



## University of Pittsburgh COVID-19 Standards and Guidelines: Research Operations and Governance

### I. Purpose

This document details the University of Pittsburgh's (University) Standards and Guidelines on Research Operations and Governance. These Standards and Guidelines are applied to each of the University's COVID-19 operational postures (High Risk, Elevated Risk and Guarded Risk). More information on these operational postures and their gating criteria can be accessed at the following website: <https://www.coronavirus.pitt.edu/operational-postures>.

The Standards and Guidelines outlined below are subject to change as deemed necessary by the Senior Vice Chancellor for Research recommendation to the University's Senior Leadership Team and approval of the chancellor. Communication about the University's current Standards and Guidelines will be announced and posted on the following website: <https://coronavirus.pitt.edu/>.

The University will always operate in compliance with federal, state and local health standards and restrictions, including [Pennsylvania Department of Health guidance](#). The University reserves the right to implement additional health standards and restrictions that reflect the needs of the University and the health, safety and well-being of its community.

**As conditions and circumstances change, this set of Standards and Guidelines may need to be revised.**

### II. Scope

The Standards and Guidelines below apply to the entire University, including all University members and campuses.

### III. Definitions

- A. Animal facilities:** Spaces for housing, breeding, husbandry and research with animal subjects
- B. Clinical research space:** Space primarily focused on patient care in which clinical faculty carry out research and clinical trials in medical sciences, dental medicine, nursing, rehabilitation sciences and pharmaceutical sciences.

- C. Conduct of Research plan:** A plan for safe conduct of research under COVID-19 conditions for a particular facility and researcher or group of researchers. Plans are developed by a Principal Investigator (PI), facility director or other research leader, and approved by the appropriate dean, director or regional campus president.
- D. Conduct of Research template:** Versions of plans, developed by research modality (clinical; pre-clinical; animal resources; STEM individual lab; STEM shared lab; field research; social sciences healthy human subjects; social science community-based/field research; and studio & performing art or libraries), that prompt PIs to describe and document the modifications they will implement to ensure the safe conduct of their research programs under COVID-19 conditions.
- E. Investigator:** An individual including the PI, project director and any other person, regardless of title or position, who directs or can materially influence, and/or who are responsible for or participate in the design, conduct or reporting of research, including collaborators and consultants.
- F. Laboratory space:** Any enclosed space, ranging from a room or multi-bay open lab, to a floor within a building to a building specially equipped to carry out research. Laboratories may be largely electronic with computers or computer interfaces; wet space designed for work with biological materials; wet space designed for work with chemical reagents; space designed for high voltage work; space designed for physical engineering; space designed for scientific instrumentation like laser spectrometers, electron microscopes, and mass spectrometers. For the purposes of this document, laboratory space includes research support facilities such as machine shops, glass shop, maker spaces and analytical facilities.
- G. Libraries and archival storage spaces:** Space for the digital and physical storage of books, journals, artworks and databases, and for scholars and researchers to access and use such resources.
- H. Multi-PI lab spaces:** Areas in which research is conducted under the direction of multiple PIs and may span more than one room, floor or building. Multi-PI spaces may be shared lab bays, floors or buildings.
- I. Non-clinical human research space:** Space designed for research with human participants who are not patients.
- J. Personal protective equipment (PPE):** please refer to the [Face Coverings, Personal Protective Equipment, and Personal Hygiene Standard and Guideline](#) for the definition of this term.
- K. Principal Investigator or PI:** The individual with the authority to direct work under a specific sponsored project or within a specific clinical trial.

- L. Research cores:** Centralized research resources providing multiple investigators access to instruments, technologies, services, training and expert consultation. They are managed by dedicated faculty or staff and typically recover all or a portion of their costs through user fees or charge back to grants and contracts.
- M. Research Restart Task Force:** One of three tasks forces formed as part of the 2020 Pitt Campus Restart planning effort. The Research Restart Task Force includes six working groups: School of Medicine; Health Sciences; Animal Resources; STEM; Arts, Humanities, Social Science, Business, Law and Libraries; Remote Research; and Logistics.
- N. Research Standards & Clearance Committee:** Established by the Office of the Senior Vice Chancellor for Research, the Committee will ensure that each dean's, institute director's or president's Conduct of Research templates comply with all applicable Standards and Guidelines. The Committee also hears appeals of decisions related to Conduct of Research plans.
- O. Shared resources:** Instrumentation, instrumentation rooms, cold rooms, warm rooms, greenhouses and similar facilities shared by multiple investigators but without the management structure of a research core.
- P. Studio, performance and rehearsal spaces:** Spaces for the creation, storage and display of the creative and performing arts and for the engagement of viewers and audiences with the creative and performing arts.

#### **IV. Conduct of Research Plan Approval**

The sections below outline the University's requirements regarding Conduct of Research plan approval, which applies to all of the University's operational postures.

