

# University of Pennsylvania Research Resumption Strategy Master Plan

*As of October 05, 2020*

## Introduction

The University of Pennsylvania, in response to the COVID-19 pandemic, discontinued all nonessential research on campus on March 16, 2020. We took this extreme measure to protect the health and safety of our community and our region. In order to prepare for a safe, and effective, resumption of research the Vice Provost for Research convened two Research Resumption Task Forces – one focused on laboratory and clinical research and one focused on nonclinical human subject studies and community engagement – and consulted with the Provost’s Council on Research, the Provost’s Senior Management Group, the Office of the General Counsel, the Council of Graduate Group Chairs, the Council of Graduate Deans, and the Graduate Council of Faculties, in addition to medical experts, epidemiologists, and ethicists.

The resulting Research Resumption Plan is guided by the following principles:

- **Minimize risks**, to protect the physical and mental health and safety of the research community, clinical patients, human research subjects, and the community at large.
- **Minimize adverse impact on early stage researchers.**
- **Sustain the highest levels of excellence in research.**
- **Prioritize COVID-19-related research** across all fields.

We have defined three phases for the resumption of research activities on campus:

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

We will resume research on campus in alignment with University policy and guidance, recommendations from the Centers for Disease Control and Prevention, and mandates from other relevant Federal agencies, the Commonwealth of Pennsylvania, and the City of Philadelphia. We must also be prepared to respond to potential cycles in community transmission and local government directives. Consequently, 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.

## Overview of Research Discontinuation

During the phase of research discontinuation, all research activity is halted except research very narrowly defined as essential. Schools developed processes to evaluate and approve this essential research activity, which includes animal care, necessary maintenance of equipment, computer cores, tissue banks and cell lines, and COVID-19-related research. COVID-19-related activities that could have immediate

impact on the pandemic are designated as essential. COVID-19-related activities that are not severely impacted by an 8-10 week delay can be planned and negotiated but not initiated until research resumes.

Penn affiliated research-related travel is not permitted. Buildings are locked. Procurement and deliveries are restricted to essential functions. The expectation is that the population density in lab and research buildings is less than 10% of normal operations. Social distancing, use of appropriate personal protection equipment (PPE), and cleaning protocols are required. When possible, workforces operate in staggered shifts to minimize population density.

### **Research Resumption Phase I**

The goal of Phase I is to enable research to begin with the fewest people possible and continued reliance on teleworking. This phase will allow us to test policies and practices intended to minimize risks, informing subsequent escalations of research activities. Population density in laboratory and research buildings should not exceed 20% of normal operations at any one time. Strategies such as extended hours, shift schedules and weekend activity can be utilized to provide access to more than 20% of the personnel. Penn affiliated business travel will continue to be prohibited until authorized by University policy. The population density increase in clinical research in medicine, dentistry, nursing, and veterinary care will be determined in conjunction with the relevant hospital systems.

Researchers participating in campus activity agree to practice physical distancing, wear face covers, comply with current CDC safety recommendations safety measures and, if requested, agree to testing and contact tracing.

The Schools are responsible for developing, in accordance with these guidelines, plans to manage and oversee research resumption. These plans should include the following components:

- Evaluation and prioritization of the most important research activities.
- Evaluation and oversight of researchers' resumption plans.
- Management of population density across floors, buildings, departments, and core facilities.
- Establishment of policies on meetings and use of general space that align with University requirements.

Criteria to prioritize Phase I research activities could include relevance to the current pandemic, time required to restart functions, number of projects served (for example, facilities and cores), deliverable deadlines, effectiveness of the social distancing plans, and impact on early stage researchers.

School plans should address how to limit crowding in and near elevators and other common spaces, how pedestrian flow can be encouraged in only one direction where possible, how frequent touch points will be regularly cleaned or contact with those touch points limited, and how hand sanitizer will be made readily available. Schools and centers should follow University guidance regarding facial coverings, symptom and/or temperature screening, and reporting COVID-19-positive cases for contact tracing to EHRS for faculty/staff and to Student Health for students. Individuals experiencing symptoms associated with COVID-19 should be instructed to stay home. School plans should be submitted to the Research Compliance Officer in the Office of the Vice Provost for Research.

Participation of graduate students and postdocs is voluntary. As part of the Research Resumption Plan, Schools and graduate groups, in collaboration with the School's Graduate Deans, are responsible for establishing processes for students to opt-in to research. The opt-in process should not involve faculty mentors; trainees should be allowed to decide independently. In addition, we strongly encourage scheduling flexibility in consideration of childcare, elder care, transportation concerns, and safety.

Students and postdocs with concerns about the School-based procedures can contact [provost-ed@upenn.edu](mailto:provost-ed@upenn.edu) for students or [vpr@upenn.edu](mailto:vpr@upenn.edu) for postdocs. Completion of the COVID-19 training module in Knowledgelinek is required.

Principal Investigators are responsible for developing resumption plans for their research effort. Requests for Phase I research resumption should address plans for social distancing, identifying PPE requirements, cleaning protocols for lab-related research, and minimizing the number of people in labs or other research spaces (for example, researchers could operate in shifts or on cyclical schedules). 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 minimizing risks to participants and researchers. Approval for a travel exception from the School Dean is required. Schools should either develop procedures for evaluating travel in conjunction with the Committee on Travel Risk Assessment (CTRA) or rely on the CTRA petition process. For more information on CTRA please visit: <https://global.upenn.edu/travel-guidance/citra>

See the resources beginning on page 5 for managing various components of resumption plan requests. 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>

The use and availability of virology and serology testing might inform prioritization of on-campus activities, when testing becomes available and is approved by the University. Testing could inform decisions to increase population density in specific labs/buildings and when to transition to the next phase of research resumption. Traditional contact tracing is in place; currently EHRS conducts tracing for faculty, post docs and staff on campus and Campus Health conducts tracing for students. This will evolve as Penn Open Pass, a symptom screening tool, is introduced on campus in July.

The impact of the measures described above will be monitored to inform the timing and implementation of Phase II. If social distancing and safety protocols are not maintained, a lab, floor, or building could be closed until remediation measures are in place.

## **Research Resumption Phase II**

An overriding goal of the phased research resumption is to minimize population density on campus while carrying out mission related activities. To this end any activity that can be done remotely should continue to be done off campus. Those engaged in on campus research should continue to conduct aspects of research remotely that do not require University infrastructure.

The goal of Phase II is to expand the scope of research operations, increasing population with social distancing enforced and telework maintained. Population density in laboratory and research buildings should not exceed 50% of normal operations at any one time. Strategies such as extended hours, shift schedules and weekend activity can be utilized to provide access to more than 50% of the personnel.

New research activities and expansions of ongoing research activities require a resumption approval through the School process used in Phase I. To implement Phase II, researchers who resumed in Phase I should provide confirmation to the School designated approval process 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. Completion of the COVID-19 training module in Knowledgelinek is required for all researchers before engaging in campus research.

Office space can be used if deemed necessary and social distancing and population density requirements can be met; however, all activities that can be performed remotely should continue to be performed off

campus. Unused conference and meeting spaces can be used to facilitate social distancing. Research resumption plans for accessing office space should be submitted through the school process for evaluation and approval. Prioritization should consider professional progress of senior post docs or students approaching the workforce and junior faculty, technology requirements, equitable access to equipment and internet connections, and access to confidential data.

For research involving field work and off-campus interactions, issues associated with travel and social distancing off-site, along with the risks to participants as well as researchers will be evaluated. Approval for a travel exception from their School Dean is required. Schools should either develop procedures for evaluating travel in conjunction with the Committee on Travel Risk Assessment (CTRA) or rely on the CTRA petition process. Quarantine will likely be a requirement after travel. For more information on CTRA please visit: <https://global.upenn.edu/travel-guidance/citra>

All clinical and non-clinical human subjects activity that can be performed remotely, should be carried out remotely. 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 subjects 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.

See the resource on Human Subjects Studies for additional guidance.

Select in-person research, including field work and research that was previously determined by the IRB to qualify as exempt, may require prospective IRB approval, please see IRB website for additional information, <https://irb.upenn.edu/>.

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.

Constraints on meeting size and use of general space align with University policy. Staff scheduling flexibility in consideration of childcare, elder care, individual risk factors, etc. is encouraged.

### **Research Resumption Phase III**

The goal of Phase III is to return to full research operations, with new awareness and hygiene practices as the norm. Research returns to pre-closure status, with new steady-state health and safety practices.

## Phases and Activities of Research Resumption

Activity	Ramp Down	Phase I	Phase II	Phase III
Population density	<10%	20%	50%	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	All that is possible	Required CDC recommendations	According to University guidelines
Undergrads	No	No	No	Yes
Grad Students/ Postdocs/shared offices	No	No	If social distancing is possible	Yes

Revised July 2

## **Resources**

Research Resumption Plans

Meeting Social Distancing and Hygiene Requirements

Research Related Travel

Phased Return for Penn Medicine Clinical Research

Resumption of Research in Cores and Other Multiuser Facilities

Research Resumption for Humanities and Social Science Including Human Subjects Studies

Resumption of Animal Research

Resumption of Research with Field Work

Procedures for Suspected or Confirmed COVID-19 Exposures

## Research Resumption Plans

Each School should develop a Research Resumption Plan that addresses social distancing, cleaning protocols, and the need to minimize the number of people in any one space. School plans should address how crowds will be limited in and near elevators and other common spaces, how pedestrian flow will be encouraged in only one direction where possible, and how frequent touch points will be regularly cleaned. Consideration should be given to the installation of physical barriers, where appropriate. Disinfectant supplies should be provided in all bathrooms and elsewhere, as appropriate, to encourage frequent cleaning by users in addition to services provided by housekeeping.

A strategy for symptom and body temperature monitoring should be in place, as well as a process for reporting COVID-19-positive cases for contact tracing. Before being implemented, this strategy should be approved in advance by Human Resources and the General Counsel's Office. Individuals experiencing symptoms associated with COVID-19 should be instructed not to come to campus.

An opt-in process should allow students and postdocs to volunteer independent of the trainees' mentors or supervisors. Completion of the COVID-19 training module in Knowledgelink is required.

The School Research Resumption Plan should outline the framework for evaluating and approving requests for research resumption. Principal Investigators are responsible for developing resumption plans for their research effort. Requests should address:

- Justification to prioritize the activity for Phase Implementation.
- Detailed descriptions of measures for social distancing, identifying PPE requirements, cleaning protocols for lab-related research, minimizing the number of people in the labs or other research spaces, training requirements, and a floor plan.
- Risk mitigation plans for travel and remote activities if the project involves field work
- Risk mitigation plans for nonclinical human subjects research if the project involves community engagement.
- Training requirements for researchers (PPE use, positive case response, deep cleaning protocols).
- Research ramp-down processes to be implemented in the event of a local spike in infections, government mandate, or University requirement.

In cases where research teams intersect in close quarters, Principal Investigators should coordinate plans with those in adjacent laboratories to avoid local population congestion. All work that can be done remotely should be done remotely.

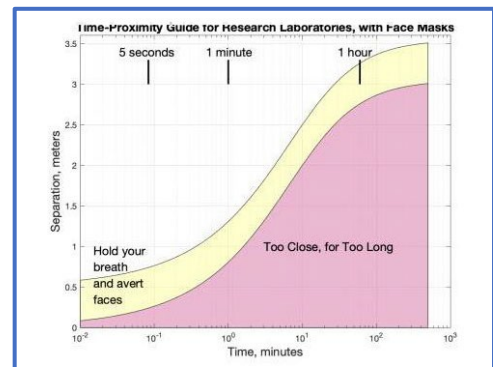
## Meeting Social Distancing and Hygiene Requirements

The first principle of social distancing is that all work that can be done remotely should be done remotely. The population density targets are not to exceed 20% of normal operations in Phase I and 50% in Phase II. The local population density includes housekeeping staff, facilities staff, and animal care staff. There must also be a building-level strategy to manage pedestrian traffic. Strategies such as extended hours, shift schedules and weekend activity can be utilized to provide access to more than 20% of the personnel. Population density increases for clinical research will be determined in conjunction with the relevant hospital system.

Shared offices should not be occupied in Phase I and should be occupied only if meeting social distancing requirements in Phase II. If social distancing and safety protocols are not maintained, labs, floors, and/or buildings could be closed until remediation measures are in place.

According to government recommendations, social distancing requires at least 6 feet of spacing between people during all activities. Floor markings should outline at least 6 feet of distancing around workstations, lab benches, and tables and indicate directions of pedestrian movement. Frequent hand washing should be the culture. Facial coverings should be used at all times and, depending on the type of research, relevant PPE should be employed. See: <https://www.cdc.gov/coronavirus/2019-ncov/php/public-health-recommendations.html>

The dispersion of viral droplets depends on many factors, including droplet size, HVAC performance, and airflow in the space. Therefore the 6-foot separation guideline is a rule of thumb rather than a quantitative metric and should be minimum separation. The figure on the right (courtesy of Christopher Stubbs at Harvard University) illustrates the relationship of time and distance on potential exposure. The goal is to minimize integrated “exposure,” which depends on both separation and duration. The graph assumes that droplet density falls off as  $1/r^2$  and that once separation reaches 3 meters, the room air mixing and HVAC filtering dominate. The normalization of 2 m at 10 minutes is taken from CDC guidance. While the parameters used in the calculation could be debated, the figure illustrates the need to consider time in proximity in designing social distancing plans.



Shifts should be established for break rooms with intervals between those arriving and those leaving. Weather permitting, breaks outdoors should be encouraged.

Scheduling research groups in shifts is an effective strategy to increase access while controlling population density. A typical shift structure has 2 or 3 groups of people working in a lab or research space at different times during the day. Arrival and departure times of the shifts should not overlap. If start and stop times are outside of maximum traffic hours, social distancing while traveling to and from work is increased.

While night shifts are not expected, in some cases extended hours may be necessary to enable social distancing. In those cases the PIs are encouraged to work with their schools and consult the Vice Provost for Research to determine whether the required and appropriate central services are available. Any request for exemption to authorized scheduling hours must be accompanied by detailed plans, which must be approved by the school research resumption team and the Vice Provost for Research. The School must ensure the appropriate safety precautions are available, including the availability of campus security, housekeeping if cleaning protocols are required, and implementation of regular safety practices such that researchers are not alone in the lab.



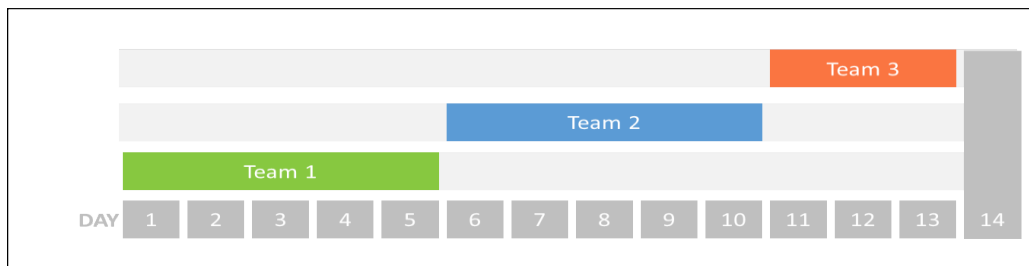
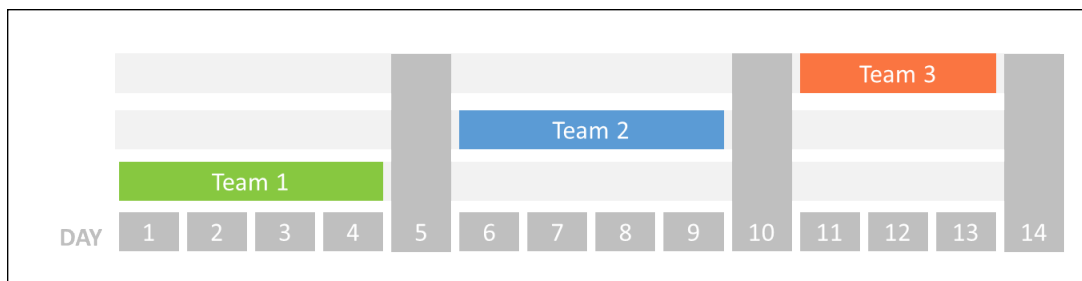
Cleaning protocols should be implemented between shifts. Lab surfaces should be cleaned with products that are EPA-approved for use against the virus that causes COVID-19. A list of products is available [here](#). Follow the manufacturer’s instructions for all cleaning and disinfection products (e.g., concentration, application method and contact time). Clean handles for sinks, DI water systems, cabinets (including acid and flammable liquid), fume hood sashes, lab benches, phones, and freezer and incubator doors. See: [CDC guidelines](#).

Researchers could also be assigned to teams, rather than being randomly scheduled across shifts. In this scenario, if a COVID-19-positive case occurs in one team, quarantine is required only for the members of that team rather than the entire research group.

A strategy of a 4 days in the lab/10 days remote series of shifts has the potential to dramatically reduce local transmission. Though this approach cannot be utilized in all types of research, it is worth considering. Laboratories considering a modified work schedule should consult with local Human Resources in advance for an assessment of whether such schedule could affect employee pay or benefits. Details and modeling are found here: <https://medium.com/@urialonw/adaptive-cyclic-exit-strategies-from-lockdown-to-suppress-covid-19-and-allow-economic-activity-4900a86b37c7>

The underlying principle of the cyclic shift strategy is to separate teams over the time period, for potential carriers to become symptomatic and inhibit cross-team transmission. If there is an asymptomatic transmitter in a team, team members should become symptomatic during the 10-day off remote period. In this case, the team could be screened and isolated as appropriate, and the whole group would not require isolation. Modeling indicates that, if applied to a whole community this strategy would result in a series of decreasing short spikes rather than future waves of infection.

For many types of research, lab members would need to share tasks to perform studies that extend beyond the four-day window. The table illustrates two possible schedules that implement the cyclic shift strategy, one with 10-day remote periods and one with 9-day remote periods.



## Research Related Travel

Penn will categorize travel in four different stages ranging from Suspended Travel to resumption of Normal Travel. During each stage, travel should be authorized by the School and a committee of informed professionals who analyze and mitigate risk to the individual traveler and to the University.

**School-Driven Travel Petition Review.** Schools can create their own committee to review travel petitions in adherence with the University's travel policy and in coordination with the Committee on Travel Risk Assessment. Units that choose to review travel petitions will be expected to understand the risk and evacuation-specific concerns at a given travel destination and the costs associated with providing extraordinary support services.

**Centralized Travel Petition Review.** Schools may opt to refer travel petitions for review and approval by the Committee on Travel Risk Assessment (CTRA), comprised of members from across the University community, specifically Global Support Services, Risk Management, the Office of Research Services (since we anticipate that petitions during the "Restricted Travel" and "Limited Travel" stages will be related to research travel), and Wellness. CTRA will consult with outside and campus experts on specific requests as needed. Penn travelers are asked to submit their applications for travel petitions as early as possible. CTRA will provide updates within one week of receiving applications.

Researchers need to determine whether travel to the proposed destination is authorized based on guidance from the University and will need a travel exception approval from their School Dean. The research plans need to justify the essential nature of the travel, in particular its time sensitive nature and whether the goal of travel might be achieved through other means.

A quarantine will be a likely requirement after travel.

Note that these processes pertain to research field work in the first stages of travel in the University Plan. Travel for conferences and meetings will not be considered until authorized by the University policy.

## Phased Return for Penn Medicine Clinical Research

This document describes PSOM's phased scaling back up for clinical research. It assumes that all faculty and staff will adhere to all Penn Medicine, University, City and State 'Shelter at Home' directives and 'return to work' requirements as they are released, inclusive of testing, use of PPE, temperature checks, and provision of strategies, such as shift work, to ensure continued social distancing practices within the workplace. These requirements will be described in detail in a separate document that will be released by the University and PSOM. It can be expected that this document may change over time, as requirements change. We will communicate these changes to you as they occur.

As PSOM actively plans for a scaling back up we encourage Clinical Research PIs to actively anticipate, discuss and address their staff's concerns and anxieties about returning to work, transportation challenges and child/eldercare responsibilities and proactively plan for how they will be responsive to them within their respective research teams, Divisions and Departments. The timing of the first phase will be determined by the University in partnership with PSOM. At this time we do not anticipate the first phase occurring prior to June 4<sup>th</sup>, 2020. The duration of time between each phase is not known at this time and it will be determined by the University in partnership with PSOM and will be driven by State and City directives.

Return to full clinical research activity will occur in a phased manner that necessitates a categorization and continued prioritization of PSOM's clinical research portfolio. This document describes the categories of clinical research that may resume during each phase of scaling back up. Departments are asked to work with their Clinical Research Faculty to prepare for the phased return by reviewing their current Clinical Research portfolio and generating a summary of which projects fall into which phase of the return using the categories described below. Please email summaries of Non Oncology Clinical Research to [Emma Meagher](#), MD and Oncology summaries to [Bob Vonderheide](#).

Existing prioritization committee structures will remain in place throughout the phased process. It is anticipated that review by the committee will only be required when there is uncertainty in the characterization of a project or when there is a desire by the department or a faculty member to begin a project that has been categorized into a later phase of the return plan. An escalation process will be available in situations where consensus has not been reached or approval to proceed has not been granted and the faculty member or department chair wishes to appeal the decision (fig 1).

Four categories are outlined below.

**Category A:** Research activity that is permitted currently. Please note that during this period the University's 'Shelter at Home' requirements remain in place.

1. Essential Clinical Trials include the following
  - a. New and existing clinical trials that hold the clear prospect of benefit for patients with life threatening or serious conditions
  - b. In-person study visits required to assess safety of patients who were enrolled in clinical trials prior to the pandemic
  - c. New and existing clinical trials where enrollment into the trial is the only available option for the patient
2. COVID Clinical Research
3. As clinical services lines begin the "resurgence" to clinical practice, new and existing clinical trials and non-interventional clinical research where the research activities that must occur on site can occur during inpatient stays and during patients' already scheduled clinical visits and those same research activities

can be executed without requiring that clinical research support staff return to campus and the PI has confirmed that imaging, IDS, CHPS, CVPF and all other research specific services are available to execute the trial.

