

COVID-19 Researcher Guidance

Guidance provided by the University of Illinois at Urbana-Champaign ('Illinois') Office for the Protection of Research Subjects ('OPRS') to protect the safety and health of our community during the COVID-19 outbreak caused by the novel coronavirus, SARS-CoV-2. This is a rapidly changing situation and these guidelines are likely to change as more information becomes available.

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Office for Human Research Protections (OHRP) Guidance for Application of the Human Subjects Protection Regulations to Actions Taken in Response to the COVID-19 Pandemic

April 9, 2020

OHRP has issued “*OHRP Guidance on COVID-19*,” responding to questions received from the research community regarding how the U.S. Department of Health and Human Services (HHS) human subjects protection regulations (45 CFR part 46) apply to actions taken by institutions and investigators in response to the COVID-19 outbreak. OHRP offers guidance on the following topics:

- (i) Public Health and Clinical Activities;
- (ii) Excluded Public Health Surveillance Activities;
- (iii) Legally Required Reporting;
- (iv) Research Changes to Eliminate Apparent Immediate Hazards;
- (v) Proposing and Reviewing Study Changes; and,
- (vi) Whether Suspensions of Research Must be Reported.

The guidance document can be accessed at: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/ohrp-guidance-on-covid-19/index.html>

**Communication from Dr. Susan Martinis, Vice Chancellor for Research and Innovation
March 21, 2020**

As you are undoubtedly aware, late yesterday the Governor issued an [executive order](#) for all individuals living in Illinois to stay at home, effective at 5 p.m. today. The order included an exemption for educational institutions performing “critical research,” provided that social distancing of six feet per person is maintained to the greatest extent possible.

Over the past several weeks, as COVID-19 has escalated across the globe, we have been preparing contingency plans across campus and in the field to ramp-down/shut-down non-essential research activities, in consultation with unit executive officers and facility managers of research infrastructure and equipment. Because of this contingency planning, many of our research investigators have already elected to work remotely and to ramp-down or shut-down non-essential activities on site, particularly when they felt that they could not maintain safe social distancing (6 feet) in their research environments.

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Effective immediately, Saturday, March 21, per the Governor's order and in compliance with [campus guidance](#) from the Chancellor and Provost, all research activities on campus, in the field, and at auxiliary sites must now ramp down to conduct only essential activities. *This means that most campus research labs, facilities, and field sites should cease in-person operations—safely— with consideration during ramp-down of requirements to effectively ramp back up to resume activities when allowed.*

Research and scholarly activities that can be continued remotely are strongly encouraged.

With the requirement that effective social distancing (6 ft) can be maintained, essential research-related activities that require campus and field sites are defined as follows:

- Work that directly relates to preventing, containing, or treating the COVID-19 pandemic
- Work that is directly related to national security
- Research support functions that are required by law
- Work to maintain critical equipment, whether in stand-by mode or operational
- Work to maintain critical biological or material samples and animal populations
- Seasonally dependent agricultural research with critical implications for human and animal health, as well as food security
- Laboratory or field work where discontinuation would result in loss of *significant* data and samples
- Longitudinal or seasonal work where discontinuation would result in loss of *significant* data and samples

Experiments, projects, and studies that do not fit these categories must ramp down immediately and cease. Executive Officers in your unit, school, institute, and college should be consulted for clarifications that are discipline-specific. If further clarification is required, then Institute Directors or Associate Deans of Research can direct inquiries to ovcr@illinois.edu.

Research personnel and their supervisors who are expected to carry out essential research activities should refer to [guidance](#) that was issued on Friday, March 20.

Remote research and scholarly activities are strongly encouraged. Many research and scholarly activities can be continued remotely and should be supported by regular electronic and virtual contact with research groups. Alternate approaches for research personnel working remotely might include data analysis, preparation and review, presentation preparation, proposal development, and grant report preparation. Do not, however, remove university chemicals, equipment, or animals in an attempt to recreate your labs at off-site locations. Research personnel should not use office spaces on campus for activities that may be conducted remotely.

