



# Research Ramp-Up Road Map:

A Guide to Considerations and Resources for Ramping Up On-Campus Laboratory, Animal and Human Subjects Research as COVID-19 Restrictions are Lifted

VERSION 1.0

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## Overview & Purpose of this Document

The COVID-19 pandemic has had an unprecedented effect on research across the campuses of academic and research institutions in America. As state and local governments issued stay-at-home orders, institutions shuttered many on-campus laboratory facilities and/or shifted the research activities taking place there to focus solely on understanding and eradicating the COVID-19 virus. Now, as governmental entities are lifting restrictions and permitting business and educational operations to reopen, institutions are grappling with the task of re-starting on-campus research in a manner that protects the safety of research staff, participants, and the myriad of personnel who support the research enterprise.

The number and diversity of tasks required to reopen on-campus activities is vast, ranging from the establishment of overarching principles for the ramp-up framework and assembling a leadership team to disinfecting buildings and ensuring a solid supply chain of personal protective equipment (PPE). Campus labs cannot be turned on and off like a light switch. Rather, they are complex structures that require a wide variety of interrelated support personnel, services and facilities to ensure the proper and efficient conduct of research. Additionally, the impact of COVID differs across geographic regions, thus some areas have reopened more quickly than others, creating a continuum of ramp-up activities.

Given the wide variety of on-campus research activities, facilities and institutions, the myriad of different state and local COVID-related restrictions, and the varying reopening timelines, it is impossible to produce a one-size-fits-all guidance document. Accordingly, this document does not attempt to describe all of the tasks or list all of the factors that must be weighed in reopening a university campus.

Written in an annotated checklist-type format, this document is intended to assist institutions in framing issues that they should consider in resuming on-campus laboratory, animal and human subjects research. It gives an overview of the issues research institutions throughout the country have weighed in ramping-up on-campus research activities, and provides a guide to some of the reopening tools, processes, policies and other documents they created for review by peer institutions in developing their own ramp-up plans.

## Organization of this Document

This document begins with an outline of the general considerations that apply to resuming all types of on-campus research activities, including the development of reopening plans and processes; personnel safety across all research facilities and types of research; and research facility and support services considerations. Next, the document discusses considerations specific to animal and human subjects research. Finally, the document concludes with a discussion of how campuses

must take steps to ensure that they have the ability to quickly revert to ramp-down status if mandated by changes in the public health situation. As noted, throughout this document references are included to specific reopening plans, policies, processes, guidance, checklists, and other tools that have been developed by numerous COGR member institutions for the reopening of research activities on their campuses. The majority of these resources, and others, can be found at the COGR website [Institutional Resources on Ramping Up and Reopening](#), which is being updated on a regular basis as additional resources are added.

## General Considerations Applicable to the Reopening of All Types of Research

### ✓ Checklist Items

- Obtain and review relevant federal, state and local directives regarding business operations.
- Obtain and review relevant public health authority recommendations and requirements regarding social distancing, sanitization, health screening and contact tracing.
- Develop a phased approach to restarting on-campus research that is based on (a) identification of research activities that cannot be conducted remotely; and (b) consideration of research criticality and time-sensitivity, as well as campus population density.
- Develop processes and tools to implement a phased reopening approach that comports with governmental requirements.
- Develop training programs to educate researchers and support staff on reopening processes and safety, hygiene and symptom reporting requirements.
- Develop a contingency plan for rapid shut-down of research in the event of a resurgence, local order, or an outbreak/cluster within the institution.

### Identifying Overarching Principles and Constraints for Reopening

All research reopening plans are premised on the general principles issued by the U.S. Centers for Disease Control & Prevention and other public health agencies regarding social distancing, hygiene, sanitization, and identification and isolation of persons infected with COVID. [See, e.g., the following CDC guidance documents: [Interim Guidance for Administrators of US Institutions of Higher Education](#); [COVID-19, Considerations for Institutes of Higher Education](#); [Interim Guidance for Businesses & Employers Responding to Coronavirus Disease 2019 \(COVID-19\)](#); [COVID-19, General Business Frequently Asked Questions](#)]. The CDC also has issued guidance

specific to healthcare facilities. [See, [Guidance for U.S. Healthcare Facilities about Coronavirus \(COVID-19\)](#)]. General principles include:

- Reduction of population density in buildings and work spaces to ensure social distancing of 6 feet or greater, or use of appropriate PPE in situations in which the work requirements cannot be accomplished while maintaining recommended social distancing.
- Use of face masks.
- Regular screening for possible COVID-19 symptoms; isolation persons with symptoms; and contact tracing protocols for persons who are diagnosed with COVID-19.
- Regular handwashing and personal hygiene measures with sufficient access to appropriate handwashing facilities and materials (e.g., soap and water or hand sanitizer).
- Regular sanitization of work spaces and common areas.

Reopening plans must incorporate any specific reopening triggers/requirements specified in overarching state and local governmental orders. Many states are taking a phased approach to reopening that permit specific types of business operations to reopen in a staged sequence, often subject to a maximum capacity, personal protective equipment and distancing requirements. The *New York Times* compiled and regularly updates an interactive map of the U.S. providing an overview of each state's reopening plans [S. Mervosh, et. al., [See How All 50 States are Re-Opening](#) (updated May 23, 2020)]. In addition to state requirements, counties and/or municipalities also may have reopening requirements that must be identified and followed. [See, e.g., [City of Boston timeline for reopening of businesses not designated as essential](#)]. Institutions with campuses or facilities in multiple jurisdictions must take care to identify and review all local requirements that may apply.

