The outbreak of Novel Coronavirus COVID-19 presents various challenges to research ethics oversight. In order to keep your human subject research projects ongoing while tackling the challenges, the following procedures will/shall be taken and remain effective until further responses triggered by situation changes or required by federal (HHS-OHRP, CDC, etc.), state, local, CSU system or CSULB campus policies, which will be communicated via subsequent notice(s) in the future.

I. 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. 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. The protocol submission and review process and the IRB meeting dates will remain as usual, but expect the turnaround time to be longer.
3. The IRB will give priority review to urgent modifications intended to better protect the safety of participants and researchers.
4. The board members can attend meetings via Zoom Meeting.

II. When Applicable/Feasible, Faculty, Staff and Student Researchers are Advised to Take the Following Actions:

2. Follow the requirements specified in the announcements from CSU Chancellor’s Office and/or CSULB President, avoid or minimize international or domestic travel related to research.
3. Submit applications for new studies, renewals and amendments as early as possible and communicate with all stakeholders as often as needed, in order to avoid delay of
your project, to meet graduating/funding agency deadlines (to prioritize in the event of a closure).

4. If your activity is such that you or your team can work remotely, do so if you determine that the off-site location(s) provides additional social distancing than would be possible on campus. Otherwise, consider engaging virtually with your team. Make sure that you provide your project team with clear remote work instructions and schedules, as applicable. For those who decide to work off campus or connect virtually, IT provides a number of technology tools that may be useful.

5. The PI should contact student researchers to provide them guidance regarding their assignments and schedules. Students should not feel as if they are at risk by coming to campus. Nor will students be penalized in any way if they request accommodations because they or those with whom they are in regular contact are at greater risk.

6. Be reminded of continuous ethical conduct in the research activities. You may need to re-assess risk factors. Pay more and closer attention to vulnerable populations, especially the senior subjects and the immune compromised subjects. If a study cannot be transferred to an online venue, assess the risks (if any) to the enrolled subjects of suspending the study. If the risks are significant, the IRB will consult with the institutional officials and legal counsel to determine the best course of action to ensure that risks to research subjects are minimized. This may require continuing the study procedures face-to-face or it may mean finding resources to support the subjects while the study is suspended.

7. Promptly report any protocol deviations, unanticipated problems or adverse events to the IRB.

8. Consider employing alternative modes of collecting data and/or delaying data collection, e.g., employ online methods for recruitment, replace in person interviews/focus group discussions with online (Zoom meeting or Skype), phone call, or other procedures.

9. In any case, additional precautions must be taken, including temporarily suspending practices in your current research activities that deal with the use of human fluids such as saliva, blood or urine. Those who need to continue these types of activities should follow the CDC guidelines, which include the use of Biosafety Level-2 containment. Such activities must get IRB permission to proceed.

10. In order to avoid delay, if you plan a change to conduct online/phone recruitment, survey or interview, as long as the main study procedures are not affected and the risk/benefits are the same, send an email request for protocol modification with sufficient details to IRB@csulb.edu. The IRB will conduct an administrative review and issue an approval. As the PI, you needs to submit a subsequent official Request for Protocol Modifications via IRBNet at a later time as soon as possible, along with copies of IRB protocol, informed consent form, and other relevant documents, so that these updates will be fully documented in IRBNet.

11. Be reminded that no changes to the research activity can be initiated prior to obtaining the IRB approval.

12. 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.
Reference:

PRIM&R Blog COVID-19 and Coronavirus: Updates for the Oversight Community

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

Axiom Mentor: IRB Response to COVID-19

USCDC: Coronavirus Disease 2019 (COVID-19)

C: Simon Kim, Associate Vice President for Research and Sponsored Programs
   Ashley Carter, IRB Chair