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.

    A. Participants in Category 2 studies (clinical research essential to the health of patients) or whose research visit includes a clinical encounter should be screened by the study teams using the self-screening tool (pdf of questions) used by UCSF Health for patients if they have not yet been screened by UCSF Health clinic staff at the time of their research visit (*no change to current practice*)
    B. Participants whose UCSF visit is for **Category 3 (clinical research not essential to the health of patients), research-only (no concurrent clinic visit) must be asked if they have traveled outside of the nine-county Bay Area in the past 14 days, in addition to the health screening questionnaire**. If the answer is YES, then the participant must comply with the mandatory 10-day quarantine requirement as ordered by the SFDPH and outlined here by UCSF Health Chief Clinical Officer, Josh Adler, MD.

    If the answer to any of the 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) 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	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.

	essential to be seen in-person	ALL PARTICIPANT-PARTICIPANTS WILL BE CONTACTED – ABOVE DETERMINES WHAT IS COMMUNICATED
2	**Scripts for participant calls**	Script for calls to **those with option to reschedule or change to video visit:** 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?
		Script for calls to those **coming for in-person visit:** 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 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. [Please ask the participant the UCSF Health Patient Daily Screen Questions] 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. The day of your meeting, either before or when you arrive, you are asked to go to https://tiny.ucsf.edu/entry to complete the UCSF Guest Daily Health Screener. You will need to show the screen stating you are cleared in order to enter any UCSF building. If you do not have the ability to complete the self-screener we can make arrangements to meet and we will ask you these questions again verbally. We will also provide you with a surgical mask if you do not have your own. 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. [Please ask the participant the UCSF Health Patient Daily Screen Questions] • **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.
		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	**When participant arrives for onsite visit**	In accordance with current Department of Health Orders, all medical center and campus guests visiting any UCSF campus must complete the following daily self-screening survey: UCSF Guest Daily Health Screener. If the participant does not have a computer or smart phone or is otherwise unable to complete the self-screening survey, the CRC should meet them upon arrival and verbally perform the screen.
4	**No answer to call**	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: 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. Otherwise, please call XXX-XXXX to reschedule your appointment. We apologize for any inconvenience and thank you for your understanding.
5	**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.