Numerous academic research institutions have developed reopening plans that acknowledge and build upon these principles and incorporate them into guidance and policies for returning personnel. For some examples of ways in which reopening guidance documents have incorporated these principles see the examples below:

- [University of Houston, Division of Research, Reopening Research, General Guidelines](#)
- [Boston University Initial Guidance for Ramp-Up of Research Lab](#)
- [University of Connecticut Lab Ramp-Up Preparedness Guide.](#)
- [Harvard University Research Laboratory Re-Entry Plan](#)

### **Development of a Phased Reopening Process**

Most governmental entities have implemented phased reopening plans, and the majority of institutions have similar phased approaches to reopening research activity on campus. These

approaches are premised on the fact that research that can be conducted effectively through remote means should continue in that vein, while research requiring on-campus facilities must be evaluated to determine whether it can be restarted in a safe manner that complies with applicable governmental orders. These phased approaches typically consider both (a) the type of research activity, with emphasis being placed on the restart of research critical to subject health or time-sensitive activities; and (b) initial maintenance of low population density within facilities in which the research is conducted to preserve social distancing.

Prime examples of institutions that have adopted this phased reopening approach can be found at universities within the University of California system. For example, the University of California San Diego (UCSD) divides reopening into four phases -- red, orange, yellow and green -- with the red phase being restricted to essential research, and subsequent phases gradually permitting additional research, until full capacity is achieved in the green phase. [[UCSD Research Ramp-Up Guidance](#)]. University of California Davis (UCD) has taken a similar approach, but with the addition of a Phase 1X under which research with very sensitive time constraints may resume (e.g., data collection with seasonal constraints; plant or animal research in which the plant varieties or animal colonies may be lost; or lab or studio based research that students or post-docs must finish to complete degree/appointment requirements). [[Guidelines for UCD Ramp-Up/Ramp-Down](#)]. Numerous other universities have adopted similar phased reopening plans, and some additional examples are listed below:

- University of Delaware's 4-phase approach -- [Return to Research Under COVID-19](#)
- East Carolina University's 6-phase approach -- [Principles and Framework Guiding a Phased Approach to Restarting Research Activity](#)
- University of Florida 5-phase approach -- [University of Florida Research Resumption Plan](#)
- Penn State University's 4-phase approach -- [Gradually Increasing On-Campus Research-Related Activities at Penn State](#)

### **Development of Processes, Tools, Checklists and Training to Implement a Phased Reopening**

Lab Specific Reopening Plans: Once an institution has established the parameters of its phased reopening, it must then develop the processes and tools required to launch the plan and to ensure that its requirements are being implemented on the ground. Frequently, these processes involve the preparation of lab reopening plans by principal investigators using template documents and guidance prepared by university. These plans then undergo multiple levels of review before final approval.

One example of such a reopening plan development and review process is that instituted by Harvard University. Harvard's process requires each principal investigator (PI) to work with their research team and department to develop a [Research Lab Re-Entry Plan](#) for resumption of

activities. This plan must be reviewed and approved by the department, school and university before it can be implemented. To assist in developing the plan, the PI is provided with tools such as the [University PI Lab Re-Occupancy Planning Form](#) to identify key personnel who will prepare the lab for resumption of activities; personnel who will perform on-campus activities; lab schedules to manage lab density; and plans for using shared equipment and facilities with other labs.

The University of Michigan has taken a similar approach by requiring PIs to develop a lab/studio reopening plan that must be approved by the pertinent school with concurrence from the Office of the Vice President for Research. [See, [Research Re-engagement, Guidelines for preparing the workspace and operating a safe laboratory/studio](#)]. The plan must include, among other items, a list of duties to be performed by personnel and a performance schedule; a process to identify who is in the lab/studio at any specific time; designation of an on-site supervisor to monitor COVID-19 control strategies; signage for maximum occupancy; and demarcation of social distancing boundaries. A form is provided to collect this information. [[UMOR Master Laboratory Space Usage Request Form](#)].

Other universities that have adopted similar processes and forms include:

- [Yale University](#) -- Requires application approval by department/section/center head, dean and provost. [See, [Overview and Instructions for Faculty for Phase 1 Research Reactivation, Faculty Guidance for Preparing for Return to Campus in Phase I](#)].
- [University of Virginia](#) -- Requires submission of draft ramp-up plan to be developed using [Research Ramp-Up Tool Kit](#) and submitted to university via web portal.
- [University of California Santa Cruz \(UCSC\)](#) -- Requires officials in charge of buildings to develop occupancy plans and to review researcher-developed reopening plans for space within that building, with final approval for all plans from the Office of Research. Researchers are provided with [templates and web forms](#) to develop and submit their plans. [See, [Planning for the Ramp-Up of UCSC Research](#)].
- [Michigan State University](#) -- Requires development of staging plans by colleges/units, along with a *Laboratory Plan for a Safe Return* developed by every research group. [See, [Reactivating On-Site Research Operations at MSU During COVIC-19: Preparing the Next Stages](#)].

In some cases, instead of adopting a master approval process that applies to all research, universities have delegated the task of developing reopening processes and tools to individual schools. [See, e.g., Columbia University, [Planning for Research Ramp-Up](#) (“Each school will determine the order of priority and its own strategy for how best to restart on-site research, taking account of its particular portfolio, physical plant, and any distinct needs of the community of researchers.”)].