4. All research activities that can be conducted remotely should continue to be conducted remotely with all staff working remotely. This includes:
  - a. Trials where in person visits can be eliminated or conducted remotely via telemedicine and investigational meds can be delivered to the participants' home
  - b. Non interventional research where research participants do not need to come on campus, research staff can effectively execute the research activities remotely and direct contact with participants is not required.

***Caveats:** PIs and CRCs conducting 'Essential Clinical Trials' and 'COVID Research' work (# 1 and 2 above) are considered essential employees and are required to work on-site and adhere to all requirements to reduce likelihood of infection of staff and research participants. Research staff involved in # 3 above, and monitoring, auditing, training, SIVs, research systems support, financial management, contracting, and regulatory support activities are not permitted to return to campus at this time. Clinical research participants are not permitted on campus unless they are a participant in an approved essential trial, a COVID research study or they are on campus for clinical care reasons as in-patients or outpatients.*

**Category B.** Describes additional clinical research that will be permitted to re-commence and associated staff that will be permitted to return on-site during the **first** phase of re-entry. We do not anticipate this happening prior to June 4<sup>th</sup>, 2020.

1. Investigator initiated existing and new FIH clinical trials of Penn developed products.
2. Existing investigator-initiated NIH or other 'not for profit' funded research that do not meet the criteria defined in category A.
3. Existing investigator-initiated industry-funded research that do not meet the criteria defined in category A.
4. All research activities that can be conducted remotely should continue to be conducted remotely with all staff working remotely. This includes:
  - a. Trials where in-person visits can be eliminated or conducted remotely via telemedicine and investigational meds can be delivered to the participant's home.
  - b. Non-interventional research where research participants do not need to come on campus, research staff can effectively execute the research activities remotely and direct contact with participants is not required.

***Caveats:** Clinical research staff involved in direct contact with research participants enrolled in the research described in 1-3 above will be required to be on site (PIs and CRCs). Research staff involved in #4 above and in training, SIVs, research systems support, financial management, contracting, and regulatory support will continue to work remotely. Penn monitors and auditors would be permitted on site only to review documentation that is not accessible remotely. Industry and CRO monitors will be permitted on site if they meet all standards required for Penn employees.*

**Category C.** Describes additional clinical research that will be permitted to recommence and associated staff will that be permitted to return on-site during the **second** phase of re-entry. We do not know when phase 2 will begin.

1. New investigator-initiated NIH or other 'not for profit' funded research.
2. New investigator-initiated industry-funded trials.
3. New and existing industry-sponsored clinical trials.

4. All research activities that can be conducted remotely should continue to be conducted remotely during the second phase of re-entry. This includes:
  - a. Trials where in person visits can be eliminated or conducted remotely via telemedicine and investigational meds can delivered to the participant's home.
  - b. Non interventional research where research participants do not need to come on campus, research staff can effectively execute the research activities remotely and direct contact with participants is not required.

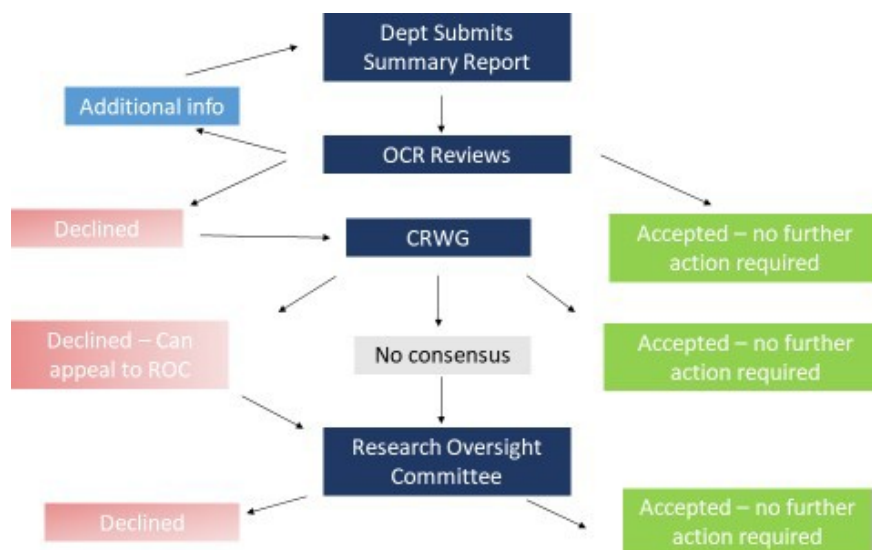
**Caveats:** Staff involved in direct patient contact would be required to be on site (PIs and CRCs). Research staff involved in #4 and in the following activities would continue to work remotely: training, SIVs, research systems support, financial management, contracting, and regulatory support. Penn monitors and auditors would be permitted on site to review documentation that is not accessible remotely. Industry and CRO on-site monitoring, auditing and SIVs will be permitted on-site if they meet all standards required for Penn employees.

**Category D.** Describes additional clinical research that will be permitted to recommence during the **third** phase of re-entry.

1. Everything else that has been conducted remotely during the pandemic and there is a wish to return to campus
  - a. Chart reviews
  - b. Data collection
  - c. Observational studies
  - d. Journal clubs/ lab meetings
  - e. In-person/on-site trainings

**Caveats:** At this stage, all clinical research support staff required for optimal execution of clinical trial work would be required to be on-site. A new normal of staff working full- or part-time remotely would be considered appropriate for PIs, CRCs, and staff who support the execution of research with no required in-person patient, staff, or system interactions.

Fig 1: Prioritization and Escalation process



## Resumption of Research in Core and Other Multiuser Facilities

Resuming research in the many core facilities around campus presents challenges over and above resumption of research in individual PI laboratories. Examples include (i) significant numbers of distinct individuals and/or samples/material interacting with the core facility staff and equipment (as opposed to the relatively closed community within a single PI laboratory); (ii) the small spaces allocated within some core facilities or subsections of these facilities that house animals or equipment; (iii) the requirements for training of users within some facilities that challenge standard approaches to social distancing; and (iv) the fact that core facilities can often serve users from beyond Penn – ranging from external users in the Philadelphia region to users around the nation and world.

**Formulation of facility resumption plans:** Core facilities contemplating the resumption of research in Phase I must develop a *facility resumption plan*, which addresses essential operational issues. For the purposes of formulating these plans, it is useful to largely divide core facilities into two groups (acknowledging that many facilities operate in a hybrid model under normal circumstances): facilities where the research is primarily performed by staff (a ‘staff facility’); and facilities where the research is primarily performed by users, potentially with the training and assistance of the staff (a ‘user facility’).

Regardless of whether a core facility is primarily a staff or a user facility, all core facilities should address at least the following issues:

1. What activities need to be completed *in advance* of safely and effectively resuming work, and what is the timeline for these activities? Although the diverse nature of our core facilities precludes an exhaustive list, examples include understanding timelines for re-ordering animals, supplies, replenishing stocks of PPE that may have been donated previously for medical purposes and may have extended timelines, and updating of policies and procedures to contemplate social distancing and inter-user disinfection protocols.
2. How will social distancing requirements affect staffing and operations? What specific steps will your facility take to comply with these requirements? Will your facility benefit from staggering of shifts or personnel? Will your facility benefit from rearrangement of furniture, equipment, or workflow to enhance social distancing? How will you maintain staff safety monitoring (e.g., a ‘buddy system’) under social distancing requirements?
3. What changes to your current policies and procedures will be necessary to safely re-open your facility? Examples might include a disinfection protocol between shifts or maintaining hygiene associated with sample boxes that pass into or out of your facility.
4. Will you restrict the total number of users within your facility at any time? If so, what are your plans for scheduling and prioritization? Many users of user facilities are individual members of the same research group. Is it desirable to reduce user count during the yellow period by having each group nominate a subset of users authorized for your facility? (There may be negative pedagogical implications both for those nominated and those not nominated).
5. Have you developed a communications plan to transmit new policies and procedures to your user base? How will you enforce your new policies and procedures? What are the ‘penalties’ to users for non-compliance, and how will they be communicated?
6. If permitted and/or required by federal, state, and local law, and Penn policies and guidelines, will your user facility require any special procedure before allowing non-Penn personnel to enter the user facility (e.g., temperature check required to be admitted?) If so, how will this be implemented?

**Additional challenges for user facilities:** In addition to addressing the questions above, user facilities should address additional issues in their resumption plan including:

1. During Phase I, does it make sense to consider transforming your user facility into a staff facility, rather than allowing users to enter and utilize core resources? Workflow, capacity, and pedagogical issues should be considered. This approach may be possible with some facilities and not possible with other facilities; issues specific to your facility should be discussed in your resumption plan.
2. If your facility remains a user facility during Phase I and II, who will your user base be? Will your facility be restricted to internal Penn users only, at least initially? Since most internal Penn users live in Philadelphia or the surrounding regions, is it possible to safely allow external users from our geographical region (this may be particularly important for those facilities that serve the region)? Are wider geographical user bases than our region appropriate?
3. Are there particular areas within your user facility which are at most danger for contamination, and if so, what procedures will be taken to minimize risk? Examples might include gowning areas, repositories for safety glasses, computer keyboards, microscopes, and overall traffic flow through the facility.
4. Will you restrict the total number of users within your facility at any time? If so, what are your plans for scheduling and prioritization? Many users of user facilities are individual members of the same research group. Is it desirable to reduce user count during the yellow period by having each group nominate a subset of users authorized for your facility? (There may be negative pedagogical implications both for those nominated and those not nominated).
5. Have you developed a communications plan to transmit new policies and procedures to your user base? How will you enforce your new policies and procedures? What are the ‘penalties’ to users for non-compliance, and how will they be communicated?

**Approval and oversight of core facility plans:** Resumption plans for Core and other Multi-User Facilities require approval through the process developed by the schools. For core facilities that do not clearly fit into one School or Department, or in cases of disagreement as to which entity should have oversight, the Office of the Vice Provost for Research can act in an oversight capacity.

## **Research Resumption for Humanities and Social Science Including Human Subjects Studies**

Research in the humanities and the social sciences relies on campus infrastructure as well as resources in various communities such as archives, libraries, museums, and private collections, in addition to engaging human subjects. For colleagues in the humanities and social sciences using laboratories, animal research, computer labs, maker spaces, etc., guidance is provided in other sections of this document. The range of activities in humanities and social science research is broad including focus groups, observational studies, canvassing and surveying, individual and group interviews, accessing library resources and archives, laboratory and field experiments. Much research can inherently transition to remote work supported by telework technology and adjusted services in many of the libraries and has done so.

### Campus Office Use

One time visits to offices to retrieve materials are encouraged. In cases where research materials cannot be removed to a remote location, a proposal for office research should be submitted to the school. Office space can be used if deemed necessary and social distancing and population density requirements can be maintained; however, all activities that can be conducted remotely should continue to be done off campus. Unused conference and meeting spaces can be used to facilitate social distancing. Research resumption plans for accessing office space should be submitted through the school process for evaluation and approval.

