DRAFT

Research Reopening Guidelines for The George Washington University Milken Institute School of Public Health

Collated by:

Office of Research Excellence
GWSPH

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ACKNOWLEDGEMENTS

SECTION 1: INTRODUCTION

The George Washington University (GWU) Milken Institute School of Public Health (GWSPH) is engaged in an intensive planning effort aimed at resuming on-campus activities to the greatest extent possible, as quickly as is prudent, in light of the ongoing COVID-19 pandemic.

This document titled *Research Reopening Guidelines for GWSPH* contains recommended health and safety protocols to put in place during the gradual, multi-phase resumption of on-campus activities.¹ It is intended to apply to all members of our community—faculty, staff, students, post-doctoral fellows, trainees, contractors, vendors, visitors, guests—who are engaged in GWSPH research. This is a companion document to other GWSPH guidelines for 'Operations' and 'Academics' (see separate documents). If you are collaborating with another school, either within or outside GW, please ensure that you are also following their guidance and get approvals from all involved institutions.

This document additionally contains references to essential resources, detailed guidance for specific research domains, and steps for the reopening laboratories and projects. It is recommended that all GWSPH principal investigators (PIs) carefully read Sections 1-3 and Section 5 for the approval process as well as the appropriate entry or entries in Section 4. The domains in Section 4 should also be considered by study coordinators and others responsible for implementing detailed procedures for the project.

We anticipate that these guidelines will evolve as the changing severity of the pandemic and our ability to respond to it allow us to move through the phases of our return to campus framework, subject to state and local regulations and our own public health assessment. The guidelines will be updated, edited and recirculated to the community in later phases of our response as we are able to increase the density and level of activity on campus.

The initial resumption (Phases 1 and 2) of on-campus activities under these guidelines may not mean a return to "business as usual":

- Once GWSPH decides to begin its gradual resumption of on-campus activities, they will be limited
 to those that require a person to be present. Any and all activities that can be accomplished at
 home via telework should continue to be done at home until further notice, and persons should
 only be on campus for the time periods necessary to accomplish required on-campus activities.
- Among other changes, face coverings will be mandatory on campus (except in very limited circumstances), cleaning procedures will be greatly augmented, and social distancing will remain the rule.
- Central to these guidelines is an understanding that some members of our community face a
 greater risk from COVID-19 than others, and we have set forth the mechanisms that are available
 for faculty, staff, and students to seek accommodations or adjustments as warranted by their
 individual circumstances.

This *Research Reopening Guidelines for GWSPH* is also informed by the following principles (which GW espouses):

¹ These guidelines benefitted tremendously from similar documents publicly available at the following universities: University of California, Johns Hopkins, Columbia, Harvard, and University of Maryland amongst others. We are thankful to our colleagues in academic institutions around the country.

- The health and safety of our community is paramount.
- Science, evidence, and pragmatism guide decisions.
- Flexibility and innovation in the face of evolving circumstances.
- We will strive to provide inclusive and equitable solutions.

The Research Reopening Guidelines for GWSPH flows from the broadest guidelines to the most narrowly focused (Figure 1). All guidance is set within the context set by DC and GW, and as the situation evolves, so too may this document. With this layered approach, principal investigators (PI) can tailor a plan for his/her individual projects. Investigators may request exceptions to GWSPH guidelines, but these cannot directly contravene rulings made at higher levels (DC and GW OVPR).

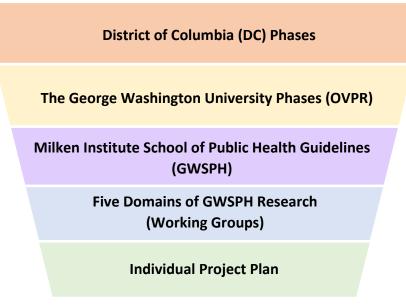


Figure 1. Hierarchy of GWSPH COVID-19 guidance

SECTION 2: OVPR PLANS FOR REOPENING RESEARCH

GW's research community has a plan for reopening that coincides with the greater effort to return to campus. The following guidance has been proposed by the Office of the Vice President of Research (OVPR) as a baseline framework for reopening campus for research and should be tailored to the needs of the school. The following text is copied from OVPR's Memorandum dated 28 May 2020.

2.1 Guiding Principles

Principle 1: The university's top priority is the emotional and physical health and safety of its faculty, staff, and students, as well as the health and safety of those living in the District of Columbia/Maryland/Virginia (DMV) region. No one should feel pressured to return to a research laboratory setting if they are uncomfortable doing so.

Principle 2: All schools and units will coordinate their plans to reopen with those of other schools and units sharing adjacent space as well as with central administration while following directives from local, state, and national public health authorities regarding stay-at-home orders and social distancing. Prematurely opening buildings may result in a sharp increase in infection rates that threatens the lives of the GW community and DMV residents.

Principle 3: COVID Research Task Force(s) has/have been established to provide guidance and oversight for the reopening process. In the event that research labs must ramp down again, appropriate protocols should be followed and the <u>Laboratory Ramp-Down Checklist</u> should be consulted. In addition, the Office of the Vice President for Research continuously updates information on the impacts on research activities here: https://sponsoredprojects.gwu.edu/covid-19.

Principle 4: The ramp up of research will follow a carefully planned, orderly, transparent and phased process, as outlined below.

2.2 Phases of Reopening

Research (both lab-based and social sciences research) will not be the same as it was before the pandemic. While much of the research at the university has been put on hold, we have not shut down completely. Select laboratories have continued with projects using appropriate safety equipment and maintaining proper social distancing. The Office of Animal Research, the Office of Laboratory Safety, the Division of Safety and Security, and Facilities staff will continue to provide essential services and oversight.

2.2.1 Research Phase 0

- Continue research that is possible through entirely online means.
- Select research projects, including COVID-related research, are allowed to continue or commence.
- Only essential personnel are allowed on campus.
- Core facilities are available under special consideration and maintain specific requirements for safety.
- Strict observation of all safety protocols to include, but not limited to, social distancing, personal hygiene, decontamination and appropriate use of personal protective equipment (PPE).

2.2.2 Research Phase 1: Limited Reopening (June 8, 2020)

- Population density may be increased in a manner consistent with university, federal and district or state guidelines (12.5 25% of a lab's or program's staff may be allowed on campus at any one time subject to considerations in the sections below).
- Strict observation of all safety protocols to include, but not limited to, social distancing, personal hygiene, decontamination and appropriate use of PPE.
- Projects not involving chemical or radiological hazards, stopped as part of ramp-down, will be identified and prioritized for phased restart.
- Priority will be given to graduate students and postdocs who are close to completing their degrees/terms of appointment. This includes students and postdocs working on analytical and computationally oriented research.
- Priority will be given to principal investigators (PIs) with grants within four months of their end dates, and/or where the sponsor is not flexible with no cost extensions.
- Research projects conducted on campus using human subjects, and involving direct subject interactions and interventions, can be restarted in a manner consistent with the GW Medical Faculty Associates (MFA), university, federal and district guidelines.
- Necessary core facilities will be reopened in a limited capacity. Staffing and operations of the facilities will be kept at a minimum and training of new users may be suspended.

2.2.3 Research Phase 2: Expanded Reopening (Date TBD)

- Population density will be increased over Phase 1 in a manner that is consistent with university, federal and district and state guidelines.
- Projects involving biological, chemical or radiological hazards, stopped as part of ramp-down, will be identified and prioritized for phased restart.
- Research projects conducted off campus using human subjects, and involving direct subject interactions and interventions, can be restarted in a manner consistent with MFA, university, federal and district or state guidelines (to include travel restrictions).
- Other core facilities will be reopened. Staffing and operations of the facilities will be expanded as needed.

2.2.4 Research Phase 3: Resume Total Research Programs (Date TBD)

- All personnel may return to campus following any new and/or permanent implementation of safety guidelines.
- New projects may be started.
- All research facilities will be reopened.
- Undergraduate researchers will be allowed back in laboratories subject to safety guidelines.

2.3 Determination of Phase 1 Personnel

Each PI or unit head will determine who from their teams should return to work during this phase. Some considerations:

- PhD students and postdocs who must complete experiments to meet a thesis deadline, submit a paper for publication, or submit a grant proposal.
- Team members who volunteer to return.

- Undergraduate and high school students will not be allowed in laboratories. Requests for exceptions must be approved by the school's associate dean for research and forwarded to askovpr@gwu.edu for review and final approval.
- Expertise needed to operate facilities.
- Attempt to allow each lab member to return to campus at least one day a week in order to enjoy some progress on their projects.

2.4 Scheduling and Coordination of Work Hours

Each laboratory, facility and team should develop a calendar system to schedule work shifts throughout the week, including weekends. Shifts should be flexible and could range anywhere from 2 to 12 hours in length. An example would be to have specific people on campus on certain days of the week.

- Team members should communicate openly and often to coordinate and adjust schedules as necessary.
- Team members should plan to use their time in the laboratory for bench time only. Updating notebooks, reading, and writing should be done remotely.
- For laboratory work, a team member's bench should be used only by that team member. If this is
 not possible due to space constraints and benches must be shared, complete and proper decontamination of the bench space must be done before and after each use.

2.5 Health and Safety

- Students, staff, and faculty who feel ill, no matter the cause, must stay home and not perform work of any kind in the laboratory. They should follow standard protocols for unplanned absences and communicate by phone or email to relevant parties (professors, supervisors, etc.) to let them know they are sick.
- Workers must maintain a minimum distance of six feet from others when in the laboratory and other shared facilities.
- Workers must wear face masks at all times and access to PPE and cleaning supplies is critical.
- Labs and core facilities may require additional PPE and cleaning protocols.
- If you think you or someone you know has been in contact with someone who is exhibiting COVID-19 symptoms, please complete this form: GW Possible Contact Form.
- GW's live-answer Information Line for COVID-19 related questions is available Monday through Friday (9am 5pm) and can be reached at 1-855-GWU-INFO (855-498-4636).
- Consequences for not following health and safety protocols are at the discretion of the PI or lab/unit head, but should be approximate to the following. If the non-compliant individual is the PI or lab/unit head then the Associate Dean for Research should be notified.
 - First infraction documented warning.
 - Second infraction suspension from the lab or facility for one (1) week. Notification should be provided to the non-compliant individual's supervisor and directed to the Associate Dean for Research to manage the suspension.
 - Third suspension from the lab or facility for one (1) week. Notification should be provided to the non-compliant individual's supervisor and directed to the Associate Dean for Research to manage the suspension.

 Subsequent infractions – Notification should be provided to the non-compliant individual's supervisor and directed to the Associate Dean for Research to take appropriate action.

All faculty, staff, and students must adhere to GW policies regarding COVID-19. We are confident that faculty and staff understand the importance of these policies and will operate their laboratories accordingly.

SECTION 3: GWSPH GENERAL GUIDELINES

The following information will be covered in detail in the GWSPH **General Operational Reopening Plan**,² a separate document that accompanies the Research Reopening Guidelines for GWSPH. The GWSPH general guidelines provide the philosophy motivating the GWSPH Research Reopening Plan and how it fits into the wider plans for the University and the District of Columbia.

The general guidelines cover the Milken Institute School of Public Health's phased approach to resuming school operations through a gradual ramp-up of activities delineated by phases that run in parallel with, while elaborating upon the phases established by DC and GW. For more information about GWSPH's phases, see [Appendix 1: UNDER DEVELOPMENT].

GWSPH values the health and safety of its faculty, staff, students, and research participants above all else, and these guidelines are in place to ensure risk mitigation.

The general guidelines outline the signifiers of a COVID-19 infection and the protocols if an individual displays these symptoms. Only people free of symptoms will be allowed to return to the campus for work.

It also contains guidelines for universal face coverings and the process involved in donning and doffing them, social distancing practices, handwashing/hygiene, glove use for laboratory personnel, and cleaning procedures (including individual responsibility and what is handled by cleaning staff).

It has sections covering entry requirements to GWSPH facilities and a broad overview of our current procedures. It details best practices in the following situations: public transportation, office environments, meetings, restrooms, elevators, and meals.

The general guidelines also consider <u>CDC risk factors</u> that describe a "vulnerable person," and lays out contacts for those who fall into this category or believe they have other concerns related to returning to campus. The guidelines also call for compassion and empathy during operations in the midst of the global pandemic.

Please also note the GW Office of Human Research (OHR) has released guidance on their website: https://humanresearch.gwu.edu/covid-19#Phase%201%20Guidance. For specific instructions regarding international travel, refer to the Interim Policy for International Travel: https://global.gwu.edu/interim-policy-international-travel.

² Please note this document coordinated by the Executive Associate Dean for Operations Natasha Kazeem

SECTION 4: PROTOCOLS FOR THE FIVE DOMAINS OF GWSPH RESEARCH

4.1 Community-Based Research

4.1.1 General Principles:

- The safety and well-being of research study participants and staff is paramount in the continued conduct of community-based research.
- Research on COVID-19 has proven that the health costs of reopening any research enterprise will not be borne equally across demographic groups. Communities that are vulnerable and/or marginalized will be disproportionately impacted by any disease spread that results directly or indirectly from research activities. It is incumbent on investigators to acknowledge and weigh these risks in determining whether to restart their individual research programs.
- Any in-person interactions must be justified and consistent with the Phase (both GW and D.C) under which the investigator is operating. The risk of in-person interactions will need to be considered for both participants and study staff. In some instances, risk to others connected to the research participants will need to be considered (e.g. a young healthy participant living in a household with immune-compromised or otherwise high-risk individuals).
- The GW Office of Human Research has released guidance and documents related to human subjects and COVID-19 concerns: https://humanresearch.gwu.edu/covid-19#Phase%201%20Guidance.
- During any Phase, accommodations should be made for persons with underlying conditions and/or heightened vulnerability when considering in-person interactions. To maximize COVID-19 related safety, investigators should be prepared to allow for online and in-person options for study participation or to justify why they do not have a plan to allow for online participation.
- Any team that wishes to interact in-person with participants during any Phase must have a written plan that clearly addresses the points outlined below for in-person contact (included in a research restart request see *Section 5*). All research modifications must be approved by the GW IRB.

4.1.2 Research Phase 1: Limited Reopening (as of 8 June 2020)

Community-based research operations should proceed as in Phase 0 (e.g., virtual data collection with participants and staff teleworking).

- In-person interactions with research participants in any setting (community and/or SPH Building) are strongly discouraged.
 - If in-person interactions are necessary (see Section Y below), these interactions must be carefully justified in writing to ORE, including a plan that addresses the issues identified in Section Z below, and weighed against the real risks of those interactions to the participant, staff, and community.
- In-person interactions among research team members should be minimized.
 - Research team members should continue to telework whenever possible, and activities that can be conducted remotely should continue to be done remotely.
 - If research staff require access to GW offices/buildings, those requests need to be coordinated centrally (as per GWSPH-wide plan) across teams to limit the total number of people in these spaces.

4.1.3 Research Phase 2: Expanded Reopening

In-person research interactions in community and university spaces may be considered within applicable federal, state/local, and community organization guidelines, but must be justified. The risks to participants and staff must be weighed carefully.

- In-person interactions with research participants may be considered within applicable federal, state/local, and community organization guidelines and appropriate COVID-19 precautions (e.g., PPE, social distancing, decontamination procedures). If in-person interaction with participants is deemed to be necessary, these interactions must be carefully justified and weighed against the real risks of those interactions to the participant, staff, and community.
 - A critical consideration in determining the safety and necessity of in-person interactions must be the location of the research interaction relative to the places where participants reside. Studies that require participants or research team members to travel to meet one another (either at GW or at other community facilities) may increase participants' risk of exposure (as well as research staff), particularly if use of public transportation, taxis, or ride-sharing services is required.
 - In-person interactions with research participants in the SPH building need to be coordinated centrally across teams to limit the total number of people in these spaces, as per GWSPH guidelines. Please refer to the GWSPH General Reopening Guidelines.
 - O Biological specimens may be collected, but procedures must adhere to federal, state/lo-cal, and community organization guidelines and appropriate COVID-19 precautions. Investigators must consider any additional risk associated with the procedure (e.g., phle-botomy requires researchers to be physically closer to participants than interviews) and have in place appropriate safety precautions necessary to adequately protect participants and research staff. Researchers must also weigh the risk of collecting a specific specimen against its importance to the research in determining whether it is truly necessary.
- In-person interactions among research team members should be minimized. Research team members should continue to telework whenever possible, and activities that can be conducted remotely should continue to be done remotely. For essential study activities that may require inperson interaction at the SPH building or in the community, study staff should follow federal, state/local and community organization COVID-19 guidelines (e.g., PPE, social distancing, decontamination procedures). If research staff require access to GW offices/buildings, those requests need to be coordinated centrally across teams to limit the total number of people in these spaces, additional information can be found in the GWSPH General Reopening Guidelines.

4.1.4 Research Phase 3: Resume Total Research Programs

In-person research interactions in community and university spaces are allowable within federal, state/local, and community organization guidelines but the risks to participants and staff must continue to be carefully weighed.

In-person interactions with research participants will be allowable within federal, state/local, and community organization guidelines and appropriate COVID-19 precautions. However, in-person contact should be minimized as much as possible (e.g., continue virtual data collection if possible). As with Phase 2 above, biological specimens may be collected only if critical to the research, and if the benefit of biological specimen collection is well-justified (e.g., specimens are collected as

- part of a community-based study to understand COVID-19 transmission) and is performed within university, federal, state/local, and community organization guidelines.
- In-person interactions among research team members will be allowable within university, within federal, state/local, and community organization guidelines and appropriate COVID-19 precautions.

4.1.5 Determining Necessity of In-Person Contacts for Research (Among Staff or Staff and Participants)

- Degree of direct benefit to participants and/or community
- Immediacy of benefit to public health response to COVID-19
- Immediacy of benefit to another problem of urgency to community
- Degree to which research is truly infeasible to conduct remotely (e.g., online)
- Importance of the timing of the assessment to the research design (e.g., how much does waiting several months to collect the data impact the integrity of the outcome?)
- Inflexible funder requirements and deadlines
- Importance of project to individual research team members (e.g., doctoral students over undergraduate projects)

4.1.6 Procedures for Any In-Person Contact

Research teams that plan to have in-person interactions between research staff members and/or research participants at any phase must have a written plan that addresses each of the following issues. In certain instances, those plans might rely on previously-drafted federal, state/local, or university guidance. Where existing guidance is lacking or inadequate, it is incumbent upon investigators to draft detailed plans for their team (and submit to ORE for approval; see approval guidelines from GWSPH), including but not limited to the following:

- PPE requirements, including discarding of used PPE
- Partition/barrier controls
- Screening prior to interaction (e.g., recording of temperature, symptoms)
 - Including recommendations for what to do if team has concerns about screening information gathered
- Considerations for physical spacing of people
- Density (i.e., limiting number of people in space at one time and/or number of people through the space in a given period of time)
 - Note that adjustments for density and/or spacing might require reducing the # of participants typically seen in a protocol (e.g., fewer members of a family at once, or smaller focus groups)
- Plan for coordinating with GWSPH operations to address spacing/density in relation to other research teams
- How data collection procedures will be adapted to minimize COVID-19 exposure risk (e.g., using self-collection of specimens in lieu of researcher collected)
- Plan for maintaining/cleaning of spaces/surfaces frequently touched by multiple individuals
- Scheduled handwashing breaks for research staff and participants upon arrival to the research site
- Consideration of the risks of participant and research team transportation to the research site

- Procedures for managing the situation in which a research team member or participant tests positive or is identified as a contact.
 - Guidance for participants regarding what to do if they test positive after having interactions with a research team (e.g., a study e-mail or hotline to contact if they test positive).
 - Plans for how to contact research participants if a research team member tests positive
 - Policy for research team members regarding their obligation to notify study PI about symptoms, exposures, positive tests (to facilitate contact tracing within a research team or with participants).

Return

4.2 Clinical Research

There are two types of clinical research scenarios at SPH: (1) clinical research that occurs in SPH or a clinic run by an SPH faculty member; or (2) clinical research that occurs in a healthcare setting. Resuming clinical research will be different for an SPH PI depending on where the clinical research is occurring because in the first scenario, the clinical research guidelines need to be developed by SPH whereas when the clinical research is occurring in the healthcare setting, the SPH PI will need to integrate his/her research into the clinical processes that have been put into place at the healthcare setting to treat both COVID-19 and non COVID-19 patients.

4.2.1 Clinical Research Issues Regardless of Setting

Policy that Distinguishes Essential and Non-Essential Research Visits

All in-person research participant visits should be limited to "essential" visits.

