Appendix B

Necessary steps to protect human subjects:

- All research must follow university, department, and local/national health authority requirements

- Participant screening for COVID-19 symptoms must occur prior to in-person visits:
  - If conducted in a HIPAA-covered setting, health information collected as a part of this screening is subject to HIPAA.
  - Remotely interview participants for potential exposure and/or symptoms of COVID-19
    - Participants who have recently (within the past 14 days) interacted with someone who had been diagnosed with COVID-19 within 14 days prior to the interaction
    - Participants who have been diagnosed with COVID-19 in the past 14 days
    - Participants who have one or more symptoms of COVID-19 such as cough, fever, shortness of breath, chills, muscle pain, new loss of taste or smell
    - Willingness to adhere to all safety and sanitation procedures during in-person study visits, including agreeing to use appropriate personal protective equipment.
  - Screen for factors that place participants at greater risk from COVID-19, and assess participant vulnerabilities, any unique risk mitigation plans, and appropriateness of participation for these individuals:
    - 65 years of age or older
    - Participants with chronic lung disease or moderate to severe asthma
    - Participants with a heart condition
    - Participants who are immunocompromised
    - Participants with a body mass index (BMI) of 40 or higher
    - Participants with diabetes or pre-diabetes
    - Participants with chronic kidney disease undergoing dialysis
    - Participants with liver disease
  - Pre-visit risk assessment questions should preclude in-person visits with:
    - Participants who have recently interacted with someone who had been diagnosed with COVID-19
    - Participants who have been diagnosed with COVID-19 in the past 14 days (unless for COVID-19 related research such as COVID-19 treatment clinical trials)
    - Participants who have one or more symptoms of COVID-19 such as cough, fever, shortness of breath, chills, muscle pain, new loss of taste or smell
  - As per previous guidance, pre-visit COVID-19 risk assessment does not require IRB review or approval, as the information collected is not research data
All research participants should be advised to arrive at the research site wearing a face mask or covering that covers the mouth and nose, which should be worn at all times in the research facility unless the participant has a medical condition that precludes wearing a face covering.

Screening of research participants upon arrival at the research site. Research personnel must rescreen participants upon arrival per unit or building guidelines, which may include temperature checks and interviewing for COVID-19 symptoms. Participants failing screening should not be admitted to the building if screening is conducted at the building entrance, or should be immediately isolated in a private room if already in the building. Appropriate clinic personnel or EH&S must be contacted and requirements for referral for testing should be followed.

All research participants who will undergo in-person research activities must receive a copy of the GW OHR COVID-19 information sheet.

- This information sheet outlines the risks of COVID-19, considerations for populations vulnerable to COVID-19, and the risk mitigation strategy that has been developed at GW research sites.

- Studies that do not have a waiver of consent documentation must obtain a wet or electronic consent signature on the information sheet. Studies that have a waiver of consent documentation do not need to obtain a wet or electronic signature on the information sheet. In all cases, researcher conversation with participants regarding the risks of COVID-19, risk assessments regarding subject participation, and outcome of the discussion regarding subject participation should be documented in the research record.

- **Provided that the GW OHR COVID-19 information sheet is used verbatim (except where clearly marked for study specific information), this document is considered to have IRB approval.**
  - Existing studies that have received departmental approval to resume in-person interactions should submit a Promptly Reportable Information Form (PRIF) to the IRB indicating their intent to resume and certifying use of the GW OHR COVID-19 information sheet. No other information is necessary.
  - Existing studies that never paused do NOT need to submit a PRIF to use the GW OHR COVID-19 information sheet. The PRIF submission is only for HSR that is resuming.
  - New studies that have received departmental approval to include in-person interactions should mention in the initial IRB submission that the GW OHR COVID-19 information sheet will be used.

- You will need to submit a protocol modification for IRB approval if:
  - If you would like to make changes to this information sheet (outside of adding study language where indicated) either to add, remove, or change language, or
b. the procedures for risk mitigation are different than those described in this appendix or in the information sheet.

- You must retain a copy of the GW OHR COVID-19 Information Sheet in the study record and document provision of this information sheet to each study participant who attends an in-person study visit; discussion regarding risks of participation and subject decision regarding participation should also be documented in the study record.

- This information sheet is institution-wide and should be used for all research involving in-person interactions being conducted at GW and/or by GW personnel regardless of the IRB of Record. If GW is not the IRB of Record for your research study, you may need to contact the IRB of Record to determine if they require review of the information sheet. You may also contact the GW OHR for more information if necessary.

- If your research involves non-English speakers, you do not need a certified translation of the Information Sheet. If the use of an independent translator is available to you as part of clinic or other research procedures, they can assist with sharing the information with the subject and explaining the risks. The research record should reflect that the information sheet was shared with participants via interpreter or translator.

- Research including COVID-19 positive patients does not need to perform the screening described above, nor is the GW OHR COVID-19 information sheet required for this population. However, special precautions must be taken with these patients following hospital and clinic guidelines.

- Maintain physical distancing (>6 feet) between people including researchers and human subjects:
  - Rooms should be set up to allow for physical distancing.
  - Participant visits should be scheduled to avoid crowding and use of waiting areas
  - Researchers who plan to perform in-person research interactions on campus must plan their research visits in consideration of clinic schedules and other research so as to prevent overlap between participant visits or unnecessary exposure of participants to unrelated clinic personnel.

- Use of face coverings during all research interactions with participants. Both researchers and participants must use face coverings unless participant face covering is prohibited by research activities or an underlying medical condition. In these cases, participant face coverings should be removed only during research activities that prohibit face coverings (e.g., nasopharyngeal swab, endoscopy) and immediately replaced once the prohibitive research activity is complete. Researchers should wear appropriate face coverings at all times when interacting with human subjects.

- Research personnel conducting in-person study visits must use personal protective equipment (PPE) appropriate for the type of in-person interaction and the COVID-19 risk status of the research participant. PPE must not be reused if it cannot be appropriately
sanitized between use, as per departmental, institutional, local and/or national guidelines. PPE includes: personal use face covering, gloves for direct physical contact, disposable gowns and face shields.

- Hand washing with soap and water by participants and researchers before direct contact with each other, equipment and high touch surfaces. Use of alcohol-based hand sanitizer can be substituted if hand washing is not available.

- High touch surfaces must be cleaned using standard cleaning methods before and after use by the researchers and participants.

- Multi-user equipment (laptop keyboards, tablets, etc.) should have protective, cleanable surfaces to the extent possible and cleaned after every use.

- Equipment that has an increased capability of being contaminated with the SARS-CoV-2 virus such as respiratory tubing, face masks, saliva traps, etc., should be cleaned with medical grade cleaners per manufacturer’s guidelines.

- Maintain a daily list of all participants and the researchers who have interacted with them, to allow for contact tracing if necessary. This list should be kept in a private location and be subject to all study data privacy and security protections.