

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 June 1 2021 face-to-face research may qualify for Exempt research status if it falls into one of the [Exempt categories](#) and COVID-19 precautions are taken so that the research poses minimal risk. Researchers who believe their research qualifies for Exempt status should complete IRB Form 2.

For any research that does not qualify for Exempt status, researchers should complete IRB Form 1.

Researcher responsibilities for face-to-face research:

1. Researchers must follow COVID-19 policies currently in place at CSBSJU and/or COVID-19 policies in their location of study (whichever is more stringent). Where possible, the researcher must make efforts to encourage the research participants to follow these protocols as well.
2. If the research is being conducted in a location where it is not possible to ascertain the vaccination status of the participants (for example, a crowded public event), the researcher must wear a mask and maintain distance where possible.
3. Researchers must describe in their IRB application 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.
4. Researchers must describe in the IRB form and informed consent how they will follow COVID-19 protocols to reduce risk of virus transmission.
5. Researchers may ask research participants to wear a mask if they are not vaccinated, but may not ask the vaccination status of the research participants.

6. In cases where contact tracing is possible and provides safety benefits for researchers and research participants, researchers should collect participant names to allow for contact tracing if 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 that codes and code keys are necessary for contact tracing and how participant confidentiality will be maintained.
 - c. If contract tracing is not possible and/or does not provide safety benefits to the researchers or research participants, please explain why in your application.
7. 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.)

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.