Deans, institute directors and regional campus presidents are responsible for the conduct of research in their units based on the [University's Health and Research Standards and Guidelines](#) and the [planning templates](#) developed by the Office of the Senior Vice Chancellor for Research and the Research Restart Task Force working groups. Depending upon the range of research modalities in a school (clinical, wet lab, animal research, healthy human subjects, field research, etc.), a dean may need multiple modality-specific templates. The Research Standards & Clearance Committee will ensure that each dean's or president's modality-specific Conduct of Research template(s) comply with all applicable Standards and Guidelines. After review, deans will provide their suite of Conduct of Research templates to chairs and faculty. Faculty will, in the creation of their individual Conduct of Research plans, show how they have applied the appropriate modality-appropriate templates to their specific work process and research spaces. Individual Conduct of Research plans will be reviewed and approved by deans or their designees (e.g., associate dean of research or department chairs).

**All Conduct of Research plans should address how the research will be conducted under the three [University operational postures](#).** Investigators should amend any Conduct of Research plans that were approved as part of the research restart effort in June 2020 to address the three operational postures including any modifications that will be made to the conduct of the research as the University shifts between postures.

Deans, institute directors and regional campus presidents are responsible for ensuring processes are in place for maintain distancing and density limitations for shared resources. They may delegate that responsibility to chairs or division directors.

#### *Research Cores*

In the case of a research core, the facility director develops a core-specific Conduct of Research plan based on the [University's Health and Research Standards and Guidelines](#) and the planning templates developed by the Office of the Senior Vice Chancellor for Research and the Research Restart Task Force working groups. Each of those core facility plans needs to define clearly an approach for scheduling users in order to maintain distancing and density limitations and a process for allocating time/access to address any COVID-driven reductions in the resource.

#### *Multi-PI Spaces*

In the case of multi-PI spaces, the dean controlling the majority footprint designates a lead PI for each space. The lead PI applies a modality-appropriate Conduct of Research plan to the shared space with input from all PIs assigned to that space. The plan must identify an approach for scheduling work in space (shifts, calendaring, etc.) and for resolving conflicts. After consultation with chair(s)/deans of other PIs assigned to the space, the lead dean reviews and approves the plan.

#### *Research Standards & Clearance Committee*

The Research Standards & Clearance Committee will also serve as a forum for PIs to appeal the decisions of their dean, regional campus president or institute director and will only review and approve the Conduct of Research plans of resources or individual labs in cases of special complexity, such as plans for labs that span school boundaries.

Two diagrams outline the review, approval and appeal processes in Appendix A.

### **V. Research Area-Specific Guidelines for the Use of Face Coverings and Personal Protective Equipment**

Personnel in clinical settings, laboratories or other areas with Personal Protective Equipment (PPE) requirements established before the COVID-19 pandemic must maintain all previously established clinic-, lab- or area-specific requirements for PPE as defined in the [University's standards and guidelines on Face Coverings, PPE and Personal Hygiene](#). Face coverings do not protect individuals performing procedures involving risk of splash or spray of chemical or biological agents. Face coverings are not a substitute for any established PPE. In some cases, such as (i.) aerosol-generating clinical research procedures or (ii.) research procedures that cannot be performed safely while maintaining social distancing requirements (i.e. complex

animal surgeries, etc.), enhancements to established PPE requirements may be necessary to protect against COVID-19 infection.

While reducing occupancy of research areas and maintaining six feet distance between personnel should be prioritized in all University operational postures, additional guidance for face coverings and PPE have been developed for the following use cases: (i.) tight spaces or close-proximity work activities; (ii.) interacting with research participants (on or off campus); (iii.) off-campus studies; (iv.) performing arts involving singing, brass instruments or woodwind instruments; and (v.) theater arts. This additional guidance can be found on the [Environmental Health and Safety Office website](#).

For detailed guidance on health and hygiene practices refer to the University's Standards and Guidelines on 1) [Face Coverings, PPE and Personal Hygiene](#), 2) [Shared Spaces](#) and 3) [Cleaning, Disinfection and Hygiene](#).

## **VI. Research Spaces**

Research spaces should be used for their intended purposes while maintaining a safe workplace. Mutual cooperation and strict adherence to safety protocols are essential for maintaining health and safety.

The definitions above classify various research space in ways that reflect the COVID-related risks of using them, and the University's utilization of each class of space will correlate with the University's operational posture at any point in time. When the risk posture changes to a more restrictive posture, the University expects usage to change within 72 hours (inclusive of weekends) or more rapidly if the University's Senior Leadership Team reduces the response time.

Individual spaces within some categories may have significant variations from typical COVID-19 risks for general categories (e.g. a large instrument requiring multiple operators in a constrained space). These particularities will be accounted for in the Conduct of Research plan for such spaces.

Laboratory occupancy guidelines can be found on the [EH&S website](#).

