

Guidelines to Sustaining Safe, Research-related Activities during the COVID-19 Pandemic

College of Nursing – Center for Nursing Research

Introduction:

While we would prefer not having to implement another ramp-down for research, we must recognize that COVID-19 is a very infectious and complex disease, and we must have a contingency plan in place if circumstances warrant a ramp-down in research activities.

During this pandemic, *all research-related activities that can be conducted remotely should continue in that manner*. By working remotely, we can de-densify campus and other locations and enable research that requires explicit on-campus access to continue. The underlying principle is to help ensure the health and wellness of our participants are at the forefront and that our healthcare systems do not become overwhelmed.

Ramp-ups will be aligned with circumstances observed within the COVID-19 Operations Control Center (COCC) and include evaluating if numbers of infections are moderately decreasing or if impacts are campus-wide.

Scope:

This guidance applies to Penn State CON researchers and students, including those at University Park, the Commonwealth Campuses, and the College of Medicine.

Principles:

1. All research teams should plan for a phased ramp-down that balances safety, community responsibility, and research productivity to best sustain critical research while maintaining the health of individuals. This should be conducted in accordance with University and Commonwealth guidance, on the availability of personnel to safely conduct and support the research, infection trends (local, state, national), local healthcare system capacities, and testing and contact tracing status.
2. All data analysis, computer work not requiring specialized hardware or software, seminars, group meetings, and one-on-one meetings that can be conducted remotely must continue to be remote.
3. All ramp-down plans should have a clear, responsive, and transparent approach to sustaining critical research activities amidst the ramp-down
4. Human subjects research should continue to adhere to the [Revised Standards for Human Subjects Research and related FAQs](#). This guidance applies to human subjects research that is conducted both on-campus and off-campus, and in-person and remote.
5. The plans listed below are reversible for when research ramps-up, again. Ramp-up activity could also adopt re-using plans from the May 2020 ramp-up of research activity.

Ramp-down Plans:

We understand that this will be disruptive to the scholarly activities of you, your students, and your research teams, and we will work to support your efforts. We are not saying that research must stop, but rather that research activities in Penn State facilities must be reduced. We encourage you to take this time to redirect personnel toward research activities that can be completed remotely, such as analyzing data, writing research papers, developing grant proposals, and training your graduate students and postdocs to do so as well. Research group meetings should continue remotely.

- **Reschedule any one-on-one meetings** to remote if possible. If you need to meet one-on-one, you must obtain a critical care activity approval plan. See Decision Chart, below.
- **Critical Care Activity Essential Research-Related Activities Include:**
 - Activity that if discontinued would generate significant data and sample loss.
 - Activity that if discontinued would pose a safety hazard.
 - Activity that maintains critical equipment in facilities and laboratories.

- Activity that maintains critical samples, reagents, and materials.
- COVID-19 related activity that has a timeline for deployment that could address the crisis.
- Activity in support of essential [human subjects research](#) (IRB approval is necessary)
- Clinical trial activity that if discontinued would negatively impact the patient's care.

If you are unsure whether aspects of your research constitute essential activities, please consult with Dr. Hupcey, the Associate Dean for Research & Innovation or Jen Hoffman, Director of Grants & Contracts.

Research in isolation:

Any work in isolation for a long period of time can be difficult for mental health and well-being. We continue to stress that working remotely with best. However, we ask that you are aware of your fellow researchers, faculty, staff and students. If you notice a change of behavior, check in with them, schedule regular zoom meetings, and ensure that they are healthy. If you feel you need help, reach out to a trusted faculty or staff person. Here are additional links:

[Managing Stress](#)

[Student Resources](#)

