Penn Nursing Research Resumption Plan

as of 7-6-2020

OVERVIEW

The University of Pennsylvania Research Resumption Plan is guided by the following principles:

- Protect the physical and mental health and safety of the research community, clinical patients and human research subjects, and the community at large.
- Protect careers of early stage researchers.
- Sustain the highest levels of excellence in research,
- Prioritize COVID-19 related research across all fields.

Penn Nursing research resumption on campus aligns with University policy, recommendations from the Centers for Disease Control (CDC), as well as mandates from other relevant Federal agencies, the Commonwealth of Pennsylvania and the City of Philadelphia. Please refer to relevant resources in University of Pennsylvania Research Resumption Strategy Master Plan available at the Vice Provost for Research website (https://research.upenn.edu/). The University of Pennsylvania resumption of research activities will be accomplished in three phases.

- Phase I: Increase of prioritized research, with enforced population density restrictions and telework continued.
- Phase II: Expanded scope of research operations, increasing population with social distancing enforced, telework continued.
- Phase III: Return to full research operations, with new awareness and hygiene practices as the norm and telework utilized where possible.

This table from the University Master Plan provides a summary of the three phases.

Phases and Activities of Research Resumption

Activity	Ramp Down	Phase I	Phase II	Phase III
Population density	<10%	20%	50%	100% new normal
Research type	Essential	Essential + prioritized	Approved	All
Travel (per Penn policy)	None	Approved field work Only	Approved field research only	According to university policy
Telework	Most activity done remotely	All that is possible	All that is possible	When reasonable
Hygiene Masks, etc.	Required	Required CDC recommendations	Required CDC recommendations	According to University guidelines
Students/post docs occupy shared offices	No	No	If social distancing is possible	Yes

Revised June 10,2020

PENN NURSING RESEARCH RESUMPTION PLAN

The Penn Nursing research resumption plan is grounded in the University principles and the 3 phases detailed above. It is important to recognize that while the principles are unwavering, the plans and implementation of these phases at the University and at Penn Nursing should be considered malleable in this fluid COVID-19 environment. The Penn Nursing Plan encompasses this understanding and individual Principal Investigator (PI) plans must include contingencies for changes in COVID-19 spikes, temporary quarantines that require ramp-downs, CDC and state advisories, and Penn advisories. PI plans must anticipate potential short-notice quarantines that would require ramp-downs of activity in labs, floors, and buildings. University restrictions, if any, on travel, meeting size, and use of general spaces will be superimposed on the gradual escalation of research activities on campus.

Framework for Evaluating & Approving Requests for Research Resumption

Research resumption must be phased such that studies currently paused for in-person interventions and/or data collection during the COVID-19 ramp-down will be activated for on-campus and in-community ramp up through Phases I, II, and III. The most stringent resumption occurs in Phase I with progressive additions over Phase II and Phase III.

Criteria for Prioritization:

Continuation without approval

Research that converted to virtual interventions and data-collection and continued through the ramp-down and that requires no presence of research faculty, staff, students, and research participants on campus, in health systems, and community agencies may continue uninterrupted. Faculty are asked to formally notify the Associate Dean for Research & Innovation (ARD) the specific project name, funding source and plan to continue all research activities remotely and without patient/participant contact.

Involvement of human subjects in clinical research (University Master Plan Guidance)

To the extent possible, studies involving human subjects should be done remotely. Those who are not Penn faculty, students or staff will not be admitted to campus for the purposes of research in Phase I. Admission in Phase II can occur only if allowed by the University campus policy. Research resumption requests involving interactions with human subjects must consider the risk to the subjects and the subjects' community, as well as that to the researcher and to the campus. Resumption plans should include social distancing in research space and buildings, as well as disinfectant protocols for any instrumentation, computers, etc. that are contacted by subjects. Potential issues associated with subjects' transportation should be addressed.

Priority during Phase I Resumption

Research activity that was not permitted during the pandemic (ramp-down) will now be considered for resumption. Phase I will include only essential (COVID-19) and prioritized research to maintain less than 20% population density in any given site (research offices, laboratory, clinical and community sites). In all cases maximal virtual and telework is required except for those activities that require direct on-site contact with research participants (humans, animals, specimens). Plans must demonstrate the ability to maintain social distancing and maintain <20% density on-site. The Penn Open Pass, a symptom screening tool, will be introduced on campus in July and is required to access Fagin Hall.

