Human Subjects Research Return to Campus Operations

The Office for the Protection of Research Subjects [OPRS] has been following guidance shared by Chancellor Jones; return to campus operations will be in a gradual, disciplined manner that is guided by scientific evidence and the safety and well-being of our staff, faculty members and the greater research community. In turn, the campus is guided by Governor Pritzker's "Restore Illinois" plan, which establishes a five-phase approach to reopening the state's economy throughout the remainder of the pandemic. The plan does not provide any timetable or specific dates, but rather relies on public health data such as new case growth, hospital surge capacity, and testing/tracing ability. These factors will serve as the basis for moving forward, or reverting to an earlier phase of "Restore Illinois" as necessary.

Emergency change requests per COVID-19 with limited approval period

Revised data collection procedures submitted through an Emergency Change request are approved until June 30, 2020. Beginning July 1, 2020, all protocols will return to data collection processes as detailed in the previously approved IRB protocol, subject to updated University guidance on safety practices as described below.

Safety guidance for on campus research activities

In coordination with the Research & Scholarship Return team appointed by the Chancellor, OPRS has been planning a safe return to campus with input from compliance units, departments, and researchers across campus. In order to assist with your return to onsite research when the Governor's directive allows and your unit approves, all investigators will be required to put COVID-19 safety steps in place. The OPRS will work in conjunction with the Division of Research Safety [DRS] to ensure precautionary safety steps are sufficient.

1. Be sure your safety measures include all necessary parts. Use this Laboratory Ramp-Up checklist or any equivalent checklist, if already provided by your unit, to determine if your planning is complete.
2. Write your COVID-19 Safety Procedures and incorporate them into an amended IRB protocol.
3. Be sure that all your returning personnel have:
   a) Taken the COVID-19 Safety training provided by DRS, and
   b) Read and acknowledged your updated COVID-19 Safety Procedures.
4. After completing these steps, inform your Department Head using this Online Verification. This verification confirms that your COVID-19 Safety SOPs are in place. You should complete this step even if you have been previously approved to conduct essential research on campus.

For additional information please visit the COVID-19 Campus Safety webpage and OPRS website; please do not hesitate to contact OPRS with any questions.

Amending data collection procedures from in-person to remote/virtual

If research can be completed remotely, please submit an amendment form and a revised protocol that details the changes in data collection procedures and all human subject interaction.

- Changes from in-person study visits to virtual/remote or phone options must be approved in advance by OPRS as an amendment to the approved study. Exempt studies do NOT need to submit a modification unless the change would alter the review level of the study.
- When submitting, please note in the submission to the IRB that the PI is adding the option to perform research remotely under the COVID-19 revised standards for human subjects research. **Include in the amendment submission that once in-person research is allowed again, the study will return to previously approved procedures.** (Doing so will eliminate the need to submit another modification later when/if the PI wishes to resume normal study activities.)
- OPRS staff reviewers are available to discuss moving a study from face-to-face to remote interactions. Please contact OPRS with any questions: irb@illinois.edu.

In the modification, please consider and address the following:

- Potential impact on subject safety and protections
- Potential privacy and confidentiality concerns
- Data security requirements and obtaining IT security approval
- Consider different remote data collection platforms. Information on Zoom and other virtual resources can be found at: https://oprs.research.illinois.edu/sites/oprs.research.illinois.edu/files/upload/illinoisoprs_virtualresourcesguidance_05192020.pdf
- Consider how informed consent will be obtained. Guidance on verbal and electronic consent can be found at: https://oprs.research.illinois.edu/sites/oprs.research.illinois.edu/files/upload/illinoisoprs_electronicandverbalconsentguidancedocument_05192020.pdf
- Potential impact on scientific integrity and/or benefits of the study
- Plan for how existing subjects will be notified (if their participation will be affected by the modification)
- Note: if the subject population and/or research questions differ from the original protocol, OPRS may request the submission come in as a new protocol application

COVID-19 related research activities

The OPRS is available to assist researchers who are planning COVID-19 related activities. Applicable human subject research will be prioritized. Please include "COVID-19" in the initial or revised protocol application form for easy identification. Please contact the office and staff reviewers can assess the circumstances, determine whether IRB oversight is required, provide advice, and issue determination letters, when necessary.

FDA guidance

The FDA has released the following guidance regarding COVID-19: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency.