Research Laboratory
Re-Entry Plan

Harvard University
May 14, 2020

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Harvard University
Laboratory Reopening Planning Committee

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Preamble

This document is meant to establish clear and consistent guiding principles for the conduct of research in the era of COVID-19, to define operational protocols and precautions that minimize risk of viral transmission in a laboratory/research environment, and to provide examples of how the physical and temporal space of laboratories might be organized to enact these protocols in accord with these principles.

This report draws on the collective wisdom of experts in epidemiology, virology, public health, and emergency preparedness, as well as highly experienced research investigators and senior research officers, heads of hospitals and research institutions, and research building operations and facilities managers. We have benchmarked and compared our plan with those of many of leading universities and hospitals in the U.S., and our plan is in line with best practices.

The protocols and proposed guidance provided in this document also have been informed by, and are consistent with, the experience of Harvard hospital and health care workers and of essential research personnel in these settings who have continued to carry on COVID-related research programs while other laboratories ramped down. It is notable that adherence to the practices of social distancing, universal masking, and attentive avoidance and disinfection of surfaces has been highly successful in suppressing workplace transmission in these settings, despite the fact that they almost certainly represent higher risk environments due to the close proximity of COVID-19 patients. Thus, it is reasonable to expect that the rigorous adoption of these same precautions, which are already familiar to most research staff and have been demonstrated as effective in related research settings, will likewise prove effective in preventing workplace transmission and safeguarding the health of personnel returning to Harvard's research labs.

Core principles for staged ramp-up of on-campus research at Harvard

- At this time, use of on-campus research space should be limited to those activities that cannot successfully be done remotely.
- Individuals should access only those areas of campus buildings that are necessary to do their work.
- On-campus research should be organized/prioritized to limit person density and simplify personal interaction networks while maintaining personal safety.
- On-campus researchers should adopt "universal precautions" designed to mitigate the risk of viral transmission, including frequent handwashing, physical distancing, proper use of University-issued or -approved masks, avoidance of contact with high-touch surfaces, and attention to surface and equipment disinfection protocols.
- Explicit training on implementing these practices should be provided and demonstration of proficiency required prior to lab re-entry.

[1] Committee members are listed in Appendix 1.

Introduction

With the spread of the COVID-19 pandemic, many communities and institutions took steps to reduce the spread of infection by promoting social distancing and aggressively limiting the number and size of gatherings. We now need to plan for the staged resumption of lab research on campus, with an eye towards returning to work as prudently and safely as possible. This document provides a road map for achieving that goal.

We present guidance for institutional actions prior to ramp-up, as well as guidance for principal investigators (PIs) and research groups to help them develop lab-specific plans based on the needs of the program, the nature of the work, and the layout of facilities. **This guidance will be continuously reviewed and may be revised as new information and effective COVID-19 treatment and prevention options emerge.**

The measures for ramp-up of lab and research activities outlined in this document aim to protect to the greatest extent practicable (i) individuals working in the labs (i.e., students, postdoctoral fellows, faculty, and staff), and (ii) individuals authorized to be on campus to support this community (i.e., staff, vendors, shipping/delivery personnel). We expect all individuals working on campus to adopt "universal precautions" designed to mitigate the risk of viral transmission. We expect lab groups and departments to take steps to reduce the occupancy density of campus buildings and rooms (to the greatest extent practicable while maintaining personal safety) and to limit person-to-person contact within our facilities.

The development of this plan is based on the following guiding principles:

- Our highest priority is to support community health and well-being.
- We will sustain the excellence of Harvard in both teaching and research.
- We will adopt an evidence-based risk management approach to the COVID-19 challenge, and our decisions will be guided by public officials and health experts.
- We will clearly communicate our policies and decision-making processes as they change over time, acknowledging that we are facing considerable uncertainty.

The resumption of on-campus research will occur in phases with timing based on governmental policies and the state of the disease, the health care system, and society at large. Research groups will need to develop and implement a coordinated and flexible plan for phased re-entry and to prepare for the possible short-notice quarantine of an individual or teams of individuals within the lab groups.

These guidelines have been developed by the Harvard University Laboratory Reopening Committee, the HMS/HSDM/Harvard Chan Lab Ramp-Up Committee, the FAS Dean of Science and Dean of SEAS, and in coordination and consultation with Harvard Schools and affiliated hospitals. This document aims to assist Schools, departments, and PIs with the development and implementation of School-specific plans and to ensure consistency across our University community. The School representatives have adopted the plan and their School-specific templates to be used for PI-specific plans are attached in the appendices. These templates were reviewed and approved by the Office of the Vice Provost for Research (OVPR) in consultation with the Committee. The individual PI plans will be reviewed by the Schools in coordination with the OVPR to ensure alignment with University-level guidelines.

Societal context and risk management

Our Schools are embedded in the greater Boston metropolitan area, and we are intimately linked to this region. We anticipate that once governmental restrictions are lifted, instances of infection will be detected within the Harvard community. This plan is designed to (i) keep the SARS-CoV-2 infection risk to individuals who conduct and support research at a level no greater than what they encounter in typical life off campus, and (ii) minimize the spread of any SARS-CoV-2 infection that may occur within the Harvard community.

The prerequisites for a resumption of research on campus include:

1. The local health care system has sufficient capacity to handle both COVID-19 cases and routine health care needs. We presume this assessment will be conducted by government officials.
2. The Commonwealth of Massachusetts permits lab re-entry. We presume this assessment will be conducted by government officials.
3. Adequate University-authorized masks and personal protective equipment (PPE) are accessible and available without compromising their availability to health care workers. This assessment will be conducted by Harvard's Environmental Health and Safety (EH&S) offices.

Parts of the University are currently operating as an essential business under restricted-access protocols. However, because of the need for de-densification, some proposed activities are not currently being pursued or are being conducted remotely.

