

# Penn Nursing Research Resumption Plan

*as of 2-11-2021*

Spring 2021

## **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/>). We are currently in the Spring 2021 Semester Phase which builds on the already enacted earlier phase resumption activities.

- Phase I: Increased 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.
- Fall 2020 Semester Phase: Continued Phase II processes, eliminated explicit population density limits\* but required social distancing, expanded fieldwork and human subjects' studies, and defined exception criteria for meeting space use, and optimized telework. (\*Note: Return to Fagin Plan <https://penno365.sharepoint.com/teams/COVID-19/SitePages/Return-to-Fagin-Plan.aspx>).
- **Spring 2021 Semester Phase:** Continues all Fall 2020 Semester rules and expands undergraduate research activity with required review and approval.
- Phase III (The future): Return to full research operations, with new awareness and hygiene practices as the norm and telework utilized where possible.

## **PENN NURSING RESEARCH RESUMPTION PLAN**

The Penn Nursing research resumption plan is grounded in the University principles and the 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 and new research requiring in-person activities must be approved at Penn Nursing for prioritization.

**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. Human subjects' admission to campus in Spring 2021 Semester Plan can occur only as allowed by the University campus policy, Penn Nursing policy, and approved individual PI plans. 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, and conform with current IRB rules. 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.

***Phase I and Phase II Resumption is now complete.*** If you were approved to resume research during these phases you may continue. However, changes in the scope of your prioritized projects including changes that affect social distancing or incorporate undergraduate students must be updated and submitted for approval prior to implementation. Specifics relevant to Phase I and Phase II can now be found in the appendix of this document.

***PRIORITY DURING SPRING 2021 SEMESTER***

All research that can be done remotely must continue to be done remotely. On campus activities require mandatory mask use, complying with social distance requirements (at least 6 feet), completing Penn Open Pass for access to building (provides guidance for anyone with symptoms, including access to testing and health care providers) and complying with all University, Penn Nursing, and health system rules. Regular compliance sweeps by Environmental Health and Radiation Safety and/or school building administrators will continue to monitor the status of social distancing compliance and provide advice on safe practices. A series of escalating consequences is in place for repeated non-compliance. In Spring 2021, all faculty, students, and staff must be compliant with university testing requirements.

<https://coronavirus.upenn.edu/content/fall-2020-2021-covid-19-testing-approach>. All students must adhere to the Spring 2021 Campus Compact. <https://coronavirus.upenn.edu/content/student-campus-compact>

***Resumption Activities that will be considered:***

- Expanded scope of work of currently approved individual PI resumption plans from previous phases. Any expansion requires the submission of a modification to the ARD. Expanded activities may not take place until formal approval is received.
- Faculty and Post-Doctoral Trainees who have secured new extramural funding for studies that cannot be conducted remotely may follow the procedures outlined in Phase II (see Appendix).
- Faculty with intramural funding to collect preliminary data and who cannot do so remotely, may apply for prioritization by developing and submitting an individual PI plan for approval - also following procedures outlined in Phase II (see Appendix).

- PhD dissertation research that has been approved by the Chair of Graduate Group and the Associate Dean for Academic Programs.

***Graduate Student, Post-doctoral Fellow and Other Researcher Involvement in Research in the Spring Semester Resumption Phase***

Participation in research is not optional for graduate students, post-docs and other researchers. Trainees must be fully engaged, making reasonable progress in their research, whether on campus or at a remote location. All activities that can be done remotely should continue to be done remotely. Full deployment in research does not imply that researchers are required to be on campus continuously. Flexible schedules for research should be encouraged to help accommodate full deployment for those with children/elder needs or to enable social distancing requirements when on campus.

Our primary responsibility to mentor our students and post docs is critical as they navigate through pandemic related challenges. Faculty advisors, department chairs, graduate group chairs and graduate thesis committees should actively engage trainees to ensure that the scope and goals of their research plans are appropriate given the current evolving circumstances. If reasonable progress in research is fundamentally restricted due to pandemic related challenges, consideration should be given to restructuring research directions. Trainees should be supported by academic processes within the departments, graduate groups and schools as they adapt research plans.

***Penn Nursing PhD Student Dissertation Research in the Spring 2021 Semester Resumption Phase*** - The conduct of PhD student dissertation research balances the twin objectives of timely progression and University/School Fall Research Resumption plans. To that end, PhD dissertation research should be designed and conducted remotely, with every effort being made to use remote methods wherever possible. In instances where in-person research is essential to complete the work, the student and dissertation chair will complete and submit a Request for In-Person PhD Dissertation to the School's Graduate Group Chair and Associate Dean for Academic Programs for their review. If approved by the Graduate Group Chair and Associate Dean for Academic Programs, the student and dissertation chair will follow the process for developing an individual PI research plan and submit that for consideration to the Associate Dean for Research and Innovation for review and final decision.

***Undergraduate Student Involvement in Research in the Spring 2021 Semester Resumption Phase***

In Spring, 2021, research activity for Penn Undergraduates in the following categories is allowed in select circumstances, including: research activity required/associated with scholars' programs, independent study, research assistants, work study, or very limited volunteer research experience. Whenever possible, research activities that can be done remotely, should be done remotely.

