Updated April 9th, 2020 new/changed denoted by purple text

Guidance for Screening of Research Participants by Clinical Research Staff

Background

The <u>Interim UCSF Policy on Human Subjects-Related Research Visits at San Francisco Campuses</u>
<u>during COVID-19 Outbreak</u>, effective March 11th, 2020, states that research visits should be performed remotely (e.g., by phone, Zoom, or other means) whenever possible.

Research visits that **cannot** be performed remotely and are <u>essential to a participant's health and/or well-being</u> may be performed in person.

In these cases, all study participants should be:

- 1. 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.
- Screened for <u>new</u> cough, flu-like illness, <u>new</u> trouble breathing, or fever (measured or subjective) or muscle
 aches by research staff prior to the in-person research visit if possible, and with repeat screening by research
 staff at the time of an in-person visit.
- 3. If a participant screens positive, i.e. is reporting credible COVID-19 symptoms
 - a. If on the phone, instruct them to stay home and contact their primary care doctor
 - b. If in-person, follow site-specific/institutional guidance and triage algorithms

Screening Protocol

	eening Frotocoi	
1	Identify	Work with your PI or Providers to identify participants who may be rescheduled or converted
	participants	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	Script for calls to those with option to reschedule or change to video visit:
	participant calls	
		I'm calling from Dr's office at UCSF. I see you have an appointment with her/him on
		Our clinic/research site 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 essential to health/well-being of the
		participant:
		Hello, I'm calling from the Clinic / Lab / Study Team at UCSF. I see you are scheduled to
		see the doctor/receive treatment with us tomorrow. Due to the COVID-19 virus, we're calling
		all of our participants with scheduled office appointments to provide information and see
		how they're feeling.
		Do you have ANY of the following: New cough, flu-like illness, new trouble breathing, or
		fever?
		If answer is YES to any question: 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.
		appointment of the same a telephone of the same control of the

		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, 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. When you arrive for your 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.
3	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.
4	Call documentation	Please document all screening calls/phone encounters in the participant's research chart.
6	Resources for	If you have questions about the Coronavirus, please call our hotline at 415-514-7328. You can
	Participants	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	If they have an upcoming appointment, please screen as described in #2 above
	participant	If they do not have an upcoming appointment but have a question/concern about their health
	phones you	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. <u>UCSF COVID-19 Website</u> (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.