Individual responsibilities

To be permitted to enter laboratory areas, individuals must:

1. Complete COVID-19 training relevant for one's access.
2. Comply with occupational health policies regarding reporting and contact-tracing of individuals with any COVID-19 symptoms or test-confirmed diagnosis.
3. Comply with the safety measures defined in the approved plan specific to their research group and with School policies on face coverings and distancing protocols.
4. Agree that each and every access of buildings represents an attestation – that one declares her/himself symptom-free, consent to the opt-in health policy, and agree to comply with all safety measures on and between campuses, both inside and outside buildings.

Staged ramp-up

Currently, the University is operating under "restricted access" criteria, a state in which the overwhelming majority of research is conducted remotely. There are very limited approvals in place for essential personnel to manage critical research and COVID-related activities.

This plan proposes the establishment of a staged-return process with the next stage being defined as "low density (Phases 0-2)." Entry into this stage will include a phased approach:

- **Phase-0: Planning and training.** Develop, review and approve PI/lab-specific plans for return to on-campus research. Train everyone prior to entry onto campus, including those who have been on campus during the restricted access stage.

- **Phase-1: Re-entry of key personnel required to restart research projects.** Includes (i) researchers (e.g., those needed to restart critical equipment, identify supply requirements for lab restart, prepare core

facilities, sustain tissue or cell cultures, and sustain breeding animal colonies) and (ii) key support personnel required to restart critical infrastructure and core facilities.

- **Phase-2: Research and Support**. Includes (i) personnel whose research is ready to start (based on the work completed in Phase-1) and (ii) corresponding support personnel required to be on campus to support researchers in Phase-2.

Subsequent phases of ramp-up will be developed and managed based on the trajectory of the pandemic, University and government guidance, and emerging information and experience gained in the low-density phases. A road map for such subsequent phases will be presented at a later date.

A PI-driven approach, with oversight

The principal investigator (PI) of a research program—with detailed knowledge of workflow, layout, personnel, shared instrumentation, and program priorities—will work with his/her/their research group and departmental administrators to craft a plan to resume a program's research activities. The research group's plans will be subject to departmental review. School approval of departmental plans will ensure commonality of principles in implementing approaches across the enterprise and coordination between multiple departments using the same building. ***No new work can begin until a lab's plan receives School and University approval.***

Culture of safety

To safely and successfully open the labs, we must consciously cultivate a culture of **safety**. In occupational health and safety guidance, there are several key elements to building a workplace culture of safety that we incorporate in this effort: (i) communication, (ii) involvement of employees, (iii) training, (iv) leadership by example, and (v) a well-defined reporting process.

With these principles in mind, labs should consider the optimization of their phased re-opening a collective effort guided by the PI, who bears ultimate responsibility for compliance. COVID-19 safety is in a sense a new type of consideration for lab safety but has some similarities to biosafety and radiation safety. For COVID-19 safety, however, we do not have years of experience to draw from and instead must establish new protocols, guided by available evidence and common sense, to begin re-entry back to the labs.

Labs will formulate their draft plans in different ways. In some cases, this will be the work of a few individuals and in some cases many. However, after the plan is developed, every member of the lab should review this plan and raise and discuss concerns. The plan should be revised as necessary in light of this discussion, recognizing that in some cases it may not be feasible to address every concern and that some decisions will need to be made against a backdrop of considerable uncertainty. Early investment by PIs in engaging their entire lab community is critical to defining best solutions, ensuring equity, promoting compliance, and mitigating risk. ***All lab members should review plans prior to submission for approval and be informed should there be any changes prior to implementation.***

Rationale and specific guidelines

The goal of this plan is to minimize the risk that the resumption of on-campus lab activity will contribute to the transmission of SARS-CoV-2 within the University and in the broader community. To do this, we must limit physical contact and proximity among people. The University will achieve this in three ways:

- Limiting total person density within the University (where we expect that the target density will be established by both Harvard and the state and local governments based on local conditions),

- Establishing space usage guidelines that optimize the distance between people, and
- Constraining transmission by having individuals work in shifts.

The specifics of this plan are informed by the current Massachusetts Department of Public Health definition of the type of contact that creates high risk of SARS-CoV-2 transmission and would trigger a quarantine recommendation, recognizing that testing of asymptomatic contacts is not yet available. According to current state guidelines, a high-risk contact is someone who has been in contact with a COVID-19 case for greater than 15 minutes at a distance of 6 feet or less. After this type of contact, an individual would be asked to self-quarantine for 14 days.

We recognize the current uncertainty inherent in this definition and seek to achieve a higher standard of workplace safety than simply the elimination of high-risk contact according to this definition. To do so, we will initially employ the following additional five layers of protection:

- Required self-evaluation for COVID-19 symptoms and attestation as symptom-free for entry,
- Mandatory use of University-issued or -approved protective face coverings—currently defined as surgical masks—while on campus and in buildings,
- Enhanced density and distance requirements,
- Limited physical contacts through shift work,
- Enhanced facilities maintenance and custodial support.

These supplemental layers of protection are designed to maximize safety and to establish a workplace environment in which the state-mandated quarantine standards will be implemented if any COVID-19 cases emerge in our workforce, while still allowing most individuals working in the same area to continue their work. The details of the cleaning protocols and occupational health responses to a case of COVID-19 on campus are described below. A component of the overall strategy is a University-wide Occupational Health Plan that is currently under development.

We plan to assess the efficacy of the described policy by occupational health monitoring for case clusters among individuals who share proximate spaces but do not meet the definition of a close contact. Emergence of a cluster of infections may trigger a broader requirement for quarantine than that mandated by the state and initiate re-evaluation of the lab distancing plan.

As we gain experience or as the SARS-CoV-2 testing landscape evolves, we may find that some of these restrictions can be relaxed or otherwise modified.

Self-evaluation for COVID-19 symptoms

- Individuals will follow the symptom screening protocol defined by EH&S and Occupational Health Services.
- Any individual who uses their ID card to enter a building is making an attestation that they are free of COVID-19 symptoms. Schools are encouraged to adopt an affirmative daily declaration that is submitted electronically.
- Any individual who has had a COVID-19 diagnosis will follow occupational health guidelines for return to work.

Viral and serological testing

- Viral and serological tests for SARS-CoV-2 are increasingly available but not yet at a scale that would support near-universal, frequent screening for asymptomatic infection. The University's approaches to screening will be modified as testing technologies evolve.

Protective face coverings

- University-approved face masks, initially provided by the institution, will be worn at all times while in campus buildings except when eating or drinking. Face coverings will also be worn outdoors on campus.

- Mask usage (i.e., donning, doffing and storage) will follow the EH&S protocols described in a required training module.
- Any exceptions to the described mask usage policy require approval at the School level.

Density and distance guidelines

- Density targets will conform to state and University guidelines.
- School-specific implementation protocols will be provided separately.
- Work that can successfully be done remotely should continue to be done remotely. For example, typical lab group and 1-1 meetings will continue to be held remotely.
- Workstations will be distanced from one another. CDC recommendations are that individuals maintain a minimal distance of 6 feet from one another, but labs should try to achieve a distance of 9 feet or greater between workstations where feasible. Whenever possible, researchers should be assigned a particular workstation. For shared workstations, only one researcher should work at a given workstation at a time, with disinfection of equipment and surfaces between users.
- Experimental situations that require individuals to work in proximity to one another (<6 feet) will be rare. Such exceptions to the standard distancing guidelines should be clearly outlined in the proposed lab plan and require approval through the School's processes.
- The position of equipment and a given lab's workflow will dictate the final plan. If significant deviations from the recommended distance requirements are proposed, they should be called out for discussion during review.
- Desk seating for individuals should be separated by at least 6 feet and ideally 9 feet or greater.
    - In general, time in lab should be dedicated to experimental and/or computational work that cannot be done remotely. Other activities like analyzing data, reading, writing and meeting with lab members should continue to be done remotely.
    - Use of shared offices is discouraged and efforts should be made to maximize a floor's office space capacity (e.g., administrative offices and faculty not in use) to provide well distanced, pre-defined places to sit during experimental downtimes.
- Lab plans should identify places for individuals to eat and drink separately from others.
- If sharing space is unavoidable, seats should be separated by a minimal distance of 6 feet and ideally 9 feet or greater.

Constraint of social contacts through shift work

For almost all labs, shift work will be an important component of low-density phased re-entry planning, independent of distancing. **Fixed shift teams** limit the size of any given person's potential interactions over time and serves as a buffering function that distance alone does not accomplish. Fixing shift teams – at least in the earliest phase of reopening – functionally limits the number of people in the lab who would potentially be at risk for infection as well as the number who may need to be quarantined should a lab cluster emerge. If a shift team is not fixed, then there is higher likelihood that everyone in a lab would interact at some point over a given infectious period, and if a lab cluster emerges, the whole lab would be at risk for infection and may need to be quarantined. Where multiple labs share space, it is important to get a consensus across all users on the appropriate model.

Shift schedules should be developed that are consistent with the following **guiding principles**:

- All researchers and workers should be informed of safety measures that are being taken, due consideration given to concerns that are raised, and, where appropriate, reasonable accommodations made. Any issues related to an individual's return to work should be discussed on a case-by-case basis with the PI, in consultation with department administrators and Occupational Health Services.
- Everyone who is coming into labs should be familiar with the plans, safety procedures, and guidelines and should know who to contact if there are concerns.
- The ability to participate in lab research should be granted in accordance with all applicable University policies and regulations, including non-discrimination.

Below, three different shift models are described; other models may be developed as well. The most appropriate model will depend on a lab's work and space layout (e.g., need to access animals, experimental duration) and staff preference. It is important to note at the outset that inevitably people will have experiments that extend past the boundaries of their shifts. However, shift teams should be considered fixed until we better understand workplace transmission risk. Thus, for some labs, this will necessarily change how projects are structured. Implementing shift work may necessitate more team science and, if prolonged, could durably alter how we conduct research. The mechanism by which shifts are assigned are not defined, but considerations should include lab members' transportation options, childcare responsibilities, and the ability of operations in a given site to support the designated shift hours. At the current time, campus buildings will be open for low-density shift work by researchers seven days a week with hours designated at the School level.

Shift model A – divide the day
The day is divided into two shifts. Every lab member is assigned to an AM or PM shift. Individuals can only come in during their shift. Two 4-hour shifts may not be realistic for many labs. Time windows that allow closer to 8 hours per shift (e.g., 6:00 AM – 1:00 PM—lab does wipe down on exit; 2:00 PM – 10:00 PM—lab does wipe down on exit) may be possible but should address the operation's ability to support extended hours and accommodate any lab member. Plans should include a time buffer to ensure shift changes occur without cross-contact.

Shift model B - divide the week
The week is divided into two shifts. The easiest division to imagine is MonWedFri/ TueThuSatSun but other divisions are possible (Sun – Wed and Thu – Sat). This allows longer workdays for experiments that are not easily accomplished in 4- to 6-hour blocks. There is less daily concern about (and friction over) overlap. However, some people would always be working on the weekends.

Shift model C - somewhat longer blocks
A 15-day period could be divided into three blocks. Lab personnel (or physically proximate groups) are divided into three pods. Pod A works on campus the first 5 days and then works remotely for the next 10 days. Pod B works remotely the first 5 days, on campus the next 5 days, and then remotely the last 5 days. Pod C works remotely the first 10 day and then on campus for the last 5 days. That ends a 15-day period. This strategy is designed to even more strictly isolate work units.

Enhanced facilities maintenance
Schools will optimize operational protocols to minimize SARS-CoV-2 transmission risk, including:

- An entry/exit and common space management plan
- Protocols and training for outside vendors, contractors and visitors
- Protocols and training for daily cleaning of lab and office spaces by researchers
- Enhanced cleaning protocols for common spaces including bathrooms
- Specific bathroom, elevator and kitchen protocols to minimize shared occupancy and increase opportunities for surface decontamination
- Optimization of HVAC performance to maximize air exchange and enhancement of filtration where feasible
- Additional modifications to physical environment to minimize surface contact.

Compliance

It is expected that every member of the Harvard community will comply with the safety principles described above. However, building deep familiarity with safety protocols will take time and mistakes will happen. Establishing a culture of safety requires a nonpunitive system for reporting and addressing concerns, in keeping with University policies protecting good faith reporting of suspected violations of law or Harvard policy. PIs are ultimately accountable for the safe conduct of work within their labs.

- Every lab will identify a **COVID-19 safety officer** who may be the existing lab safety officer. This individual will serve as a reference for lab members and as a point of contact for the School.
- Each School will establish a **COVID-19 oversight team**. This team will review changes in individual lab plans and institutional guidance, monitor compliance, and collect and provide information relevant to any changes in policies or procedures to COVID-19 safety officers and PIs.
- Lab COVID-19 safety officers will meet regularly as a group with the respective School COVID-19 oversight structure to discuss best practices, identify deficiencies, and receive relevant information to communicate back to lab members.
- Deficiencies may also be brought directly to the attention of the PI, department or area chair, School, and University.
- The COVID-19 oversight team will work with the appropriate department or area chair to establish appropriate corrective action in case of infractions. First responses may include education, retraining, or reconsideration/modification of the lab re-entry plan.
- Repeated infractions or willful non-compliance may result in revocation of an individual's or an entire lab's ability to work on campus.

Note: The School COVID-19 oversight teams are strongly encouraged to report their findings to their representative(s) on the University Laboratory Reopening Planning Committee so that their experiences and enhancements can be shared with the broader Harvard research community.

Occupational Health Services (in development)

- Individuals working on campus must comply with the program overseen by Occupational Health Services, which will direct individuals to testing and retraining when appropriate and monitor School-wide data for possible clusters of infection in campus buildings.
- Any instances of symptoms, exposure, or a positive test will be disclosed to Occupational Health Services.
- Individuals will comply with isolation and quarantine policies established by the Commonwealth of Massachusetts and the University.
- These guidelines are subject to change pending development in availability of viral and serological testing and/or changes in state guidelines.

Appendix 1:

Harvard University Laboratory Reopening Planning Committee

Richard McCullough (Chair)	Vice Provost for Research, Harvard University; and Professor of Materials Science and Engineering, Harvard John A. Paulson School of Engineering and Applied Sciences
Paul J. Anderson	Senior Vice President, Research and Education and Chief Academic Officer, Brigham and Women's Hospital; K. Frank Austen Professor of Medicine, Harvard Medical School
Ayis Antoniou	Administrative Director, Wyss Institute for Biologically Inspired Engineering at Harvard University
Stephen Blacklow	Gustavus Adolphus Pfeiffer Professor of Biological Chemistry and Molecular Pharmacology, Blavatnik Institute, Harvard Medical School; Chair, Department of Biological Chemistry and Molecular Pharmacology, Blavatnik Institute, Harvard Medical School; Professor, Department of Cancer Biology, Dana-Farber Cancer Institute
Frank J. Doyle	John A. Paulson Dean of the Harvard John A. Paulson School of Engineering and Applied Sciences and John A. and Elizabeth S. Armstrong Professor of Engineering and Applied Sciences
Sarah Fortune	John LaPorte Given Professor of Immunology and Infectious Diseases, Harvard T. H. Chan School of Public Health; Chair, Department of Immunology and Infectious Diseases, Harvard T. H. Chan School of Public Health; Director, TB Research Program at the Ragon Institute of MGH, MIT and Harvard
Kenneth Freedberg	Director, Medical Practice Evaluation Center, Massachusetts General Hospital; Professor of Medicine, Harvard Medical School
Javier Guzman	Deputy General Counsel, Harvard University
William Hahn	Chief Scientific Officer, Dana-Farber Cancer Institute; William Rosenberg Professor of Medicine, Harvard Medical School
Laura Maliszewski	Executive Director of the Harvard Program in Therapeutic Science and the Laboratory of Systems Pharmacology, Co-Director of the Harvard-MIT Center for Regulatory Science, and Lecturer on Systems Biology, Harvard Medical School
Harry Orf	Senior Vice President for Research, Massachusetts General Hospital; Principal Associate in Genetics, Harvard Medical School

Christopher Stubbs	Dean of Science, Harvard University Faculty of Arts and Sciences; Samuel C. Moncher Professor of Physics and of Astronomy, Harvard University Faculty of Arts and Sciences
Gyongyi Szabo	Chief Academic Officer, Beth Israel Deaconess Medical Center and Beth Israel Lahey Health; Faculty Dean for Academic Affairs, Harvard Medical School; Mitchell T. Rabkin, M.D. Chair, Harvard Medical School
Ara Tahmassian	University Chief Research Compliance Officer, Harvard University
Ravi Thadhani	Chief Academic Officer, Partners Healthcare; Professor of Medicine, Harvard Medical School and Massachusetts General Hospital; Dean for Academic Programs at Partners Healthcare, Harvard Medical School
Bill VanSchalkwyk	Managing Director of Environmental Health & Safety, Harvard University Campus Services
Amy Wagers	Co-chair, Harvard Department of Stem Cell and Regenerative Biology; Forst Family Professor of Stem Cell and Regenerative Biology, Harvard University Faculty of Arts and Sciences and Harvard Medical School; Senior Investigator in the Section on Islet Cell and Regenerative Biology at the Joslin Diabetes Center
Conor Walsh	Paul A. Maeder Professor of Engineering and Applied Sciences, Harvard John A. Paulson School of Engineering and Applied Sciences; Core Faculty Member, Wyss Institute for Biologically Inspired Engineering at Harvard University
Malcolm Whitman	Professor of Developmental Biology and Associate Dean for Basic Science Research, Harvard School of Dental Medicine
David Williams	Senior Vice President and Chief Scientific Officer, Boston Children's Hospital; Leland Fikes Professor of Pediatrics, Harvard Medical School; Chief, Division of Hematology/Oncology, Boston Children's Hospital; Associate Chair, Department of Pediatric Oncology, Dana-Farber Cancer Institute

