ADDENDUM B
HSRC APPLICATION CHECKLIST
FOR ALLOWABLE HUMAN SUBJECTS RESEARCH DURING COVID-19
Academic Year 2021-2022

Carefully read this document and, if necessary, revise your application before submitting materials to the HSRC. Not adhering to this addendum may cause delays in protocol processing and review time.

The application you submit is the document of record. If you inadvertently omit necessary details from your application, it cannot be reviewed and approved. Use this checklist to ensure that your application will be processed.

The HSRC application must acknowledge and document that your study involves Allowable Human Subjects Research during COVID-19. Use the checklist below to ensure that your application provides necessary details about COVID-19 procedures for your study:

☐ Include a statement justifying any essential in-person interactions.
☐ Distinguish between in-person (e.g., data collection) and remote (e.g., informed consent) activities. Only procedures that cannot be handled remotely or online may be conducted in person.
☐ Explain any exclusion criteria related to vulnerable populations (e.g., children below 18, adults over 65) and how you will screen for health/medical conditions.*
☐ Provide detailed safety plans throughout study materials (recruitment materials, consent forms, etc.), including:
  ☐ when COVID-19 symptoms/attestation screening will occur (e.g., immediately prior to each in-person interaction) (confirm that you will use the standard CDC screening for each potential participant);
  ☐ number of investigators and participants during each in-person procedure;
  ☐ approximate distance between investigator and participant during each in-person procedure;
  ☐ personal protective equipment (PPE) to be used, whether different individuals will wear different PPE, and how often it will be changed, if necessary;
  ☐ type, timing (e.g., during recruitment, screening, consenting, and debriefing), and frequency of all cleaning measures.

*Participants with certain medical conditions are at greater risk for severe COVID-19. Check the CDC website for a regularly updated list.