

Date: March 13, 2020

To: Human Subjects researchers

From: Barry Rowan, Director of Research Integrity, Office of Research Integrity

Re: Guidance on in person human subjects research and the COVID-19 outbreak

Protecting the health and well-being of research participants as well as the campus community is our top priority. Given the current COVID-19 coronavirus outbreak, there is potentially a heightened risk of exposure to both participants and researchers. As a result, the risk/benefit ratio for research participation must be reassessed for human subjects research that requires in-person contact with research participants. Immediate steps must be taken to minimize the risk of transmission, and you should prepare for potential disruption to your research activities.

Please disseminate the following information to your research team, if their study is affected. Keep in mind that guidance from federal and state agencies is changing daily. Any restrictions imposed by state and federal agencies that contradict the below guidance must be followed.

Studies for which there is little to no direct benefit to participants

If your study has little or no direct benefit, we ask that you pause all research activities that involve working in-person with research participants. Take immediate steps to assess whether your study procedures can be changed to eliminate working in-person with research participants. To the extent possible, move to electronic communication and data collection. Carefully review your approved IRB study to determine if these methods are already approved. If a study modification is required, please submit a modification via ORahs and clearly indicate that the study is being modified in response to COVID-19 concerns. Our office will do our best to prioritize approving these study modifications.

Studies for which there is direct benefit to participants

If your study has direct benefit to participants, working in-person will be permitted if such contact is an essential component of the research and cannot be replaced by alternative procedures. An example of **direct benefit** would be a study that involves ongoing clinical care of a participant. To the extent possible, move to electronic communication and data collection. If that is not possible, make all attempts to minimize close contact by limiting group size and separating participants when possible (6 feet of separation). Carefully review your approved IRB study to determine if these methods are already approved. If a study modification is required, please submit a modification via ORahs and indicate that the study is being modified in response to COVID-19 concerns.

If these studies are being conducted at a non-UCSB affiliated location, we urge you to work closely with that facility's administrators and to follow their requirements regarding COVID-19. This is especially important if you are working with populations that are immunocompromised or have heightened risk of mortality, as based on [CDC recommendations](#).

There is no regulatory requirement for submitting an IRB Modification to pause studies
Protocols or components of protocols may be paused without a formal modification process. If your study is federally funded, you should contact your program officer if you believe that your research progress will be delayed. Most agencies are in the process of publishing guidance on this topic, and we are posting links on the [Office of Research website](#).

Resuming study activities

All previously approved components of your study may resume once UCSB resumes normal operations or as directed by the Office of Research.

Other considerations

Compensation: For ongoing studies impacted by these changes, we request that you maximize flexibility with respect to participant compensation. Compensation should not be unfairly withheld due to failure to complete the study.

Student projects: Students may be concerned about the impact of these changes on their academic progress. Instructors and/or faculty mentors are advised to make accommodations with affected students that allow them to successfully complete their coursework.

General guidance on research continuity from the Office of Research

Please review the [memo from the Vice Chancellor for Research](#), posted on the [Office of Research Website](#), and take any steps that are appropriate to your research. You should prepare in advance for disruptions to your research activities if access to campus or other research sites are restricted, or your researchers are unable to work.

We understand the concern and uncertainty that our campus may be experiencing surrounding COVID-19, and we recognize that important research may be temporarily disrupted. We are committed to protecting the health of researchers and the public, and to being responsive to the needs of our research community as the situation evolves. In these challenging times, we appreciate and thank everyone for their cooperation and efforts to limit transmission of COVID-19. Please do not hesitate to email hsc@research.ucsb.edu if you have any questions.

Sincerely,

Barry Rowan