Appendix A

Guidelines for Departmental Prioritization and Moderation of Human Subjects Research:

Per guidance issued by the Office of the Vice President for Research (OVPR), the Office of Human Research (OHR), and the GW Institutional Review Board (IRB), departmental prioritization and coordination of human subjects activities prior to review or involvement of OHR or the IRB is necessary for the successful, phased resumption of human subjects research at GW. To this end, departments and schools will be responsible for prioritizing and moderating the resumption of in-person human subjects research (resumption of HSR) to prevent overcrowding and overuse of resources. Since the COVID-19 outbreak began, IRB submissions have also increased significantly and the IRB has been operating with reduced staffing. Partnership with school/department personnel to prioritize HSR is crucial to ensure the protection of human subjects, and to prevent bottlenecking and overburdening the IRB review process.

Departmental prioritization must include:

- Sufficient space to allow for the safe accommodation GW personnel and research participants,
- Department and University resources
- Consideration and compliance with safety precautions required by the University, school, and local/national health authorities.
- Department and school research priorities,
- Type of research,
- Research funding,
- Research procedures - Departments must also be aware of, carefully consider, and closely monitor studies that involve research methods that may increase COVID-19 risk to participants. This includes:
  - Research activities that involve heightened physical activity 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 to prevent the spread of COVID-19 via airborne droplets.
  - 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 to reduce the risk of infection.

Department responsibilities are to:
• Ensure all research staff have knowledge of and adherence to each department’s plan to appropriately increase volume and OVPR’s guidance.

• Determine the types and extent of human subjects research involving in-person interactions that will be restarted in each phase of HSR resumption:
  o Phase 1a HSR ramp up – Medical research at GW Hospital and MFA with appropriate departmental prioritization and following necessary safety precautions. Consider the overlap between clinical personnel and resources and research personnel and resources in making this determination.
    ▪ Exceptions are allowed for non-medical research with funding concerns that must involve in-person interactions – exceptions will be applied for initially through the Department, followed by an exception form completed by the Department and Research team that will be submitted to OHR
  o Phase 1b HSR ramp up – Non-medical research on campus with appropriate departmental prioritization. Processes and timeline to be determined.
  o Phase 2 HSR ramp up – all research off campus with appropriate off campus permissions and safety precautions. Processes and timeline to be determined.

• Develop and enforce processes that research teams will employ to limit risk of COVID-19 transmission between research teams and study participants (e.g., use of video/telephone when possible, combining study visits with clinic visits, etc.).

• Ensure that there is an adequate supply of PPE and other sanitation or safety equipment for use by both participants and research teams.

• Develop communications to educate research teams and participants on safety precautions that will be taken, including use of PPE, reporting of COVID-19 symptoms and testing.

• Develop appropriate processes for the prioritization and monitoring of human subjects research – please note that existing pre-COVID-19 processes for departmental review are insufficient and additional processes must be developed to assess and ensure the above criteria for HSR resumption.

• Ensuring participation of school and/or department leadership in working with OVPR, OHR, and the IRB to develop an efficient process to ensure departmental prioritization and moderation of HSR resumption.
  o OVPR is assembling a working group of university, school, and department leadership to guide the prioritization and moderation of human subjects
research resumption. Involvement of school/department leadership will allow for consideration and accommodation of unique departmental concerns