For research involving field work and off-campus interactions, the plan should also address issues associated with travel and with social distancing off-site, along with the risks to participants and

researchers. The PI must include travel plans involving local off-site research as part of the PI resumption plan for Penn Nursing approval. For all other research related travel for field work, Penn Nursing will rely on the Committee on Travel Risk Assessment (CTRA) petition process. (https://global.upenn.edu/travel-guidance/travel-petitions-procedures). A quarantine will be a likely requirement after travel.

Group A: **Faculty research grounded within our partnered Health Systems** (e.g., Penn Medicine*, CHOP, Philadelphia VA, Penn Dental). Ongoing faculty research that was paused during the ramp-down and that requires in-person enrollment of patients in partner health systems, and/or interventions conducted in partner health systems, and/or in-person visits by research participants to the health system. Once approved by Penn Nursing, the clinical site must agree prior to resumption of research activities in their site. Projects considered for resumption in Phase I are:

- Federally-funded
- Industry-sponsored
- Foundation-funded

(*Note: Phase 1 research using Penn Medicine as clinical sites will be batched and sent to Dr. Meager [non-oncology clinical research and Dr. Vonderheide [oncology clinical research] to streamline clinical site agreement for resumption).

Group B: **Faculty research taking place in space managed by another school at Penn**. Ongoing faculty research that was paused during the ramp-down and that requires active on-site research activities, for example, to conduct animal experiments. Once approved by Penn Nursing, the partnered school must agree to resumption of activities in their space. Projects considered for resumption in Phase I are:

- Federally-funded
- Industry-sponsored
- Foundation-funded

Group C: **Faculty multi-site national/international trials and/or non-Penn affiliated health agencies**. Ongoing faculty research that was paused during the ramp-down and that requires in-person enrollment of patients in clinical sites, and/or interventions conducted in clinical sites, and/or in-person visits by research participants to the clinical sites. Once approved by Penn Nursing, the PI is responsible for obtaining and maintaining a record of approval to resume research activities in each clinical site. Projects considered in Phase I are:

- Federally-funded
- Industry-sponsored
- Foundation-funded

Priority during Phase II Resumption

Research that was prioritized in Phase I may expand its scope consistent with the Phase II 50% density requirements with approval by Penn Nursing. Phase I teams must submit a revised PI resumption plan confirming that Phase I implementation was effective in achieving social distancing and safety measures and that social distancing and safety measures can be maintained with increased population density. Existing and/or new research projects that had not yet commenced and were not permitted in the ramp-down or included in phase I resumption will now be considered for resumption. In all cases virtual and distant work is to be maximized except for that which requires direct on-site contact with research participants. Plans must demonstrate the ability to maintain social distancing and the intended limited (50%) density on-site.

Office space can be used if deemed necessary and social distancing and population density requirements can be met. Research resumption plans for accessing office space should be submitted as part of the PI Resumption Plan.

Group A: **Research grounded within our partnered health systems**. (e.g., Penn Medicine*, CHOP, Philadelphia VA, Penn Dental). Once approved by Penn Nursing, the clinical site must agree prior to resumption of research activities in their site.

- Newly-funded faculty research
    - Federally-funded
    - Industry-sponsored
    - Foundation-funded
- K-award research
- Post-doctoral research

(*Note: Phase II research using Penn Medicine as clinical sites will be batched and sent to Dr. Meager [non-oncology clinical research and Dr. Vonderheide [oncology clinical research] to streamline clinical site agreement for resumption). If research involves Penn Medicine Health System, follow directions provided at https://penno365.sharepoint.com/teams/COVID-19/Shared%20Documents/Forms/AllItems.aspx?id=/teams/COVID-19/Shared%20Documents/Covid-Research-Resumption_Clinical-Research-at-Penn-Medicine-Update_6-19-2020_86960.pdf&parent=/teams/COVID-19/Shared%20Documents

Group B: **Research taking place in space managed by another school at Penn.** Once approved by Penn Nursing, the partnered school must agree to resumption of activities in their space.

