Research Pause for Certain Human Subjects Research Studies

In the context of this exceptional situation, PIs should be cognizant of the cost-benefit of continuing their research. In considering the nature of critical research with human subjects, PIs should consider the health of our staff, students, faculty and human subjects as the primary criteria for consideration. 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.

Due to the risks of COVID-19, San Diego State University is recommending that all non-critical research pause, including human subjects research studies involving direct subject contact. These studies will be able to maintain telephone contact and remote data collection activities during this pause and 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 IRB Office open?
The IRB Office is currently open. If necessary IRB staff have the availability to work remotely, so IRB operations will be only minimally impacted should things change. We may consider moving all regularly scheduled outreach, training, and possibly the monthly IRB meeting to virtual meetings as much as possible. Check the IRB website regularly for updates.

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. Research Foundation (RF) will be issuing an initial institutional notification to NIH and other sponsors. After the IRB makes specific protocol determinations, they will be providing RF with information concerning those protocols that will require a pause and follow-up communications will be sent by RF for all impacted grants. RF will notify each PI prior to issuing a follow-up notification to a sponsor. All communication to external sponsors must be issued from RF. For questions concerning your NIH- and other government or non-government sponsored studies, please contact your RF grants specialist.

How will the pause in my research impact my grant expenditures?

All study-related activities that are not affected by a pause can continue to be charged as normal. Additionally, there should not be a significant disengagement of the PI or other senior key personnel from affected projects. Please contact your RF grants specialist for questions.

I have a progress report due in the near term and my study is impacted by the pause. Should I include information relating to the pause in my progress report?

Yes. If your study is impacted, a RF grants specialist will provide you with guidance on how and where this should be included in your progress report (i.e., in Section F.2 of a NIH RPPR).

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-083.html

My study may be impacted by the pause, which could lead to delays in completing my study by the end of the project period. What should I do?

Most federal sponsors, including NIH, allow for a one-time no cost extension for 12 months at the end of the project. Please discuss your specific project with your RF grants specialist, who will provide guidance on the options available to you.

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-083.html

Should I notify an industry sponsor if my research activities are paused on my clinical trial?

If the study needs to be paused, the sponsor will need to be notified.

I am a PI of an investigational drug/device trial. Do I need to pause my trial?

No, for purposes of the pause, it is assumed that trials with investigational treatments, including drugs and devices, provide potential benefit and that they should 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.

What is the procedure for pausing a study or certain elements of a study?

You should inform the IRB that you are requesting a pause and indicate the study, or components of the study, that should remain open and provide a short statement of the risks and benefits in light of the COVID-19 pandemic. The IRB will review each response and make a determination.

May we continue to collect data and follow up with subjects by telephone when in-person data collection has been paused?

Yes. **Rationale:** There is no increased risk to subjects relating to COVID-19.

May we continue conducting telephone screening of potential subjects?

Yes. **Rationale:** There is no increased risk to subjects relating to COVID-19.

May we conduct home visits to collect data in studies with no potential direct benefit to participants?

No. **Rationale:** There still may be real or apparent risk due to the fact that the occupants of the residence may be self-isolating and home visits would disrupt this process.

Do we need approval from the IRB for communications to study subjects explaining the pause in activities?

No. It is not necessary to submit a modification.

What if my study doesn't clearly fall into any of these categories?

Indicate what you think is the ethical basis for pausing or continuing the study in your response to the IRB. PI's should re-evaluate whether the protocol is essential to the health and well-being of the participant in order to continue. If you state that as the PI, you believe that there is no increased potential risk from COVID-19 and the study should continue, IRB review will be required before continuing the study.

Will the IRB provide blanket language/approvals?

The wording and language may need to be specific to each study. The guidance is as follows:

Due to the potential or perceived risks of COVID-19, San Diego State University is recommending that all non-critical research pause, including human subjects research studies involving direct subject contact. These studies will be able to maintain telephone contact and remote data collection activities during this pause and may resume when the risk of COVID-19 has abated.

May we enroll new subjects on existing studies?

This should be decided on a study-by-study basis. **Rationale:** The risk/benefit ratio for subjects may have changed from the time at which the protocol was reviewed and approved.