HMS/HSDM/Harvard Chan School Laboratory Ramp-Up Committee

Clifford Tabin	Chair of Genetics, Blavatnik Institute, HMS
Julie Huang	Director of Research Administration for Cell Biology, Blavatnik Institute, HMS
Stephen Blacklow	Chair of Biological Chemistry and Molecular Pharmacology, Blavatnik Institute, HMS
Sarah Boswell	Senior Scientist in the Laboratory of Systems Pharmacology, Systems Biology & Director of the Single Cell Core, HMS
Brian Corning	Executive Director of Harvard Center for Comparative Medicine, HMS

Carl Cowan	Assistant Director of Emergency Management, HMS
Sarah Fortune	John LaPorte Given Professor of Immunology and Infectious Diseases, Harvard Chan School
Stephen Maiorisi	Chief Campus Planning and Facilities Officer, HMS
Laura Maliszewski	Executive Director of the Harvard Program in Therapeutic Science and the Laboratory of Systems Pharmacology, HMS
Jennifer Ryan	Chief of Staff, Dean's Office, HMS
Christine Seidman	Thomas W. Smith Professor of Medicine, HMS and BWH
Amy Wagers	Co-chair of Stem Cell and Regenerative Biology, HMS/FAS
Malcolm Whitman	Professor of Developmental Biology, Associate Dean for Basic Research, HSDM

Appendix 2:

References and Helpful Resources

The following websites were consulted in drafting the Plan and are provided here as reference material

1. OSHA Guidance on Preparing Workplaces for COVID-19:
   https://www.osha.gov/Publications/OSHA3990.pdf (PDF)

2. OSHA COVID-19 Website:
   https://www.osha.gov/SLTC/covid-19/controlprevention.html

3. CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19):
   https://www.cdc.gov/coronavirus/2019-ncov/lab/index.html

4. ABSA SARS-CoV-2/COVID-19 TOOLBOX:
   https://absa.org/covid19toolbox/

5. WHO Laboratory biosafety guidance related to coronavirus disease 2019 (COVID-19):
   https://www.who.int/publications-detail/laboratory-biosafety-guidance-related-to-coronavirus-disease-2019-(covid-19)

6. CDC Guidance for Schools, Workplaces & Community Locations:
   https://www.cdc.gov/coronavirus/2019-ncov/community/index.html

7. EPA- List N: Disinfectants for Use Against SARS-CoV-2:
   https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2

8. Biosafety in Microbiological and Biomedical Laboratories (BMBL):
   https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF (PDF)

9. Use of Hydrogen Peroxide Vapor Generators for Decontamination:
   https://ohsonline.com/articles/2013/01/02/hopkins-study-proves-hydrogen-peroxide-vaporizers-highly-effective.aspx
   https://www.vaisala.com/en/blog/2020-03/combating-covid-19-h2o2-vapor-bio-decontamination

10. Back-to-work criteria for health care workers:
    https://www.cdc.gov/coronavirus/2019-ncov/hcp/return-to-work.html#practices-restrictions

Appendix 3:

University Principal Investigator Lab Re-entry List Example

The process

- Personally complete any required EH&S training and consent modules.
- Designate lab COVID-19 safety officer.
- Develop lab staffing and usage plans per guidance below.
- Review plans with lab and revise as necessary based on feedback.
- Submit for review by department and Dean's office.
- Share requirement that all lab members complete required EH&S training prior to reentry.
- Make any local adjustments to plan based on departmental and decanal review.
- Receive plan approval (end of Phase-0).
- Key personnel initiate space and workflow modifications as outlined in plan (Phase-1).
- Await notification on timing of research ramp-up (beginning of Phase-2).

Laboratory layout and configuration

- Review the layout of benches, workstations, and devices within the laboratory.
- Take full advantage of all real estate within the laboratory.
- Designate specific workstations on laboratory benches, with maximum physical separation of at least 6 feet apart and ideally 9 feet or greater, minimizing the need for individuals to pass frequently by one another. In most laboratory spaces, this will limit occupancy to 1 person per bay, although certain laboratory layouts may be permissive for different levels of occupancy. Such instances should be justified in the proposed lab plan and will be reviewed.
- When possible, relocate shared instruments to minimize "embedding" in bays and increase personnel separation.
- Identify and define usage plans and scheduling procedures for common lab spaces such as tissue culture and microscopy rooms.
- Working with your departmental leadership, identify and designate any available common and office space for eating to maintain appropriate social distancing.

Staffing plan

- Determine on-site personnel, factoring in considerations such as:
    - individual career needs and timelines
    - ability to perform work remotely
    - ability to commute to campus safely
    - ability to obtain childcare
    - personal health concerns (e.g., underlying health conditions, risk to household members)
    - grant funding regulations

    - coordination with neighboring labs on open floors as needed
    - capacity of core facilities to support projected research
- Establish a shift plan that distributes available laboratory workspaces across personnel.
    - Ability to participate in laboratory research should be granted in accordance with all applicable University policies and regulations, including non-discrimination.
    - Define shift plan and other relevant arrangements for laboratory usage.
- Consider a booking system for the use of common equipment.

Office spaces

- Review desk assignments.
- Define desk usage that allows at least 6 feet, and ideally 9 feet, of distancing.
- Define occupancy limits for shared office spaces.

Administrative support

- Alert administrators to evolving group needs and expectations.
- Consider and/or set up online calendar and work scheduling tools.