- **Research involving students:** Be sure to communicate your research activities to your students. Transparency is essential to ensure that students and researchers know what to expect and when. Ensure that they have the technology required to conduct your research work properly (computer, WIFI / Internet connection, telephone service etc.). Ensure that all students have an open channel of communication with you as the researcher. Younger students may not have experience to understand work structure especially when supervision is not physically possible.
 - **Undergraduate Students:** Most of the CON UG students on research grants are wage payroll employees or unpaid volunteers. Ensure that they are aware of PSU guidelines for COVID (washing hands, social distancing, working remotely, etc.). We are fully aware of what to do, but undergraduate students may need to be reminded that these rules also apply while working.
 - **Graduate Students:** Graduate students are required to have approval from their graduate program head to conduct on-campus research. <https://gradschool.psu.edu/covid19/>
- **Suspected or confirmed COVID: Take Immediate Action if Feeling Ill**
If you are ill with symptoms concerning for COVID-19, please contact your physician for advice. If anyone who is carrying out essential research activities displays minor symptoms of illness, including but not limited to cough or fever, that person must stay home, and they should notify their research supervisor as soon as possible so that plans for alternative coverage of those critical activities can be determined. If someone has any doubt about whether they could be ill, they should NOT come to work.
- **Travel considerations Effective March 15, 2020: Revised standards for Human Subjects-Related Research Visits during COVID-19**
In the context of rapidly evolving circumstances regarding COVID-19, and the University's focus on social distancing and the health and well-being of the community, the Office of the Senior Vice President for Research, in consultation with the Vice Dean for Research and Graduate Studies in the College of Medicine, has issued Revised Standards on Human Subjects-Related Research Visits. These Human Subjects Research Revised Standards were first issued March 15 and were revised July 10, 2020. These standards will be revised as appropriate based on new information. [Revised standards on human subjects-related research visits during COVID-19 pandemic](#)

View the Human Subjects Research Revised Standards. In summary, research visits should be performed remotely (e.g., by phone, Zoom, or other means) whenever possible. Please review the revised standards for further information on studies involving face-to-face interaction.

Due to biosafety concerns, and in conjunction with the CDC recommendations for specimen handling from COVID-19 patients, any study that aims to enroll COVID-19 subjects will require a modification to the protocol for IRB approval, which will include a biosafety review. COVID-19 patients cannot be enrolled on existing protocols without this modification approved.

Please visit the [Institutional Review Board \(IRB\) COVID-19 informational page](#).

- **Off Campus research:**

Any research participant involvement off campus will need to be vetted through the Critical Care System. This includes entering in hospitals, nursing homes and prisons. Meetings can be arranged prior to submission of a Critical Care request. Please contact [Jenifer Hoffman](#) for meeting coordination.

Screening Patients or Research Subjects:

Penn State recommends asking research participants to complete a short screening for exposure to COVID-19 or symptoms of illness before they are scheduled for any study-related visits and in-person interactions. This specific screening procedure does not require IRB approval. Penn State Health researchers and staff should also view Penn State Health-specific guidance and screening script.

All research staff and participants must follow the University's personal safety practices:

<https://virusinfo.psu.edu/stay-well>. Participants should be informed in advance of required face masks, social distancing practices, and other safety procedures.

Appropriate screening questions might include the following, which could be modified to fit your participant population and the location of in-person interactions. Any YES answer should be considered sufficient reason to postpone in-person visits.

1. Have you had any of the following symptoms in the past two weeks, even if they were mild? (Note: the incubation period for COVID-19 is believed to be 2 to 14 days. See CDC: Symptoms of Coronavirus)

- Cough
- Shortness of breath
- Fever or chills
- Headache
- Muscle aches that are not attributable to another medical condition or another specific activity
- Throat pain
- New loss of taste or smell
- Fatigue
- Congestion or runny nose
- Nausea or vomiting
- Diarrhea

2. Have you had close contact* with a person who tested positive for or is under investigation for possible COVID-19 in the last two weeks?

Decisions about in-person visits should be especially conservative for people at higher risk per public health recommendations:

- Over 60 years of age
- Underlying health conditions including heart disease, lung disease, or diabetes
- Weakened immune systems

- Pregnant

In addition, Penn State researchers should:

- Practice measures for maintaining health and safety: <https://virusinfo.psu.edu/stay-well>
 - Mandatory physical distancing (at least 6 ft), extensive hand washing, wearing of face masks, and disinfection of areas and equipment used by more than one person
- Researchers at all other campuses should follow Environmental Health and Safety (EHS) guidance for cleaning.