Checklists: To aid researchers in developing reopening plans for their labs, a number of institutions have created lab and research reopening checklists, including those listed below:

- University of California Davis -- [Laboratory and Research Ramp-Up Checklist](#)
- University of California San Diego -- [Ramp Up Checklist for Research Areas](#) & [Ramp Up Checklist for Hazardous Material Research Labs and Shops](#)
- University of Delaware -- [Ramp Up Checklist](#) (smartform)
- University of Washington -- [Checklist for Developing a Return to In-Person Research Plan](#) (see, *Links and Resources* sidebar on this page)

Training: After processes and tools are developed, institutions must develop training and communications programs to educate researchers and staff on expectations and requirements. Training is particularly important in the area of safety precautions and use of PPE, as well as in channels for reporting symptoms or possible exposure to COVID-19 and required follow-up.

## Personnel Considerations Applicable to the Reopening of All Types of Research

### ✓ Checklist Items

- Conduct a risk assessment of lab areas to determine required safety practices and necessary PPE, including practices and PPE to prevent COVID-19 transmission.**
- Develop processes that employees will follow to screen for COVID-19 symptoms along with processes for reporting symptoms and/or diagnosed illness.**
- Determine what type of COVID-19 testing/testing referral will be available to employees and/or students.**
- Develop or discern processes for contact tracing that conform to legal requirements and involve public health authorities as necessary.**
- Develop processes for identifying employees at high risk of COVID-19 complications and providing appropriate accommodations.**
- Develop mechanisms to address issues with employees who are fearful of returning to work and establish communication channels for employees to ask questions and report unsafe work conditions without fear of retaliation.**



## Risk Assessment of Areas in which Personnel will be Conducting Laboratory Operations

Workplace risk assessment is a fundamental principle of all occupational workplace safety programs. The U.S. Occupational Health and Safety Administration (OSHA) recommends that risk assessment programs include periodic inspections of work areas to identify hazards, as well as the collection and review about hazards that are present or likely to be present in the workplace, including “hazards associated with emergency or non-routine situations.” [[OSHA, \*Recommended Practices for Safety and Health Programs, Hazard Identification and Assessment\*](#)]. Both OSHA’s PPE standard ([29 CFR 1910.132](#)) and respiratory protection standard ([29 CFR 1019.134](#)) require assessment of occupational hazards, and OSHA includes encountering COVID-19 infected persons and exposure to environments that may be contaminated with COVID-19 as potential hazards that should be assessed. [See, [OSHA COVID-19 Hazard Recognition](#); see, also, [CDC Situation Summary, COVID-19 Risk Assessment](#)].

OSHA and the Department of Health and Human Services issued a joint guidance document entitled [Guidance on Preparing Workplaces for COVID-19](#) (“OSHA/HHS Guidance”), and, as previously noted, the CDC also issued a document entitled [Interim Guidance for Businesses and Employers Responding to Coronavirus Disease 2019 \(COVID-19\), May 2020](#) (“CDC Business Guidance”).<sup>1</sup> Both the OSHA/HHS Guidance and CDC Business Guidance prescribe general steps that all employers can take to reduce the exposure potential for all workers. Additionally, the OSHA/HHS Guidance recommends the development of an Infectious Disease Preparedness and Response Plan, and it classifies employees by risk of potential for exposure to COVID-19 based on job duties. For example, health care workers whose job duties include encounters with persons known to have COVID-19 are classified as “high risk,” and OSHA prescribes additional controls (e.g., ventilation, physical barriers, additional PPE) that employers should put in place to protect these employees.

Many institutions have worked with their environmental health and safety offices in assessing risk to employees and instituted the general COVID-19 controls recommended by both CDC and OSHA, along with any controls specific to the type of research being performed. General COVID-19 controls include the following practices:

- Screening employees for symptoms of COVID-19
- Separating sick employees
- General disinfection and sanitization practices
- Providing workers with PPE appropriate to their job duties and resources for personal hygiene

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<sup>1</sup> As noted, the CDC also has issued COVID-19 guidance specific to [institutes of higher education](#), which considers educational functions/settings, as well as guidance for [healthcare facilities](#). The more general guidance for businesses and employers is referenced here because it encompasses a wide variety of business activities. The basic underlying general principles for dealing with COVID-19 are the same in all of the CDC guidance documents.

- Providing worker training on social distancing and good hygiene practices.

Examples of plans in which universities have incorporated these practices can be found in Duke University School of Medicine’s [Reopening Research Laboratories, General Principles](#), as well as Duke’s [Guide for Returning to the Workplace](#) (p. 7-9). Similarly, the University of Minnesota’s working group [Report on Staged Resumption of Selected Research Operations Working Group](#) report (p. 4-5) also incorporates these practices.

### **COVID-19 Testing and Health Surveillance Considerations**

Requiring employees to self-monitor for COVID-19 on a daily basis and instructing symptomatic employees to contact occupational health units and refrain from coming to work is a sound strategy for implementing the [CDC Business Guidance](#). Examples of institutions that are requiring symptom monitoring include the following universities:

- University of Houston [[Reopening Research](#) (daily monitoring)]
- University of California San Diego [[Screening Guidance of Personnel and Visitors](#) (temperature monitoring required per county order)]
- University of Connecticut [[Research Lab Ramp-Up Preparedness Guide](#) (daily symptom screening)]
- University of Delaware [[Return to Research Under COVID-19](#) (temperature screening and documentation upon arrival to work and at mid-shift)]

Duke University, University of Virginia and University of California Davis provide examples of institutions that utilize an online symptom reporting tool for this purpose. [See, Duke University School of Medicine, [Reopening Research Laboratories, General Principles](#); University of Virginia, [Research Ramp-Up Guidance](#); UC Davis Health, [COVID-19 Online Daily Health Screening Form](#)]. Harvard University requires that returning researchers agree that access to Harvard buildings constitutes a declaration that the researchers declare themselves to be symptom free [[Research Laboratory Re-Entry Plan, Individual Responsibilities](#)]. Other universities do not require specific symptom screening on a daily basis, but rather, generally remind employees of COVID-19 symptoms and require them to stay home if they are ill. [See, e.g., [University of Washington Requirements for COVID-19 Prevention in the Workplace](#)].