Next Steps for Principal Investigators and Research Personnel:

Immediately: Determine if any of your lab or field activities meet the definition of essential.

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- For Supervisors: Specifically inform members of your research teams if they are considered essential. As per [guidance](#) from the Chancellor and Provost, unit heads of each department that has essential employees who are required to report to a campus or field location must download [this spreadsheet template](#), name the file UNIT/ESSENTIALPERSONNEL/DATE, fill it out and email to ihr@illinois.edu by Wednesday, March 25.
- Use the DRS [ramp-down checklist](#) to shut down your non-essential research operations, so that they may be effectively resumed when allowed.

Access to lab, facilities, and field sites will be available only for personnel who conduct essential related activities or are ramping down to shut-down non-essential research operations.

- Essential work should be staggered so that minimal personnel are present in the research environment at any one time. Social distancing of at least six feet should be maintained.
- Maintain contact information for your students, postdocs, and staff, and review contingency plans and emergency procedures within your group.

OVCRI offices that support research have remote-work plans in place and remain operational. Please know that the OVCRI stands by to support your research activities during these unprecedented times. Your patience, cooperation, flexibility, and dedication are appreciated as we work together through the COVID-19 pandemic.

In-Person Human Subjects Research – Temporary Stoppage

It has been determined by Illinois OVCRI that researchers must:

- **Immediately pause human research activities involving in-person contact with participants.**
During this time:
 - Begin to evaluate research protocols and work with the Institutional Biosafety Committee (IBC) and OPRS to develop safety procedures for personnel and participants, carefully considering work with vulnerable populations and group meetings.
 - Consider developing health screening procedures for both subjects and personnel as updates that should be made to protocols.
 - Use the OPRS Emergency Change of Procedures <https://oprs.research.illinois.edu/oprs-covid-19-response-update> or submit standard amendment forms <https://oprs.research.illinois.edu/forms-templates/forms/amendment-form> making needed updates.

Please review IRB decision chart for research protocols during COVID-19 restrictions – [see page ten](#).

Vulnerable and Special Populations

Though much about COVID-19 remains unknown at this time, according to information released by the [CDC](#), there is sufficient evidence in place to determine certain populations of individuals are at an elevated risk of having serious complications:

- Older adults
- People who have serious chronic medical conditions like:
 - Heart disease
 - Diabetes
 - Lung disease
- People who have compromised immune systems

Additional special populations that require higher levels of safeguards and protections, include those:

- Who are [pregnant](#)
- Who are [incarcerated](#)
- Who are living in [long-term care facilities](#)
- Who are [homeless](#)

Protocol Revisions:

- When ramping down to pause in-person, non-essential research:
 - *More than minimal risk* studies: Inform the IRB that you are pausing research on the project by reaching out to OPRS using IRB@illinois.edu.
 - *No more than minimal risk* studies: Please do not inform the IRB that you are pausing the research based on COVID-19 concerns.

- Immediately move away from in-person data collection procedures when possible (conduct Skype/Zoom visits instead of in-person visits, collect survey responses using an online [survey platform](#) instead of in-person):
 - Submit [Emergency Change of Procedures Form](#) to IRB@illinois.edu.
 - *More than minimal risk* studies: Submit [amendment](#) to IRB@illinois.edu.
 - Consider temporarily updating your [consent document](#) and procedure.
 - Remember the importance of maintaining data security by using a [university-maintained, cloud-based server](#).

- Once the restrictions on in-person human research is lifted by the University, if you make the decision to continue to conduct in-person human subjects research with your participants:
 - Cancel non-essential study visits.

- Add safeguards to your protocol based on [guidance provided by the CDC](#) under supervision of IBC and/or OPRS.
- Conduct a pre-screen by reaching out to study participants in advance of all visits.
- If you are collecting any biological samples, reach out to the [Illinois Division of Research Safety](#) to obtain specialized guidance.