- Newly-funded faculty research
    - Federally-funded
    - Industry-sponsored
    - Foundation-funded
- Newly-funded K-award research
- Post-doctoral research

Group C: **Research grounded within the community with established community agencies.**

- Ongoing externally funded faculty research that was paused during the ramp-down or new externally funded faculty research. Once approved by Penn Nursing, the community agency must agree prior to resumption of any research activities in their site.
- K-award research. Once approved by Penn Nursing, the community agency must agree prior to resumption of any research activities in their site.
- Post-doctoral research. Once approved by Penn Nursing, the community agency must agree prior to resumption of any research activities in their site.

Research involving Field Work, Off-Campus Activities, and Subject Visits to Campus Buildings

Penn Nursing Research involves field work and off-campus interactions. In this case, the PI resumption plan should also address issues associated with travel and with social distancing off-site, along with the risks to participants and researchers. The PI must include travel plans involving local off-site research as part of the PI resumption plan for Penn Nursing approval. For all other research-related travel for field work, Penn Nursing will rely on the Committee on Travel Risk Assessment (CTRA) petition process. (https://global.upenn.edu/travel-guidance/travel-petitions-procedures). A quarantine will be a likely requirement after travel.

Resumption plans for in-person clinical and non-clinical human subjects' studies and research involving community engagement should provide a rationale for why the research must be conducted at this time and why it cannot be conducted remotely. It should also address plans for minimizing risks to participants and researchers, including ensuring social distancing, hygiene and safety protocols, the ability of study subjects to comply with safety measures and University policies, and the population density in the campus building. For studies that require research subject visit to Fagin Hall, the PI plan must include specific location where subjects will be seen, an appointment process by which the research staff will meet the subject and accompany them to the designated locations, and a scheduling process ensuring population density is less than 50%. PIs are expected to work with Dr. Hoffman (LITNR) and Joe Gomez (Fagin facilities) to develop this part of the plan prior to submission for prioritization.

IRB approval is required prior to commencing research activities taking place in campus buildings that are not part of the health system. This applies to all in-person research, including field work, even if the research was previously determined by the IRB to qualify as exempt. Visitors will be required to abide by Penn's social distancing and safety practices, including use of Penn Open Pass Prioritization could consider the lower risk associated with Penn affiliated subjects, impact on patient care or subjects' well-being, and transportation risk.

Priority during Phase III Resumption (The New Normal)

Plans should include a balance for on-site presence and working remotely/virtually, staggering staff on site, and otherwise minimizing density and exposure.

- All additional faculty research that was not resumed during Phase I and Phase II including internally funded pilot projects.
- Social science research that requires on-site archival work.
- Student research with the appropriate faculty oversight.
- Research related activities such as journal clubs, research team meetings, on-site trainings.

Review & Approval Process

Individual PI plans will be submitted to the ARD who will be responsible for approval according to the Penn Nursing priority criteria. Initially Phase I requests will be solicited and only Phase I requests that are considered complete (inclusive of all components) will be reviewed. Individual PIs and their department chairs will be notified of the decision. If a resumption plan is not approved because of missing data or issues that are judged to be correctable, the PI will have a chance to revise the request. Decisions are final. If the PI appeals the decision the appeal committee will be the ARD and a designated faculty member from each department.

Phase II PI resumption plans are now being considered with an anticipated resumption date of July 13, 2020. PIs are strongly encouraged to continue as much of their research virtually with remote work.

Principal Investigator Research Resumption Application Requirements – Phases I & II

Research that was paused for in-person recruitment, interventions and/or data collection during the ramp-down and seeks to resume in-person activities may NOT resume without approval. Each faculty PI is required to submit a formal application to resume in-person research activities during Phase I. Applications must include the following components:

- a justification to prioritize the activity for Phase I or II implementation.

- a detailed description of on-site (campus, health system, community) activities that include measures for social distancing, identifying PPE requirements, strategies to minimize the number of people in labs or research spaces, and meeting training requirements.
- a detailed description of cleaning protocols for lab related research.
- a risk mitigation plan for local travel and remote activities if required by the project.
- a risk mitigation plan for human subjects' research if the project involves community engagement.
- training requirements for researchers (PPE use, positive case response, deep cleaning protocols).
- a research ramp down process to be implemented in the event of a local spike in infections.
- a floor plan, description, or photographs of where on-site research personnel will be located and coordination with adjacent laboratories or research offices to minimize population density (work with building manager to address this).