Many universities require symptom surveillance and refer symptomatic persons to healthcare providers for COVID-19 testing, but a smaller number have implemented broad-scale COVID-19 testing programs of asymptomatic persons. The institutions that are most likely to implement these broad testing programs are those that are, or are affiliated with, large healthcare institutions with diagnostic laboratories that regularly provide medical testing and thus have the supplies, experience and appropriate licenses/certifications to process these tests. The University of Florida

is one institution that has opted to establish a large-scale test and trace program for employees and students on its campus through University of Florida Health. [See, [UF Health to Provide Coronavirus Test and Trace Program to Help Reopen University](#)] Similarly, the University of California San Diego’s “Return to Learn” Program “aims to test broadly students, faculty and staff on campus on a recurring basis for presence of the novel coronavirus that causes COVID-19,” and includes “plans for exposure notification and isolation housing for on-campus resident students who test positive for the virus.” [H. Buschman & S. Lafee, [UC San Diego Introduces COVID-19 Testing Program on Campus, May 6, 2020](#)].

Other universities may offer testing for symptomatic persons. For example, Duke University requires employees to self-screen for COVID-19 symptoms on a daily basis and those who have symptoms must “call the Duke COVID hotline . . . for assessment of symptoms and COVID-19 testing.” [[Duke University Guide for Returning to the Workplace, p. 4](#)].

In addition to testing, institutions also must consider the issue of how to address a student or employee who is diagnosed with COVID-19. The CDC states that local health officials, faculty, staff and students should be notified of diagnosed cases of COVID-19 while “maintaining confidentiality in accordance with the [Americans with Disabilities Act](#) and any other applicable laws (e.g., HIPAA, FERPA) and advise those who were in close contact with the infected person (i.e., household member, intimate contact, care provider that did not use infection control precautions, and persons within a distance of less than 6 feet from the infected person for a prolonged period) to self-quarantine ([Considerations for Institutes of Higher Education](#)). [See, also, [CDC Business Guidance](#)]. The CDC has provided guidance for contact tracing programs (see, [Contact Tracing for COVID-19](#)), and although this guidance is directed to public health authorities, it provides an excellent overview of issues these programs must consider.

Most institutions have not implemented their own large scale COVID-19 testing programs, but many do require employees who are diagnosed with COVID-19 to report the diagnosis to the institution so that it can work with public health officials for tracking and follow-up. This is the case at the University of Washington, which requires employees whose healthcare providers diagnose them with, or suspect that they have, COVID-19, to contact employee health services. [See, [University Requirements for COVID-19 Prevention in the Workplace](#)]. Harvard University requires employees who are diagnosed with COVID-19 to contact occupational health services and agree to comply with any policies regarding contact tracing. [[Research Laboratory Re-Entry Plan, Individual Responsibilities](#)]. Yale University requires labs to notify human resources in the event an employee tests positive so that public health authorities can be notified and start contact tracing. [[Research at Yale, Safety Contacts and Guidance](#)]. In all cases, institutions should consult with their legal counsel and human resources units to ensure that any communications regarding personnel’s private health information are conducted in conformance with applicable

federal and state privacy laws and that any contact tracing is carried out in accordance with applicable public health laws.

### **Handling Higher Risk and Vulnerable Employee Populations**

Institution's policies must give recognition to the fact that some employees may be at risk for suffering greater complications from contracting COVID-19 because of age or individual health considerations (e.g., employees with compromised immune systems). The [CDC Business Guidance](#) encourages employers to protect these higher risk employees by letting them work remotely or modifying job duties to minimize contact with other individuals. An example of the manner in which one institution has implemented this guidance can be found in the University of Michigan's [Research Re-Engagement Guidelines for Individuals Returning to Work](#). This guidance states that individuals with a high risk of complications from COVID-19 may not be required to return to work and encourages persons who believe that they may be at high risk to contact occupational health or their personal health care provider. Institutions should be sure to work with human resources and legal counsel in addressing the needs of such individuals to assure compliance with legal requirements that may apply such as the [Americans with Disabilities Act](#). [See also, [U.S. Equal Employment Opportunity Commission, What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws](#)].

In addition to policies regarding employees at higher risk, institutions must consider how to address populations who are not medically vulnerable, but because of power and status differentials, may feel pressured to work in unsafe conditions, or to return to work on campus when their work could be conducted remotely. Many institutions have addressed one such population - undergraduate students -- by prohibiting their return to research labs during early stages of reopening. For example, Johns Hopkins University's reopening plan does not permit undergraduates to return to research labs until Phase 2B of the plan at the earliest. [See, [Report on JHU University Research Return to Campus: Phase 1 Guidance](#), p.4]. Similarly, University of Michigan's [Guidelines for Individuals Returning to Work](#) prohibits undergraduate students, visitors or visiting researchers from returning to labs in its initial stage, and Principle #4 of Kansas State University's [Framework - Guiding A Phased Approach to Restarting Research Activity](#) prohibits undergraduate students in labs until all undergraduate students are allowed back on campus.

Institutions also recognize that returning employees may be fearful of losing their jobs and thus be afraid to report unsafe conditions in their labs. For example, in its guidance on reopening research, Johns Hopkins University includes the following statement with respect to creating and communicating a "culture of flexibility and protection":

In addition, the University recognizes the power imbalance between PIs and their supervisees, including graduate students, postdoctoral fellows, staff, and more junior faculty. Employees or trainees should not be placed under any pressure by PIs to expose themselves to potentially hazardous situations (e.g. unsafe working conditions in the lab). To that end, employees and trainees will be able to voice concerns confidentially to an authority who has the ability to act on their behalf to address safety concerns. [[Report on JHU University Research Return to Campus: Phase 1 Guidance](#), p.12].