Operational Procedures

- Regularly disinfect high touch surfaces (e.g., door handles, washbasin handles, drawer handles, or common equipment such as workstations) *before and after use*.
- Restrict guests to only essential visitors such as contractors and vendors.

Appendix 4:

University PI Lab Re-Occupancy Planning Form

Faculty/PI Information

Name (Last, First)	
HUID	
Department(s)	
Email Address	

Laboratory Information

Building(s)	
Room Numbers	
Core Facilities or other units	

Lab COVID-19 Safety Officer

Name	
Phone number	
Email address	

Key Personnel who will prepare the lab for re-entry (Phase-1)

Name (Last, First)	HUID	Position/Appt Type	Email Address	Cell Phone number
Harvard, John	*12345678*	*G4 Student*	*johnharvard@harvard.edu*	*617-555-5454*

Lab Personnel (Phase-2)

Identify all personnel who will be performing research or essential services on campus. Those who can continue to work remotely should do so.

Name (Last, First)	HUID	Position/Appt Type	Email Address	Cell Phone number
Harvard, John	*12345678*	*G4 Student*	*johnharvard@harvard.edu*	*617-555-5454*

Lab Schedule

Provide the frequency and duration of work on campus for each lab member. Membership should not overlap across different shift teams.

Shift	Proposed Work/ Access Times	Name
Shift team 1		
Shift team 2		
Etc.		

Shared Research Space Use

(1) Identify procedure rooms, equipment rooms, tissue culture rooms, microscopy suites, environmental rooms, autoclave and glass washing facilities, etc. Describe distancing plan for these spaces.

(2) Identify facilities/spaces shared by groups outside your lab which may need centralized scheduling system to be coordinated by department or School.

(3) Please list anticipated Core Facility usage here. We expect that Core Facilities will be establishing independent scheduling systems.

Shared Office Needs

To the extent possible, all planning and analysis should take place off campus to limit the amount of time lab members spend on campus. If your laboratory has a common desk area outside the laboratory, please note that below and estimate its use per person.

Ancillary Space Considerations & Schedule

Please identify common areas that will be reserved as designated places for meals as assigned by your lab or department.

For Admin Use

Department Chair(s) Approval	
School Approval	

Appendix 5:

Guidance for Human Subject Research

Summary

The following guidance was developed through a collaboration between the Harvard Institutional Review Boards (IRB) from the Harvard Longwood Campus and the Harvard University Area as well as faculty across FAS, SEAS and HMS to assist the research community with the preparation for research studies that involve in-person interactions with study participants. For more information on any modification that may be required to already approved IRB protocols, please see this link - https://cuhs.harvard.edu/what-does-and-does-not-require-irb-review-and-approval.
This guidance adheres to Harvard University's Core Principles for On-Campus Research which include:

- At this time, use of on-campus research space should be limited to those activities that cannot successfully be done remotely.
- Individuals should access only those areas of campus buildings that are necessary to do their work.
- On-campus research should be organized/prioritized to limit person density and simplify personal interaction networks while maintaining personal safety.
- On-campus researchers should adopt "universal precautions" designed to mitigate the risk of viral transmission, including frequent handwashing, physical distancing, proper use of University-issued or approved masks, avoidance of contact with high-touch surfaces, and attention to surface and equipment disinfection protocols.
- Explicit training on implementing these practices should be provided and demonstration of proficiency required prior to lab re-entry.

The extended guidelines in this Appendix build off these guidelines and are specific to the different stages involving human subjects research, from planning to follow ups. The overall guiding principles remain the same but additional considerations are outlined given the unique aspects of human subjects research (e.g. setting time bounds and additional PPE for continuous interactions <6 feet and considering risk to study participants, in particular those at higher risk of COVID-19).

PIs are responsible for developing plans for the resumption of human subjects research that demonstrate how risk is mitigated. For approval, PIs will have to follow the same process their institution has implemented for general lab reopening. Review will be done at the institutional level (FAS-SEAS as one unit) with input from the Chief Compliance Officer, Vice Provost for Research and outside experts as needed. Department/area chairs will lead the process and report into School Deans. Each institution will set their own deadline for initial submissions and any follow-on windows as needed. For multi-institutional collaborations, the guidelines of the institution where the research is being conducted are to be followed. More information may be found here - https://cuhs.harvard.edu/instructions-returning-person-human-subjects-research?admin_panel=1

Phased Approach to Minimize Risk

The restarting of human subjects research will be based on a phased approach using a clear set of guidelines for each phase. Given the diversity of human subjects research across the University, each institution will set their own criteria for a phased return to human subjects research. Institutions will be encouraged to share their criteria with others in order to have consistency where possible. ***Investigators should reach out to their local institutional and IRB leadership for specific guidance.***

