**GWSPH New Project Initiation & Research Project Reopening Approval Request**

Principal Investigators who intend to initiate new project as well as those intending to restart projects that were halted due to COVID-19, are required to develop a reopening plan and gain approval prior to initiating or 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 initiation and reopening plans will be initially submitted and approved by a department chair. The plan will then be sent to the Senior Associate Dean for Research via email to GWSPHResearch@gwu.edu.

A complete project initiation and 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 detailed safety 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 project initiation/re-opening plan using the template that addresses the following nine elements:

|  |  |  |
| --- | --- | --- |
| **No.** | **Plan Element** | **Plan Specifics** |
| 1 | Project Information | 1. Provide location (and name) of lab or location of research.
2. Name of sponsor or entity for whom work is to be performed, including complete contact details.
3. Provide pertinent department/program under which the lab/study falls, title of the project, and IRB/IBC details if applicable.
4. Are you using any core services of the University (eg. genomics core, high-performance computing)
5. Are you requesting an exception to GW or GWSPH guidelines? If *Yes*, please list the exceptions and add a justification.
 |
| 2 | Physical Distance Plan | 1. Provide details for providing ample physical distance that is consistent with the current GW recommendation.
2. Establish max occupancy for space based on GW/GWSPH guidelines.
3. Establish workspace markings (distances) where appropriate.
4. Provide separate sections/discussion for specialized/shared equipment that need their own personnel distance guidelines and markings.
5. 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/SpaceLogistics Plan | 1. 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.
2. A list of all personnel who are allowed in the lab/space. If cohorts are utilized, the cohort groups may be provided.
3. Work (open) hours for the lab/space should be stated (staggered schedules recommended).
4. 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 Research Reopening Guidelines for GWSPH)* |
| 4 | Personnel Responsibilities | 1. State personnel responsibilities and how they will know their roles.
2. Document standard safety rules and point to relevant existing guidance.
3. Provide additional COVID-19 related personnel responsibilities, refer to the latest guidance from GW/Health & Safety.
 |
| 5 | Cleaning Plan | 1. A plan should be provided for how the lab/space will remain cleaned/sanitized.
2. PIs and personnel are advised that given the desire to maximize social distancing, additional cleaning duties are expected of personnel. Areas to be considered: trash receptacles, bench/work areas, touch spots, equipment, and general housekeeping.
 |
| 6 | Human SubjectsPlan | 1. Explain steps to be taken to ensure that participants are protected against COVID-19 exposure.
2. Explain how you intend to manage research volunteers who test positive for COVID-19.
3. If the project involves community-based research techniques such as data collection and/or interviews, describe updated safety procedures.
 |
| 7 | ResearchSpecimen Plan | 1. Explain steps to be taken to ensure safety in handling research specimens.
2. 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 | 1. Project initiation as well as re-opening requires appropriate PPE and cleaning materials.
2. Document (list) materials required before initiation/re-opening.
3. State how the lab/study is procuring necessary PPE and/or specific cleaning materials for the initial initiation/re-opening phase.
4. Indicate if support from GWSPH is needed and specify for what PPE or other materials.
 |
| 9 | Ramp-DownProcedures | 1. The PI should provide a plan for how to ramp down the project or lab/space safely in minimal time.
2. Protocols for shutting down the project or lab, 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*.  |

**GWSPH Research Project/Laboratory Initiation & Reopening Procedures**

*Instructions: The following form must be completed in full for each new project or laboratory as well as for those 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 project initiation/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 |

|  |
| --- |
| **Project Information** |
| Is this a new project OR a project/lab that is restarting/reopening? Choose one |
| Is this sponsored research? Choose one | Project end date: Click or tap to enter a date |
| Sponsor name/entity for whom work will be performed (*or N/A*):  |
| Contact information for sponsor/responsible entity (*or N/A*):  |
| Name and/or location of lab or research:  |
| Title of the project:  |
| Does the project have IRB/IBC approval (*or N/A*)?  |
| List any university provided core services you are using (eg. genomics core, high-performance computing):  |
| Are you requesting an exception to any GW or GWSPH guidelines? Choose one |
| If *Yes*, please explain:  |

|  |
| --- |
| **Physical Distance Plan** – should be consistent with GW and GWSPH recommendations |
| 1. *Details regarding physical distancing*
2. *Max occupancy for space*
3. *Establish workspace markings and guidance on spacing work areas*
 | 1. *Sections for specialized/shared equipment that needs their own personnel distance guidance/markings*
 |
| Plan details: |

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

|  |
| --- |
| **Personnel Responsibilities** – scope of roles must include COVID-19-related responsibilities |
| 1. *List personnel responsibilities*
2. *Outline how roles are designated*
 | 1. *Document standard safety rules and point to existing guidance*
 |
| 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*
4. *If the new project requires IRB approval, investigators should ensure that it is submitted to IRB before initiation. For projects with existing IRB approval, investigators are required to complete a Promptly Reportable Information Form (PRIF) and submit to the IRB through IRIS.*
 |
| Plan details:  |

|  |
| --- |
| **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:  |

|  |
| --- |
| **PPE, Materials, and Supplies Plan** – Re-opening requires appropriate PPE and cleaning materials |
| 1. *Document required materials*
2. *How will lab/study procure PPE and/or specific cleaning materials for re-opening?*
 | 1. *Will support from GWSPH be needed and in what capacity?*
 |
| 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 |  |  |