Finally, institutions must work with human resources and legal counsel to plan in advance the steps that they will take if an employee unreasonably refuses to return to work, although the institution has put appropriate safety measures in case.

### **Availability of Personal Protective Equipment**

As previously noted, OSHA regulations require the performance of a risk assessment to determine the PPE that employees require to perform their specific job functions. Most institutions have such a risk assessment process in place through their occupational health and/or environmental health and safety offices, and they have already prescribed the type of PPE that individuals should wear to perform lab duties, with the most common PPE in lab settings being lab coats, goggles and/or face shields, and disposable gloves.

The COVID-pandemic, however, has introduced a new complication in that PPE generally used in laboratory settings may not be available because supplies have been diverted to clinical use and manufactures have not been able to keep up with the backlog. [See, [A. Jacobs, et. al. At War with No Ammo: Doctors say Shortage of Protective Gear is Dire, New York Times, March 19, 2020](#)]. Similar circumstances apply to personal hygiene products (e.g., hand sanitizer) and cleaning products. The FDA has recognized these circumstances and issued guidance on medical glove conservation strategies [[Medical Glove Conservation Strategies: Letter to Health Care Providers](#)], as well as guidance ease shortages of hand sanitizer [see, [Hand Sanitizers: COVID-19](#)]. Despite these efforts to ease regulatory constraints, shortages may persist, and institutions must work with their procurement offices to develop strategies to ensure a steady supply of all PPE required for lab use and personal hygiene products. Cost issues also may develop as prices rise in response to increased demand, and supplemental funding to replace supplies re-assigned to clinical activities may not be available. [See, [NIH FAQs COVID-19 Flexibilities, Section VI.D.6](#) (PPE acquired with NIH funds can be donated to clinical efforts but institutions “should not assume that NIH funding ICs will provide additional funds to replace the donated PPE and supplies”)].

The various types of masks that are frequently used in labs also are in short supply. Additional complications arise in the area of masks because of the various types of face coverings and their purposes. Specifically, cloth face masks do not provide the same level of protection from

droplets/particulates as do surgical masks, and respirators, such as the N95, provide greater filtering capacity. Further, the regulations that apply to face coverings differ depending on whether they are used in a healthcare setting by healthcare providers. [See, FDA [Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease \(COVID-19\)](#)]. Accordingly, laboratory personnel must be educated on the type of face protection that is acceptable for traveling to/from work and on campus, as well as that which is appropriate for use in carrying out their laboratory or healthcare job duties. In the case of personnel who are not expected to have direct contact with persons who have COVID-19 (and whose lab or healthcare tasks do not require otherwise), the CDC recommends that cloth face masks or coverings be worn. Persons with known exposure to COVID-19 (e.g., healthcare workers, lab workers performing COVID-19 research), however, should be evaluated for the use of medical face masks or respirators. [[CDC Guidance, Prevent and Reduce Transmission Among Employees](#)].

Institutions have taken different approaches to the types of face coverings that are acceptable for use in laboratories. Example approaches are described below:

- University of Florida: Requires masks or cloth face coverings in labs and in public areas where social distancing cannot be maintained. Additional protection may be required in labs depending on specific lab activity. Personnel are encouraged to provide their own washable cloth mask or disposable mask. [[University of Florida Research Resumption Plan](#), p 2].
- Yale University: Government orders require the wearing in public of a face covering, which may consist of a cloth mask. In laboratories, however, personnel must wear surgical masks, N95 respirators or powered air purifying respirators (PAPRs) depending on the work being done; cloth face masks are not permitted. [[Yale Environmental Health and Safety Fact Sheet for Laboratory Members: Face Coverings, Surgical Masks and Respirators](#)]
- University of Minnesota: Each PI-developed return to research plan must specify the type of PPE required, and plans may include alternate PPE “such as fabric based masks.” “Surgical masks should be reserved for health care and animal research activities.” For non-disposable PPE, a standard operating procedure for frequency of washing/disinfection also must be included. [[Staged Resumption of Selected Research Operations Working Group Report, Appendix E](#)].
- University of North Carolina (UNC): UNC will provide all employees with a face mask that they must wear when present with others and in public spaces where social distancing is not possible. Disposable face masks will be provided to school/department distribution coordinators for provision to research personnel. One disposable mask will be provided “for every two shifts or two days of work,” with accommodations for persons requiring more frequent mask replacement. [[Direction and guidance for All On-Campus Research, Personal Safety Practices in the Workplace](#)].

## Facility Considerations Applicable to the Reopening of All Types of Research

### ✓ Checklist Items

- Assess systems (e.g., plumbing, HVAC) in buildings that have been vacant to assure that they can be safely started.
- Identify lab facilities that will be reopened and researchers who will be returning and determine necessary support personnel to support research.
- Determine allowable lab/building population densities (including both research and support personnel) that will accomplish research and achieve social distancing requirements.
- Establish processes to track building occupancy.
- Establish processes and engineering controls (demarcated areas, signs, barriers) to enforce social distancing.
- Develop initial and continuing cleaning and disinfection practices, including disinfection of areas that housed infected individuals.