Planning for a return to in-person interaction with study participants

- To reduce interaction time, is it possible for some or all study visit procedures to be completed via telephone or virtually? For example, is it possible to screen and consent individuals prior to coming into the lab? See *IRB Guidance on flexibility in documenting informed consent* for more information- https://cuhs.harvard.edu/everything-you-wanted-know-about-documented-consent-were-afraid-ask.
- Is it possible for some study visits or visit activities (e.g. vitals assessment, gait assessment) to be completed at the subject's local clinical lab, clinical office, or imaging center? For example, can the procedures occur in the context of a needed clinical care visit and/or through interaction with only the clinical care providers the participant would see even if not participating in the research?
- Review and modify the timing and scope of specific study visits to account for essential versus non-essential study procedures.
    - Create a list of study procedures that may prevent safe distancing or require modified use of PPE by participants (e.g., If there is a need to make oxygen measurements for energetics this will preclude a participant wearing surgical face mask). Document safety precautions and procedures that can be put in place to mitigate risk of infection of participants or research team members.
- Consider the study population and whether the research aims/questions could be sufficiently addressed without recruiting those at greatest risk of COVID-19 infection. It is recognized that some research studies require working with specific populations.
- Those that might be at higher risk for severe illness from COVID-19 include:
    - Older adults
    - People with underlying medical conditions
    - Also consider those that may need to take extra precautions such as: people with disabilities, those that are homeless, or those that are pregnant.
    - See *CDC guidelines* for a complete listing- https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-higher-risk.html
- Consider what adjustments can be made to procedures and locations when study participants may not be able to wear masks. For example, this may apply to studies that involve infants and toddlers. Consideration should be given to not only mitigate risk for study team members interacting with the participant but also for the entire time that the participant will be on the Harvard campus.
- Minimize the use of paper forms.
- Identify applicable requirements or restrictions that have been or may be put into place at a national, regional, organizational or facility level and how these may impact the research (e.g., travel restrictions, school closings, remote work mandates).
- Be mindful of current federal, state, local, and institutional restrictions and guidelines on the conduct of research and face-to-face contact with human subjects.
- Before the resumption of any human subjects research, each Principal Investigator should develop standard operating procedures (SOP's) specific to their own research activities (including operations, equipment and procedures). This should also include the location of the research and the risk of exposure both due to geographical location and the facility types. (e.g., on campus, hospitals, clinics, schools, community, home). The locations of work should be evaluated room by room where participants and staff will be present, with a general guideline to have a minimum of 100 CFM (cubic feet per minute) of airflow per person. These SOP's should be submitted to local institutional leadership following the same guidelines for general lab re-opening.

Area/Department Chairs will lead a review process that will involve having SOP's peer reviewed by faculty either within or outside the PI's institution. See *Harvard Research Laboratory Re-Entry Plan* - https://provost.harvard.edu/files/provost/files/harvard_university_research_laboratory_re-entry_plan_5.14.20.pdf

- A small number of PIs from across FAS and SEAS have developed SOPs for specific activities that have undergone peer review. Example FAS-SEAS SOPs and templates for creating SOPs can be found here - https://cuhs.harvard.edu/instructions-returning-person-human-subjects-research?admin_panel=1. ***Please also check if your local School/Department has any specific templates or guidance.***
- Develop a plan for Cleaning and Disinfecting Lab space. See "***Cleaning and Disinfecting of the Lab"*** found at the end of the document.
- Determine what additional supplies may be needed: PPE, cleaning supplies, implementing disposable items.

Prior to interaction with study participants

Restrictions

- Restrict study visits to essential individuals and limit interactions.
    - Only those individuals that are necessary to complete the study procedures should be present: study personnel, study subject, guardians, and those that may be there to assist the study subject, if necessary. If possible, designate a single individual to interact with the participant for the entire study visit, with all others at safe distance.
- Limit the number of people present in an area at any given time.
    - This may involve creating a schedule for study team members, using multiple rooms for study visits, waiting areas, etc.
    - Consider whether it is possible to move study procedures to conference rooms or classrooms that have greater airflow and greater feasibility of maintaining social distance. For example, computers could be transported on carts to alternative testing spaces.
    - Consider using video conversations with individuals in different rooms/locations where possible to limit personal interactions.
    - Consider approaches to train personnel on study procedures virtually, if possible. If this is not possible, researchers requiring to be trained on specific study procedures may only be present at study visits if the training is required for them to perform their job. If this happens, the study team needs to be conscious of room occupancy and to maintain a safe environment for all.
- Prepare a schedule for visits to ensure sufficient time between visits.
    - It is recommended to plan for sufficient time between visits of different participants to ensure proper sanitation of any materials or equipment as well as sufficient turnover of air where the study visit is being performed. Groups sharing spaces for human subjects research should have a schedule to enable this to be coordinated across groups and studies. A 2-hour time window is a good benchmark for a well-ventilated space. A shorter time gap may be possible if the airflow allows 6x changeover more quickly. PI's should contact local institutional leadership for any questions related to space and HVAC systems.

Screening

- Study Team: All study team members that will be present in the lab space and/or that may come in contact with study participants, are required to self-screen prior to coming to the lab each day (see *Harvard University Screening Procedures for Harvard Affiliates* – https://crimsonclear.harvard.edu/. Note that those Study Team members who at higher risk for severe illness from COVID-19 should consult with their Harvard School/Department on institutional guidelines.
- Study Participants: Study participants should be contacted and screened both on the day before the visit and immediately upon arrival (see *Screening Procedures* – https://cuhs.harvard.edu/instructions-returning-person-human-subjects-research?admin_panel=1 as well as *CDC COVID-19 current screening guidelines* - https://www.cdc.gov/coronavirus/2019-ncov/index.html)).
    - If the participant is unable to be reached the day before, the visit screening should be attempted the morning of the study visit in addition to the required screening immediately upon arrival.

Testing

- To keep Harvard healthy, Harvard affiliates who will be on campus must adhere to public health measures and participate fully in University programs to control the spread of COVID-19. Frequency of testing and other responsibilities may be found here - https://www.harvard.edu/coronavirus/testing-tracing#current

Training

- All essential personnel should review proper PPE use prior to interaction with participants and have completed the state-mandated COVID-19 training (available in the Harvard Training Portal).

Preparing Study Participants for the Visit

- Communication to participants: Research teams should consider communicating to participants before their study visit, outlining the following:
    - Depending on the level of information to be shared, consider developing a simple informational sheet that can be provided to all participants describing how the study team is making the environment as safe as possible when they come in for their research visit and so they know what to expect. If there are special procedures for visitors (e.g., parking, building access, or location change). Please see example template titled *COVID-19 Information Sheet for Participants* - https://cuhs.harvard.edu/instructions-returning-person-human-subjects-research?admin_panel=1
    - As part of communication to participants, share with them latest CDC guidelines on risk factor associated with COVID-19 - https://www.cdc.gov/coronavirus/2019-nCoV/index.html.
    - Instruct participants to bring water and a snack, if applicable.
    - Advise participants that they should put on a facemask, regardless of symptoms, before leaving their home.
    - Inform participants of transportation options. It is recommended that a risk-based approach be used in considering the best method of transportation. Consider whether the individuals can safely walk to the lab or provide their own transportation. If this is

possible, consider checking if your institution can offer free parking. Next, consider an Uber or taxi and whether the fee be reimbursed. Lastly, public transportation is strongly discouraged if it is the only option.

