



CALIFORNIA STATE UNIVERSITY, LONG BEACH
OFFICE OF RESEARCH & SPONSORED PROGRAMS (ORSP)

DATE: October 21, 2020

TO: Faculty, Staff and Student Researchers

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Director, Research Integrity & Compliance

SUBJECT: IRB GUIDE FOR PROJECTS WITH IN-PERSON PROCEDURES DURING COVID-19 PANDEMIC

[Please refer to IRB Memo Phase 2 posted on April 17th 2020](#), “In response to COVID-19, it is strongly recommended for human subject’s research (HSR) to choose alternative recruitment and data collection methods. In-person interactions shall be halted until further notice from CSULB Director of Research Integrity & Compliance.” If the PI plans to continue/initiate in-person recruitment/data collection, (1) a new protocol or an appeal must be submitted to the IRB to provide strong justification for doing so, (2) this protocol must include statements of the risk of potential COVID-19 infection and a detailed description of all necessary precautions to mitigate the risk, and (3) the protocol must go through Expedited Review or Full Board Review.

This document is to provide generic guidelines for the PI to consider. It should not be considered a standard for approval of any particular IRB protocol, and the PI has the responsibility to provide protocol specific measures for IRB to make a better informed decision.

Based on the Office of Research and Sponsored Programs (ORSP)’s [Update: Guiding A Color-Coded Tiered Approach To Ramping Up Laboratory Research Activities issued on October 12, 2020](#), the PI should promptly communicate with the Department Chair and/or College Dean to obtain an administrative approval prior to initiating or continuing HSR involving in-person procedures on campus in order to avoid overcrowding, etc.

I. Before Meeting with HSR Participants

- A. The IRB package must be submitted to and approved by the IRB before contacting HSR participants. In the IRB protocol and/or informed Consent Form, in addition to the requirements prior to COVID-19 pandemic, the following specific information should be included:
- 1) A justification for work that cannot be done remotely.
 - 2) A description of how social/physical distancing (6 feet or greater) will be established during HSR activities/assessments/interventions.
 - 3) If six feet of physical distance cannot be maintained, a description of activities that require close contact, direct physical contact (touching) and how exposure will be minimized. If touching of participants is necessary minimize contact to very brief interactions (<30 seconds) if possible.

- 4) If applicable, a description of HSR activity in a community setting and risk mitigation plan that includes how exposure will be minimized for HSR participants and research staff (see Important Considerations “mode of transportation” below). IN-PERSON interactions in a participants personal home must be well justified.
- 5) Consideration of the risk/benefit ratio for HSR participants. Consider if there is additional risk by coming to campus and interacting with research staff or in the community for field research.
- 6) A description of the use of Personal Protective Equipment (PPE) by research staff and HSR participants.
- 7) A description of decontamination of equipment and surfaces that will come into contact with participant.
- 8) An enrollment strategy. Clarify whether only participants currently enrolled in the study be will be contacted. If no, justify why the recruitment of new participants is necessary. Indicate an approximate number of all participants (current or new) that will be asked to come to campus or meet off campus within a specific timeframe (e.g. 2-week increments). NOTE: Minors are allowed to come to campus or be contacted in a community setting for studies only where (a) the IRB has determined there is a direct benefit or the potential of a direct benefit to the minor study participants, and (b) with a parent/legal guardian’s signed Informed Consent Form, and (c) documentation of minor Informed Consent. See “Important Considerations” below for more guidance.
- 9) Exercise restraint in the number of participants contacted. Only schedule appointments for the minimum number of people necessary for the study to remain sustainable.
- 10) Provide sufficient details on protocol specific measurements to minimize the risk of COVID-19 infection.

B. When required by IRB, complete CITI Online training course “COVID-19: Back to Campus (Fall 2020)”.

C. Obtain IRB approval.

D. Create a COVID-19 Pre-screening guide for research staff (self-assessment) and HSR participants. Minimum questions that must be asked:

- 1) Have you had a fever of 100°F (38°C) or above, any symptoms of a COVID-19 infection in the last 14 days (e.g., cough, sore throat, shortness of breath, loss of smell/taste, muscle pain, chills, severe headache, diarrhea, or nausea)?
- 2) Have you had close contact with a confirmed COVID-19 patient within the past 14 days? Close contact is defined by the CDC as:
 - i. being within approximately 6 feet of a COVID-19 case for a prolonged period. Close contact can occur while caring for, living with, visiting, or sharing a health care waiting area or room with a COVID-19 case, or
 - ii. having direct contact with infectious secretions of a COVID-19 case (e.g., being coughed or sneezed on).
- 3) Have you traveled to any locations confirmed by the Centers for Disease Control and Prevention to have widespread community transmission of COVID-19 in the past 14 days?
See <https://www.cdc.gov/coronavirus/2019-ncov/travelers/index.html> for an updated list of areas with widespread community transmission.