### Reopening Buildings that have been Vacant - Ventilation & Plumbing

The [CDC Business Guidance](#) contains specific recommendations for reopening buildings that have been vacant or run at reduced capacity for a prolonged period. These buildings are subject to issues with mold and *Legionella* bacteria, and the CDC provides guidance with respect to the restart of water and HVAC systems to reduce these risks. [[Guidance for Reopening Buildings After Prolonged Shutdown or Reduced Operation](#)]. In addition, the CDC recommends assessing building ventilation rates to ensure adequate indoor air quality, ventilation, and filtration. [[CDC Business Guidance, Maintain a Healthy Work Environment](#)]. Accordingly, persons developing reopening plans should involve appropriate campus facilities and environmental health and safety personnel in the review building systems prior to re-occupation, and the University of Michigan has developed a [COVID-19 Building Preparedness Checklist](#) for facility managers.

### Monitoring Building Population Density and Promoting Social Distancing

A key tenet of all guidance to prevent the spread of COVID-19 is the maintenance of appropriate social distancing. The CDC recommends a distance of at least 6 feet between individuals and avoidance of large gatherings. [[CDC Business Guidance, Prevent and Reduce Transmission Among Employees](#)]. In implementing processes to ensure social distancing, institutions have taken into account not only the population in specific lab settings, but also population density in

buildings as a whole and in common areas within the building (e.g., elevators, restrooms, shared lab equipment areas). Planning also must consider where employees will eat while on campus and how social gatherings such as “hallway meetings” will be discouraged.

One mechanism institutions have used to ensure social distancing is scheduling approaches such as the use of staggered shifts and scheduling the use of shared equipment. For example, the University of Connecticut requests researchers to consider splitting lab groups into teams that work in the labs on different schedules and to pair more experienced lab members with less experienced personnel. [[Research Lab Ramp-Up Preparedness Guide](#)]. Harvard University suggests various work shift models to stagger personnel presence on campus, such as dividing the work day, work week, or a two-week period among lab members. [[Research Laboratory Re-Entry Plan, p. 7](#)].

Institutions also use physical measures to promote social distancing, such as delineating building ingress and egress points, marking six foot spacing in lab areas, erecting physical barriers and posting maximum occupancy signage. [Duke University’s Guide for Returning to the Workplace](#) (p. 10) provides the following examples of physical space demarcation:

- Place visual cues such as floor decals, colored tape, or signs to indicate to customers where they should stand while waiting in line.
- Place one-way directional signage for large open work spaces with multiple through-ways to increase distance between employees moving through the space.
- Consider designating specific stairways for up or down traffic if building space allows.

Duke also requires employees to use their Duke cards/badges to enter and exit the building to assist in monitoring building density, as well as staggering arrival and departure times to ensure that points of ingress and egress do not become crowded. [*Id.* at p. 12]. The University of Michigan similarly monitors building populations by requiring each entering employee to present identification and have his/her/their name verified against a list of authorized personnel. [[Research Re-Engagement, Guidelines for Entrance into any U-M Laboratory Building](#)]. Another tool in this area is the University of Washington’s one-page document that lists many of the steps discussed above to promote social distancing. [[Guide for Returning to In-Person Research -- On-Site Facilities and Social and Physical Distancing](#)].

### **Disinfection and Sanitization**

The CDC provides a general framework for cleaning/disinfection, which can serve as a starting point for developing cleaning plans. [[Reopening Guidance for Cleaning and Disinfecting Public Spaces, Workplaces, Businesses, Schools and Homes](#)]. Some institutions, such as Stanford University, may require buildings to undergo an initial deep cleaning prior to reopening. [See, [COVID-19 Health Alerts, Campus Hygiene](#) (all unoccupied buildings will receive a one-time,



detailed deep cleaning and disinfection”). Thereafter, regular disinfection and sanitization of buildings is crucial to prevent the spread of COVID-19, and institutions must develop schedules for regular cleaning of common areas and touch points. PIs must do the same with respect to their lab areas, if individual lab cleaning is delegated to the research team. In this regard, the University of Florida has developed cleaning recommendations for lab members, including the cleaning of common touch points within the lab and shared tools. [[UF Environmental Health & Safety COVID-19, Cleaning](#)]. The University of Washington also has developed similar guidance. [[Guide for Returning to In-Person Research Phase 1 -- Cleaning and Disinfecting your Workplace](#)].

Cleaning plans must be taken into account in personnel scheduling to accommodate social distancing requirements and to ensure that proper cleaning can occur between shift changes. In addition to regular periodic cleaning, institutions also must consider plans for deep cleaning of labs and common spaces should a person in that space be diagnosed with COVID-19. [See, e.g., University of Florida [Facilities Services Takes Proactive Measures Against COVID-19](#) (describing disinfection measures taken for areas occupied by persons who tested positive); and [Yale Environmental Health & Safety, Safety Guidelines for Facilities/Custodial/Outside Vendors: Proper Disinfection of Areas with Confirmed/Suspected Cases of COVID-19](#)].

### **Availability of Support Services**

Institutional plans for reopening research must consider not only the research facilities themselves, but also the various services and facilities that support that research. These support services include information technology, core laboratories, and veterinary/animal care services, facilities maintenance, food service and parking. Although some of these services may be able to operate remotely for the most part (e.g., information technology), the nature of other services may effectively prohibit any remote operations (e.g., custodial services). Accordingly, ramp-up plans must take these services and their personnel into consideration in developing scheduling and social distancing plans. Additionally, at many institutions the pandemic’s economic fall-out has resulted in cut-backs and furloughs, and thus institutions also must consider whether there are sufficient support services available to permit the conduct of the research that is contemplated to reopen.