Preparing the Study Visit Area

- Clean and Disinfect study lab/visit space. This may include tables, chairs, equipment such as MRI machines, VR headsets, wearable systems, and other non-disposable equipment or items used during the study visit. See "***Cleaning and Disinfecting of the Lab"*** found at the end of the document as well as *CDC guidance on Cleaning and Disinfecting* - https://www.cdc.gov/coronavirus/2019-ncov/community/reopen-guidance.html
- Space utilized for study visits should be cleaned and disinfected daily, in between each participant study visit, and after all visits are completed for the day.
- Designate experiment areas and areas for guardians / other visitors and their belongings.
- Preparing the lab space before the participant arrives (e.g. propping open doors, calibrating all equipment, etc.).
- Covering keyboards, mice, tablets and other devices in plastic (e.g. saran wrap).
- Have PPE available for study participants (which includes face masks, and hand sanitizer).
- Study team should also have a supply of bottled water and non-perishable snacks on hand in case needed.
- If study procedures prevent being two meters/6 feet apart, it is encouraged to set up a plexiglass barrier to separate study staff and participant when possible.

During the Study Visit

- Study staff should be ready for study participant by wearing PPE and having all materials, equipment, and all other items ready for the visit. Study staff should wash or sanitize their hands just before study visit begins, and throughout study visit (I.e. both before and after contacting a study participant or piece of equipment or surfaces in vicinity of participant).
- Screen all study participants and family members, caretakers, legal representatives, etc. before entering the lab/building (see *Screening Procedures* – https://cuhs.harvard.edu/instructions-returning-person-human-subjects-research?admin_panel=1 as well as *CDC COVID-19 current screening guidelines* - https://www.cdc.gov/coronavirus/2019-ncov/index.html))
- Provide all study participants and anyone else present (e.g., family members, caretakers, legal representatives) with PPE to wear during the visit in accordance with University guidelines, even if they have their own.
- If and when possible, study staff should maintain distance from participant. Remain two meters/6 feet apart and it is encouraged to use a plexiglass barrier to separate study staff and participant when possible.
- Consider monitoring experiments using (non-recording) cameras, if possible, to create additional physical separation.
- Consenting should be conducted virtually when possible. If the consent process will happen in person, consider a contactless method by which to obtain consent (i.e., not having to use pen and paper), for example, sending the form electronically and having the individual document using their phone or iPad.

- If study protocol prevents safe distancing, seek local institutional guidance to see if additional PPE measures should be taken (e.g. a gown, a face mask, and/or a face shield or goggles). Ensure that PPE is being used by all for the duration of the study visit. Also consider if it is possible to have study team member and participate face in opposite directions.
- Anyone who needs to take a break to eat or drink does so at least 6 ft away from others and in advance notifies all the others present in the testing location to ensure adequate distancing during the break.
- If participants are able, advise them to announce their movements, when possible, in the space to avoid accidental broaching of distance.

After the Study Visit

- Clean and Disinfect study lab/visit space and space utilized for study visits (this includes all areas used by study participants, including restrooms). These spaces should be cleaned and disinfected daily, in between each participant study visit, and after all visits are completed for the day. This may include tables, chairs, equipment such as MRI machines, VR headsets, wearable systems, and other non-disposable equipment or items used during the study visit. See "***Cleaning and Disinfecting of the Lab"*** found at the end of the document. As well as *CDC guidance on Cleaning and Disinfecting* - https://www.cdc.gov/coronavirus/2019-ncov/community/reopen-guidance.html
- Ensure that stock of PPE is replenished. This may include facemasks, hand sanitizer, etc.
- Study teams are advised to ask the participant to get in touch with their study coordinator if within 14 days if they or anyone in their living group has any of the above COVID-19 symptoms or a positive COVID test.
- If it is found out that a study team member has contracted COVID-19 following a study visit, follow *University guidelines regarding positive test results* - https://www.harvard.edu/coronavirus/testing-tracing/test-results
- As well as *University guidelines on quarantine and isolation* - https://www.harvard.edu/coronavirus/testing-tracing/quarantine-isolation
- Surfaces in their workspace should be cleaned and disinfected. See "***Cleaning and Disinfecting of the Lab***" found at the end of the document. As well as *CDC guidance on Cleaning and Disinfecting* - https://www.cdc.gov/coronavirus/2019-ncov/community/reopen-guidance.html

Cleaning and Disinfecting of the Lab Space where Study Visits Occur

Perform routine environmental cleaning and disinfection of lab areas:

- Routinely clean and disinfect all frequently touched surfaces, such as workstations, keyboards, telephones, handrails, and doorknobs.
- If surfaces are dirty, they should be cleaned using a detergent or soap and water prior to disinfection. For disinfection, most common EPA-registered household disinfectants should be effective. A list of products that are EPA-approved for use against the virus that causes COVID-19 is available here - https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2. Follow the manufacturer's instructions for all cleaning and disinfection products (e.g., concentration, application method and contact time, etc.).
- Discourage study team members from using shared phones, desks, offices, or other tools and equipment, when possible.
- Provide disposable wipes so that commonly used surfaces (for example, doorknobs, keyboards, remote controls, desks, other work tools and equipment) can be wiped down before each use.
- Examples of equipment that would need to have cleaning protocols developed for would be MRI machines, VR headsets, wearable robots, robot arms, treadmills, wearable sensors, tablets and other computer input devices.
- If persons suspected/confirmed to have COVID-19 have been in the facility, check with local institutional leadership for appropriate measures. These may be enhanced cleaning and disinfecting or leaving a space vacant for a period of time.