Prioritization should consider professional progress of senior post docs or students approaching the workforce and junior faculty, technology requirements, inequity issues such as equipment and internet access, access to confidential data etc.

To facilitate research during these constraints the Library offers Faculty Express book-delivery service <https://guides.library.upenn.edu/resourcesharing/facex> (with home delivery rather than office delivery), and Books by Mail <https://guides.library.upenn.edu/circulation/vpbooksbymail> for those not eligible for Faculty Express (lifting the restriction on sending books no further than 75 miles from Penn's campus..

### Engaging subjects on campus and in the field

All clinical and non-clinical human subject activity that can be performed remotely, should be carried out remotely. Those who are not Penn faculty, students or staff will not be admitted to campus for the purposes of research in Phase I. All Penn researchers are expected to follow their associated School's research resumption plan. 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 subjects and researchers, including ensuring social distancing, hygiene and safety protocols, the ability of study subjects to comply with safety measures and University policies, any external risks to subjects, subjects' transportation options, the ability of subjects to comply with safety measures and University policy, a plan to inform subjects of Covid-19 related risks, and potential requirements for reconsenting subjects. If the research involved field work is performed in an outside facility, the researcher must obtain a letter of support from the facility authorizing research to resume at that facility in light of Covid. Once school authorization has been obtained, select in-person research, including field work and research that was previously determined by the IRB to qualify as exempt, may require prospective IRB approval, please see IRB website for additional information, <https://irb.upenn.edu/>.



It is expected that all researchers follow the ‘Required General Precautions for In-Person Engagement with Research Participants’ that was released by the IRB. Additionally, all research teams interacting in person with participants are expected to inform subjects of the potential risks of in-person contact related to COVID-19. The IRB has developed an informational sheet that can be utilized if the study consent form does not address this information. The above information can be accessed on the IRB website, <https://irb.upenn.edu/>.

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.

Constraints on meeting size and use of general space align with University policy.

#### Field work and other off campus activities

Much research takes place in communities defined by geography, history, poverty, etc.; therefore, field work is often a component of research in these disciplines. General guidance for the resumption of field work is provided in the section on Field Work. In many cases research activities in the social sciences cross regulatory jurisdictional boundaries, for example when working in other countries, or across state borders. Interactions in the local region involve city and state requirements and sometimes specific institutional requirements such as those associated with schools or prisons. Issues such as privacy and data management can arise as well. In this climate of rapidly evolving regulatory requirements, resumption plans should address compliance with relevant regulations.

The resumption plans of those studies associated with delivering care, such as some in medicine, nursing, and dentistry, will be done in conjunction with the relevant hospital or care giving facility.

## **Resumption of Animal Research**

1. Social-distancing plans.
  - a. PIs will be required to develop their own social-distancing plan for their lab.
  - b. These distancing plans need to be coordinated with other laboratories and ULAR in the same floor, suite, or other defined “functional unit” of laboratory/vivarium space.
  - c. Individual lab plans and “functional-unit” plans need to be approved through the Research Resumption process in the school.
  - d. Working groups should be developed to facilitate communication among the labs and ULAR.
  - e. Only work that needs to be done in wet space should be conducted; all work that can be done remotely should still be done remotely.
2. Use of shared ULAR vivarium space needs to be coordinated with laboratory staff and ULAR.
  - a. ULAR will post [electronically and on vivarium rooms] scheduled ACT (animal care technician) work [cage changes etc.]. ULAR leadership will determine whether laboratory staff can be in vivarium rooms while ACTs are working in the room.
  - b. An electronic calendar should be developed so that laboratory staff can access shared space safely with other labs, ULAR ACTs, veterinarians, and vet techs.
3. As described elsewhere in more detail, PIs will be responsible for developing work-shift rotations that should follow University/School guidelines with the understanding that different research programs may need different rotation schedules.
  - a. PIs should be sensitive to student and staff issues that surround personal life [e.g., child and family care, use of mass transportation, etc.] during the COVID-19 pandemic. Please consult your Human Resources professional contact for additional information and help
4. PIs will need to develop approved plans to disinfect their lab spaces between workershifts, consistent with School/University guidelines.
5. PIs will be responsible for developing PPE plans consistent with BSL in their laboratory space and with School/University COVID-19 guidelines.

## **ULAR Procedures during Restricted Operations**

ULAR’s goals during restricted operations are to (1) protect ULAR’s workers, other Penn employees and the community and (2) protect Penn’s research animals and research programs. We are following University, City and Commonwealth guidelines and expectations for management of staff during the epidemic.

### **Social Distancing:**

After approximately one month in the Research Discontinuation phase, husbandry staff were re-organized to work in shifts (by days, not hours, at work) to assist with social distancing. Social distancing was further enhanced by having caretakers use the break room in shifts.

Published cage change schedules have facilitated physical separation of husbandry staff and scientific staff in rodent housing rooms. Alterations to change schedules (due to staff availability or equipment outages) have been announced electronically so that social distancing can be maintained.

Veterinarians and veterinary technicians have been allocated to stable teams. If one team is incapacitated by infection, the remaining teams (who have not had contact with the one that must be absent) will pick up the incremental workload.

New Bolton Center has had the advantage of outdoor activities, making social distancing easier to

accomplish.

**Personal Protective Equipment (PPE):**

All ULAR employees are required to wear facial coverings in common areas of the vivaria (except when eating or drinking). This coincides with the Commonwealth's requirement that all individuals wear facial coverings when in situations where social distancing is more challenging (such as grocery stores).