- Essential visits: Study visits that require assessments that cannot be performed by phone or video
 conferencing. Examples include study visits that require blood draws or specimen collection, and
 study visits that will pose an additional risk for the research participant if not performed. If study
 enrollment is occurring in a clinical setting and the patient is already coming to the facility for
 healthcare services, then study enrollment can be included as part of this essential health care
 visit.
- Non-essential visits: Study visits that will not add risk to the research participant if not performed, or visits that can be delayed or performed remotely (with sponsor approval).

Modifications to IRB Consent Process and Protocol

SPH PIs will need to obtain IRB approval for all modifications to their study protocols. Implement video or electronic consent if allowable by relevant IRBs. Please follow GW OHR guidance (https://humanre-search.gwu.edu/covid-19#Phase% 201%20Guidance) especially the pre-approved COVID-19 information and screening document.

Research Participant Screens Positive for COVID-19 Symptoms

What should SPH PIs do if a research participant that they want to bring on campus for a research visit screens positive over the phone when being questioned about COVID-19 symptoms? Follow the current GWSPH guidelines for operations (see the *GWSPH General Reopening Guidelines*) regarding when someone is allowed to be in a campus building. Please also refer to the GW OHR approved script (*Informed Consent Addendum*) and information for COVID-19.

Contact Tracing Protocol If Research Participant Contracts COVID-19

Each study will need a set of steps to follow if a research participant reports that he/she has been diagnosed with COVID-19. At a minimum, the GWSPH should be notified (send an email to GWSPHResearch@gwu.edu), as well as all team research staff who may have come into contact with either the participant or other exposed research team members. Contact tracing of research participants is the responsibility of local health departments, not the study team. Please refer to GWSPH General Reopening Guidelines and the GW OHR approved documents (https://humanresearch.gwu.edu/covid-19#Phase%201%20Guidance).

Personal Protective Equipment (PPE) Protocol

It is clear research staff will need to wear PPE when interacting face-to-face with research participants but who will pay and supply this PPE needs to be decided.

Virus Testing For SPH Faculty and Staff

SPH PIs and their research teams need to follow the school's protocol for COVID-19 testing outlined in the *GWSPH General Reopening Guidelines*. The only cases which might call for an exception would be for studies with higher infection risk to the study team, in which additional precautions should be added to the restart protocol with GWSPH and IRB approval.

Training of Research Staff

All research staff at risk of exposure as a result of their work on the research project (excluding those who are working remotely) must receive training on all relevant guidelines and study-specific plans. Periodic refresher training is advised as well, at intervals up to the PI's discretion. No new staff allowed in facilities during GW Phase 1.

Reviewing Clinical Research

Does all clinical research need to be reviewed to make sure the PIs and study teams are proceeding safely and in compliance with university-wide guidelines? For research that takes place in the SPH building, should each Department Chair and the Office of Research Excellence review and approve the clinical research project before it resumes? For clinical research that takes place outside of the SPH building, should the project also be reviewed?

4.2.2 Clinical Research in SPH or SPH-Run Clinic

Pre-Visit Screener and Protocol

Use a pre-visit screener and protocol to assess whether the research participant is symptom-free and can be scheduled for an in-person research visit. For research being conducted within SPH building, it is recommended that one pre-visit screener and protocol be used for all projects (see GW IRB guidance).

PPE Protocol for Research Staff and Research Participants

The following are recommended:

Surgical Mask: to be worn by research staff throughout their entire study visit. Cloth mask is acceptable for research participant if brought from home. If the research participant does not bring a cloth mask, the study team must supply a surgical mask or reschedule the study visit.

- N95 Mask: should be worn by research staff when performing an evaluation where exposure to airborne particles or large droplets (such as during treadmill test) OR if the research subject is a patient under investigation (PUI) for COVID-19.
- Gloves: Gloves should be worn when performing any assessments that require examination of the research participant or using tablets where you will be alternating use of the tablet between you and the research participant or other personnel.
- Gown: Should only be worn if research participant is suspected to have COVID-19 or had been exposed to someone infected with COVID-19 (such as a family member or the research participant is an essential worker).

Research Clinic Space Protocol

SPH needs to develop a general protocol for all SPH PIs and research participants to follow.

- Subjects will be informed that no one can accompany them to a study visit unless necessary for their safety or a requirement of the study.
- All individuals (research staff and research participants) are to wear a surgical or cloth mask covering both their nose and mouth at all times in the SPH building/clinic.
- All individuals (research staff and research participants) must remain 6 feet apart at all times unless otherwise indicated (i.e. vital signs being taken, procedure being performed, etc.).
- N95 to be worn when in close proximity to a patient (within 6 feet of a patient for more than a few minutes*) or if the subject is being tested for COVID-19.
- After the use of each clinic room, all surfaces and equipment are to be wiped down and sprayed with disinfectant prior to reuse of the clinic room.

Communication System for Space Capacity

Every PI is responsible for building out a tracking system to monitor the density of research staff in their facilities at any time. This will extend to participants scheduled to be in the SPH building or research clinic. Follow the *GWSPH General Reopening Guidelines* and also note the comprehensive reopening approval form requirements found in <u>Section 5</u>.

Protocol if a Research Participant Contracts COVID-19

All SPH PIs should follow *GWSPH General Reopening Guidelines* if a research participant tests positive for COVID-19. The following are for guidance only:

- Participants will be instructed to call the research coordinator if they test positive for COVID-19.
 Coordinator will need to document this and report this as an Adverse Event to the IRB and sponsor
 if applicable. The privacy risk associated with this may vary across studies. Decisions regarding
 further study participation should be made by the study PI in discussion with GW IRB and according to GWSPH General Reopening Guidelines.
- If a GWU employee or participant tests positive for COVID-19 and is affiliated with a study being conducted in the SPH building, the laboratory space where the individual worked or the participant was will need to be immediately decontaminated. Laboratories in SPH where an infected individual has been identified will be closed until a thorough cleaning of areas that the employee has worked can be performed (anticipated time ~ 1-2 days).

Floors/wings where more than one individual has become infected within a two-week period will
be closed until the laboratory can be cleaned and the work plan can be re-reviewed by the chair,
Office of Lab Safety, a representative from Institutional Biosafety Committee and a representative
from facilities to identify areas of potential workplace transmission. Once it is determined that
either no changes are needed or that the necessary changes have been made, the area can be
reopened.

4.2.3 Research in a Healthcare Setting

SPH PI will use the pre-visit screener and protocol that the healthcare facility uses.

PPE Use for Research Staff

If personal protective equipment is required, consider who will bear the responsibility to purchase it (e.g., sponsor, healthcare facility). Research staff should follow guidelines set by healthcare facility regarding PPE requirements.

Communication System with Healthcare Facility

Refer to the GWSPH General Reopening Guidelines.

Clinical Space Guidelines

SPH PI must review clinical area and study protocol and make sure study staff are employing safe practices.

- Research staff must wear a minimum of a face covering at all times when in the presence of other
 people in the clinic setting and on campus. Depending on the clinical situation, PPE will be required and needs to be worked out with the clinical site.
- Examine the clinical site where research staff will be working and determine that there is adequate physical space for the research activities to be conducted.
- If possible, conduct the research in clinical space that is dedicated to non-COVID-19 patients to reduce risk of viral transmission.
- Review equipment being used by research staff and minimize the number of people touching the same equipment.
- Develop a protocol for how to handle collection of study forms from a participant such as the written consent form.

Return

4.3 Global and International Research

This document will guide faculty, staff, and trainees as they plan for the reopening of Global Health research in the coming weeks and months. These considerations are intended to complement the phased opening of the research as defined in the OVPR document and the GWSPH general guidelines.

4.3.1 Guiding Principles Applicable to All Phases

Decisions to restart research activities at field sites should be collaboratively made by study investigators at all institutions.

- The 'reopening status' at other institutions and in other countries may be different than those at GW and in the US. Decisions regarding research should be based on the local country condition, regardless of GWU reopening phase. Any restrictions in place at the local research institutions or countries should be prioritized for guiding research decisions.
- Regardless of host institution or country guidelines, investigators should implement the most rigorous public health measures for research staff and participants. Such measures should include ensuring access to hand washing, use of face coverings, and modification of procedures to encourage physical distancing practices. Efforts to ensure best public health practices should be applied similarly in high-income and low-income country contexts.
- Research involving collection and handling of biologic samples should consider the assurance of virus free samples, or special handling if needed. Studies that involve importation of biological specimens from other countries into the US, need plans to ensure that specimens are virus free, or are handled safely. (Note that CDC current does not currently consider SARS-CoV-2 a select agent. But researchers should continue to monitor the situation and incorporate this higher level of safety consideration. https://www.cdc.gov/cpr/ipp/faq.htm). Researchers should follow all GW guidelines for handing biospecimens.
- Investigators from all institutions should collectively develop guidance regarding the institutional responsibility related to prevention and treatment of COVID for staff and students/trainees working on the project.
- Investigators from all institutions should develop guidance on how they will handle research participation for volunteers who become infected (or are suspected to be infected) with COVID (e.g. When a volunteer is infected or suspected to be infected, do they continue participating in the study data collection activities?)
- Investigators should comply with any donor guidance related to international research.
- In the case that investigators make modifications to the study protocol for purposes of risk-mitigation and/or to accommodate the reopening plans, they should consult with GW and local IRBs to decide if an official modification to the study protocol is warranted.

The following provides special considerations for global health research as it relates to the GWU phased reopening plan.

4.3.2 Guiding Principles for International Travel Applicable to All Phases

- Travel, regardless of reopening phase, should be guided by the GW essential travel policies. Given the current state of widespread transmission in the US, GW faculty, staff, and students should be aware of the possibility that they themselves may spread COVID-19 through international travel. Investigators requesting international travel approval for research purposes (given by the Dean, GWSPH) should provide clear justification for the travel and provide documentation from local investigators that a) the host country is allowing active research and b) the host institution has restarted research activities.
- Before deciding to travel internationally, ask yourself these questions as recommended by the CDC: Is COVID-19 spreading where you're going? Is COVID-19 spreading in your community? Will you or those you are traveling with be within 6 feet of others during or after your trip? Are you or those you are traveling with more likely to get very ill from COVID-19? Do you live with someone who is more likely to get very ill from COVID-19? Does the state or local government where you

- live or at your destination require you to stay home for 14 days after traveling? If you get sick with COVID-19, will you have to miss work or school?
- The World Health Organization (WHO) has published guidance materials regarding the state of travel and provides some precautions to take for various modes of transportation on their website: https://www.who.int/travel-advice.
- Do not travel if you are sick, or if you have been around someone with COVID-19 in the past 14 days. Do not travel with someone who is sick.
- Travel plans should incorporate quarantine requirements at all stops and destinations.
- If investigators are exempt from on-campus teaching because they themselves or family members
 are at high-risk for COVID-related complications, then they should not travel internationally for
 research.
- Investigators should, as always, ensure they are up-to-date on all relevant vaccines (including seasonal influenza when appropriate and available) before traveling and remain vigilant in preventing infectious disease during travel.
- Investigators that travel internationally should ensure that they have adequate PPE supplies to last the duration of the trip.
- Personal behavior while in other countries should be an example of best practices to mitigate risk
 and should prioritize the health and safety of both GW researchers and host country researcher
 teams and the community.
- When you return home from international travel, stay home for 14 days and self-monitor for symptoms as recommended by the CDC. Follow CDC guidance if symptoms develop.