External Restrictions & Closures:

Due to restrictions and closures at external sites, it may be necessary for you to pause your research immediately for an indefinite period of time. It is impossible for us to list every location that is closed or has restrictions in place – but here are a few to be aware of:

1. Schools in Illinois are closed.
Please reach out to [Illinois School University Research Relations](#) to ask about research status in area school districts before continuing your project.
2. The Illinois Department of Corrections (IDOC) has suspended all visits effective March 14, 2020 until further notice - [message](#).
3. Hospitals and long-term care facilities are restricting who may visit their facilities. Carle is currently not allowing visitors.
4. The State of Illinois issued an Executive Order in Response to COVID-19 resulting in immediate restrictions & closures - <https://www2.illinois.gov/Documents/ExecOrders/2020/ExecutiveOrder-2020-10.pdf>

OPRS will attempt to stay current with changing guidance and closings as they become available. If you have any information about closings or restrictions that you wish to share with us, please email us at IRB@illinois.edu so that we can convey that information to the research community.

Emergency Procedure Change Form

It may be necessary to make a temporary change in research procedures to protect the safety and welfare of subjects. To limit researcher burden, OPRS has instituted an emergency process to administratively allow for the changing of procedures through the use of this form without an official amendment or document revision. Upon intake, OPRS will review proposed changes to the procedures and provide approval for a temporary change **until June 1, 2020**. At the end of the approval period, all research procedures must return to their originally approved status unless another Emergency Change of Procedures Form is submitted.

- This form is a *temporary* approval of updates/changes to procedures that are a direct result of the outbreak of COVID-19. Any changes that are intended to be permanent or are not related need to go through the normal amendment process.

- This form is applicable for *no more than minimal risk* studies only. All *more than minimal risk* studies should submit a formal amendment for any changes.
- Do not submit this form for emergency changes in procedures for exempt protocols. Temporary changes in protocol for exempt studies may be implemented at the PI's discretion.
- Unless receiving notification of an office-wide extension, no emergency change procedures forms will be accepted after June 1, 2020.
- Reach out to the OPRS office (via email) to discuss any questions about what is or isn't approvable under this form.
- OPRS suggests the use of university software (e.g., Zoom, Skype, Box) for data collection/storage if transitioning from in-person to online procedures.

Important Note: *If moving interviews to Zoom, meeting organizers must enable password protection. The process to manually modify security settings is available at <https://go.illinois.edu/ZoomSecurity>. Meeting organizers will need to share the password with the meeting participant(s) ahead of the Zoom meeting.*

IRB Meetings

IRB meetings planned for dates later than March 12, 2020 will be held virtually on Zoom. Dates listed on the OPRS website remain the same at this time.

New Submissions

OPRS continues to accept new submissions. There may be a delay in processing times as we work to navigate the very dynamic situation surrounding responses to COVID-19. Please note that though some protocols can, and will, be approved, there may be a necessity to delay the implementation of the research procedures to protect the research community. Although OPRS is currently continuing to process and approve new applications, no face-to-face research interactions are authorized until further notice.

Reliance/Single IRB (sIRB)

OPRS manages a large number of projects that are under oversight of a single IRB. If you need to pause or emergently change a protocol that has a Single IRB of oversight:

- Contact the reviewing IRB to notify them of study pause or to ask what their institutional requirements on protocol revisions are at this time in relation to COVID-19.
- If Illinois is the reviewing IRB, OPRS will:
 - Consult with relying site IRBs as needed before making determinations on emergency changes to protocols
 - Copy the relying site PI and IRB contact on emergency change determination notices

Please note that if the reviewing site requires researchers pause a project, Illinois investigators must follow any and all determinations made by the reviewing IRB. Contact IRB-Reliance@illinois.edu to notify us of study pauses on sIRB projects.

Carle-Illinois Collaborative Research

Illinois investigators should continue to follow guidance received from the Illinois OVCRI on March 16, 2020 and avoid in-person data collection with human participants until at least March 29, 2020.

Per communications received from Carle Health on March 19, 2020:

Stephens Family Clinical Research Institute (SFCRI) staff continue to follow Carle's COVID-19 guidance to limit face-to-face contact and work remotely as much as possible.

