

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
Informed Consent Form Addendum
Information about COVID-19 Testing for Participants in Research

The purpose of this form is to tell you about new and important information about the research study that you have agreed to participate in. The original consent form you signed is still valid except for the additional information described here.

Testing for COVID-19: A test for coronavirus, the virus that causes COVID-19, will need to be done within several days before every study visit that involves any procedures that could cause you to cough, sneeze, or otherwise spray solid particles or liquid droplets into the air from your mouth or nose. If you have COVID-19, this spray could spread the virus. Because of this, it is necessary to test you to make sure that you do not have COVID-19, even if you do not have symptoms.

Your COVID-19 test results must be received within the 4 days prior to your study visit. If the results are older than 4 days, you may be asked to get re-tested before your visit.

The test may be done at UCSF but could also be done at a non-UCSF testing site. If you get tested for COVID-19 outside of UCSF, talk to your study team about (1) what documentation you need to bring to your visit or whether you need to repeat the test at UCSF, and (2) what costs you will be responsible for related to the COVID-19 test and whether you will be reimbursed for these costs.

About the COVID-19 Test: The test is a procedure called nasopharyngeal (NP) swab. The NP swab involves placing a swab (like a very long Q-tip) in your nose to collect cells and secretions. The swab will go into your nasal cavity, above the roof of your mouth. In some cases, the swab may only go into the nostril and you may be able to collect the sample yourself. The swab will be sent to a laboratory for testing to see if you are infected with COVID-19.

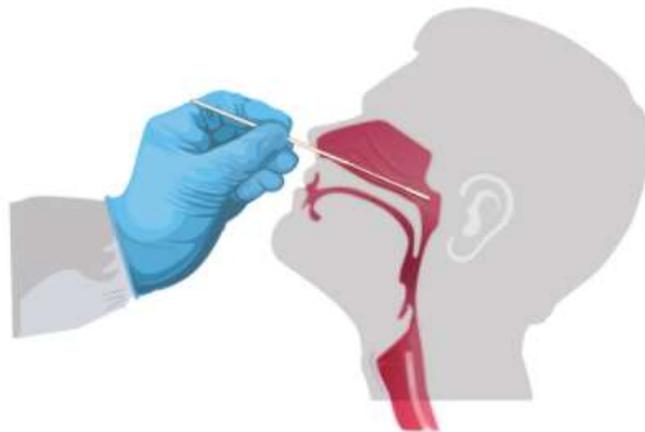


Photo Source: <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>

Risks associated with Nasopharyngeal (NP) Swab:

Likely: The NP swab test can cause discomfort and stuffiness in your nose, and it may cause your eyes to tear up temporarily.

Less Likely: You may experience a nosebleed and/or a gag reflex.

Risks associated with a positive test result:

If the test result shows that you are infected with COVID-19 (this is called a laboratory confirmed “positive” test result), there are several implications:

1. You will need to contact your doctor to arrange for management of the infection. If you do not have a doctor, the study physician will help you find medical care.
2. You should follow the isolation steps (home quarantine steps) that are recommended by your local Department of Public Health and by the Centers for Disease Control and Prevention.

An information sheet on COVID-19 infection developed by the San Francisco Department of Public Health (<https://www.sfdph.org/dph/alerts/covid-guidance/Guidance-Isolation-and-Quarantine.pdf>) will be provided to you and you should share this information sheet with everyone with whom you have had close contact. A close contact is defined as any individual within 6 feet of you for at least 15 minutes within the past 48 hours. These contacts need to follow home quarantine steps as well.

It is possible that someone from your local public health department will contact you to perform contact tracing. (<https://www.cdc.gov/coronavirus/2019-ncov/php/open-america/contact-tracing/index.html>)

3. Being in home quarantine may affect your ability to work, if you work outside your home.
4. If any children live with you, they may be asked to stay home from their usual daycare or school until you have completed your quarantine.

Privacy and Confidentiality

Your COVID-19 test result will be added to your medical record. If you do not already have a UCSF medical record and your test was conducted at UC Health, a record will be created for you. If you have not already authorized access to your UCSF medical record for this study, you will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

California regulations require laboratories to report all COVID-19 test results (positive, negative, or inconclusive) to the county public health department. The reports include your name and other identifying information. Information about these new infections is used to track diseases statewide and nationwide. Other than this required reporting, your results will be treated confidentially by the study staff. Personally identifying information will not be reported to other departments or agencies.

Questions?

If you have questions about the research study or about the COVID-19 test, please contact the study team. Contact information for the study team is included in the main Consent Form for this study.

If you have questions about your rights as a research participant, please call the UCSF Institutional Review Board at (415) 476-1814.

If you have questions about COVID-19, please call the UCSF Health COVID-19 hotline at 415-514-7328. You can also find additional by searching these websites:

- UCSF websites: <https://coronavirus.ucsf.edu/patients>
- San Francisco Department of Public Health: <https://www.sfdph.org/dph/alerts/coronavirus.asp>

The above information has been explained to me and all of my questions have been answered. By signing this form, I indicate that I have received this new information and plan to continue to participate in this research study. A copy of this document will be given to me.

Date

Participant's Signature for Consent

Date

Person Obtaining Consent