Principal Investigators should communicate to collaborators, students, postdocs, and staff that non-compliance with social distancing may be reported confidentially to: https://secure.ethicspoint.com/domain/media/en/gui/22868/index.html .

Opt-In Process for Graduate Student* & Post-doctoral Fellow Involvement in Faculty Research in Phase I & II *For the purposes of this opt-in process graduate students are defined as matriculated PhD students.

Students (undergraduate, masters and doctoral students) and post-doctoral trainees are not expected to participate in research activities until the University enters Phase III.
Goal: To maximize safety of students, staff, faculty, and research participants.

- **Phase I & II - Research Activities that are fully remote/virtual**
  - All students who serve as research assistants may ONLY be involved in faculty research that is remote/virtual with NO presence on campus, health system, or communities and no direct in-person contact with research participants (humans, animals, specimens).
  - Graduate Students & Post-Docs may continue involvement in remote/virtual activities with NO presence on campus, health system, or communities and no direct in-person contact with research participants (humans, animals, specimens).

- **Phase I & II – Research Activities that are prioritized and approved to resume on campus, in health systems, community and require direct contact with human participants, animals, and/or specimens.**
  - Graduate students/Post-docs participation is voluntary. This means the default choice is they do not return to involvement in faculty research.
  - The opt-in process is separate from the faculty mentor to minimize the potential for coercion. If a graduate student/post-doc chooses to opt-in they may submit a request to the Office of Academic Affairs. A plan will be required and the faculty mentor will review the opt-in request and sign-off on it, but the determination will be made in the Office of Academic Affairs.

Process

Coordinating Staff - Janae Lamoureux, Associate Director of Graduate Academic Affairs, will serve as the resource for students and faculty in navigating these issues. She will oversee the opt-in process.

- Student/Post-doc submits a formal request to opt-in during Phases I and II. This request includes:
  - Project title, funding source, faculty PI of the grant.
  - Rationale for choosing to opt-in.

- Proposed activities with specific details for in-person responsibilities (campus, health system, community, laboratory) and why these activities could not be completed remotely.
- Proposed work hours (and safety plan if working non-traditional hours), location, and name of direct supervisor.
- Evidence of completion of COVID-19 training (available in Knowledge Link) and awareness of confidential compliance reporting mechanisms for work situations that do not meet the university and school requirements for social distancing, population density, cleaning and deep cleaning (https://secure.ethicspoint.com/domain/media/en/gui/22868/index.html).
- Commitment to adhere to social distancing, use of appropriate PPE for the proposed activities, and work space that must be below 20% population density.
- A signed statement that they will self-monitor for symptoms and daily temperature and not report to work if they are symptomatic, have a fever, or have known exposure to a COVID-19 person. Further that they will immediately notify their direct supervisor.
- Faculty sign-off is required along with a statement that faculty will work with the students/post-doc. agree with the rationale for opting-in, maximize remote activities whenever possible, and to be flexible to accommodate child care, family needs and so forth.

PENN NURSING PLANS WHICH MUST BE IN PLACE FOR RESEARCH RESUMPTION TO COMMENCE

The research resumption policy and process are synchronized with the overall Penn Nursing plan to address the COVID-19 requirements for the safety of faculty, staff, students, and research subjects. This plan is detailed below. Effective July 6, 2020 to enter Fagin Hall all faculty, staff, students and research subjects must enroll in PennOpen Pass and perform symptoms checks before entering the building.

Plan for research infrastructure support

Until further notice, all staff in the Office of Nursing Research (ONR) will continue to work remotely. This includes all grants management, BECCA, LITNR and innovation. If there is a need to enter Fagin Hall, approval must be sought from the Executive Director of ONR.

Plans to minimize population density and maximize social distancing and compliance; for regular cleaning and deep cleaning for COVID-19 exposure; for symptom monitoring and body temperature surveillance; Plan for addressing COVID-19 positive faculty, staff, students, and research participants

See the following Return to Fagin Plan_5-21-2021 that addresses these items.