UI staff and student access to Carle for research purposes

- Visitors, including unpaid University of Illinois clinical research affiliates, are not allowed in Carle Health facilities at the current time.
- Shared UI/Carle employees may continue access to Carle facilities in accordance with Carle employee guidelines and subject to the discretion of their Carle supervisor.

Human Subjects Research

- The Carle IRB office will continue to function remotely to accept new protocol applications and study documentation, however initiation of new studies will be limited to urgent clinical treatment priorities. Investigators should follow the existing processes for study feasibility and protocols submission. These include working through departmental clinical research coordinators and the Investigator Initiated Research Services office.
- Research participant enrollment has been suspended in most clinical locations. Enrollment of new patients should occur only if participation in the research is essential to a participant's health or the research can be conducted remotely.

Investigator-initiated research services

- The IIRS staff will work off-site and continue to facilitate study design and protocol development through distance collaboration.

Please reach out to your local research staff members for further guidance and clarification.

Education & Outreach

- OPRS is beginning to ramp up education & outreach remotely, including limited presentations over Zoom as well as virtual IRB consultations.
 - To request a Zoom consultation, provide us with a completed request form found [here](#).
 - To request a presentation, please send an email to IRB@illinois.edu.

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Contacting OPRS

- Effective immediately – do not come in-person to the OPRS office location.
 - Phone calls will continue to be answered as usual. However, due to volume of calls we are receiving at this time, to receive a more expeditious response to your inquiry, we strongly recommend sending an email to the general OPRS inbox at IRB@illinois.edu.
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Useful Links:

Illinois Office of the Vice Chancellor for Research & Innovation (OVCRI):

<https://research.illinois.edu/mitigating-impact-covid-19-research-enterprise>

Illinois Office for the Protection of Research Subjects (OPRS): <https://oprs.research.illinois.edu/>

Illinois Division of Research Safety: <https://www.dr.s.illinois.edu/>

University of Illinois at Urbana-Champaign COVID-19 Guidance: <https://covid19.illinois.edu/>

CDC COVID-19 Guidance: <https://www.cdc.gov/coronavirus/2019-ncov/index.html>

Sponsored Programs Administration (SPA): <https://sponsoredprograms.illinois.edu/covid19-sponsoredprojectFAQs>

Illinois COVID-19 Mental Health Resources – <https://oprs.research.illinois.edu/covid-19-mental-health-resources>

NIH / NSF FAQs:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-083.html> (Question 2)

<https://www.nsf.gov/pubs/2020/nsf20053/nsf20053.jsp#q8> (Question 9)

State of Illinois Coronavirus (COVID-19) Response -

<https://www2.illinois.gov/sites/coronavirus/Pages/default.aspx>

State of Illinois COVID-19 Executive Order No. 8 -

<https://www2.illinois.gov/Documents/ExecOrders/2020/ExecutiveOrder-2020-10.pdf>

OCVRI Mass Mail – Sent March 21, 2020 - <https://massmail.illinois.edu/massmail/5295343.html>