May we enroll new subjects while the IRB is making the determination whether to keep enrollment open?

Yes. **Rationale:** The presumption is that most PI analyses of risks and benefits will be accepted by the IRB. The IRB will review these case-by-case situations very rapidly.

May I initiate a new trial that involves a drug or device?

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 have a subcontract with another site impacted by COVID-19. Do I need to pause as well, if the pause applies to my protocol at SDSU?

Yes. **Rationale:** The same ethical issues relating to the changed risk/benefit ratio that apply to a SDSU site apply elsewhere.

If my study is being conducted off-site, may it continue?

For SDSU research sites in any COVID-19 impacted areas, relating to the changed risk/benefit ratio that apply to a SDSU site apply elsewhere. **Rationale:** The same rationale applies regarding the risks relating to COVID-19.

How will the pause in research impact studies conducted outside of SDSU, both domestic and international?

If a study is deemed to have potential benefit to individual subjects, the study may continue, unless there is concern that the risks from COVID-19 outweigh the potential benefits to subjects. Study-by-study guidance should be obtained from the IRB. Studies that are determined to not provide direct potential benefit to subjects must be paused. Investigators may present a risk/benefit analysis to the IRB that takes into account the prevalence of COVID-19 at the other study sites.

Will the pause or change to the method of data collection be considered a protocol violation?

You should inform the study sponsor and/or the overall PI of the study and the IRB of the modified procedures and what documentation requirements will need to be modified (e.g., changes to questionnaires, surveys and ICF's etc.).

If I am pausing study procedures, do I need to notify the IRB of Record, in addition to responding to the questions from the SDSU IRB?

Yes, as soon as feasible. The regulations allow implementation of a change to study procedures without prospective IRB approval when it is necessary to avoid imminent hazards to subjects. The IRB of Record will need to approve resumption of study procedures.

Continuing Human Subjects Research

I need to modify my existing IRB submission immediately because of the COVID-19 impact. What do I do?
Should you need to modify an existing IRB submission immediately, please contact the SDSU IRB main email at IRB@sdsu.edu. In the email, list the study number and the reason for the revision. Your email will be routed to the IRB Analyst and will be reviewed as soon as possible.

Should I continue to be in contact with study subjects?
Below are some guidelines to consider before interacting with study subjects, please keep the following in mind:

- If possible contact the study subject(s) **before** an appointment or visit to the study site and ask about their current health condition, particularly the symptoms of COVID-19 exposure.
    - Is the participant 65 or over or have underlying health conditions (these persons are at increased risk of COVID-19 infection and should **not** be contacted for in-person procedures)
    - Fever
    - Coughing, sneezing, or difficulty breathing
    - Any other mild symptoms such as headache, runny nose.
    - Recently visited known areas where COVID-19 is present or suspected to be present (currently defined within the last 14 days)
    - **This screening information will not be part of the study record so will not require IRB approval**
- Remind study staff and study subjects of simple measures to lower risk and prevent spread of viruses (not shaking hands, practicing social distancing, etc). Ensure easy access to handwashing facilities, and make sure alcohol-based sanitizers are readily available.
- Limit the size of groups, currently the CDC has recommended that group size of less than 10 and maximum (6 feet or greater) social distancing be observed.
- Follow any guidelines or instructions from the specific facility where study subject interaction would occur. As some research may occur in another state, with another institution, or under the direction of another IRB (as in a reliance agreement situation), this is especially important. Please also pay attention to the Department or College that you are associated with as additional restrictions may be in place.
- Consider the participant population (e.g., are they considered “high risk” for COVID-19?) and the setting in which the interaction would occur.
- Know and understand restrictions and other considerations based on the COVID-19 status of the areas that study subjects may be traveling from.
- Develop possible alternatives to in-person study visits such as using remote technology instead of meeting in person, *e.g* Zoom, FaceTime, or other video chat platforms.

Where can I find up-to-date information about COVID-19 for the SDSU Community?

SDSU has created a dedicated website that provides updates and community messages, school and program information, travel policies and campus restrictions, and other advice and resources related to the COVID-19. The website may be found at:

https://sa.sdsu.edu/student-health-services/coronavirus