The following provides special considerations for global health research as it relates to the GWU phased reopening plan.

4.3.3 Research Phase 0: Previous State

OVPR Considerations	Special Considerations for Global Health Research	
 Continue research that is possible through entirely online means. Select research projects, including COVID-related research, are allowed to continue or commence. Only essential personnel are allowed on campus. Core facilities are available under special consideration and maintain specific requirements for safety. Strict observation of all safety protocols to include, but not limited to, social distancing, personal hygiene, decontamination and appropriate use of personal protective equipment (PPE). 	International travel is not permitted	

4.3.4 Research Phase 1: Limited Reopening (8 June 2020)

OVPR Considerations

- Population density may be increased in a manner consistent with university, federal and district or state guidelines (12.5 25% of a lab's or program's staff may be allowed on campus at any one time subject to considerations in the sections below).
- Strict observation of all safety protocols to include, but not limited to, social distancing, personal hygiene, decontamination and appropriate use of PPE.
- Projects not involving chemical or radiological hazards, stopped as part of ramp-down, will be identified and prioritized for phased restart.
- Priority will be given to graduate students and postdocs who are close to completing their degrees/terms of appointment.
- Priority will be given to principal investigators (PIs) with grants within four months of their end dates, and/or where the sponsor is not flexible with no cost extensions.
- Research projects conducted on campus using human subjects, and involving direct subject interactions and interventions, can be restarted in a manner consistent with the GW Medical Faculty Associates (MFA), university, federal and district guidelines.
- Necessary core facilities will be reopened in a limited capacity. Staffing and operations of the facilities will be kept at a minimum and training of new users may be suspended

Special Considerations for Global Health Research

Research may reopen in a limited way and the following work should be prioritized:

- Research intended to support host-country response to the COVID-19 pandemic
- Follow up visits / appointments for already enrolled participants if possible remotely or if allowed by both GW and host country (IRB permission may be needed)
- New research that is time constrained due to sponsor/host institution requirements should be prioritized.

However, even for these high priority activities, risk-mitigation approaches such as online, phone, or distanced data collection should be considered.

Mission critical international travel may resume in accordance with the GW travel policy, and if exceptions are obtained from the Dean GWSPH, but should be reserved for faculty and staff. Students and fellow should not be sent on international assignments.

4.3.5 Research Phase 2: Expanded Reopening

OVPR Considerations

- Population density will be increased over Phase 1 in a manner that is consistent with university, federal and district and state guidelines
- Projects involving biological, chemical or radiological hazards, stopped as part of rampdown, will be identified and prioritized for phased restart.
- Research projects conducted off campus using human subjects, and involving direct subject

Special Considerations for Global Health Research

- All international, human subjects research involving direct subject interactions and interventions, can be restarted in a manner consistent with university, CDC and WHO guidance, and the country's practices.
- Any restrictions in place at the local research institutions or countries should be prioritized in case guidance from these bodies is conflicting.

- interactions and interventions, can be restarted in a manner consistent with MFA, university, federal and district or state guidelines (to include travel restrictions).
- Other core facilities will be reopened. Staffing and operations of the facilities will be expanded as needed.
- Practice strict public health mitigation strategies—such as wearing a mask and ensuring physical distancing—should be continued, out of respect to, and as an example to our collaborators.
- Continue to consider lower risk options for data collection (e.g. alternate/outdoor location of interviews, maintaining 1.5 - 2 meters distance during interview, technology-based/ assisted data collection).

4.3.6 Research Phase 3: Resume Total Research Programs

OVPR Considerations	Special Considerations for Global Health Research	
 All personnel may return to campus following any new and/or permanent implementation of safety guidelines. New projects may be started. All research facilities will be reopened. Undergraduate researchers will be allowed back in laboratories subject to safety guidelines. 	Refer to overall guiding principles for Global Health Research.	

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4.4 Laboratory-Based Research

4.4.1 Use of GWSPH Research Laboratories (Non-Clinical/Non-Instructional)

Every laboratory must have in place an approved reopening plan, inclusive of a shut-down plan (in the event of increased infection rates), before re-occupancy. Safe reopening of laboratories is a high priority. A preliminary list of PI responsibilities for lab reopening includes: developing a lab-specific reopening plan, providing primary points of contact and communication for lab personnel, establishing appropriate training and monitoring for all lab personnel, demonstrating behavioral best practices, and reporting concerns and sharing best practices to Office of Research Excellence.

Recognizing that some of the most important questions regarding operations under current conditions are not fully known, PIs need to consider: best practices (e.g. for spacing, disinfecting protocols, etc.), practical information (e.g. laboratory floor plans), materials (e.g. PPE, cleaning supplies), signage detailing proper PPE use, disinfecting, reporting, and general support to prepare plans, initiate laboratory purchases and deliveries (see details in the Lab section of the Reopening Plan and also general guidelines). A detailed plan is necessary to maintain health and safety during reopening and so laboratory reopening plans should address at a minimum: responsible party, physical distance, logistics (e.g. shifts, density), personnel responsibilities, cleanup, PPE and supplies, and lab shutdown contingency plan (see <u>Section 5</u> for details and <u>Appendix 3</u> for the approval form).

It is equally important that lab members other than the PI understand the plan, agree with the implementation, and become conduits for best practices. It is not expected that the reopening plans or shut-down plans are a pro-forma exercise.

COVID-19 Contingencies

When creating a plan, PIs need to consider what steps will be necessary to safely ramp down the lab again if necessary. Given the possibility that research may have to be scaled-back again with little notice, PIs are strongly advised to ramp up only those projects that can be ramped down quickly and at relatively little cost and complexity. For the time being, PIs should de-prioritize projects that depend on non-renewable resources, such as primary cell cultures or high-volume animal experiments, for which scaling back would be costly. As such, care should be taken in choosing projects to ramp up in the early phases.

Operational Recommendations During GW Phase 1

During the initial phase of resumed on-campus research, density will be limited to 12.5 – 25% capacity per OVPR's guidance. This percentage does not qualify how many individuals may return to work, but rather dictates that density not exceed this amount at any time. With staggered scheduling, it would be possible to return more than 25% of staff. Exceptions will be addressed through Senior Associate Dean for Research and Executive Dean for Operations; increased density may also be permitted in labs where the nature of the work requires higher level PPE that will otherwise limit potential for exposure. Labs may require higher PPE levels based on existing hazards and should follow existing GW guidelines.

Recommended best practices include alternate schedules to minimize density, having employees be present only for the amount of time specifically required to conduct experiments, and physically labeling space separations in lab areas. Each lab group is responsible for ensuring lab equipment is functional before startup. Users should test all emergency equipment—eye wash, showers, fume hoods, BSCs—as necessary. General lab housekeeping is critical as usual.

For some additional guidance provided by OVPR regarding laboratory operations, please visit the Updated GW COVID-19 Lab Resources web page:

https://labsafety.gwu.edu/updated-covid-19-laboratory-resources

Rotations

Pls of labs are allowed to consider non-standard lab open hours as a potential means to increase productivity while managing social distance (density) requirements. The underlying principle of the cyclical shifts is to separate teams over the time period, for potential carriers to become symptomatic and inhibit crossteam transmission. 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.

The right model will depend on the type of research and space layout (e.g., need to access animals, experimental duration) and personnel preference. The mechanism by which shifts are assigned are not defined, however considerations should include lab members' transportation options, childcare responsibilities, and the ability of infrastructure to support designated shift hours (e.g. security).

For example:

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. Plans should include a time buffer to ensure shift changes
occur without cross-contact.

- The week is divided into two shifts. The easiest division to imagine is Mon, Wed, Fri/Tue, Thu, Sat, but other divisions are possible (Mon-Wed and Thurs-Sun). 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 may always work Saturdays.
- A 15-day period could be divided into three blocks. Lab personnel are divided into cohorts. Cohort 1 works on campus the first 5 days, then works remotely for the next 10 days. Cohort 2 works on campus the next set of 5 days, then remotely the next 10 days. Cohort 3 works on campus for the next 5 days, then remotely the next 10 days. That ends a 15-day rotation period. This strategy promotes more isolated work units.

Core Facilities or Shared Equipment

GWSPH recognizes that bringing core facilities online is an important step towards providing equitable research opportunities. However, shared use equipment presents special challenges. Please consider if exposure risks with shared use equipment can be minimized by a smaller set of consistent operators on a specific piece of equipment. Consider staged opening of your facilities bringing low-risk equipment online first. It is possible that some items/equipment may be too high of a risk for initial re-opening. In addition to specific disinfecting protocols for the instrument, pre-defined downtime between users is encouraged. Plans for core facilities will be reviewed with the same rigor as other labs, and due to the special conditions for cores, some discretion will likely be necessary in developing and provisioning for the re-opening plan.

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4.4.2 Science and Engineering Hall (SEH) 7th Floor Labs

This document will guide faculty, staff, and students as they plan for the reopening of SEH 7th floor. These considerations are intended to complement the phased opening of the research as defined in the OVPR document and the GWSPH general guidelines.

As the health and safety of our staff, faculty and students is of the utmost importance, several changes will be in place to prevent or slow down the spread of COVID-19. All students, faculty, staff and visitors (please see GWSPH general guidelines for visitor policy) are expected to fully comply with the information outlined in this document.

Our knowledge and understanding of the COVID-19 virus continues to evolve, and our policies and plans will be updated as appropriate as more information becomes available. Information on how to protect yourself and others during the pandemic are available at: www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html

The Phase Plan addresses the following:

- Social Distancing
- Personal Protective Equipment (PPE)
- Cleaning and Decontamination
- Reporting Exposure and/or Illness
- Compliance
- Other Resources Regarding Laboratory Safety and COVID-19

The following are Phase 1 plans specific to the SEH 7th floor laboratories.

Social Distancing

Physical Distancing – Six feet apart social distancing rules must be obeyed at all times while in the building.

