CSB/SJU IRB COVID-19 Policies

Due to state, local, and campus safety protocols implemented in response to the COVID-19 pandemic, the CSB/SJU IRB has temporarily revised policies for researchers. The CSB/SJU IRB places the utmost importance on the health and safety of research participants and researchers. Therefore, our COVID-19 policies include revised criteria for approval of in-person research (see below).

Research that can be conducted without in-person contact may be conducted during this time following typical CSB/SJU IRB Policies and Procedures. This includes online surveys or experiments and remote interviews.

If researchers wish to amend previously approved research protocols to replace in-person data collection with online or remote data collection, they should complete and submit IRB Form 4. During this time, the IRB is still accepting new IRB applications. Please contact the IRB at irb@csbsju.edu with any questions.

Revised Criteria for Approval of In-Person Research

Beginning the fall semester 2020, limited face-to-face research may be conducted if the following criteria are met:

1. CSB/SJU campuses are open and faculty, staff, and students are allowed on campus.
2. The direct benefits to research participants outweigh the risks associated with in-person participation.
3. Research protocols allow for mask wearing and social distancing (6 feet or greater separation between individuals) to be implemented. See below for possible exceptions.
4. Researchers must describe how they will mitigate risk of COVID-19 exposure for research participants such that risk is not higher than what they would experience on a typical day. At minimum, this may include a description of how researchers will implement CSB/SJU COVID-19 protocols.

Researcher responsibilities for face-to-face research:

1. Researchers must describe in the IRB form and informed consent how they will follow CSB/SJU COVID-19 protocols to reduce risk of virus transmission. No face-to-face data collection will qualify for an exemption at this time. Researchers should submit IRB Form 1 when proposing face-to-face procedures.
2. Researchers must collect participant names in the event that contact tracing is needed.
   a. Participant names should not be associated with participant data. Researchers should use codes as participant identifiers and should keep a key to the codes in a password-protected or locked document to maintain confidentiality of participants and have access to names if contact tracing becomes necessary.
   b. Researchers will be required to describe the use of codes and coding key in the IRB form and informed consent. Researchers should explain to participants
codes and code keys are necessary for contact tracing and how participant confidentiality will be maintained.

3. Researchers will be required to include possible infection with COVID-19 in the risk sections of the informed consent and IRB form.

For example: “One of the risks of this study is that you might be exposed to COVID-19. (Researcher will describe how they will minimize risk such as disinfecting computers and surfaces, maintaining social distance, appropriate use of masks and other personal protective equipment, etc.)

Face-to-Face Research in Which Social Distancing and/or Mask Wearing Cannot be Maintained

At this time, no face-to-face research should be conducted in which social distancing (6 feet or greater separation between individuals) cannot be maintained unless the IRB determines there is high direct benefit to participants or unless the IRB determines risk for COVID-19 exposure is appropriately mitigated.

Researchers proposing face-to-face research in which social distancing cannot be maintained will have all of the researcher responsibilities expected of face-to-face research with social distancing listed above. Additionally, researchers must:

1. Provide evidence that the direct benefits to research participants outweigh the risks associated with in-person participation. If there are not high direct benefits to participants, researchers must address the points below.
2. Describe why social distancing or masking cannot be maintained for participants and/or describe how a participant or researcher might be at increased risk for COVID-19 exposure (e.g., exercising without a mask or appropriate protective equipment).
3. Describe how the researcher will mitigate risk of COVID-19 exposure for research participants and the researcher such that risk is not higher than what they would experience on a typical day.

CSB/SJU IRB will review research applications for protocols where social distancing and/or mask wearing cannot be maintained; however, approval may be delayed until the IRB consults with the Office of Health and Safety regarding the feasibility of the research. Approval of any face-to-face research will be suspended if the CSB/SJU campuses close to faculty, students, and staff for the health and safety of the community. Additionally, any approved research will be suspended if the proposed risk mitigation is not effective and researchers report participant exposure to COVID-19.

All researchers are required to report adverse events which occur during testing. If a researcher learns a research participant has been exposed to COVID-19 during the research process, they must immediately report the incident to the IRB and to the appropriate CSB/SJU COVID response personnel in order to initiate contact tracing procedures.