

## Clinical Research Resilience Plan

**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:**

<u>High-Risk Posture</u>	<u>Elevated Risk Posture</u>	<u>Guarded Risk Posture</u>
Meets the minimum standards of Pennsylvania’s red phase. The University is open, but activity is heavily restricted.	Meets the minimum standards of Pennsylvania’s yellow phase. Campus activities are at a minimal level, prioritizing activities that have high value but lower risk.	Meets the minimum standards of Pennsylvania’s green phase. 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.

**To safely conduct clinical 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

**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 in 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 gatherings of more than 10 people
  - In Elevated Risk posture: no gatherings of more than 25 people
  - In Guarded Risk posture: no gatherings of more than 250 people

*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 will be required to complete a [Mandatory Training](#) and complete the university’s [Daily COVID-19 Health Check](#).
- 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 subjects, researchers, and the community	may continue if research can be conducted in a safe manner that protects subjects, researchers, and the community	may continue if research can be conducted in a safe manner that protects subjects, 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 a significant reduction of in person visits. Research activities are encouraged to be conducted remotely	may continue if research can be conducted in a safe manner that protects subjects, researchers, and the community
3	must minimize in person study visits and instead conduct all research activities remotely	may continue with a significant reduction of in person visits. Research activities are encouraged to be conducted remotely	may continue if research can be conducted in a safe manner that protects subjects, researchers, and the community

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.