This requirement should also be implemented in the laboratories as best as possible. As each PI has very specific needs, it is appropriate for each to implement their own policy regarding how many people should be present in a certain square footage of area. A general guidance is no more than 2 people at a time per 400 square footage.

For open labs or those with large groups, use of shifts are encouraged to allow for maximum utilization of laboratory spaces. At no time should the number of people assigned to a floor exceed the maximum allowed capacity by GW/GWSPH.

Use of Core Facilities and Shared Equipment – Use of Core facilities and shared equipment will require prior arrangement through prearranged appointments or sign-up sheets. Placement of equipment that is shared by multiple laboratories should be optimized so that users can access while preserving the 6 ft minimal distance from others on the floor. Equipment sharing with PIs from other buildings and floors should be restricted during Phase 1.

Limiting Visitors and New Personnel – Visitors are not permitted on the 7th floor of SEH during phase 1 reopening. This includes vendors and food delivery services. Social distancing rules must be maintained while accepting packages from FedEx and UPS. Use of gloves are recommended using when picking up packages. Sanitization with 70% ethanol is recommended before opening packages.

It is recommended that new faculty and staff should not move into laboratory and office spaces during Phase 1, until existing faculty have reopened their work – and each new faculty or staff will need approval from both Research and Operations Deans. For example, right before the closure, the new Department of Biostatistics and Bioinformatics was scheduled to move in to the 7th floor of SEH. We recommend that this is postponed during Phase 1.

Common Seating Areas – Seating areas in the kitchens and lobbies need to be rearranged such that chairs and tables are appropriately distanced.

Seating areas in cubicles should be appropriately distanced as well. If feasible, the cubicles that seat four should potentially seat two and those that seat two should seat one.

Entry/Egress – There are four entrances to SEH and none require card access. Three of those have multiple doors. We recommend one of each can be designated for entry and one for egress. The entry on 22nd and I St should be designated as either entry or egress.

Guidance is needed from both GW and GWSPH leadership regarding who will have access to the building during Phase 1 and 2. Currently, only those on the "essential personnel" list have access. However, if the University opens up the building to anyone in the GWU community, we will have difficulty maintaining occupancy requirements and social distancing. For example, students from non-SEH departments often come in to study in the common areas of SEH. Additionally, the SEH parking lot is a public parking lot that opens into the building. This will allow non-GWU individuals to enter the building and compromise safety of those working there.

Elevators/Stairs: Elevators will be limited to two people per elevator to maintain social distancing. Floor decals are in place to show where to stand to maintain distance. Use of stairs is encouraged when going to 1st and 2nd floors if possible. There is only one main staircase. Floor decals have been placed to encourage distancing and directionality.

Other Suggestions from SEH Faculty if Feasible – Designate certain elevators to go up to certain floors only. For instance; Elevator 1; Trips only to 7 and 8, Elevator 2; Trips only to 5 and 6, Elevator 3; Trips only to 2, 3 and 4, Elevator 4; Trips only to B1 and B2. This would minimize the amount of time people would be in the elevator.

Encourage elevators for upward travel only and use stairs (if feasible) for downward travel. There are three other stairways in addition to the main stairway.

Restrooms – Restrooms should have limited occupancy and social distancing rules must be maintained. Recommend using signage and decals to block alternate sinks as well as urinals (men's rooms). Hand dryer use is discouraged. Hand sanitizers, paper towels, cleaning spray should be provided in the restrooms for users.

Personal Protective Equipment (PPE)

Masks – GW has a mandatory mask policy that must be followed:

https://campusadvisories.gwu.edu/mask-guidelines

GW also created the following mask safety video:

https://vimeo.com/407269656/d917d00b4a

In addition, as some of the faculty and staff are going back and forth to the hospital and labs, we recommend use of different sets of masks for inside hospital/lab and outside common area. These must be distinct, for example, N95 respirators vs fabric face masks.

Hand Hygiene – Hand sanitizer stations will be located on each floor in front of the elevators.

Hands should be washed frequently with soap and water for at least 20 seconds. If soap and water are not available, use hand sanitizer with at least 70% alcohol.

PPE Resources and Guidance:

- CDC Strategies for Optimizing the Supply of Eye Protection: https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/eye-protection.html
- American Academy of Ophthalmology Eye Care During the Coronavirus Pandemic: https://www.aao.org/eye-health/tips-prevention/coronavirus-COVID-19-eye-infection-pinkeye
- CDC Guidelines on When to Wear Gloves: https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/gloves.html
- Instructions for Donning/Doffing PPE: https://www.youtube.com/watch?v=YoEn4 qKE2k&feature=youtu.be
- CDC Handwashing Guidance: https://www.cdc.gov/handwashing/videos.html

Cleaning/Decontamination

All high-touch surfaces in the workplace, such as workstations, door handles and knobs, shared refrigerators, lunch areas, shared printer, kitchen areas, should be cleaned routinely. It is recommended that these surfaces are wiped clean twice a day, once in the morning and once in the afternoon. Checklists (with initials, date and time fields) should be placed on/next to each surface that custodians will be asked to disinfect. Wipes will be made available near cubicles, kitchen areas and reception area.

If hard surfaces are visibly soiled (dirty), they should be cleaned using a detergent or soap and water before disinfection. For disinfection, most common, EPA-registered, household disinfectants should be effective as well as diluted household bleach solutions or alcohol solutions with at least 70% alcohol. A list of products that are EPA-approved for use against the virus that causes COVID-19external icon is available on the EPA website. Manufacturer's instructions must be followed for all cleaning and disinfection products (e.g., concentration, application method, and contact time).

The Teaching Lab (SEH 7750) must be fully disinfected prior to students returning in Fall as classes are scheduled to be held in this space. This room was being used by Curative Inc. as a testing facility for Covid-19. We recommend H2O2 vapor cleaning for this and other lab spaces in SEH which were occupied by Curative.

CDC's Best Practices for Cleaning and Decontamination:

https://www.cdc.gov/coronavirus/2019-ncov/community/disinfecting-building-facility.html

Reporting Exposure/Illness

Routine testing is not yet available for the GW community unless they are experiencing symptoms or think they have been exposed. Surveillance testing for SEH faculty and staff may be available in the future – in which case those should be followed. Until then, the following guidelines are offered.

Symptoms Self-Monitoring – It is our shared duty as a community to act responsibly. Symptoms self-monitoring should be done every day before engaging with or coming to campus. Faculty, staff and students must be free of ANY symptoms related to COVID-19 to be on campus. If individuals have any concerns regarding their health status, they should notify their supervisor/department chair that they are reviewing their health status prior to the start of any scheduled work period or time on campus.

Positive Case, Isolation/Quarantine and Contact Tracing – Members of the community who test positive for COVID-19 must isolate until they have recovered and received a 'Return to Campus' order.

For specific issues related to contact tracing, please refer to the GWSPH General Reopening Guidelines.

Reporting Illness or Suspected Exposure to COVID-19 – Anyone with symptoms of COVID-19 or have a sick family member at home with COVID-19 should stay home and follow the appropriate notification protocol of GW/GWSPH (See Operational Guidelines for GWSPH). Each designated supervisor will inform the next as per GWSPH guidelines.

- Students: Specific reporting guidance for students
- Faculty: Faculty members should contact their department chair and Senior Associate Dean for Research

• Researchers: Researchers should contact their Principal Investigator, who will inform the relevant department chair and Senior Associate Dean for Research.

Return to Campus – Individuals who are sick should follow current CDC-recommended steps. Lab employees should not return to work until the criteria to discontinue home isolation are met, in consultation with their healthcare provider. All employees must follow the most current GW return-to-work guidance.

Decontamination of Laboratories When an Individual Tests Positive – Laboratories where an infected individual has been identified will be closed until a thorough cleaning of areas that the employee has worked can be performed (anticipated time ~ 1-2 days).

Floors/wings where more than one individual has become infected within a two-week period will be closed until the laboratory can be cleaned and the work plan can be re-reviewed by the chair, Office of Lab Safety, a representative from Institutional Biosafety Committee and a representative from facilities to identify areas of potential workplace transmission. Once it is determined that either no changes are needed or that the necessary changes have been made, the area can be reopened.

Compliance

All members of the SEH 7th floor community are expected to adhere to and act in accordance with this guidance. Chairs and supervisors are asked to regulate the expectations set forth in this document within the campus spaces for which they are responsible.

Please partner with us to protect your health and the health of our entire community. Violations of GW policies may result in the revocation of building access privileges, as well as disciplinary action up to and including termination or dismissal.

Report Concerns to Senior Associate Dean for Research, <u>GWSPHResearch@gwu.edu</u> and if needed, the Office of Ethics, Compliance, and Privacy.

Return

4.4.3 Metabolism & Exercise Testing Laboratories (SPH Basement Level 1)

General Laboratory Preparation Guidelines for Research & Public Testing

Signage:

- Highly visible and easily readable disinfection, sanitization, and hand-washing guidelines should be posted on each laboratory door and in at least two separate areas within each laboratory space.
- PPE requirement guidelines to prevent SARS CoV-2 transmission for each laboratory space should be posted on each laboratory door and in at least two separate areas within each laboratory space.
 - Note: These guidelines will be posted in addition to the standard PPE requirements for conducting laboratory procedures in the specified space.
- Highly visible and easily readable signs should be posted on the backside of each laboratory door regarding PPE removal prior to exiting each space:
 - o Reminder to remove PPE and wash hands (or hand sanitize) prior to exiting the room
 - Utilize CDC guidelines for removing gloves (doffing).

Equipment Spacing Designation:

- Tables and chairs must be arranged such that each seat location is separated by a distance of ≥6ft to maintain CDC-stipulated social distancing practices in applicable laboratory spaces.
- A 6ft safety zone must be labeled on the laboratory floor around each piece of laboratory equipment.
- Locations for safe testing observation (≥6ft) must be labeled on the laboratory floor near each
 piece of laboratory equipment for researchers and laboratory staff not directly involved in protocol operation.

Sanitation and Disinfection:

- Trash and recycling
 - At least 1 trash and 1 recycling bin should be located in each laboratory space. Additional bins should be added in proportion to space size.
 - Trash and recycling bins should be handled with gloves when placed in the laboratory hallway for disposal by the SPH custodial team.
- Disinfection and hand sanitization
 - At least 1 container of disinfecting wipes will be provided in each laboratory space with additional containers provided based on laboratory size and user capacity.
 - At least 1 container or dispenser of hand sanitizer (liquid or foam) will be provided in each laboratory space with additional containers or dispensers provided based on laboratory size and user capacity.

