



CALIFORNIA STATE UNIVERSITY, LONG BEACH
OFFICE OF RESEARCH & ECONOMIC DEVELOPMENT (ORED)

DATE: November 4th, 2021

TO: Faculty, Staff and Student Researchers

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SUBJECT: Guide for Projects with In-Person Procedures During COVID-19 Pandemic

[Please refer to CSULB IRB MEMO Phase 3 approved on Nov 4th, 2021](#), "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 are now allowed on a protocol specific basis 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 amendment 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 description of necessary precautions to mitigate the risk, and (3) the protocol should 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 IRB protocol, and the PI has the responsibility to provide protocol specific measures for IRB to make a better-informed decision.

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 considered when applicable:
- 1) A justification for work that cannot be done remotely.
 - 2) A description regarding whether research team members and subjects are fully vaccinated and how to verify their vaccination status.
 - 3) A description of how social/physical distancing will be established during HSR activities/assessments/interventions.
 - 4) If 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 if possible.
 - 5) 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 Additional Considerations "mode of transportation" below). In-Person interactions in a participant's personal home must be well justified.

- 6) 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.
- 7) A description of the use of Personal Protective Equipment (PPE) such as face mask by research staff and HSR participants.
- 8) A description of decontamination of equipment and surfaces that will come into contact with participant.
- 9) An enrollment strategy. Indicate an approximate number of all participants (current or new) to participate in-person interactions. 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 Assent. See "Additional Considerations" below for more guidance.
- 10) Exercise restraint in the number of participants contacted. Only schedule appointments for the minimum number of people necessary for the study to remain sustainable.
- 11) 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 should include symptoms of a COVID-19 infection (e.g., fever, cough, sore throat, shortness of breath, loss of smell/taste, muscle pain, chills, severe headache, diarrhea, or nausea) and exposure history.

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, Consider:

- A. Contact the participant 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.
- 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 being cleared.
- C. If all is well, proceed with scheduling the visit and inform participant regarding applicable visit procedures for on-site screening (e.g., registration screening; temperature checks), requirement to wear masks, etc.
- D. Decontaminate surfaces/equipment that may have participant contact, wipe down sanitizing wipes or hand sanitizer should be available for research staff and participants.
- E. 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.
- F. Provide participants with a face covering/mask if they do not have any. Provide the option of wearing gloves during the interaction.
- G. Wash hands frequently.

H. For anonymous participants only the minimum information (name/phone # or email) is to be collected so they can be reached, only if necessary, for COVID-19 contact tracing purpose. The key to the code allowing the PI to de-identify the data must not be broken. The information collected from research anonymous persons should be promptly destroyed after the contact tracing period has ended.

III. Additional 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 appropriate mode of transportation for HSR participants, research staff and investigators.
- 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, a strong justification is required about why this must happen in phase 3. 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