Please read these updated guidelines in full as several instructions have been updated, including instructions for submitting completed forms.

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, 7/20/20 and 8/31/20.

Overview
This document provides guidance to researchers who wish to conduct in-person research either on or off campus. Note: All work that can be done remotely must continue to be done remotely.

On-campus human subjects research at UC Berkeley will follow the general protocol for resumption of laboratory research activities, with specific attention to relevant issues as described below. This document is intended as a supplement to the UC Berkeley Guidelines for Increasing Onsite Laboratory Research Activities for researchers whose research involves human subjects. Please review the Guidelines for health and safety principles and restrictions on use of undergraduate volunteers that apply to human subjects research. Please contact VC Research at researchrecovery@berkeley.edu with questions.

Off-campus research must follow the relevant guidelines detailed below and must be approved through the VC Research critical field research continuity review process (see below).

You may not commence any human subjects research until approved by both CPHS, and your Building Oversight Committee or VC Research, as applicable.

Please review the above and below guidelines before filling out the Human Subjects Research Proposal Supplement Form.

Note: On-campus, in-person human subjects research is currently only allowed using participants from the UC Berkeley community (e.g. faculty, staff, postdocs and students), unless the research is deemed essential to the health and well-being of the participant. As of 10/08/20 the VC Research is awaiting approval from the City of Berkeley Dept of Public Health to allow non-UCB affiliated participants; please check the VCR0 website for updates.
On-Campus Research: Density Management Guidelines

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. Use the person per square foot guidelines outlined in the UC Berkeley Guidelines for Increasing Onsite Laboratory Research Activities (p3), *even if the research is not conducted in a laboratory building.* Do not use other campus guidelines for instruction; etc. Please contact VC Research at researchrecovery@berkeley.edu with any questions.

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. Multi-subject interaction (e.g. focus groups) must also use the laboratory density guidelines.

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:

- 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.
- If servers are housed in a building that is not reopened for research or instructional preparation and delivery, contact VC Research at researchrecovery@berkeley.edu to discuss exceptional access approval.
- 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.

**On-Campus, In-Person Human Subjects Research**

**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. As of 10/08/20 the VC Research is awaiting approval from the City of Berkeley Dept of Public Health to allow non-UCB affiliated participants; please check the VCRÖ website for updates.

1. Work with your Building Oversight Committee to develop a personnel ‘density budget’ for your research/lab space to accommodate experimenters, participants, and other research personnel who must be on site. See On-Campus Research: Density Management Guidelines, above. Check with your Building Manager or Department Chair if you are unsure who your Building Oversight Committee lead is.
2. Review the Guidelines for Specific Situations, below.
3. Complete the Human Subjects Research Proposal Supplement Form; and
   a. Submit one copy of this form to CPHS as a protocol amendment through eProtocol: https://cphs.berkeley.edu/eprotocol.html. If you don’t have an approved protocol, submit the form as part of a new protocol through eProtocol.
   b. Email a second copy to your Building Oversight Committee contact for approval. Forms can be submitted to CPHS and Building Oversight Committees simultaneously.
   c. Once approved, the Building Oversight Committee should email a copy of the approved form to researchrecovery@berkeley.edu (lab buildings) or jpcab@berkeley.edu (academic buildings) for VC Research review. VCRO will notify the PI once the addendum is fully approved.
4. Once the PI receives approval from both CPHS and VC Research, the project can commence.
5. Submit the names of required researchers and support staff for essential campus access (ensure that all personnel complete required training and the daily symptom screener prior to returning to campus):
   a. Laboratory buildings: PIs should add the names to their Personnel Data Sheet and email the sheet to their building manager
   b. Academic buildings: Contact your Building Oversight Committee lead for your building’s process.
   c. Buildings not yet open or other types of campus-managed/outdoor spaces: email researchrecovery@berkeley.edu for instructions.
6. Research personnel may escort study participants in/out of the building; please alert your building manager of their presence.

Off-Campus Human Subjects Research

1. Review the UC Berkeley Guidelines for Increasing Onsite Laboratory Research Activities. While these guidelines are geared towards on-campus research, the same health and safety principles apply to off-campus research, as do restrictions on use of undergraduate volunteers. Contact VC Research at researchrecovery@berkeley.edu with any questions.
2. Review the Guidelines for Specific Situations, below.
3. Complete the Human Subjects Research Proposal Supplement Form; and
   a. Submit one copy of this form to CPHS as a protocol amendment through eProtocol: https://cphs.berkeley.edu/eprotocol.html. If you don’t have an approved protocol, submit the form as part of a new protocol through eProtocol.
   b. Submit a request through the VC Research critical field research continuity review process and email a copy of your Supplement Form to researchrecovery@berkeley.edu. [Note: the critical field research form is being updated to reflect human subjects research – please fill out requested fields in the interim and send questions to researchrecovery@berkeley.edu.]
   c. a) and b) can be submitted simultaneously.
4. Once the PI has received approval from both CPHS and VC Research, the project can commence.

Guidelines for Specific Situations

Special Considerations for In-Person Human Subjects Research
**See caveat at the top of this document regarding in-person research involving non-UC Berkeley-affiliated human subjects.**
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. Research 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 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.*

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. More information on populations at risk is available on the [US Centers for Disease](https://www.cdc.gov)
Control website. 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.
- Please submit requests for all human subjects research requiring off-campus travel to the VC Research critical field research continuity review process. [Note this form is being updated to better reflect off-campus/international human subjects research – please use it in the interim.]
- All international travel by UC Berkeley researchers must be approved in advance. Visit the Global Engagement Office website for more information.

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.