Virtual Sessions & Electronic Paperwork Considerations for Research & Public Testing

Research Recruitment, Consenting, and Familiarization:

- Facilitate IRB approved virtual sessions for research recruitment, consent, and familiarization whenever feasible and applicable within the scope of the overall research study protocol.
- Utilize IRB approved and secure electronic methodologies for participants to complete any research-related paperwork prior to their initial in-person appointment. Purpose is to avoid transfer of paper materials between participants and research staff.

Research Protocols and Data Collection:

- Determine if the research is time sensitive or necessary to complete in-person within a laboratory facility.
- Determine if all or parts of the research protocol/data collection can be conducted virtually to maximize participant and research staff safety.

Public Testing Health History and Consent:

Utilize secure electronic methodologies that fall within the HIPAA guidelines for clients to complete any health history, consent, and/or testing-related paperwork prior to their in-person appointment. Purpose is to avoid transfer of paper materials between clients and laboratory staff.

Pre-Visit Guidelines for Research Participants & Testing Clients

Research/Testing Appointment Scheduling:

- Schedule the research or testing visiting in the appropriate laboratory space using the laboratory calendar provided.
- Appointments cannot overlap with any other laboratory activities in the same space.

• Cleaning and sanitation time must be included in the appointment scheduling for each participant/client.

Provide a list of expected research/testing-associated visitors to the SPH security desk at the beginning of each day, indicating the following:

- Project name or public testing
- Principal investigator or laboratory coordinator
- Research/laboratory staff meeting participants/clients
- Appropriate contact information for the research/laboratory team

Standardized CDC COVID-19 Pre-visit Questionnaire for Research and Testing:

- Must be provided to the participant/client electronically via email or verbally via phone prior to their scheduled visit to mitigate risk as a result of currently known COVID-19 related symptoms published by the Centers for Disease Control (CDC).
- Must be completed by the participant/client prior to each visit if the research/testing protocol constitutes multiple visits.
- Must be completed by each of the visitors escorting the participant/client to their appointment (if applicable).
 - Note: Should any of the visitors be unable to complete the questionnaire or understand the questions provided on their own, a parent or guardian may assist in the completion of the information on their behalf.
- Flagged responses upon questionnaire completion (for the participant/client or escorting visitors),
 the research or laboratory team should:
 - Immediately contact the participant/client (if questionnaire completed electronically) and recommended that they reschedule their appointment.
 - Provide appropriate COVID-19 recommendations and resources as determined by the University.

Standardized and IRB Approved Participant/Client Pre-visit Reminders (provided electronically and/or verbally):

- As best as possible, limit the number of additional visitors accompanying participant and client to help minimize exposure and maintain proper social distancing protocols within each laboratory space. See Appendix A for additional guidance.
- Limit personal belongings and items brought into the SPH building and laboratory facilities. Individuals should only be bringing essential items in addition to anything required for research/testing.
- Close-toed footwear must be worn at all times unless the research/testing protocol specifies otherwise.
- No outside food or drink will be permitted in the laboratory hallway and individual spaces.
- Locker room facilities (showers) will not be available for use. We recommend that participants/clients make plans to shower at an alternative location after their appointment.
- A member of the research/laboratory team will meet the participant/client in the main SPH lobby.
- Will be provided with a disposable clinical-style face mask (even if already wearing one upon entry).
- Recommendation: bring a secondary pair of clothes and shoes to change into post-appointment.

Research Participant/Testing Client PPE:

- Disposable ASTM Level 2 clinical facemask
- Disposable nitrile gloves (if applicable)

Pre-Appointment Guidelines for Research/Testing Staff & Faculty

Standardized and IRB Approved COVID-19 Questionnaire for Research/Laboratory Staff:

- Must be completed electronically by any research/laboratory staff each week participant/client appointments are scheduled to mitigate risk as a result of currently known COVID-19 related symptoms published by the Centers for Disease Control (CDC).
- Responses will be reviewed by the research primary investigator (PI) or the laboratory coordinator (Johannah Zabal) each week.
- Flagged responses upon questionnaire completion, the PI or laboratory coordinator (Johannah Zabal) should:
 - Immediately contact the research/laboratory staff member to coordinate alternative working plans and coverage.
 - Provide appropriate COVID-19 recommendations and resources as determined by the University.

Research/Laboratory Staff Pre-Appointment Reminders:

- Limit personal belongings and items brought into the SPH building and laboratory facilities. Individuals should only be bringing essential items into the laboratory space.
 - Note: Lockers within the SPH building can be used to temporary store and secure additional unnecessary items.
- Close-toed footwear must be worn at all times unless the research/testing protocol specifies otherwise.
- No outside food or drink will be permitted in the laboratory hallway and individual spaces.
- Locker room facilities (showers) will not be available for use. We recommend that participants/clients make plans to shower at an alternative location after their appointment.
- Understand the B1 level traffic flow pattern as delineated in Appendix A.

Research/Laboratory Staff PPE:

- Disposable ASTM Level 2 or 3 clinical facemask (or N95 mask if available)
 - ASTM level 2 facemask: no exercise testing involvement and social distancing (≥6ft separation) during laboratory activity.
 - ASTM level 3 or N95 facemask: involved in conducting exercise testing and/or direct subject interaction during laboratory activity (≤6ft separation).
- Reusable full-length face shield or safety goggles (if applicable)
- Disposable nitrile gloves

SPH Building & Laboratory Entry Guidelines for Research Participants & Testing Clients

Greeting Participants/Clients in SPH Building Lobby:

- A single member of the research/laboratory team will greet the participant/client in the main SPH lobby prior to their appointment using the following PPE:
 - o Disposable ASTM Level 3 clinical facemask (or N95 mask if available)
 - Nitrile gloves

- Required supplies to be brought to lobby for participant/client and any accompanying visitors:
 - o Touchless temporal thermometer
 - Disposable clinical-style facemask(s)
 - Hand sanitizer
- Provide all visitors with disposal clinical-style facemask (even if already wearing one into the building).
- Measure temporal temperature.
- Temperature must NOT exceed 100.4°F to permit building access.
 - If an individual is exceeding the temperature threshold, that individual cannot be admitted into the facility.
 - Provide individual with the appropriate COVID-19 recommendations and resources as per University guidelines.
- Provide hand sanitizer to all visiting individuals.
- Check-in with SPH security team at front desk.
- Ensure that the "No Entry" laboratory door sign is placed appropriately on the door to prevent individuals from entering the specific laboratory space during research activities or testing.

Laboratory Entry Guidelines for Research/Testing Staff & Faculty

- Pre-Entry Guidelines for SPH B1 Laboratory Facilities:
 - Maintenance of proper social distancing (≥6ft separation)
 - o Required PPE: Disposable ASTM Level 2 clinical facemask
- If unable to maintain stipulated social distancing (≥6ft separation) due to necessary participant/client interaction requirements
 - o Required PPE: Disposable ASTM Level 3 clinical facemask (or N95 mask if available)
 - o Full-length face shield or safety glasses
 - Nitrile gloves
- Measure temporal temperature daily.
- Temperature must NOT exceed 100.4°F to permit laboratory access.
 - Exceeding temperature threshold:
 - Staff/faculty cannot be admitted into the facility.
 - Provide individual with the appropriate COVID-19 recommendations and resources as per University guidelines.
- Use hand sanitizer or wash hands upon entry.

General Laboratory Operation, Safety, & Cleaning Guidelines for Research & Testing

Pre-Research/Testing Preparation:

- Protocols that are performed with ≥6ft social distancing from participants, clients, or other users
 - o Required PPE: Disposable ASTM Level 2 clinical facemask
- Protocols are only performed with <6ft social distancing from participants, clients, or other users
 - Required PPE: Disposable ASTM Level 3 clinical facemask (or N95 mask if available)
 - Nitrile gloves
 - Full length face shield or safety glasses

 Wipe down projected laboratory surfaces to be touched/used: including door handles, chairs/chair arms, countertops, laptops, tablets, other specialized laboratory equipment/implements with a disinfecting wipe or spray.

Laboratory Use Guidelines:

- Follow general laboratory entry protocols (please refer to Appendix 2 for the floorplan).
- All subjects/participants are required to wear a facemask throughout the entire duration of the research/testing appointment.
- Exceptions to facemask guideline:
 - A specialized mask designed for exercise may be necessary to help a participant/client breathe normally while exercising.
 - A plexiglass surround suspended from the ceiling or ground may be used as a transparent COVID-19 barrier where masked exercise is not appropriate or feasible.
- All user personal items should remain on the floor in a dedicated area while conducting the assigned tasks or tests.
- Recommendations:
 - Users keep their mobile technology inside of their personal belongings or in a pocket throughout the laboratory session unless required for a specific lab-related task.
 - All forms, surveys, and data collection paperwork remain electronic to avoid transfer of paper materials between participants/clients and research/laboratory staff.
- Follow general laboratory exit protocols.

Post-Research/Testing Decontamination:

- Wipe down laboratory surfaces touched/used: including door handles, chairs/chair arms, countertops, laptops, tablets, other specialized laboratory equipment/implements with a disinfecting wipe or spray.
- Use an appropriate floor mop with disinfecting solution to clean the laboratory floor surface.
- Follow all aforementioned general laboratory exit protocols.
- Laboratory supply communication:
 - Notify the laboratory coordinator, Johannah Zabal, immediately if essential lab cleaning supplies are running low—do NOT wait until supplies are completely out of stock.
 - Notify the laboratory coordinator, Johannah Zabal, when biohazard boxes and/or sharps containers are reaching full capacity and they have been packed appropriately for disposal (if applicable).

Laboratory Exit Guidelines for Research Participants & Testing Clients

Guidelines for Exiting the Laboratory Facility and General SPH Building:

- Properly dispose of single use PPE (e.g. nitrile gloves) in the waste receptacle provided following the posted laboratory instructions. CONTINUE WEARING A FACEMASK.
- Thoroughly wash hands in the laboratory facility for at least the 20-second CDC recommended minimum duration.
 - Alternative: hand sanitizer
- Continue wearing the clinical-grade facemask until safely leave the SPH building or return home.
- Remove all personal belongings from the laboratory space.
- Recommendation for garments and shoes:

- Traveling to another area of SPH or GW: change clothes and shoes before leaving the B1 laboratory facility.
- Traveling directly home: change clothes and shoes upon home entry.
- Wash clothes and wipe down shoes/personal belongings (with a disinfecting wipe or spray) worn in the laboratory facility.
- Shower upon returning home.

