

Updated December 2nd, 2020 by adding the following to the list of screening questions in Background #1, and Screening Protocol #2:

- In the past 14 days, have you experienced any of the following new, unusual, or worsening symptoms?
Unusual = not explained by a pre-existing condition
- Do you live with someone who is waiting for COVID test results due to symptoms of a COVID type illness?
- In the past 14 days, have you returned from travel outside the United States?
- In the past 14 days have you had unprotected close contact with someone diagnosed with COVID-19 (such as a household contact)?
Unprotected = without a face covering or without appropriate PPE at work if a healthcare worker
Close contact = within 6 feet for 15 minutes or longer, live with a person diagnosed
- Do you confirm the answers you have provided are true, and that you understand the information is critical to your safety and to the safety of our patients, faculty, students, staff and other Vendors, contractors and campus guests?
- (In Screening Protocol, item 2 only) changed “Script for calls to those coming for in-person visit essential to health/well-being of the participant” to “Script for calls to those coming for in-person visit.”
- (In Screening Protocol, item 2 only) changed “Please note that, at this time, UCSF is not permitting any guests or visitors at the following UCSF campuses: Parnassus Heights (including Langley Porter Psychiatric Hospital & Clinics), Mission Bay, and Mt. Zion.” to “Please note that at this time, restrictions exist for guests and visitors of UCSF; please consult the [UCSF Health website](#) for current information and guidance.”

Guidance for Screening of Research Participants by Clinical Research Staff

Background

The [Guidance for Onsite Clinical Research Activities](#), effective May 13, 2020, provides guidance on the partial resumption of onsite clinical research at UCSF health facilities located in the City and County of San Francisco.

1. All participant research visits conducted in-person, regardless of visit location, should be screened for COVID-19 symptoms by phone (or telehealth) prior to and at the time of arrival for the visit as follows:
 - In the past 30 days, have you or someone you live with been diagnosed with COVID-19? [YES / NO]
 - In the past 14 days, have you had unprotected close contact with someone diagnosed with COVID-19 (such as a household contact)? [YES / NO]

close contact = within 6 feet for 15 minutes or longer, live with a person diagnosed

unprotected = without a face covering or without appropriate PPE at work if a healthcare worker

- In the past 14 days, have you had any of the following new, unusual, or worsening symptoms?
 - Fever, Chills, Shivering/Shakes (temp $\geq 37.8^{\circ}$ C/ 100° F) [YES / NO]
 - Cough [YES / NO]
 - Sore Throat [YES / NO]
 - Runny or congested nose [YES / NO]
 - Difficulty breathing or shortness of breath [YES / NO]
 - Unexplained muscle aches [YES / NO]
 - Feeling unusually weak or fatigued [YES / NO]
 - Loss of sense of smell or taste [YES / NO]
 - Diarrhea (*defined as > 3 loose stools in 24 hours*) [YES / NO]
 - Eye redness with or without discharge (“pink eye”) [YES / NO]

Unusual = not explained by a pre-existing condition (*e.g. allergies*)

- Do you live with someone who is waiting for COVID test results due to symptoms of a COVID type illness? [YES / NO]
- In the past 14 days, have you returned from travel outside of the US? [YES / NO]
- Do you confirm the answers you have provided are true, and that you understand the information is critical to your safety and to the safety of our patients, faculty, students, staff and other Vendors, contractors and campus guests? [YES / NO]

If the answer to any of these screening questions is YES (other than the confirmation statement), the research visit should be postponed and the participant referred to their medical provider. If the reason for postponement is a positive COVID-19 test, additional screening may be required on a site-by-site basis (please contact research@ucsf.edu for more information).

2. Research teams should consider that certain populations of study participants may have increased risk for severe COVID-19 infection (see CDC guidance; <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-higher-risk.html>) and incorporate this in decisions about conducting in-person research visits; please consult with your PI if your cohort is at increased risk.
3. Participants should be informed that UCSF’s top priority is public health: the health of research participants, UCSF personnel, and the city and region and the plan to begin resumption of clinical research aligns with state and local Public Health ‘shelter-in-place’ orders. Participants should be given the option to postpone the planned clinical research if they are uncomfortable coming onsite and/or meeting with research staff due to the COVID-19 outbreak.
4. All research visits should be conducted with face coverings as per institutional [policy](#)
5. Whenever possible, there should be a minimum of 6 feet between participants and research staff consistent with public health directives
6. Participants should be provided with information regarding the current COVID-19 epidemic and how best to reduce their risk of infection. This information may be provided in multiple forms suited to the type of contact, including a website link, a telephone script and an in-person handout. If possible, this information should be shared **before** the research visit. See [the CDC COVID-19 link](#) for reference and materials.