## Resumption of Research with Field Work

Field research is a vital component of research in fields as varied as astronomy to anthropology to education. This activity that is carried out at a remote site off campus. The off-site location could be a remote wilderness area, a community defined by geography, history or poverty, a research station such as a telescope, national lab or foreign lab. The matrix below summarizes field research conditions with risk profiles requiring different mitigation measures.

Locality	Lodging	Research site
Local (driving distance)	N/A	Field
		Field station, remote lab
Remote (driving distance)	Hotel or equivalent	Field
		Field station, remote lab
	Camp	Field
Remote (public transportation; air and ground)	Hotel or equivalent	Field station, remote lab
		Field
	Camp	Field

Research resumption plans for projects with a field component should outline the types of activities, the risks involved, risk mitigation strategy, and the plan for response in the event of a suspected or confirmed COVID-19 incident.

For some field researchers, unique factors such as a specific “field season,” which require that observations/collections be made at specific dates of the year, can impact a multi-year research opportunity. Some research involves developing remote infrastructure (e.g., building telescopes) and delay might not only have negative opportunity impact but also have budget impact. Some involving longitudinal studies of a specified populations in which timing is important to the scientific outcome.

The evaluation of research resumption plans should consider the additional risk as well as the research opportunity. Research resumption requests must consider the risk to the remote community, as well as that to the researcher and to the campus. In some cases, the risk might not be manageable.

*Group related risk for teams*—some field work is done as a group with close interaction within the group. Interactions range from traveling together in a field vehicle, close quarters sleep arrangements (e.g, tents), as well as physical coordination. If permissible under then-applicable laws, guidelines and University policy, the resumption plan for this nature of work should require that each participant be tested and found to be negative for SARS-CoV-2 before commencing travel as a group. In addition, the plan must include an assessment of the risk of exposure during the project. The PI is responsible for detailing in the plan who is responsible for conducting the pre-travel testing and how results will be kept confidential (in accordance with the University's guidance on this issue.)

*Housing/meals risk*—the type of housing used and meals acquired will be highly variable and have different degrees of risk; e.g., outdoor camping amongst a group that tests negative (minimal risk), to normal hotel and restaurant (moderate risk comparable to Philadelphia), to communal housing and meals (high risk). Details of housing and meal plan will be assessed for risk level in comparison to risk expected for residing in hotels/dormitories within Philadelphia.

*Location risk*—Social distancing amongst team members while traveling may be extremely difficult. As a result, if permissible under then-applicable federal and local laws and University policies and guidelines, all proposed team members should be tested and receive a negative test result before

commencing travel.

During remote work, a member of the team might show symptoms and/or test positive for COVID-19. Plans must be in place for seeking treatment (local facilities, evacuation) and quarantine options for rest of the team (e.g., all evacuate or quarantine in place).

- Social distancing amongst team members while traveling will be nearly impossible. All members should be tested and cleared before travel.
- Risk during travel has the three components outlined above; travel risk, food and lodging risk, and research activity risk. The authorization request should address each component separately.
- International travel should consult Penn Global guidelines and account for any local quarantine/testing rules and as well as same rules when returning to Philadelphia. For example, schedules should take these regulations into account such that onsite Penn activity (e.g., teaching) is not compromised by unexpected regulation compliance.
- A plan, coordinated with Penn Global, should be in place for the event that a team member falls sick during research travel.
- Prioritization of travel authorization should consider as criteria (1) feasibility of risk mitigation in comparison to not traveling; (2) necessity of the research in terms of opportunity costs including that of meeting field season windows; and (3) budget impact of delaying research travel.

## **Procedures for Suspected or Confirmed COVID-19 Exposures**

This guidance pertains to the response to a suspected or confirmed exposure to COVID-19.

In the event of a suspected or confirmed infection by COVID-19 the following precautions must be taken. These actions are aimed at limiting the transmission of infection and survival of the novel coronavirus in key environments. These recommendations are adapted from the [CDC guidelines](#) focused on community, non-healthcare facilities (e.g., schools, institutions of higher education, offices, daycare centers and businesses) and will be updated as more information is available.

If you feel any symptoms of infection (i.e., fever, cough, or shortness of breath), immediately self-isolate and inform your supervisor. The supervisor notified should contact Environmental Health and Radiation Safety, with notice to Human Resources, for advice regarding testing, contact tracing, and disinfection.

### Suspected COVID-19

Begin enhanced health monitoring including temperature screening each morning. Contact Environmental Health and Radiation Safety at (215) 898-4453, which does contact tracing for campus faculty and staff. Student contact tracing is conducted by Student Health (215) 898-4453, which does contact tracing for campus faculty and staff. Student contact tracing is conducted by Campus Health (215)746-3535.

Notify Housekeeping for enhanced cleaning outside the laboratory. Cleaning should include areas used by the ill lab worker including all restrooms, interior high contact surfaces such as door handles/knobs/crashbars, light switches, elevators, bottle fill stations and building entrances.

Lab workers should clean all lab surfaces with products that are EPA-approved for use against the virus that causes COVID-19. A list of products is available [here](#). Follow the manufacturer's instructions for all cleaning and disinfection products (e.g., concentration, application method and contact time). Clean handles for sinks, DI water systems, cabinets (including acid and flammable liquid), fume hood sashes, lab benches, phones, freezer and incubator doors.

Launder employee lab coat. Disinfect employee safety glasses, face shields, keyboards and books (including lab notebooks) used by the employee.

### Confirmed COVID-19

Restrict access to lab until FRES arranges for enhanced cleaning of lab and areas outside the lab and EHRS has been contacted to provide support related to contact tracing and close contact.

<https://www.cdc.gov/coronavirus/2019-ncov/community/reopen-guidance.html>