Laboratory Exit Guidelines for Research/Testing Staff & Faculty

Pre-Exit Guidelines from Laboratory Spaces and the B1 Laboratory Hallway:

- Perform required post-laboratory session decontamination and cleaning duties.
- Check laboratory cleaning supply inventory.
- Properly dispose of single use PPE (e.g. nitrile gloves) in the waste receptacle provided following the posted laboratory instructions. CONTINUE WEARING A FACEMASK.
- Thoroughly wash hands in the laboratory facility for at least the 20-second CDC recommended minimum duration.
 - Alternative: hand sanitizer
- Disinfect and clean the reusable PPE (e.g. face shield) in the laboratory, EXCEPT the N95 mask.
- Continue wearing the clinical-grade facemask until safely leave the SPH building or return home.
- Remove all personal belongings from the laboratory space.
- Recommendation for garments and shoes:
 - Traveling to another area of SPH or GW: change clothes and shoes before leaving the B1 laboratory facility.
 - o Traveling directly home: change clothes and shoes upon home entry.
 - Wash clothes and wipe down shoes/personal belongings (with a disinfecting wipe or spray) worn in the laboratory facility.
 - Shower upon returning home.
- Store your reusable PPE in a clean and safe space until next use.

Supplies and Equipment

New Laboratory Equipment or Supplies:

- Remove from the original shipping box outside of the laboratory space
- Clean product packaging or individual item with a disinfecting wipe or spray before storing in the designated laboratory location.

Note: it may be more appropriate to clean certain equipment and supplies, particularly those related to food and beverage consumption, with soap and water.

General Laboratory Faculty & Staff Responsibilities

Maintaining Everyday General Laboratory Space Cleaning Duties:

• Paying particular attention to general surfaces contacted most by users (e.g. tables/desks, chairs, phlebotomy chairs, door handles, floors, laptop/computer keyboards, laboratory phones, and specialized laboratory equipment).

Maintaining Everyday General Laboratory Hallway Cleaning Duties:

• Supplementing and supporting SPH custodial staff cleaning protocols.

• Paying particular attention to B1 hallway laboratory/gym door handles, locker room/bathroom main entry door handles, and end of hallway fire door (brown door) push bars.

Frequent Hand Washing:

- Encourage and practice frequent hand washing when using the laboratory facilities.
- Be particularly cognizant about cleaning personal computer keyboards, mice, and cell phone surfaces—wipe down on a regular basis.

Return

4.5 Virtual/Digital Research

4.5.1 Principles

- Virtual/digital research is research that does not require in-person interactions with people or shared physical space. Examples include (but are not limited to) computer- or phone-based data collection and qualitative or quantitative data analysis.
- As for other types of research, virtual/digital research benefits from in-person interactions to enhance collaboration and communication. Although virtual/digital research can continue with all faculty and staff working from home, the quality and speed of research may be impacted without in-person interaction. Some virtual/digital research requires support services that may require office use (e.g. mailing gift cards to participants).
- Returning to in-person virtual/digital research will lag behind reopening other types of research (e.g. clinical, laboratory, community-based) for which faculty and staff need to be on campus.
 Phasing the on-campus return of virtual/digital research after other types of research can help maintain low population density on campus.
- Information technology resources and other support services are critical to ensure that virtual/digital research can continue through all phases of reopening.

4.5.2 Critical Issues

The following critical issues have been identified as pain points that faculty and staff are either experiencing now, or could experience if certain services are impacted by GWU cost cutting. Information technology resources and services in particular are critical to ensure that virtual/digital research can continue through all phases of reopening.

4.5.3 Critical Issues Related to University-Level Resources and Support Services

Support for High Risk Individuals and Those Who Live with High Risk Individuals

High risk individuals and those who live with high risk individuals may not be comfortable returning to campus during any phase of reopening. IT support should be available to allow remote work whenever technologically feasible for these individuals. Refer to the *GWSPH General Reopening Guidelines* for more comprehensive information on how to best support these individuals during all stages of GW's reopening.

Ensuring That All Employees Have Computers and Remote Access to On-Campus Resources

Individuals who expect to continue to work remotely should have the option to bring their GWU-based computers home, if they have not already. Transition to laptops should be prioritized where appropriate when computing resources are replaced or for future employees.

Coordinating Shared Space on Campus

Most "labs" with virtual/digital research share office or cubicle space with other labs or administrators. Return of lab members to on-campus work will need to be coordinated with others on the floor or area. These and other general issues will be covered by the *GWSPH General Reopening Guidelines*.

4.5.4 Research Phase 0: Previous State

Research Phase and OVPR Guidelines GWSPH Virtual/Digital Research Plan Continue research that is possible through en-All faculty and staff work remotely. tirely online means. Ensure that everyone has remote access to Select research projects, including COVID-recomputing resources, data, and other needs lated research, are allowed to continue or (see Critical Issues below). commence. Only essential personnel are allowed on campus. Core facilities are available under special consideration and maintain specific requirements for safety. Strict observation of all safety protocols to include, but not limited to, social distancing, personal hygiene, decontamination and appropriate use of personal protective equipment (PPE).

4.5.5 Research Phase 1: Limited Reopening (8 June 2020)

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Research Phase and OVPR Guidelines		GWSPH Virtual/Digital Research Plan	
	 Population density may be increased in a manner consistent with university, federal and district or state guidelines (12.5 - 25% of a lab's or program's staff may be allowed on campus at any one time subject to considerations in the sections below). 	 All faculty and staff work remotely. Ensure that everyone has remote access to computing resources, data, and other needs (see Critical Issues below). 	
	 Strict observation of all safety protocols to include, but not limited to, social distancing, personal hygiene, decontamination and appropriate use of PPE. Projects not involving chemical or radiological hazards, stopped as part of ramp-down, will be identified and principle of for phonod restort. 		
	 identified and prioritized for phased restart. Priority will be given to graduate students and postdocs who are close to completing their degrees/terms of appointment. This includes students and postdocs working on analytical and computationally oriented research. Priority will be given to principal investigators 		
	computationally oriented research.		

- end dates, and/or where the sponsor is not flexible with no cost extensions.
- Research projects conducted on campus using human subjects, and involving direct subject interactions and interventions, can be restarted in a manner consistent with the GW Medical Faculty Associates (MFA), university, federal and district guidelines.
- Necessary core facilities will be reopened in a limited capacity. Staffing and operations of the facilities will be kept at a minimum and training of new users may be suspended.

4.5.6 Research Phase 2: Expanded Reopening

Research Phase and OVPR Guidelines

- Priority will be given to graduate students and postdocs who are close to completing their degrees/terms of appointment. This includes students and postdocs working on analytical and computationally oriented research.
- Priority will be given to principal investigators (PIs) with grants within four months of their end dates, and/or where the sponsor is not flexible with no cost extensions.
- Research projects conducted on campus using human subjects, and involving direct subject interactions and interventions, can be restarted in a manner consistent with the GW Medical Faculty Associates (MFA), university, federal and district guidelines.
- Necessary core facilities will be reopened in a limited capacity. Staffing and operations of the facilities will be kept at a minimum and training of new users may be suspended.

GWSPH Virtual/Digital Research Plan

- Faculty and staff can (but should not be required to) return to campus for mission critical reasons (e.g. access to data on restricted machines), on a preset schedule, following guidelines, and maintaining physical distancing. Oncampus work is limited to mission critical tasks because: 1) otherwise the work can be performed at home, 2) adding people in this group to campus increases on-campus density which can increase risk for people in this group as well as people who have to be on campus to perform their work (including for other types of research as well as support staff like cleaning crews; 3) consistency with Reopen DC - telework is Strongly Recommended in Stages 1 and 2 and Encouraged in Stage 3.
- Employees who can complete their work remotely, with appropriate IT support, should not be required to return to campus if they are unwilling to do so.
- Ensure that everyone has remote access to computing resources, data, and other needs (see Critical Issues below).

4.5.7 Research Phase 3: Resume Total Research Programs

Research Phase and OVPR Guidelines

- All personnel may return to campus following any new and/or permanent implementation of safety guidelines.
- New projects may be started.
- All research facilities will be reopened.

GWSPH Virtual/Digital Research Plan

- Return to campus possible within guidelines of university and School of Public Health.
- Ensure that everyone has remote access to computing resources, data, and other needs (see Critical Issues below).

- Undergraduate researchers will be allowed back in laboratories subject to safety guidelines.
- Under DC Stage 3: All faculty and staff encouraged to continue working remotely.
- Under DC Stage 4: Managers encouraged but not required to allow employees who can complete their work remotely, with appropriate IT support, to continue to work remotely.

SECTION 5: APPROVAL PROCESS [UNDER REVIEW SEPARATELY]

Principal Investigators of research projects are required to develop a reopening plan and gain approval prior to reopening any laboratory (lab/core/shared facility), on-campus research study, or location to personnel (e.g., staff, graduate students, technicians).

In GW Phase 1 of reopening, any work that can be performed away from the GW campus should still be done remotely. All normal laboratory and research safety protocols should be maintained and personnel should be reminded of traditional safety policy and resources. Safety is always paramount for laboratories and research, but as we move through Phase 1 into Phase 2 and beyond, additional measures are needed for laboratories and research to operate under pandemic conditions.

All laboratory and research study reopening plans will be initially submitted and approved by a department chair in accordance with the guidance released by the Office of Human Research (OHR). The plan will then be sent to the Senior Associate Dean for Research via email to GWSPHResearch@gwu.edu.

A complete reopening approval request form should include demographic and project information as well as the following detailed plans (see table below for a full breakdown): a physical distancing plan compliant with GW and GWSPH recommendations, lab/space logistics, and a list of personnel responsibilities. Additionally, projects that include human subjects and/or handle COVID-19 specimens should provide updated procedures. Lastly, each form should include a plan for using/procuring PPE, cleaning materials, and supplies, plus a ramp-down procedure in the event a positive COVID-19 test result or similar situation requires the project to be ramped-down on short notice.

PIs must provide a reopening plan that addresses nine elements; a template form is available (being developed <u>Appendix 3</u>). The following table summarizes the details required.

