Overview and Introduction

For the foreseeable future, the novel coronavirus that causes COVID-19 will be circulating on campus and in the community. COVID-19 remains a risk until effective treatments and vaccines are widely available. COVID-19 represents a new risk to research participants. Therefore, all GW researchers performing research with human subjects must inform research participants of the risks of COVID-19 that might be encountered due to the research, and take appropriate steps to mitigate these risks.

During a pandemic, infection prevention requires a multi-layered approach. No one infection control plan or piece of personal protective equipment is 100% effective and similarly human subjects protections must occur at multiple levels within the University. While GW as an institution is enacting a phased and cautious reopening, so too is human subjects research reopening in phases, with all necessary precautions being followed. This guidance, issued by OVPR, OHR, and the IRB, outlines the next phase of resuming human subjects research involving in-person interactions with participants.

There are three necessary components to safe and effective resumption of human subjects research at GW:

1) Appropriate methods to mitigate risk of infection or transmission of COVID-19 to and among research participants – this will re-balance the risk/benefit ratio of research involving in-person interactions

2) Appropriately informing prospective research participants of the risks of COVID-19 related to research participation, their status or risk if they are particularly vulnerable to COVID-19, and of the COVID-19 infection mitigation strategies undertaken by the University, department, and research team – this will address the need for informed consent of prospective research participants

3) Departmental prioritization and monitoring of human subjects activities – as per recently released COGR guidance, in which universities and departments are tasked with determining what types of human subjects research can resume and ensuring that all such research is carried out in a manner that minimizes the chance of COVID-19 transmission between research participants and the study team, departmental prioritization of this nature is necessary to avoid overuse of space and resources and involves department assessment and allocation of space allowance, departmental resources, and research priorities to identify those research studies that will be allowed to resume at this time.
Steps to Resumption of Certain Human Subjects Research for Both Existing and New Studies

The first step for researchers hoping to resume research involving in-person interactions with human subjects is to obtain departmental approval for resumption of the research. Researchers must work directly with their departmental and school leaders to determine if their research with human subjects may proceed during phased re-opening. Lack of departmental or school involvement in research prioritization leads to multiple, overlapping studies that strain resources and space. In order to protect human subjects at GW, the role of departments and schools in prioritizing and moderating human subjects research will need to increase.

Departments and schools are responsible for prioritizing and moderating the resumption of human subjects research to prevent overcrowding and overuse of resources. Departmental prioritization will be related to:

- Space to allow for physical distancing to safely accommodate GW personnel and research participants
- Department and university resources
  - To allow for sufficient PPE, sanitation equipment, and other necessary resources
  - To avoid bottlenecks and over-burdening of OHR and IRB resources which will result in research delays, frustration, and likelihood of error and reduced human subjects protections
- Department, University, and local/national health authority requirements to protect the safety and well-being of human subjects and research personnel
- Department and school research priorities
- Type of research
- Source of research funding and research funding concerns
- Research procedures - Departments must also be aware of, carefully consider, and closely moderate studies that involve research methods that may increase COVID-19 risk to participants:
  - Research activities that involve high metabolic processes such as exercising may increase the participant's respiratory rate and minute volume. Additional space, PPE, or other precautions may be necessary for these studies.
  - Research activities that involve food or item handling or food or item exchange. Additional resources may be needed to prevent cross contamination and infection in these studies.
  - Research activities involving collection of biological samples that may contain viral particles. Additional space, PPE, safety precautions, and resources will be necessary for these studies.
More information regarding university, school, and department prioritization and monitoring of human subjects research is found in Appendix A.

At this time, OVPR, OHR, and the IRB are allowing the resumption of some human subjects activities involving in-person interactions. All human subjects research involving in-person interactions must follow the safety precautions outlined in Appendix B.

For new studies, once the department has issued approval for the research, IRB approval for the research can be sought.

For existing studies that already have IRB approval, once the department has issued approval for resumption of the research, the study may resume, provided the instructions outlined in Appendix B are followed.

Allowable Human Subjects Research Activities

The following human subjects research activities may resume provided appropriate Department approval has been granted as per prioritization guidance issued by OVPR and found in Appendix A, and provided the necessary steps to protect human subjects are taken as outlined in Appendix B:

1) Research posing direct benefit to participants, approved by pertinent departments, and in compliance with all university, local, and national health and safety requirements
2) Research not posing direct benefit and involving in-person interaction with human subjects, approved by pertinent departments, and in compliance with all university, local, and national health and safety requirements
3) Research not posing direct benefit and not involving in-person interaction with human subjects
4) Research not posing direct benefit that has been revised to be conducted remotely should continue to be conducted remotely unless there is a sponsor-mandated reason to change procedures

OHR, OVPR, and the IRB will continue to work with departmental and school leadership to develop further prioritization and monitoring guidelines and processes as necessary. This guidance may be updated as those guidelines and processes are developed.

Modification of Previously Approved Research

Previous guidance regarding modifications to research and reduction of in-person activities remain in place regarding Modifications to conduct study visits and research remotely and to reduce or remove in-person interactions. For more information, please see previous guidance
regarding study modification and reduction of in-person interactions: https://humanresearch.gwu.edu/covid-19.

As always, because risks from Covid-19 will wax and wane, and remain unpredictable, remember that investigators may implement changes to approved research prior to IRB review and approval, if the changes are necessary to eliminate apparent immediate hazards to the subject. Please follow previous guidance regarding changes to research, IRB review of changes, and reporting necessary and immediate changes to the IRB.