E. If activity is conducted at CSULB, create a calendar to schedule activities and use shared equipment.

Shared workspace/equipment calendars must be accessible by **all** potential users so that there is no overlap when using space and equipment.

II. On the Day of Meeting with HSR Participants

- A. Contact the participant 1-3 hours before arrival for their appointment and ask the COVID-19 pre-screening questions. If there is an indication of COVID-19 symptoms, cancel the appointment and reschedule when symptoms clear. The minimum recall time is at least 14 days after the clearance of symptoms.
- B. Research Staff must perform a COVID-19 self-assessment and must not come to campus or meet in a community setting if symptoms are indicated. Staff can only resume work after a self-quarantine time of a minimum 14 days after the clearance of symptoms.
- C. Screening outcomes:
 - 1) Document participant responses. If all is well, proceed with scheduling the visit and inform participant and/or caregiver regarding applicable visit procedures for on-site screening (e.g., registration screening; temperature checks), requirement to wear masks, and prohibition on bringing guests to the visit.
 - 2) If at least two weeks have passed since leaving an area of widespread transmission or exposure to a known COVID-19 case, and they have no symptoms of a lower respiratory tract infection, then the study visit may occur.
 - 3) If it is less than two weeks since their potential COVID-19 exposure and the participant has no symptoms, the study investigator should assess the potential risks and benefits of continuing the research visit versus rescheduling the visit until after the two-week period, if feasible.
- D. If activity is at CSULB, research staff must decontaminate surfaces/equipment that may have participant contact, wipe down before first participant arrives and between each appointment. It may be difficult to do this in a community setting, sanitizing wipes or hand sanitizer should be available for research staff and participants.
- E. If meeting at CSULB, there must be no overlapping HSR appointments to allow time for decontamination between participants
- F. At CSULB, research staff must wear gloves and face covering/mask when interacting with participants. Face covering/mask (gloves optional) is required if meeting in a community setting.
- G. Provide participants with a face covering/mask if they do not have any. Provide the option of wearing gloves during the interaction.
- H. Wash hands frequently.
- I. All names (or codes) of participants, even anonymous participants (i.e. anonymous for the research study not for COVID-19 contact tracing, for research anonymous participants only the minimum information is to be collected so they can be alerted, if necessary, to COVID-19 related issues, name/phone # or name/email) and research staff must be retained in case of contact tracing. The key to the code allowing the PI to de-identify the data must not be broken. The information collected from research anonymous persons must be destroyed after the contact tracing period has ended (e.g. 4 weeks after appointment).

III. Important Considerations

- A. Remember HSR participants are volunteers. If they choose not to come to campus or meet in a community setting, respect the decision and do not pressure them. Ask when/if they would like to be contacted again.
- B. Do not offer more incentive to come to campus or community setting for HSR activity. This would be

considered non-compliance with the approved IRB protocol.

- C. Determine the mode of transportation for HSR participants, research staff and investigators, especially travelling to sites outside of the CSULB campus. If public transportation will be used to get to an appointment and there is a potential for an increased risk of exposure (e.g. cross border studies) these IN-PERSON activities should stay paused.
- D. Continue to conduct data analysis and research staff meetings remotely.
- E. Research not conducted at CSULB must follow the organization/location specific protocols where participants will report. If not available CSULB requirements will apply.
- F. Do not ask participants who may be at higher risk of COVID-19 infection to come to campus or meet in a community setting. If persons with risk factors are necessary for IN-PERSON interaction, justification is required about why this must happen in phase 2. Risk factors considered to put an individual at higher risk are (not an exhaustive list): <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html>
 - 1) Adults aged 65 and over
 - 2) Asthma
 - 3) Chronic lung disease
 - 4) Diabetes
 - 5) Serious heart condition
 - 6) Immunocompromised
 - 7) Kidney disease requiring dialysis
 - 8) Liver disease