## **VII. Considerations for Shifting Work from On-Campus to a Remote Posture**

The shift of on-campus work to a remote posture may present export control risks, particularly if research duties will be performed by faculty, staff, postdoctoral fellows, or students who are located outside the United States. In such cases, investigators should consult with the Office of Trade Compliance prior to engaging in international research to determine whether there are any export controls risks and develop a plan to manage this risk. Specifically, the review focuses on any research activities that are proposed to take place in [embargoed and sanctioned countries](#), are performed by their citizens or involve [research topics](#) that carry elevated risk and require review.

Researchers should not transport, or make arrangements for shipments of chemicals, biological agents, or other potentially hazardous materials to their homes or other non-laboratory areas. Researchers making physical shipments overseas via express mail or ground shipments must use the University's [ProShip](#) system. This system contains both export controls and hazardous shipping questions and will serve as the clearing house for all items sent to a foreign location.

#### **VIII. Related Authorities, Guidance and Resources**

[Pennsylvania Department of Health COVID-19 guidance](#)

[Pitt Research COVID-19 Research Restart](#) (see the School and Unit Plans expander)

[Process to Reopen Pennsylvania](#)

[University's COVID-19 Operational Postures and Gating Criteria](#)

[University of Pittsburgh COVID-19 Standards and Guidelines: Shared Spaces](#)

[University of Pittsburgh COVID-19 Standards and Guidelines: Face Coverings, PPE and Personal Hygiene](#)

[University of Pittsburgh COVID-19 Standards and Guidelines: Buildings and Occupancy](#)

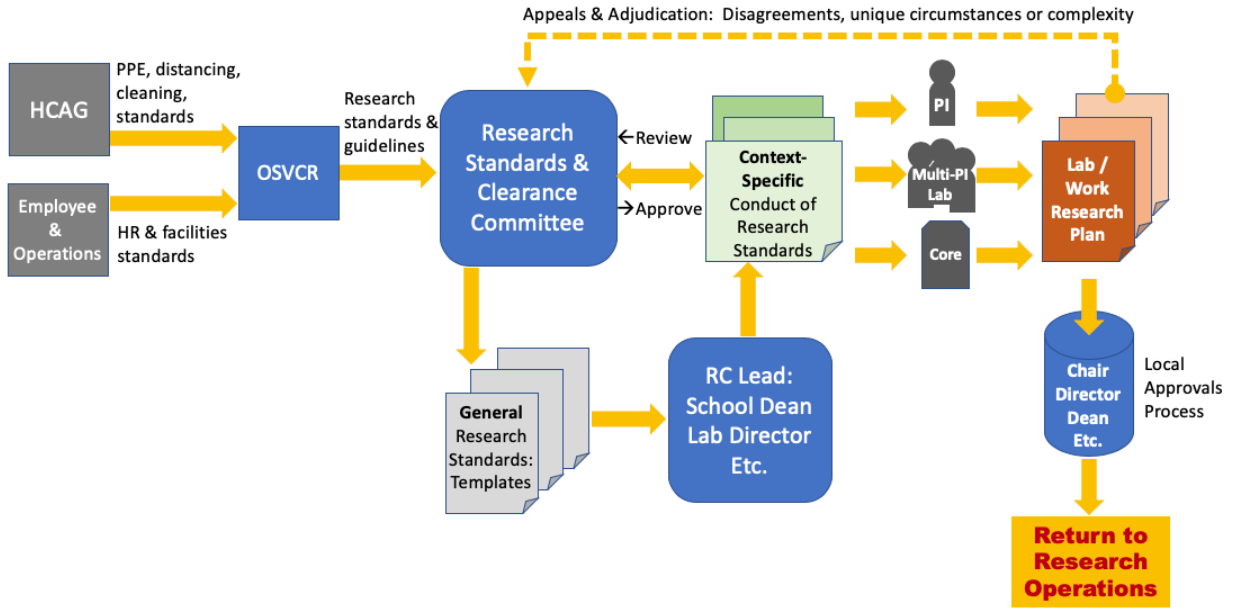
[University of Pittsburgh COVID-19 Standards and Guidelines: Cleaning, Disinfection and Hygiene](#)

#### **IX. Contact Information and Public Accessibility**

This document is posted on the University of Pittsburgh COVID-19 Standards and Guidelines website and can be found at: <https://www.policy.pitt.edu/university-policies-and-procedures/covid-19-standards-and-guidelines>. For questions related to this document, please contact: [researchcovid@pitt.edu](mailto:researchcovid@pitt.edu).

## Appendix A

**Figure 1:** Research Conduct Governance Process: Role of Research Standards & Clearance Committee in Federated Review<sup>1</sup>



<sup>1</sup> HCAG = Healthcare Advisory Group, HR = Human Resources, OSVCR = Office of the Senior Vice Chancellor for Research, PI = Principal Investigator, PPE = personal protective equipment, RC = Responsibility Center

**Figure 2: Research Conduct Governance Process: Detailed Review by “Scale” of Research Operations**