No.	Plan Element	Plan Specifics
1	Project Information	 Provide location (and name) of lab or location of research. Name of sponsor or entity for whom work is to be performed, including complete contact details. Provide pertinent department/program under which the lab/study falls. Are you using any core services of the University (eg. genomics core, high-performance computing) Are you requesting an exception to GW or GWSPH guidelines? If Yes, please list the exceptions and add a justification.
2	Physical Distance Plan	 Provide details for providing ample physical distance that is consistent with the current GW recommendation. Establish max occupancy for space based on GW/GWSPH guidelines. Establish workspace markings (distances) where appropriate. Provide separate sections/discussion for specialized/shared equipment that need their own personnel distance guidelines and markings. Provide guidance on spacing for work areas (or benches), consider supply cabinets, refrigerators, and secondary equipment etc. and any other features of the lab/space that require distance plans and appropriate marking for personnel.
3	Lab/Space Logistics Plan	• The PI is responsible for creating a system whereby it is known in near real- time who is in the lab/space and when they are in the lab/space.

4	Personnel Responsibilities	 A list of all personnel who are allowed in the lab/space. If cohorts are utilized, the cohort groups may be provided. Work (open) hours for the lab/space should be stated (staggered schedules recommended). Logistics for special shared equipment, if varied from established practice (e.g. how to reserve) should be explained. Note: the use of non-standard work hours ("shifts") may be allowed (see Scheduling and Coordination of Work Hours) State personnel responsibilities and how they will know their roles. Document standard safety rules and point to relevant existing guidance. Provide additional COVID-19 related personnel responsibilities, refer to the latest guidance from GW/Health & Safety and the Office of Laboratory Safety. Note: Undergraduates are not allowed in facilities during GW Phase 1.
5	Cleaning Plan	 Provide a plan for how the lab/space will remain cleaned/sanitized. Pls and personnel are advised that given the desire to maximize social distancing, additional cleaning duties are is expected of personnel. Areas to be considered: trash receptacles, bench/work areas, touch spots, equipment, and general housekeeping (see GWSPH General Reopening Guidelines).
6	Human Subjects Plan	 Explain steps to be taken to ensure that participants are protected against COVID-19 exposure. Explain how you intend to manage research volunteers who test positive for COVID-19. Ensure participants receive information regarding potential COVID-19 exposure risk by having them read and sign the OHR Informed Consent Addendum. If the project involves community-based research techniques such as data collection and/or interviews, describe updated safety procedures.
7	Research Specimen Plan	 Explain steps to be taken to ensure safety in handling research specimens. If the study involves collection and/or handling of COVID-19 specimens, describe the safety procedures to be implemented.
8	PPE, Materials and Supplies Plan	 Re-opening requires appropriate PPE and cleaning materials. Document (list) materials required before re-opening. State how the lab/study is procuring necessary PPE and/or specific cleaning materials for the initial re-opening phase. Indicate if support from GWSPH is needed and specify for what PPE or other materials
9	Ramp- Down Procedures	 The PI should provide a plan for how to ramp down the lab/space safely in minimal time. Protocols for shutting down, cleaning, and restarting a lab/space if personnel tests positive for COVID-19 or for personnel with a positive test in their household need to be considered. Note: GWSPH will follow GW protocols for testing.

APPENDIX

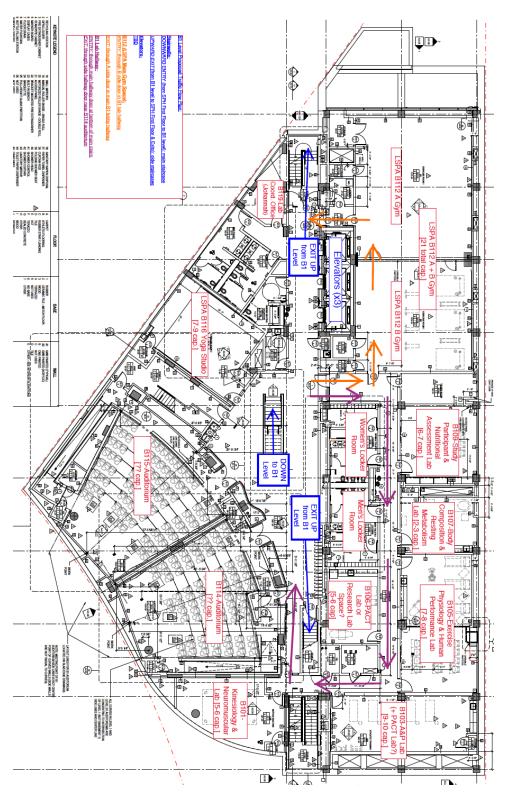
Appendix 1. GWSPH Phases of Research Resumption [under separate review]

Below is a summary of restrictions that will be applied during our anticipated phases of recovery.

	Minimal Density – COVID-Specific Research Only Phase 0	Low Density – Increase Research Activity Phase 1	Medium Density – Expanded Scope of Research Operations Phase 2	Near 100% Density – Return to Full Research Operations Phase 3
Primary Work/ Lab	Minimal on-campus presence for research operations; still remote when possible; approved PI plan in place for essential research	Minimal on-campus presence for re- search operations; still remote when possible; approved PI plan in place	Remote preferred for those at higher risk; approved PI plan in place	Telework still utilized where possible; new hygiene practices as the norm
Building Access	Highly limited	Limited, with possi- ble shift work	Wider access	Open access
Occupancy of Shared Offices	No	No	Yes, with appropriate distancing	Yes
Density of Lab Spaces	Minimal	Managed through approved PI plans; 1 person per 400 ft ² of gross lab area	Managed through approved PI plans; capacity limits will be revisited	Near full capacity
Group Meetings	None	None	Constraints on meet- ing size and use of general space align with university policy	Larger meetings; normal limits on room occupancy
Hygiene – Follow CDC Guidelines	Strict distancing, required face covering, minimal lab density, frequent hand-washing	Strict distancing, required face covering, minimal lab density, frequent hand-washing	Required face cover and strict distancing	Recommended face covering; some potential lessening of distancing requirements
Cleaning	Lab-specific as per Phase 0 plans	New cleaning proto- cols in place; no shared surfaces such as desks, keyboards, phones; common ar- eas closed	Cleaning protocols remain; limited shared surfaces; some common areas reopen with distanc- ing rules	Routine cleaning of labs and common areas
Health Monitoring/ Testing	Symptomatic persons only	Testing and contact tracing of sympto- matic trainees and employees only	Testing and contact tracing of symptomatic trainees and employees (TBD)	Vaccine, effective therapeutics, or substantial immunity amongst community
Undergradu- ates	No	No	No/Possibly ³	Yes
Graduate Students/ Postdoctoral Fellows	Only for COVID-re- lated research	Yes	Yes	Yes

³ Subject to university decision to resume on-campus undergraduate education

Appendix 2. Metabolism & Exercise Testing Lab Floorplans



Appendix 3. Approval Form for Research Reopening

GWSPH Research Project/Laboratory Reopening Procedures

Instructions: The following form must be completed in full for each project or laboratory that had been suspended as a result of COVID-19 (collaborating PIs need to submit a single form for the same project).

The form should be submitted to your department chair. Send the approved form to the Office of Research Excellence (ORE) at GWSPHResearch@gwu.edu to request re-opening of a GWSPH laboratory or study. To avoid delays, complete all fields and provide details in the planning sections. All plans must adhere to both GW and GWSPH guidance. For sections that are not applicable, please indicate N/A.

Demographic information		
PI Name:	PI Title:	
Email:	Phone:	
Department: Select Department	Date: Click or tap to enter a date	
Duals at Information		
Project Information		
Is this sponsored research? Choose one	Project end date: Click or tap to enter a date	
Sponsor name/entity for whom work will be perfor	med (<i>or N/A</i>):	
Contact information for sponsor/responsible entity (or N/A):		
Name and/or location of lab or research:		
List any university provided core services you are u	sing (eg. genomics core, high-performance compu-	
ting):		
Are you requesting an exception to any GW or GWSPH guidelines? Choose one		
If Yes, please explain:		

Details regarding physical distancing Max occupancy for space Establish workspace markings and guidance on spacing work areas 4. Sections for specialized/shared equipment that needs their own personnel distance guidance/markings ance/markings

Plan details:

Daws a swampia Informatio

Lal	Lab/Space Logistics Plan – PI must create system for tracking lab occupancy in near real time				
1.	Details about tracking system	3.	State work hours		
2.	List of authorized personnel/cohorts allowed	4.	Logistics for special shared equipment, if it		
	in the lab		deviates from established practice (e.g. how		
			to reserve)		
Pla	Plan details:				

Pei	Personnel Responsibilities – scope of roles must include COVID-19-related responsibilities				
1.	List personnel responsibilities	3.	Document standard safety rules and point to		
2.	Outline how roles are designated		existing guidance		
Pla	Plan details:				

Cleaning Plan – expectation that personnel will assume additional cleaning workload 1. How will the space be cleaned/disinfected and how will it be maintained? Plan details: Human Subjects Plan – Additional COVID-19 considerations (if applicable) 1. Steps to ensure participants are protected against COVID-19 exposure 2. How to manage research volunteers who test positive for COVID-19? 3. Describe safety procedures if project involves community-based data collection/interviews

Research Specimen Plan – Laboratory precautions for specimens and samples (if applicable)

- 1. Steps to ensure safely handling research specimens
- 2. Describe safety procedures if collecting/handling COVID-19 specimens

Plan details:

Plan details:

1. Document required materials

- 3. Will support from GWSPH be needed and in what capacity?
- 2. How will lab/study procure PPE and/or specific cleaning materials for re-opening?

Plan details:

Ramp-Down Procedure – contingency plan for safely ramping down the lab/space in minimal time

- 1. Detail protocols for ramping down, cleaning, and restarting lab/space in light of a positive COVID test
- 2. GWSPH will follow GW protocols for testing

Plan details:

Approvals – send to department chair for approval, then to the ORE for Deans' authorizations					
Position	Name	Signature	Date		
Principal Investigator					
Department Chair					
Executive Associate Dean, Operations & Chief Operating Officer	Natasha Kazeem				
Senior Associate Dean for Research	Adnan Hyder				

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- Normal Campus Advisory emails
- GWSPH Office of Research Excellence Website: https://publichealth.gwu.edu/research/sphhs-office-research-excellence
- ORE COVID-19 Webpage: https://publichealth.gwu.edu/content/covid-19-research
- GW Office of the Vice President for Research (OVPR) Website: https://research.gwu.edu/
- GWSPH Instructional Continuity Guidance Resources: https://publichealth.gwu.edu/pdf/Full_IC_Guidance.pdf
- US Centers for Disease Control (CDC) Website: https://www.cdc.gov/coronavirus/2019-ncov/index.html
- WHO Advisory Regarding Travel: https://www.who.int/travel-advice

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