NOTE: These guidelines supersede Committee for Protection of Human Subjects (CPHS) guidelines issued on March 14 and 20, 2020 governing limited research during Phase 1 ramp down of campus research. In addition, this document revises and clarifies the Phase 2 Research Recovery Guidelines issued on 6/17/20 and 7/20/20.

Updated 8/31/20: These guidelines are intended as a supplement to the UC Berkeley Guidelines for Increasing Onsite Laboratory Research Activities for UC Berkeley researchers whose research involves human subjects research. Please 1) review the above and below guidelines, 2) complete the Human Subjects Research Proposal Supplement Form, and 3) submit a copy to: the VC Research at researchrecovery@berkeley.edu, your Building Oversight Committee, and the Committee for the Protection of Human Subjects (CPHS).

Updated 8/31/20: Submit a copy of your proposal and Human Subjects Research Proposal Supplement Form to the Committee for the Protection of Human Subjects (CPHS). This form should be submitted as a protocol amendment, or, if you don’t have an approved protocol, submit as part of a new protocol, through eProtocol: https://cphs.berkeley.edu/eprotocol.html.

- For PIs in laboratory buildings, please attach a copy of your Density Management Proposal for Laboratory Research after it has been approved by your dean/Building Oversight Committee.
- For PIs in Academic Buildings, please confirm to CPHS that you and all researchers involved in your proposed research have been granted permission to return to campus as essential employees.
- If your human subjects research is conducted entirely off-campus, complete only the Human Subjects Research Proposal Supplement Form, to be submitted to CPHS as an attachment to a protocol amendment through eProtocol.

Human subjects research will follow the general protocol for resumption of laboratory research activities, with specific attention to relevant issues as described below.

NOTE: Since June 17, 2020, campus leadership has not allowed in-person human subjects research in campus facilities involving unaffiliated individuals from outside the UC Berkeley community, unless the research is deemed essential to the health and well-being of the participant. Update 8/31/20: the VC Research is currently developing
a process to allow limited numbers of in-person participants from the community; please check the VCRO website for updates.

*You may not commence any on-campus human subjects research described above until approved by both your building oversight committee/dean and CPHS.*

**Density Management**
A fundamental principle of Phase 2 resumption of campus research activity is to maintain low density of personnel in campus spaces. **All work that can be done remotely must continue to be done remotely.** While human subjects research staff typically use their offices or shared work spaces (cubicles) for their research, particularly for work that does not involve direct contact with participants (i.e., planning, data analysis), this work should continue to be done remotely.

**Research Involving in-person interactions**
In developing the density budget for the human subjects labs and exam suites/rooms, the building oversight committee and faculty PI should discuss the number of human subjects expected to come to the building/rooms, and determine maximum occupancy taking into account both research personnel and participants. Research participants must be scheduled to ensure that the total number of individuals in each lab or exam suite is kept low at all times. Although a suite may consist of multiple exam rooms, not all rooms may be occupied at all times to reduce the frequency of encounters, and overall density of public spaces outside the lab.

Faculty are not expected to be included in the density budget unless they are participating in research in the assigned spaces. When not conducting or directly overseeing patient research, faculty should continue to work remotely.

**Building access for analysis of secure data on on-campus servers**
Researchers whose work requires access to secure computers on campus (not accessible from remote) to perform data analysis:

- If the computers are housed in a laboratory sciences building the PI should speak to their Building Oversight Committee for consideration of an allocation of a minimum density budget for their server room (typically a density budget of 1 person per room). Researchers can be granted ‘regular’ or ‘emergency access.
- Until the VC Research announces plans to resume research beyond initial laboratory science buildings, if servers are housed in a non-laboratory sciences building, the PI should submit a request for essential on-campus access for consideration through the VC Research Office. Research personnel must adhere to all social distancing and hygiene requirements in the server rooms, and must only come to campus for work requiring direct server access.
Note that requests for on-campus access to servers does not require further review by CPHS.

**Guidelines for Specific Situations**

**Special Considerations for In-Person Human Subjects Research**

See caveat regarding in-person research involving third-party individuals above.

Human subjects investigators need to consider a range of additional issues when preparing detailed SOPs to support their Phase 2 research resumption proposals, based on guidance from the Centers for Disease Control, the State of California, Alameda County Health Authorities, and City of Berkeley Health Authorities.

