COVID-19 In-Person Human Subjects Research Guidance

Below you will find a succinct list of steps for investigators to restart research projects that were halted due to COVID-19. Please be advised, due to the unpredictable and rapidly evolving situation surrounding the COVID-19 pandemic, this information will be updated if/when directives from the University or elsewhere changes.

Steps to Restart Research:

STEP 1: ALL members of your lab must complete COVID-19 Safety Training provided by the Division of Research Safety (DRS) and submit all completion certificates as ONE PDF. The training can be accessed by following this link.

STEP 2. You must determine, per protocol: (i) If face-to-face interaction is necessary, (ii) if you are able to change your data collection methods from in-person to remote, (iii) or if you will only analyze previously collected data/samples moving forward. The next actions you must take regarding each research protocol will depend, in part, on the nature of your work and your data collection methods.

For existing AND new protocols where face-to-face interaction with research subjects is necessary:

1. Submit your COVID-19 safety plan to OPRS. OPRS and DRS will provide feedback throughout the review process.
   Important Note: The plan must be submitted as a separate, stand-alone, document using the DRS safety plan template. Do not submit this plan as modifications to your approved IRB protocol form or informed consent documents.

   At this time, include the following in your safety plan:
   a) A health screening policy, including asking about respiratory symptoms and temperature monitoring. These criteria should apply to lab members as well as participants. Guidance provided can be found here.
   b) Precautions you are taking to protect your research team and study participants from COVID-19 exposure. Standard precautions can be found on the CDC website here, and include: Avoiding close contact with other people, using a mouth and nose cloth face cover, maintaining good personal hygiene (e.g., covering coughs and sneezes, washing hands often for at least 20 seconds), adhering to a strict cleaning and disinfection protocol.
   c) Protocol specific precautions (e.g., collecting blood, placing electrodes on research participants, giving out surveys, DXA, MRI, bio impedance, physical function testing, etc.). Your safety plan must include the specific precautions used when performing each, separate, in-person data collection element.
   d) If research participants are of higher risk for severe illness from COVID-19, such as older adults and people of any age who have serious underlying medical conditions, provide a justification for why this population cannot be excluded and/or why this research cannot be postponed.

2. OPRS will route your safety plan to DRS for review of infection control measures for face-to-face interactions. This review will be based on CDC guidance. You may receive questions from DRS to clarify how particular measures will be mitigated. Once reviewed by both OPRS and DRS, OPRS will provide you with documentation of approval.

For research protocols where you WILL CHANGE your data collection methods from in-person to remote data collection:

1. Submit an amendment to OPRS and revise the protocol to include your new data collection approach. Note: An amendment IS needed because you are CHANGING the data collection procedure.

2. OPRS will process your amendment as usual and, once approved, provide you with an approval notification.