



Human Participant Research Resilience Plan

Updated: January 29, 2021

Purpose: The University of Pittsburgh has adopted plans for an adjustable infection prevention and control program in response to the COVID-19 pandemic. The university will shift between three [Operational Postures](#) (high, elevated, and guarded risk) based on local conditions.

Pitt Operating Postures:

<p><u>High-Risk Posture</u> The University is open, but activity is heavily restricted.</p>	<p><u>Elevated Risk Posture</u> Campus activities are at a minimal level, prioritizing activities that have high value but lower risk.</p>	<p><u>Guarded Risk Posture</u> Fewer restrictions are in place, while mitigation measures remain. Activities will account for chronic risk of operating during a pandemic while continuing to prioritize health and safety.</p>
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To safely conduct human subject research during the fluctuating severity of the pandemic, clinical research study operations must be adapted for each risk posture, in accordance with relevant university [Standards and Guidelines](#).

How to Adapt Clinical Research Operations:

1. PIs are required to categorize their research study into one of three tiers and create a written plan to mitigate risk within each operating posture.

Research Tiers:

- **Tier 1** – *Studies with High Direct Benefit to Research Participants or High Public Health Priority:* Tier 1 Studies provide the potential for direct benefit to participants (e.g., therapeutic clinical intervention trials); may lead to serious or immediate harm to research participants if stopped (e.g., some investigational drug or vaccine trials with safety assessments); or investigate diseases with high public health impact (e.g., COVID-19 research).
- **Tier 2** – *Studies with Moderate Direct Benefit to Research Participants:* Protocols that, if stopped, may pose a risk to research participants (e.g., studies in which a research intervention and clinical care are interrelated); studies in high-risk diseases where delays in clinical discovery can adversely impact patient outcomes or slow critical advances for a field of medicine.
- **Tier 3** – *Low Direct Benefit to Research Participants:* Studies such as cohort and natural history studies where delays in data collection have limited impact on participants.

PIs are required to modify study operations in accordance with relevant University-wide standards and guidelines and using the tiered framework below.

General Principles:

- Health and safety of research participants, staff, trainees, students, and faculty are the highest priority.
- Plans must abide by relevant University guidelines ([Standards and Guidelines](#))

Standards and Guidelines: Research studies are required to be compliant with all applicable University [Standards and Guidelines](#) that govern operations during the COVID-19 pandemic. Examples of guidelines that must be considered in plans include:



Healthcare Standards and Guidelines: These rules govern behavior while on Pitt’s campuses and include requirements such as:

- Face coverings are to be worn inside and outside of campus buildings, except when eating or in an enclosed private single-occupancy space such as a personal office.
- Ensure physical distancing of at least six feet.
 - Chairs and desks in shared spaces should be removed or marked as not for use to ensure proper physical distancing.
- Limits on gathering sizes and defaulting to remote gatherings when possible.
 - In High-Risk posture: no indoor gatherings of more than 10 people*
 - In Elevated Risk posture: no indoor gatherings of more than 25 people*
 - In Guarded Risk posture: no indoor gatherings of more than 250 people*

***NOTE: These guidelines are subject to change based on guidance from the Commonwealth of Pennsylvania or Allegheny County.**

Personnel Standards and Guidelines: These rules are established to help reduce the number of people on campus and include such requirements as:

- All personnel should work from home, to the maximum extent possible, for the duration of the COVID-19 pandemic.
- Every attempt should be made to minimize the number of individuals required to be on campus to support authorized activities.
- Faculty and staff who are returning to on-campus work are required to complete a [Mandatory Training](#).
- Supervisors should follow Office of Human Resources guidance when making accommodations for personnel.

Study Operations: PIs must develop plans to adapt study operations for each Pitt operating posture. Principles guiding research operations under each posture include:

Tier	High-Risk Posture	Elevated Risk Posture	Guarded Risk Posture
1	may continue if research can be conducted in a safe manner that protects participants, researchers, and the community	may continue if research can be conducted in a safe manner that protects participants, researchers, and the community	may continue if research can be conducted in a safe manner that protects participants, researchers, and the community
2	must minimize in-person study visits and instead conduct research activities remotely unless activity presents minimal added risk to participants (e.g., research performed during a scheduled clinical encounter)	may continue with enhanced mitigation plans if, by doing so, the research can be conducted in a safe manner that protects participants, researchers, and the community. Research activities are encouraged to be conducted remotely.	may continue if research can be conducted in a safe manner that protects participants, researchers, and the community
3	must suspend in-person study visits and conduct all research activities remotely	may continue with enhanced mitigation plans** if, by doing so, the research can be conducted in a safe manner that protects participants, researchers, and the community. Research activities are encouraged to be conducted remotely	may continue if research can be conducted in a safe manner that protects participants, researchers, and the community

****Update for Tier 3 research (12/14/2020 and 1/21/2021): Enhanced mitigation plans-** Standard [mitigation measures outlined in these Standards and Guidelines](#) should be enhanced to address the following as needed:

- PIs must review and update their COVID-19 symptom checklists for screening research participants and certify that they comply with [current CDC guidance](#).
- The study's research participant quarantine guideline must be reviewed and updated if needed to state that the participant must undergo a 14-day quarantine period or have a negative SARS CoV-2 PCR test 10 days from the most recent exposure to a symptomatic COVID-19 positive individual and be asymptomatic before being scheduled for an in-person appointment.
- The study's plan for participants with COVID-19 infection must ensure that no one is scheduled for an in-person appointment until 10 days after symptom resolution or a positive test, whichever is longer.
- Research with human participants conducted in a community setting, including but not limited to a home, church, community center (e.g., YMCA, Hill House, Kingsley Center) or similar site, must remain suspended at this time.
- Both participants and investigators must wear appropriate PPE (particularly masks) throughout the study visit, as described in their mitigation plan. Close contact should be minimized, as much as possible.
- In-person group research activities on campus must follow the same or more restrictive limits as those specified in University guidelines.

PIs in the schools of the health sciences who seek to resume Tier 3 research studies as of 12/14/2020 need to submit a letter to their Responsibility Center (i.e., department chair, dean, or designee) stating that they have reviewed and, as appropriate, revised their research mitigation plan. Any revised research mitigation plan must also be submitted to their Responsibility Center (i.e., department chair, dean, or designee), to ensure they are available for administrative review. PIs must maintain copies of these letters and plans in their research records. If PIs are unable to implement all of the updated mitigation measures but want to continue Tier 3 research, they may submit an alternative mitigation proposal to their Responsibility Center for review, which may be referred to the Office of the Senior Vice Chancellor for Research or the Office of the Senior Vice Chancellor for Health Sciences, as appropriate. As with all Tier 3 research under each of the three risk postures, any research activities that can be conducted remotely must be conducted remotely.

2. PIs will initiate appropriate changes in study operations when changes in the University's operational postures are announced ([Pitt Operational Postures](#)). Notifications of changes in operational postures will also be sent to the deans of the schools of the health sciences for school-wide distribution.
3. Department chairs are responsible for ensuring that each study has an appropriate risk mitigation plan for each operational posture.