SOPs must consider the following:

**Social distancing and hygiene**

- Participant waiting areas, offices where informed consent is obtained, and all experimental areas should be maintained at low density at all times.
- When research requires researchers or participants moving around the room, the total number of personnel must be limited, even in larger rooms, to ensure that social distancing and reduction of viral transmission can be maintained.
- Ensure appropriate use of social distancing between all individuals, including research personnel and human subjects participants. All researchers must maintain a minimum of six-foot distance between personnel and human subjects at all times, taking care to consider traffic flows in and out of waiting areas, patient rooms and other study spaces. Develop signage to alert participants where to sit in waiting rooms; ensure that chairs are at least six feet apart, and six feet from walkways. Remove extra tables, reading materials and surfaces that could transmit the virus. Where possible, schedule patients to avoid wait times altogether.
- For research requiring close proximity between research personnel and participants (for example positioning a patient for an MRI), specific guidelines must be put in place, and training done in advance, to ensure that it can be done safely. Researcher personnel should minimize contact, ensure washing of hands and disinfection of surfaces between contacts.
- Research personnel and participants must wear masks at all times. Participants must be instructed to wear facial coverings as soon as they arrive on campus, and in all campus buildings.
- PIs must work with their building manager, and Facilities Services or EH&S, to ensure that all spaces to be used for in-person human subjects research (waiting areas, participant rooms) are equipped with sufficient air flow per CDC, state, county and city guidelines.
- All surfaces touched by research personnel or participants in the course of the research, must be disinfected after each experiment.
• Investigators using shared laboratory spaces or equipment must have plans for coordination of work hours, minimizing occupancy, and hygiene/disinfection between participants.

Safety
• PIs should consider whether there are safety issues if experimenters are alone with participants and others are not in the laboratory.

Participant Screening and Recruitment
CPHS suggests the following actions for informing participants of screening, screening participants, and management of screening data. Compliance with these suggestions will eliminate the requirement to modify your protocol text narrative.

The following questions should be used to screen participants, with the understanding that if any participants respond positively to any of these questions, their research visits must be rescheduled and they must be told to notify their healthcare provider:

1. In the past 30 days, have you had a positive COVID-19 test?
2. In the past 14 days have you had close, sustained contact (i.e. with a household member) with someone who had a positive COVID-19 test or was sick with COVID-19-like symptoms (see below)?
3. In the last 14 days, have you experienced any of the following new or worsening symptoms: Fever, unexplained muscle aches, trouble breathing or cough, sinus congestion or runny nose, sore throat, nausea or vomiting, diarrhea, loss of taste or smell, eye redness or discharge, confusion, dizziness or falls?

Management of screening information:
• Do not store the screening data or use it in research
• Do not link the screening data to an identifiable participant
• Destroy the screening data soon after collection
• Modify your recruitment materials to include standard language as pre-approved by CPHS (see below) so potential subjects know in advance that they will be screened for COVID-19 signs/symptoms/history when they arrive for their HSR session appointment.

Participant recruitment text should use standard language to notify participants that specific COVID-19 procedures have been put in place. The following can be used as standard, CPHS-approved language:

Please note that participation in this on-campus research project will require that you be screened for COVID-19 exposure and/or symptoms upon arrival for your research appointment. If deemed ineligible to participate in the study, no compensation is available for your time or effort in coming to said appointment.
New 8/31/20: Use of the above recruitment language will not require you to change any text in your approved protocol narrative (text). Any changes that go beyond use of the recommended above language and/or screening processes may be included in the protocol amendment as long as they are directly related to research resumption. All other changes to the protocol and/or research materials must be described in a separate amendment.

Exclusion of Participants at Increased Risk from COVID-19
- PIs should consider that certain populations of subjects are at increased risk from COVID-19 and should be excluded from human subjects research. Any exceptions to this policy must be granted approval by the Vice Chancellor for Research.

Human Subjects Research Requiring Travel
- Human subjects research carried out off campus, in California, in the US, or internationally must comply with regulations from local public health authorities and follow best practices for minimizing risks to potential subjects and the researchers.
- Travel by UC Berkeley faculty/staff must comply with local, national and international travel restrictions and 14-day self-isolation may be required on arrival and return. The City of Berkeley and Alameda County shelter-in-place orders currently disallow non-essential domestic or international travel.

Human Subjects Research by Third Party Researchers
- Human subjects research conducted on UC Berkeley researchers' behalf by third parties (e.g. in-country data collection as part of international research), precautions must be in place to safeguard the health of third party researchers and human subjects they encounter. This includes validating and complying with local health and travel restrictions in the study area, and ensuring similar standards of social distancing, facial coverings and disinfection as if the research was conducted on campus.