a large volume of highly sensitive data, including clinical, genetic, socioeconomic, and financial information. Among the IT projects currently managed by PMACS are: (1) the capture and organization of complex, longitudinal clinical data via web and clinical applications portals from cancer patients enrolled in clinical trials; (2) the integration of genetic array databases and clinical data obtained from patients with cardiovascular disease; (3) computational biology and cytometry database management and analyses; (4) economic and health policy research using Medicare claims from over 40 million Medicare beneficiaries. PMACS requires all users of data or applications on PMACS servers to complete a PMACS-hosted cybersecurity awareness course annually, which stresses federal data security policies under data use agreements with the university. The curriculum includes Health Insurance Portability and Accountability Act (HIPAA) training and covers secure data transfer, passwords, computer security habits and knowledge of what constitutes misuse or inappropriate use of the server. We will implement multiple, redundant protective measures to guarantee the privacy and security of the participant data. All investigators and research staff with direct access to the identifiable data will be required to undergo annual responsible conduct of research, cybersecurity, and HIPAA certification in accordance with University of Pennsylvania regulations.

Data will be stored, managed, and analyzed on a secure, encrypted server by the Penn Medicine Nudge Unit and/or the Penn Center for Mental Health. All study personnel that will use this data are listed on the IRB application and have completed training in HIPAA standards and the CITI human subjects research. Data access will be password protected. Whenever possible, data will be de-identified for analysis.

Will information about this study be available to the public?

Information about this study may be disclosed to the public to help inform the global efforts to contain the COVID-19 epidemic. Any information will be de-identified to minimize or eliminate the risk of information being linked to individual study participants.

What may happen to my information collected on this study?

Collection of Information

You will be given a study number. Answers to the questionnaires will be linked to your study number. This information will be de-identified. De-identified means all identifiers have been removed. The information could be stored and shared for future research in a de-identified manner. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected on this study. Your information may be stored and used for future research purposes for an indefinite amount of time.

There is a risk of breach of confidentiality (unintentional release of your information). We will do our best to make sure this doesn't happen. However, we cannot guarantee total privacy. We will protect your confidentiality during storage and sharing by destroying the link to your name and study number after the study is completed. There is the possibility that your involvement in the study may be made known to other participants during test kit collection or test administration, as other study participants may be visiting the lab during the same time. Other study participants will not have access to any of your personal information or other information collected throughout this study.

If you change your mind about participating in this study, we will not collect or store any additional information. Information collected prior to your withdrawal of consent will continue to be accessed and used as initially planned.

What information about me may be collected, used or shared with others?

Study participation will involve collection of the following information:

- Name, email address
- Job and workplace information
- Data collected from surveys
- Demographic information

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information are used to:

- do the research
- oversee the research
- to see if the research was done right
- to evaluate and manage research functions

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The investigator for the study and the study team
- Other authorized personnel at Penn, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside of the School of Medicine, might receive my information?

There are no plans to share any identifying information with researchers outside of the University of Pennsylvania. The U.S. Office of Human Research Protections (OHRP) has oversight over the research conducted in the US, and might receive information or require access to the research records to ensure the research was properly conducted.

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the IRB at the number on page one of this form.

Coronavirus Specific Information:

Due to the coronavirus public health crisis, the federal government has issued an order that may limit your right to sue if you are injured or harmed while participating in this COVID-19 clinical study. If the order applies, it limits your right to sue the researchers, healthcare providers, any study sponsor or manufacturer or distributor involved with the study. However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. To find out more about this "Countermeasures Injury Compensation Program" go to https://www.hrsa.gov/cicp/about/index.html or call 1-855-266-2427.

When you check the box and proceed to the next page, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

ELECTRONIC CONSENT: If you agree to participate, please check the box below and click the "NEXT" button. By checking the box and proceeding to the next page, you indicate that:

- You have read the above information
- You voluntarily agree to participate
- You are 18 years of age or older