Screening Protocol

1	Identify participants essential to be seen in-person	<p>Work with your PI or Providers to identify participants who may be rescheduled or converted to video visit vs those essential to be seen/treated in-person.</p> <p>ALL PARTICIPANT-PARTICIPANTS WILL BE CONTACTED – ABOVE DETERMINES WHAT IS COMMUNICATED</p>
2	Scripts for participant calls	<p>Script for calls to those with option to reschedule or change to video visit:</p> <p>I’m calling from Dr. _____’s office at UCSF/on behalf of Dr. _____’s research team. I see you have an appointment/research visit with her/him on _____. Our clinic/research site/team is working to minimize exposure for our participants, many of whom have compromised immune systems, so we’re calling all participants to see if you are willing to have a video visit instead of in person. The other option is to reschedule for a later date. Would either of these work for you?</p> <hr/> <p>Script for calls to those coming for in-person visit:</p> <p>Hello, I’m calling from the _____ Clinic / Lab / Study Team at UCSF. I see you are scheduled for a research visit/to see the doctor/receive treatment with us tomorrow. Due to the COVID-19</p>

virus, we're calling all of our study participants with scheduled office appointments to provide information and see how they're feeling prior to coming in for their appointment.

- In the past 30 days, have you or someone you live with been diagnosed with COVID-19? [YES / NO]
- In the past 14 days, have you had unprotected close contact with someone diagnosed with COVID-19 (such as a household contact)? [YES / NO]

close contact = within 6 feet for 15 minutes or longer, live with a person diagnosed

unprotected = without a face covering or without appropriate PPE at work if a healthcare worker

- In the past 14 days, have you experienced any of the following new, unusual, or worsening symptoms?

Unusual = not explained by a pre-existing condition

- Fever, Chills, Shivering/Shakes ((T > 37.8° C/100° F) [YES / NO]
- Cough [YES / NO]
- Sore Throat [YES / NO]
- Runny or congested nose [YES / NO]
- Difficulty breathing or shortness of breath [YES / NO]
- Unexplained muscle aches [YES / NO]
- Feeling unusually weak or fatigued [YES / NO]
- Loss of sense of smell or taste [YES / NO]
- Diarrhea (*defined as > 3 loose stools in 24 hours*) [YES / NO]
- Eye redness with or without discharge ("*pink eye*") [YES / NO]

- Do you live with someone who is waiting for COVID test results due to symptoms of a COVID type illness? [YES / NO]
- In the past 14 days, have you returned from travel outside of the US? [YES / NO]
- Do you confirm the answers you have provided are true, and that you understand the information is critical to your safety and to the safety of our patients, faculty, students, staff and other Vendors, contractors and campus guests? [YES / NO]
- **If answer is YES to any question (other than the confirmation statement):** Thank you, please contact your primary care doctor. For the time being, please **plan to stay at home** and we will reschedule your research appointment or schedule a telephone or web-based conference.
- **If answer is NO to every question:** If you should develop ANY OF these symptoms before your appointment tomorrow, **we're asking you to stay home and call us at 415-XXX-XXXX**. We will further assess how you are doing and determine next steps to reschedule your appointment.

Please note that at this time, restrictions exist for guests and visitors of UCSF; please consult the [UCSF Health website](#) for current information and guidance.

When you arrive for your research visit/appointment, you will be screened and provided with a surgical mask. Everyone entering the building, whether staff, physician or patient is being issued a mask. You are required to wear the mask for the duration of your time at UCSF. This is for your protection and for the protection of all visitors, patients and staff at UCSF. We

want to thank you for your cooperation with these policies and we look forward to seeing you tomorrow.

Script for calls to those **participating in off-site research visits**:

Hello, I'm calling from Dr. _____'s study team at UCSF. I see you are scheduled to meet with us tomorrow at _____[location]. Due to the COVID-19 virus, we're calling all of our research participants with scheduled meetings to provide information and see how they're feeling prior to meeting with a member of our study team.