Undergraduate research participation in in-person research activities with Penn Nursing Faculty may not take place until the PI resumption plan is approved by Penn Nursing. All students (whether Penn Nursing students or students from other schools) should discuss their plan to participate in in-person research activities with their advisor or school advising office prior to the submission of the PI Resumption Plan.

Specific to the integration of undergraduate research for in-person research the following must be addressed in the PI Resumption plan.

- Student attestation that he/she discussed his/her plan to participate in in-person research activities.

- The faculty member/PI must be willing to supervise and provide support for the activity of the student and have the capacity for increased population density, while maintaining social distancing in the research spaces.
- The associated density change must be compliant with the social distancing requirements in the general spaces.
- The faculty member's research resumption plan must be revised to detail the inclusion and activities of the undergraduate student and be reapproved by the ARD.

### ***Co-op Workers and Student Interns***

Co-op workers and interns can now be employed in research positions. These personnel/researchers are often non-Penn students at the undergraduate or graduate level. Both of these categories of personnel are eligible to participate in on campus research only if:

- The activity is approved within a research resumption plan that considers social distance requirements in local general spaces as well as the relevant research spaces.
- The position is managed in Workday.
- The personnel use PennOpen Pass, as required by all Penn employees.
- The personnel are enrolled in the Penn Cares testing program, if they meet the testing criteria of 4hrs+/week on campus.

**REVIEW & APPROVAL PROCESS** – Required for all new in-person research activities, expansion of previously approved activities and involvement of undergraduate students in in-person research activities. Individual PI plans will be submitted to the ARD who will be responsible for approval according to the Penn Nursing priority criteria. 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.

***Principal Investigator Research Resumption Application Requirements*** – In-person activities may NOT resume without approval. Each faculty PI is required to submit a formal application using the Penn Nursing Template to resume in-person research activities. Applications must include the following components:

- a justification to prioritize the activity for 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.
- verification of participation in university testing requirements.
- student commitment to adhere to the Spring 2021 Student Compact
- 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 should be reported confidentially to:

<https://secure.ethicspoint.com/domain/media/en/gui/22868/index.html> .

### **Use of Penn Nursing Meeting Space During Spring 2021 Semester Resumption Plan**

At Penn Nursing, all activity that can be done remotely should be done remotely, including meetings. In person meetings are generally not allowed. Technology such as video conferencing, small room video meetings, including advanced capabilities such as digital white boards, annotation tools, joint screen sharing options, and audio feeds should be leveraged to maximize the effectiveness of virtual meetings and minimize the need for in person meetings.

### **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 him/her to the designated locations, and a scheduling process to ensure social distancing. PIs are expected to work with Dr. Hoffman (LITNR) and Joseph 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. For all research involving human contact (clinical research and human subjects research taking place outside of the clinical encounter), the IRB's 'Required General Precautions for In-Person Engagement with Research Participants' should be followed. Additionally, all research teams are expected to inform subjects of the potential risks of in-person contact related to Covid-19 when interacting in person. Please see IRB website (<https://irb.upenn.edu/>) for more details.

### **Visiting Scholars**

Visiting Scholars and Visiting Faculty who have appointments at Penn are been considered Penn personnel in the Research Resumption Plans. Their participation in on-campus research requires that their activity is included in the Research Resumption plans that are assessed and approved by the appropriate school committee or official. New appointments are restricted by the status of local,

regional or federal COVID requirements, including those regarding travel. These requirements continue to pertain to the Spring 2021 Semester Resumption Phase.

### **Close Contact Research**

Some specialized research activities that are critical to research progress involve procedures or training in which contact is closer than that designated in current guidelines. To the extent possible, alternative approaches to the research should be developed, including modifying the research goals and procedures, as well as utilizing video feeds and remote technology when feasible.

For close contact procedures that are essential and cannot be substituted, exceptions to the social distancing requirement must be included in the research resumption plan, as described below, and receive approval. The PI resumption plan should address the type of activity, location of the research, plan to minimize the number of people in the research space, necessity and duration of close contact, ventilation at the location, personal protective equipment use, cleaning protocols and identify those involved in the procedures. The conditions of the exception should be included in the research resumption plan and approval by Penn Nursing is required.

### **PHASE III RESUMPTION (The Future)**

Phase III resumption is in the future and will move the research endeavors into a new normal. We are not yet in Phase III but in looking forward, 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.

### **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. Entry to Fagin Hall and call campus buildings required the use of Penn Open Pass. See the following Return to Fagin Plan\_9-9-20 that addresses these items.

<https://penno365.sharepoint.com/teams/COVID-19/SitePages/Return-to-Fagin-Plan.aspx>

### **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.

**Appendix: Phase I & Phase II Resumption Plans – These phases are now closed**

***Priority during Phase I Resumption – This phase is now complete.***

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 - This phase is now complete.**

Research that was prioritized in Phase I may expand its scope consistent with the Phase II social distancing 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.

Office space can be used if deemed necessary and 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](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.