



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

**DATE:** April 17, 2020  
**TO:** Faculty, Staff and Student Researchers  
**FROM:** Jason Wang, Ph.D., CPIA  
Director, Research Integrity & Compliance

**SUBJECT: IRB Response to COVID-19 Challenges, Phase-2**

The ongoing outbreak of COVID-19 has brought increasing challenges to research ethics oversight. **In order to prevent researchers and human subjects from getting infected by COVID-19 while minimizing COVID-19 impacts on human subject research projects, the following procedures will/shall be taken immediately and remain effective until further notice** based on updates from federal (HHS-OHRP, CDC, etc.), state, local, CSU system or CSULB campus policies.

- I. When Applicable/Feasible, Faculty, Staff and Student Researchers are Advised to Take the Following Actions:
  1. **In general, in-person human subject research activities (including in-person recruitment, interview/focus group, collection of biological samples, etc.) must be halted until further notice from the Director of Research Integrity & Compliance.**
  2. **Appealing Process - If the PI plans to start/continue in-person human subject research activities during this COVID-19 pandemic period, an amendment must be submitted to the CSULB IRB:**
    - A) The amendment must be submitted via IRBNet, with copies of completed IRB Request for Protocol Modifications Form, updated IRB Protocol and Informed Consent Form to specifically address the risk and methods of mitigation regarding COVID-19, and when applicable, updated Permission Letter from the 3<sup>rd</sup> party, etc.
    - B) The amendment must provide a strong justification why the benefits of such in-person interactions outweigh the potential risks of COVID-19 infection.
    - C) The amendment must also specify the methods of mitigating this risk, such as keeping minimal social distance of six feet, using appropriate sanitizer, personal protection equipment (PPE) such as a face cover/mask, following [CDC guidelines on Biosafety Level-2 containment](#), etc.
    - D) **No in-person interactions can start/continue prior to the amendment being approved by the IRB.**

3. Employ less risk, alternative modes of research subject recruitment and data collection, e.g., replacing in-person interviews/focus group discussions with online (Zoom meeting or Skype), phone call, or other virtual procedures. Make sure to take extra precautions to protect confidential information, such as following vendor's policy and terms on privacy protection, assigning pseudonyms to participants, avoiding video chat to show faces unless deemed necessary, disabling online recording, securely encrypting software, etc. **From now on until further notice, such changes to less risk activities are considered minor protocol modifications, thus are allowed to initiate without the need of amendment submission.** The PI should report such changes in future amendment or continuation report.
4. Closely follow the updates from Federal agencies such as [CDC's Guidance](#), [HHS OHRP](#), state and local governments on how to prevent COVID-19 spread in communities, including social distancing, wearing face cover, etc., and on how to protect individual COVID-19 test results and clinical data. Also promptly check the announcements of CSU Chancellor's Office, CSULB President regarding working from home, international or domestic travel related to research, etc.
5. Consult with IT department to get a number of technology tools that may be useful for working and connecting virtually.
6. Promptly report any protocol deviations, unanticipated problems or adverse events to the IRB via submission to IRBNet or email [IRB@csulb.edu](mailto:IRB@csulb.edu).
7. Do not report temporary suspension of research if the suspension of research is not likely to affect the health or well-being of human participants.

## II. IRB Protocol Submission & Review Process:

1. The IRB Office will remain open. Communication in response to PI's inquiries and adverse event reports, etc. and with other campus staff will be primarily conducted via shared email address [IRB@csulb.edu](mailto:IRB@csulb.edu). Face to face consultation services will be minimized. Staff will continue to monitor voicemail to provide a prompt response. Zoom meeting will also be a communication resource.
2. Submissions of new studies, renewals and amendments are processed as usual, and the IRB attempts to retain the same turnaround time. The PIs are recommended to submit as early as possible and to communicate with all stakeholders as often as needed, in order to avoid delaying the project, to meet graduating/funding agency deadlines.
3. The IRB will give priority review to new protocols focused on studying response to COVID-19 crisis to improve individual or public health and safety outcomes, and to urgent modifications intended to better protect the safety of participants and researchers.

4. The board members can attend meetings via Zoom Meeting. If deemed necessary, an ad hoc committee will be assembled to conduct a prompt review of time sensitive protocol submission(s), and the review outcome will be reported at the next full board meeting.

**References:**

[The President's Coronavirus Guidelines for America, 30 Days to Slow the Spread](#)

[HHS OHRP Guidance \(April 8, 2020\) on COVID-19](#)

[HHS OHRP Guidance \(May 14, 2018\): Effects of Disasters on Human Research Protections Programs](#)

[USCDC: Coronavirus Disease 2019 \(COVID-19\)](#)

[US CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 \(COVID-19\)](#)

[PRIM&R Blog COVID-19 and Coronavirus: Updates for the Oversight Community](#)

[PRIM&R Webinar "COVID-19: How HRPPs Are Preparing and Responding, a Discussion Forum" March 23, 2020](#)

[Axiom Mentor: IRB Response to COVID-19](#)

[COGR: Institutional and Agency Responses to COVID-19 and Additional Resources](#)

[CITI Program: Coronavirus \(COVID-19\) Resources](#)

[HRP COVID-19 Update: Guidance for Institutions and Researchers](#)

CSU Office of the Chancellor: Research and Sponsored Programs Update March 27, 2020

C: Simon Kim, Associate Vice President for Research and Sponsored Programs

Ashley Carter, IRB Chair