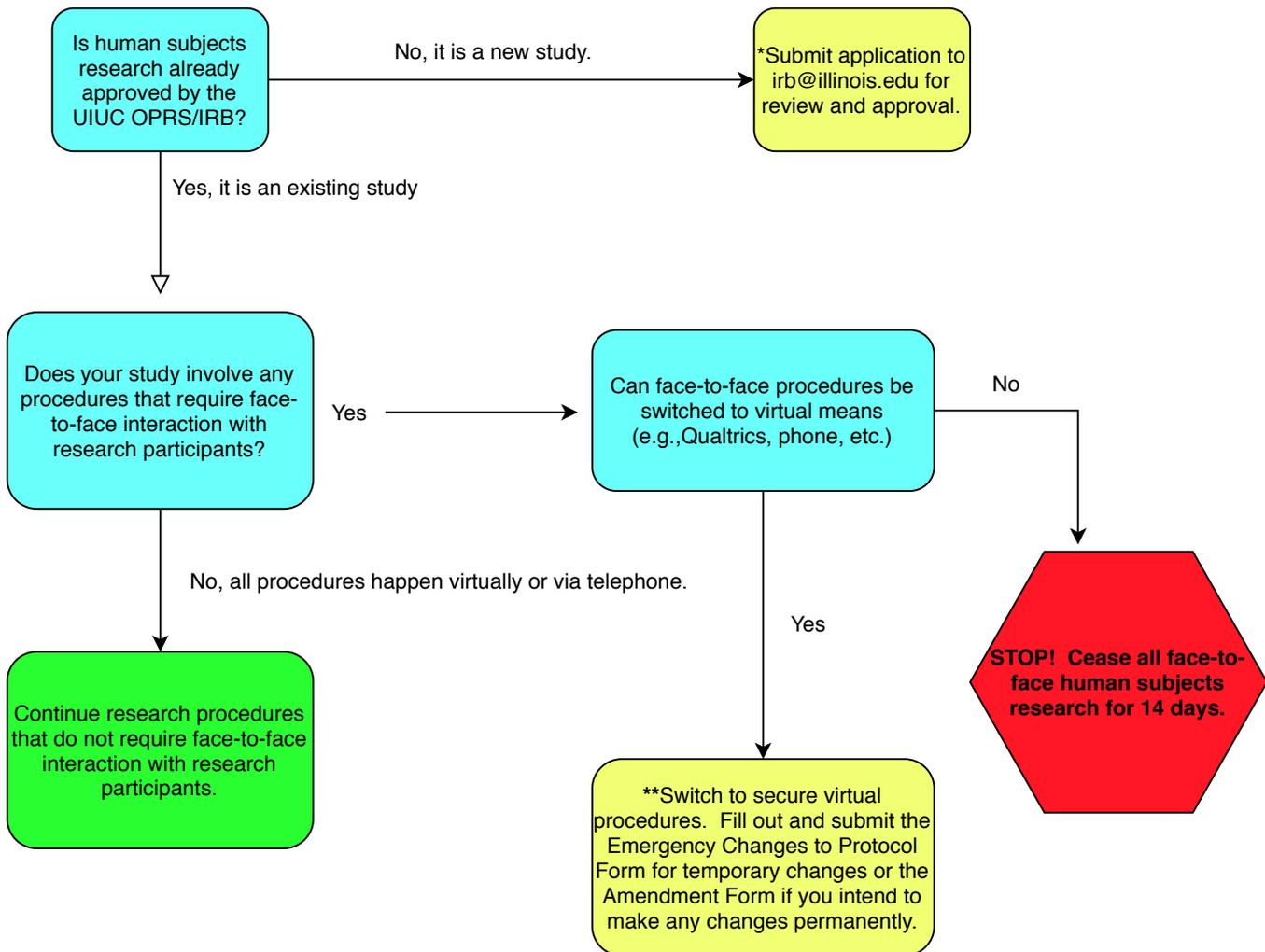
NSF Important Notice No. 146 - <https://www.nsf.gov/pubs/issuances/in146.jsp>

OHRP COVID-19 Guidance - <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/ohrp-guidance-on-covid-19/index.html>

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UIUC OPRS/IRB Decision Chart for Research Protocols During COVID-19 Restrictions

* OPRS is currently continuing to process and approve new applications, however, please note that face-to-face interactions should not take place until further notice.



**** Please visit oprs.research.illinois.edu for full guidance on the Emergency Changes to Procedures form, including restrictions and usage.**

Useful Links:

Illinois Office for the Protection of Research Subjects (OPRS): <https://oprs.research.illinois.edu/>

Illinois Division of Research Safety: <https://www.dr.s.illinois.edu/>

University of Illinois at Urbana-Champaign COVID-19 Guidance: <https://covid19.illinois.edu/>

CDC COVID-19 Guidance: <https://www.cdc.gov/coronavirus/2019-ncov/index.html>

Sponsored Programs Administration (SPA): <https://sponsoredprograms.illinois.edu/covid19-sponsoredprojectFAQs>