SFSU Guidance for Human Subjects Research Studies
Updated August 2020

Physical distancing guidelines and the transition to remote modalities as a result of the COVID-19 pandemic have raised many questions for researchers conducting human subject research. Investigators need to evaluate the cost-benefit of continuing their research, particularly the risks associated with conducting research with human subjects. PIs should work to optimize the health of staff, students, faculty, and human subject participants as the primary criteria for conducting research with human subjects. Other criteria might include the potential risks for at-risk individuals or populations for whom the benefit to the recipient *clearly* outweigh the risks of infection. All research should use the Belmont ethical principles of respect for persons, beneficence, and justice:

HHS Guidance: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

Due to the potential risks of COVID-19, San Francisco State University is recommending that all non-critical research studies involving direct contact with human subject to be put on pause. Studies that can maintain telephone contact and remote data collection activities may continue. All non-critical research may resume when the risk of COVID-19 has abated.

NIH Guidance: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-087.html

Is the Human and Animal Protections (HAP) Office open? Is the IRB meeting and reviewing protocols during this time?
The HAP Office and the Institutional Review Board (IRB) are fully functional. We continue to support researchers during this unprecedented time. Our scope of work includes helping investigators navigate through study design and data collection processes and consulting on switching from in-person to 'remote' methods, such as recruiting participants and conducting interviews online. If you have questions, please reach out to HAP by sending an email to protocol@sfsu.edu. Please note that staff is currently working to capacity. This means correspondence falling under our scope of work may require additional time to respond. We appreciate your patience.

I need to modify my existing IRB submission because of the COVID-19 impact. What do I do?
Procedures for modifying an existing IRB have not changed. To modify an existing IRB submission, please see the instructions on the Protocol Modifications page on the HAP website at:

https://research.sfsu.edu/protocol/approved_projects/modify_project.

Modification requests may be submitted to protocol@sfsu.edu. In the email, please include the study number and a brief reason for the revision. HAP staff will follow-up with questions if they are necessary.

May we continue conducting telephone screening of potential subjects?
Yes. Rationale: There is no increased risk to subjects relating to COVID-19. However, if the study did not originally propose telephone or online data collection methods, apply for a protocol modification to register the shift in data collection procedures from in-person to remote modalities.

May we continue to collect data and follow up with subjects by telephone or online audiovisual platforms, such as Zoom, when in-person data collection has been paused?

Yes. Rationale: There is no increased risk to subjects relating to COVID-19. However, if the study did not originally propose telephone or online data collection methods, please apply for a protocol modification to register the shift in data collection procedures from in-person to remote modalities. In the modification, please briefly address privacy risks related to any recordings, as you would any modification of research processes or data collection procedures in an existing protocol.

May we conduct home visits to collect data in studies with no potential direct benefit to participants?
No. Rationale: There is a risk for COVID-19 infection since the occupants of the residence may be self-isolating and home visits would disrupt this process.

Do we need approval from the IRB for communication to study subjects explaining a pause or delay in activities?
No. It is not necessary to submit an amendment if a research study or data collection is paused or delayed.

May I enroll new subjects on existing studies?
Maybe. Rationale: This decision should be made on a study-by-study basis. If the enrollment is completely remote without person-to-person contact then enrollment can continue (e.g., Qualtrics surveys, questionnaires, interviews). For other methods of enrollment, the risk/benefit ratio for subjects may have changed from the time at which the protocol was reviewed and approved. Contact the IRB office (protocol@sfsu.edu) for guidance regarding if the risks and benefits will still be acceptable to the IRB. The IRB will review these on a case-by-case basis.

Should NIH or other sponsors (government, industry, or non-profit) be notified that select protocol activities or in-person visits of a funded research study will be paused?
Yes. Investigators with externally sponsored studies should contact their ORSP Grant Administrator for guidance regarding delays in their projects.

I am listed on an approved protocol at a different institution which has a reliance agreement with SFSU's IRB. If I have questions about how to proceed with my study, who should I contact?
Please contact the IRB that approved the protocol for your study.

Will a pause or change to the method of data collection be considered a protocol violation?
No, but you must inform the study sponsor, if it is a funded study, and the IRB of the modified procedures and what documentation requirements will need to be modified (e.g., changes to questionnaires, surveys, and consent documents, additional risk-benefit analysis, etc.). For more information regarding protocol modifications, please see: https://research.sfsu.edu/protocol/approved_projects/modify_project. Modification requests may be submitted to protocol@sfsu.edu. In the email, please include the study number and the reason for the revision.

May I initiate a new trial that involves a drug or device?
Maybe. Rationale: This will be decided by the IRB on a trial-by-trial basis. The PI should provide a revised risk-benefit statement that explicitly takes the COVID-19 risks into account.

I am a PI of an investigational drug/device trial. Do I need to pause my trial?
Maybe. Rationale: This will be decided by the IRB on a trial-by-trial basis. Trials with investigational treatments, including drugs and devices, that provide potential benefits may be allowed to continue.

However, the investigator should re-evaluate the intervention and conclude that it is truly necessary for the health and well-being of the participant. There should be no new enrollment of participants to the protocol.

Where can I find up-to-date information about COVID-19 for the SFSU Community?
SFSU has created a dedicated website that provides updates and community messages, travel policies and campus restrictions and other advice and resources related to the COVID-19. The website may be found at: https://news.sfsu.edu/covid-19