

GWSPH Plans for Reopening Research

Adnan A. Hyder, MD MPH PhD
Senior Associate Dean for Research
Professor of Global Health
Milken Institute School of Public Health



Milken Institute School
of Public Health

THE GEORGE WASHINGTON UNIVERSITY

THE GEORGE
WASHINGTON
UNIVERSITY

WASHINGTON, DC

GWSPH Research Reopening Guidelines

Brief Introduction

Milken Institute School
of Public Health

THE GEORGE WASHINGTON UNIVERSITY

THE GEORGE
WASHINGTON
UNIVERSITY

WASHINGTON, DC

SECTION 1

Introduction to the Reopening Guidelines

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

- 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

SECTION 2

OVPR Plans for Reopening Research - 1

- OVPR released a guidance document for research reopening (28 May 2020)
- GWSPH guidelines are consistent with OVPR
- OVPR established **4 Guiding Principles**
 - Safety as a top priority
 - Will follow government directives and coordinate across GW
 - COVID Research Task Force(s) will provide guidance and oversight
 - The GW Research “Re-Opening” will be through a transparent and phased

SECTION 2

OVPR Plans for Reopening Research - 2

- GW Phases of Reopening
 - **Phase 0** (Previous) – only select research projects are allowed to be conducted with minimum essential personnel
 - **Phase 1** (Present since June 8) – *Limited Reopening* - population density increase consistent with guidelines, priority personnel and projects
 - **Phase 2** (TBD) - *Expanded Reopening* – population density increase consistent with guidelines, additional priority projects and labs
 - **Phase 3** (TBD) – *Resume Total Research Programs*

SECTION 3

GWSPH General Guidelines

- The *General Reopening Plan* is a separate document being developed by Dean Kazeem and the operations team
- Those guidelines will cover:
 - General procedures for returning to the building, basic use of facilities
 - Protocols if an individual displays COVID-19 symptoms or tests positive
 - Use of PPE, social distancing requirements, hygiene, cleaning
 - Best practices for situations (ex. public transport, meetings)
 - And additional materials related to opening the school

SECTION 4

Protocols for the Five Domains of GWSPH Research - 1

Community-Based Research

Lead: Irene Kuo; Co-Lead: David Huebner

Content:

- General Principles
- Research Phase 1: Limited Reopening
- Research Phase 2: Expanded Reopening
- Research Phase 3: Resume Total Research Programs
- Determining Necessity of In-Person Contacts for Research
- Procedures for Any In-Person Contact

SECTION 4

Protocols for the Five Domains of GWSPH Research - 2

Clinical Research

Lead: Melissa McCarthy

Content:

- Clinical Research Issues Regardless of Setting
- Clinical Research in SPH or SPH-Run Clinic
- Research in a Healthcare Setting

SECTION 4

Protocols for the Five Domains of GWSPH Research - 3

Global Research

Lead: Emily Rose Smith

Content:

- Guiding Principles Applicable to All Phases
- Guiding Principles for International Travel Applicable to All Phases
- Research Phase 0: Previous State
- Research Phase 1: Limited Reopening
- Research Phase 2: Expanded Reopening
- Research Phase 3: Resume Total Research Programs

SECTION 4

Protocols for the Five Domains of GWSPH Research - 4

Laboratory-Based Research

Lead: Mimi Ghosh

Content:

- Use of GWSPH Research Laboratories (Non-Clinical/Non-Instructional)
- Science and Engineering Hall (SEH 7th Floor Labs)
- Metabolism & Exercise Testing Laboratories (SPH Basement Level 1)

Milken Institute School
of Public Health

THE GEORGE WASHINGTON UNIVERSITY

THE GEORGE
WASHINGTON
UNIVERSITY
WASHINGTON, DC

SECTION 4

Protocols for the Five Domains of GWSPH Research - 5

Virtual/Digital Research

Lead: Susan Anenberg

Content:

- Principles
- Critical Issues Related to University-Level Resources and Support Services
- Research Phase 0: Previous State
- Research Phase 1: Limited Reopening
- Research Phase 2: Expanded Reopening
- Research Phase 3: Resume Total Research Programs

Milken Institute School
of Public Health

THE GEORGE WASHINGTON UNIVERSITY

THE GEORGE
WASHINGTON
UNIVERSITY
WASHINGTON, DC

SECTION 5

Approval Process - 1

- In accordance with all the guidance from GW, SPH has created an approval process for reopening labs/restarting research projects
- This approval process, outlined in this section, is considered a living document in itself, and may evolve as our understanding of the situation changes
- Each plan must address nine elements (if applicable) and a fillable template will be included, along with detailed instructions

SECTION 5

Approval Process - 2

Nine plan elements:

1. Demographic and Project Information
2. Physical Distance Plan
3. Lab/Space Logistics Plan
4. Personnel Responsibilities
5. Cleaning Plan
6. Human Subjects Plan
7. Research Specimen Plan
8. PPE, Materials and Supplies Plan
9. Ramp-Down Procedures

**Appendices or additional documents can be added if required*

SECTION 5

Approval Process - 3

- All PIs must submit a request for each project or lab that is restarting/reopening to their chair for approval
- The Chair's office will then submit the request to the SADR for approval
- The request will also be reviewed by Dean Kazeem as needed

Please note that the GW Office of Human Research (OHR) has released documentation that now requires this approval

Office of Human Research Institutional Review Board Guidance

Milken Institute School
of Public Health

THE GEORGE WASHINGTON UNIVERSITY

THE GEORGE
WASHINGTON
UNIVERSITY

WASHINGTON, DC

IRB Guidance - 1

What to Submit to the IRB

- **Existing studies:**
 - Receive departmental/school approval to resume in-person interaction
 - Submit a Promptly Reportable Information Form (PRIF) to the IRB that indicates the intent to resume research & certify use of the information form/addendum
- **New studies:**
 - Receive departmental/school approval to include in-person interactions
 - Include in the IRB application that the information sheet/addendum will be used

IRB Guidance - 2

New Information Sheet/Consent Addendum

- COVID-19
- Now posted on website with consent templates
- Does not need IRB approval; can be used as-is
- **For currently enrolling studies:**
 - Use with the consent process as a consent addendum and obtain signature on both the consent and the COVID-19 information sheet
- **For studies re-opening where subjects have already consented:**
 - Provide subjects the form, explain information, and obtain signature

IRB Guidance - 3

Office of Human Research Institution Review Board

- Contact information:
 - www.humanresearch.gwu.edu
 - 202-994-2715
 - ohrirb@gwu.edu
- The IRB review is a collaborative process, so please contact them early if you need guidance or have questions
- *Please feel free to reach out to the ORE for any additional clarification and contact Paul Ndebele (pndebele@gwu.edu) for ethics related issues*

Thank you

To get a copy of the DRAFT *GWSPH Reopening Guidelines* please see:

<https://publichealth.gwu.edu/content/covid-19-research>

For any questions, please email us at:
GWSPHResearch@gwu.edu

Milken Institute School
of Public Health

THE GEORGE WASHINGTON UNIVERSITY

THE GEORGE
WASHINGTON
UNIVERSITY
WASHINGTON, DC

THE GEORGE
WASHINGTON
UNIVERSITY

WASHINGTON, DC