## Considerations Specific to Ramping Up Animal and Human Subjects Research Activities

### ✓ Checklist Items

#### *Animal Research*

- Develop an emergency preparedness plan for the animal care and use program that encompasses circumstances arising from the pandemic (e.g., chronic absenteeism, shortages of PPE).**
- Determine what limits must be placed on the type and volume of animal research activities that can be implemented in each phase of the ramp-up plan to ensure provision of adequate support for animal activities while maintaining social distancing requirements.**
- Determine what limits must be placed on animal breeding colonies and animal purchasing to ensure an appropriate level of support.**
- Identify PPE supplies for animal care facilities.**
- Determine how social distancing and other COVID-19 precautions will be put in place in animal care, procedure and housing facilities.**
- Develop processes to accommodate IACUC and regulatory inspections.**

#### *Human Subjects Research*

- Determine the types and extent of human subjects research involving face-to-face interactions that will be restarted in each phase of the ramp-up plan. Consider overlap between clinical personnel and resources and research personnel and resources in making this determination.**
- Develop processes that research teams will employ to limit risk of COVID-19 transmission between research teams and study subjects (e.g., use of video/telephone when possible, combining study visits with clinic visits, etc.).**
- Ensure that there is an adequate supply of PPE for use by both participants and research teams.**
- Develop communications to educate research teams and participants on safety precautions that will be taken, including use of PPE, reporting of COVID symptoms and testing.**
- Develop processes to accommodate IRB oversight and regulatory inspections.**

## **Animal Research**

The [\*Guide for the Care and Use of Laboratory Animals\*](#) (“Guide) requires animal research facilities to have an emergency preparedness plan that encompasses animals and animal care and research personnel. The Office for Laboratory Animal Welfare (OLAW) has indicated that this plan should encompass circumstances arising from the COVID-19 pandemic. [See, [\*OLAW Guidance in Preparing for the Coronavirus Disease 2019 \(COVID-19\) Outbreak\*](#)]. Any emergency plan must take into consideration how animal populations will be cared for in the event that COVID-19 significantly impacts the number of veterinary and animal care personnel who are available to provide veterinary and animal husbandry services.

During the initial ramp-down process, many institutions were able to place animals on holding protocols and maintain them until research could resume. Nevertheless, institutions must consider the potential situation in which COVID-19 affects so many individuals that it becomes impossible to muster the personnel necessary to provide appropriate animal care. Even short of this worst case scenario, the gradual resumption of research activities on campus, while trying to maintain social distancing will, of necessity, affect the number of individuals available to care for animals and thus impact the volume of animal research that can be conducted in the early stages of ramp-up.

In response to staff limitations and social distancing requirements, institutions have placed limitations on the types of animal research that can be conducted during the early stages of ramp-up. The University of Michigan’s [\*Research Re-Engagement Plan\*](#) provides one example of steps taken to address the fall-out from reduced availability of animal care personnel due to social distancing requirements. The plan provides for the following restrictions on animal research:

- Animal studies will be limited to those that can be easily ramped back down; full volume animal research is not possible because full animal care staffing is not available.
- Animal studies are limited to those that can be performed on animals that are currently in the animal facility; no new animal orders will be processed, except for animals needed for COVID-19 research.
- Breeding colonies will remain in maintenance mode, and new studies can’t be initiated on animals produced by breeding colonies.

Michigan State University takes a similar approach by requiring research staging plans to “acknowledge that animal studies will be limited to work that can be done with animals presently housed, or that could be bred in-house to meet research objectives” [[\*Reactivating On-Site Research Operations at MSU During COVID-19: Preparing the Next Stages, Section IV.1\*](#)]. Michigan State also limits new animal studies “to time-sensitive work with specific goals, such as grant deadlines, publication deadlines, graduate student completions, etc.” and requires the delay of “staff intensive studies.” [[\*Id.\*](#)].

In addition to limitations on initiation of new animal research, institutional policies also consider the need to maintain social distancing requirements in animal facilities, taking into account daily husbandry and veterinary activities. Shared procedure rooms must be included in scheduling protocols, with time for cleaning and disinfection between users. Some institutions have taken steps to reduce contact between research and animal care personnel such as (a) cancelling in-person training classes and limiting research to personnel who have completed all required in-person training [see, University of Michigan, [Research Re-Engagement](#)]; and (b) conducting meetings with researchers via phone or teleconference [see, University of Houston, [Reopening Research, Animal Research](#)]. Further, given that animal research and clinical care provided for humans sometimes puts competing demands on stocks of PPE and, in some cases, pharmaceuticals, institutions must plan ahead to ensure adequate supplies for any animal research that they choose to conduct.

Finally, institutions must continue to be prepared for IACUC and U.S. Department of Agriculture (USDA) site inspections. In this regard, the USDA Animal & Plant Health Inspection Service (APHIS) announced that it would “continue to conduct inspections when it became aware of serious welfare concerns,” but was “limiting routine inspections based on [its] assessment of the risk to the inspectors and facility personnel.” [[Message to AWA Licensees and Registrants: Animal Care Inspections During COVID-19 Pandemic](#), March 27, 2020]. Nevertheless, given that there will be fewer personnel on campus, protocols should be in place for contacting necessary personnel (e.g., institutional official, attending veterinary, IACUC director) in the event that inspectors come on campus.

### **Considerations Specific to Ramping Up Human Subjects Research**

Throughout the pandemic, many institutions have continued to conduct three general types of research: (a) COVID-19 research; (b) clinical research for serious or life-threatening conditions that has the possibility of direct therapeutic benefit to the participants; and (c) research that can be conducted without face-to-face interactions. As institutions begin to reopen on-campus research activities, broader types of human subjects research involving face-to-face interactions may begin to resume, although frequently in the later stages of phased plans. In some cases, whether such research can begin may depend on what research activities are permitted under applicable governmental orders. Additionally, institutions must consider the congruence of research activities with clinical operations in determining the types and volume of human subjects research that can resume. Where there is substantial overlap between clinical and research personnel, facilities and resources, institutions must be prepared for the situation in which these assets must be reassigned for COVID-19 patient care, and the impact of such reassignment on the safety and welfare of research participants must carefully be considered.