- In the past 30 days, have you or someone you live with been diagnosed with COVID-19? [YES / NO]
- In the past 14 days, have you had unprotected close contact with someone diagnosed with COVID-19 (such as a household contact)? [YES / NO]

close contact = within 6 feet for 15 minutes or longer, live with a person diagnosed

unprotected = without a face covering or without appropriate PPE at work if a healthcare worker

- In the past 14 days, have you experienced any of the following new, unusual, or worsening symptoms?

Unusual = not explained by a pre-existing condition

- Fever, Chills, Shivering/Shakes ((T > 37.8° C/100° F) [YES / NO]
- Cough [YES / NO]
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- Runny or congested nose [YES / NO]
- Difficulty breathing or shortness of breath [YES / NO]
- Unexplained muscle aches [YES / NO]
- Feeling unusually weak or fatigued [YES / NO]
- Loss of sense of smell or taste [YES / NO]
- Diarrhea (*defined as > 3 loose stools in 24 hours*) [YES / NO]
- Eye redness with or without discharge ("*pink eye*") [YES / NO]

- Do you live with someone who is waiting for COVID test results due to symptoms of a COVID type illness? [YES / NO]
- In the past 14 days, have you returned from travel outside of the US? [YES / NO]
- Do you confirm the answers you have provided are true, and that you understand the information is critical to your safety and to the safety of our patients, faculty, students, staff and other Vendors, contractors and campus guests? [YES / NO]
- **If answer is YES to any question (other than the confirmation statement):** Thank you, please contact your primary care doctor. For the time being, please **plan NOT to meet with the study coordinator**. We will reschedule your research appointment or schedule a telephone or web-based conference.
- **If answer is NO to every question:** If you should develop ANY OF these symptoms before your appointment tomorrow, **we're asking you to not meet with your study coordinator and call us at 415-XXX-XXXX**. We will further assess how you are doing and determine next steps to reschedule your appointment.

		When you arrive for your meeting, we will ask you these questions again, and provide you with a surgical mask if you do not have your own. All UCSF clinicians and staff, as well as everyone meeting with them, are required to wear the mask for the duration of your meeting. This is for your protection and for the protection of those around you. We want to thank you for your cooperation with these policies and we look forward to seeing you tomorrow.
3	No answer to call	<p>Call the participant up to 3 times - document # attempts made. Intent is to give the participant the opportunity to answer screening questions. If you are not able to speak with the participant before their in-person visit, on the final attempt leave a voicemail saying:</p> <p style="padding-left: 40px;">This is _____ calling again about your appointment tomorrow at UCSF. Since we were unable to reach you prior to your visit, we are advising participants not to come to their appointments until they have been screened for respiratory symptoms. Our clinic/research site is working to minimize exposure for our participants, many of whom have compromised immune systems. If you've had new cough, flu-like illness, new trouble breathing, or fever, please contact your doctor.</p> <p style="padding-left: 40px;">Otherwise, please call XXX-XXXX to reschedule your appointment. We apologize for any inconvenience and thank you for your understanding.</p>
4	Call documentation	Please document all screening calls/phone encounters in the participant's research chart.
6	Resources for Participants	If you have questions about the Coronavirus, please call our hotline at 415-514-7328. You can also find additional information about the Coronavirus by searching the San Francisco Department of Public Health site, the Center for Disease, Control and Prevention website or go to www.ucsf.edu/coronavirus
7	If your participant phones you	If they have an upcoming appointment, please screen as described in #2 above If they do not have an upcoming appointment but have a question/concern about their health as relates to COVID-19, please instruct them to call their Primary Care Provider / Provider's clinic (Specialist Provider, if/as appropriate)

Additional resources and supporting documents

1. [UCSF COVID-19 Website](#) (Materials available in the Research Guidance Tab)
2. <https://infectioncontrol.ucsfmedicalcenter.org>
3. [Centers for Disease Control and Prevention](#)
4. Text "COVID19SF" to **888777** to receive updates from the San Francisco Department of Public Health

Where to Direct Questions

1. Coronavirus: emer.mgt@ucsf.edu
2. Research visits and/or screening participants: research@ucsf.edu
3. If your Investigator/Supervisor has information that conflicts with any of the above, please contact research@ucsf.edu for clarification.