Follow any additional guidelines or instructions from the specific facility (e.g., Penn State College of Medicine, Penn State Health) where participant interaction would occur.

*Close contact is defined by the CDC as (a) being within approx. 6 feet (2 meters) of a COVID-19 case for a prolonged period of time. Close contact can occur while caring for, living with, visiting, or sharing a health care waiting area or room with a COVID-19 case OR (b) having direct contact with infectious secretions of a COVID-19 case (e.g., being coughed on).

- **Non-compliance:**

Any research that is found to be non-compliant with these guidelines, those set by Penn State, the outside entity they are approved to work with, or CDC guidelines will have their research frozen. Their research may resume only after careful consideration by Judith Hupcey, Associate Dean for Research and Innovation, Candy Yekel, Associate Vice President for Research, and Laurie Badzek, Dean, College of Nursing.

- **PSU Guidelines and links regarding COVID-19:**

<https://www.research.psu.edu/covid>

[Revised Standards for Human Subjects Research and related FAQs](#)

[Human subjects research](#)

[Managing Stress](#)

[Student Resources](#)

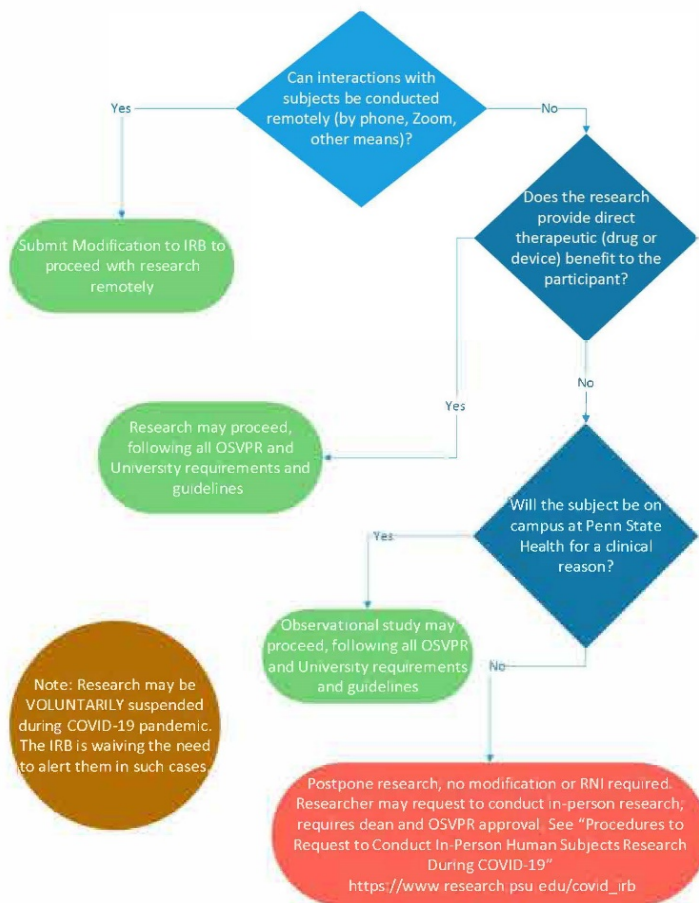
[Graduate School](#)

[Institutional Review Board \(IRB\) COVID-19 informational page](#)

[Personal Safety Practices](#)

[Revised standards on human subjects-related research visits during COVID-19 pandemic](#)

[Mitigating Impacts for Human Research Subjects](#)



All research must follow Penn State’s Phases for Gradually Increasing On-Campus Research-Related Activities (https://www.research.psu.edu/COVID_return_research) and Revised Standards for Human Subjects Research (<https://psu.box.com/v/COVIDResearchVisits>).