Michigan State University, the University of Florida and the University of Washington's treatment of the expansion of human subjects research in the initial phases of their ramp-up plans provides an interesting comparison in this regard. Michigan State University's research reactivation plan states that restrictions on non-clinical trial human subjects research involving face-to-face interactions will continue. [See, [Reactivating On-Site Research Operations at MSU During COVID-19: Preparing the Next Stages, Section IX](#)]. The University of Florida, however, permits the resumption of clinical research with study visits that are concurrent with clinical visits to resume in Phase I of its reopening plan, and anticipates that virtually all interventional and observational research will resume by Phase III. [See, [Clinical Research Resumption Plan](#)]. The University of Washington's phased reopening plan permits in Phase I the resumption of certain clinical trials conducted in specific locations, as well as some clinical trials involving only brief encounters for the collection of biologic specimens. [See, [Resuming Some Human Subjects Research](#)]. Florida State University's reopening plans also provide for the limited resumption of some human subject research that involves in-person interactions. [See, [COVID-19 and Human Research Studies](#)].

In addition to determining what types of human subjects research can resume, institutions must implement processes to ensure that all such research is carried out in a manner that minimizes the chance of COVID-19 transmission between research participants and the study team. Some of these considerations are set forth in the [COGR Research Ethics and Compliance Committee's Human Subjects FAQ](#). Another useful tool in this area is the draft guidance that Harvard University developed to outline items that researchers must consider to reduce COVID-19 related risks in research involving face-to-face interactions. [[Research Laboratory Re-Entry Plan, Appendix 5 -- Guidance for Human Subject Research \(draft, under review by faculty groups\)](#)]. These considerations include, among others, the following items:

- Minimize face-to-face interaction time with subjects by using mechanisms such combining study visit with clinical visit; conducting visits by telephone or teleconference when possible; and modifying specific study visits to account for essential vs. non-essential study procedures.
- Consider the study population and determine if study aims can be met without recruiting those at greatest risk for COVID-19.
- Restrict study visits to essential individuals (e.g., subject and legally authorized guardian/representative) and only essential study personnel.
- Include processes for screening study participants for COVID-19 symptoms and require them to wear a cloth mask.
- Clean and disinfect study areas initially, between participant visits, and after all visits are complete for the day.
- Have PPE available for study subjects.
- Maintain social distancing to the greatest extent possible during the visit.

The University of Washington developed a similar checklist that covers many of the foregoing items, as well as addressing the issue of whether study subjects will undergo testing for COVID-19. [[Checklist: Human Subjects Research During COVID Pandemic](#)]. In this respect, processes for COVID-19 testing of personnel conducting the research also must be considered, as well as notification processes should a study subject or research team member test positive.

Finally, institutions must be prepared to accommodate monitoring personnel and study inspections (e.g., FDA inspections). If possible, monitors should be encouraged to conduct monitoring virtually, but when site visits must be conducted, the institution should advise monitoring personnel of its COVID-19 precautions (e.g., social distancing, use of face coverings) in advance of the visit and request compliance. Consideration should be given to producing Additionally, given that study personnel may not be on site, PIs should provide clear direction for how they can be contacted in the event that FDA inspectors or other government regulatory personnel come to the site to conduct a study inspection.

## Preparing for Possible Retrenchment

Numerous factors that are outside of the institution's control such as infection rates, national/state/local orders, and supply chain interruptions will impact how and when the institution can reopen. Given these uncertainties about the course of the pandemic, institutions also must be prepared for the possibility that after reopening, they may need to once again rapidly ramp-down on-campus activities.

Accordingly, ramp-up planning must include within its scope how the institution will collect and monitor data about COVID-19 infection rates on campus and the surrounding community to determine (a) whether infection-control measures are effective; and (b) whether the institution needs to ramp-down some or all of its on-campus activities, including research activities. Planning should include identification of the "trigger" events that will cause the institution to institute various ramp-down processes. Triggers may include governmental orders, infection rates, certain levels of absenteeism due to illness, or inability to procure PPE and other necessary supplies to conduct operations. Additionally, just as ramp-up activities are being phased in, ramp-down activities may be conducted in phases as well, depending on the circumstances that require retrenchment.

Given the need for collecting data on the pandemic's impact on both a community (i.e., campus) and local basis (i.e., city/state), institutions also must consider in its ramp-up plans what data it will collect and determine what metrics it will use to decide whether to move to the next phase of its ramp-up plan, or alternatively, retrench. Once metrics and triggers are determined, institutions

do have the advantage of using ramp-down plans that they developed at the initiation of the pandemic, including ramp-down plans for laboratories and research.

## Conclusion

Given the differences in how COVID-19 has affected different geographic areas, institutions are at various points along the ramp-down/ramp-up continuum. This variation, however, has presented the opportunity for institutions that are not as far along to learn from their predecessors and to utilize and improve the processes and tools that they developed and shared. Similarly, those who are farther along in the processes can learn from their past efforts should retrenchment once again be necessary.

Although institutions are eager to begin the process of ramping-up on-campus research activities, given the many uncontrolled variables impacting reopening, the road ahead is unclear. Accordingly, careful planning of a phased reopening must, of necessity, include planning for quick retrenchment, in large part because the COVID-19 virus has proved so very unpredictable.

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