Updated May 15th, 2020 *new/changed since previous guidance denoted by purple text* Guidance for Screening of Research Participants by Clinical Research Staff

Background

The Interim UCSF Policy on Human Subjects-Related Research Visits at San Francisco Campuses during COVID-19 Outbreak, 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:

- 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 <u>the CDC COVID-19 link</u> for reference and materials.
- Screened for <u>new</u> cough, flu-like illness, <u>new</u> trouble breathing, or fever (measured or subjective), <u>new</u> muscle aches, <u>new</u> headache, <u>new</u> eye redness and/or discharge, <u>new</u> loss of smell or taste, <u>new</u> running nose, <u>new</u> sore throat, <u>new</u> diarrhea, <u>new</u> nausea or vomiting or severe fatigue 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

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	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 study participants with scheduled office appointments to provide information and				
		see how they're feeling prior to coming in for their appointment.				
		Do you have ANY of the following:				
		 <u>new</u> cough <wait for="" no="" yes=""></wait> 				
		 <u>new</u> flu-like symptoms, including muscle aches <wait for="" no="" yes=""></wait> 				
		 <u>new</u> trouble breathing <wait for="" no="" yes=""></wait> 				

Screening Protocol

		 <u>new</u> fever, either measured with a thermometer, or you just feel febrile <wait for<br="">yes/no>?</wait>
		 <u>new</u> headache <wait for="" no="" yes=""></wait>
		 new eye redness and/or discharge <wait for="" no="" yes=""></wait>
		 <u>new</u> sore throat <wait for="" no="" yes=""></wait> new diambas (2 or more steple in 24 hours) (weit for use (no))
		 <u>new</u> diarrhea (3 or more stools in 24 hours) <wait for="" no="" yes=""></wait>
		 <u>new</u> nausea and/or vomiting<wait for="" no="" yes=""> or,</wait>
		 <u>new</u> severe fatigue (cannot perform basic functions) <wait for="" no="" yes=""></wait>
		• 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.
		 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	Please document all screening calls/phone encounters in the participant's research chart.
	documentation	
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
1		go to <u>www.ucsf.edu/coronavirus</u>

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

Where to Direct Questions

- 1. Coronavirus: <u>emer.mgt@ucsf.edu</u>
- 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.