Appendix 5:

Guidance for Human Subject Research (draft, under review by faculty groups)

The following guidance was developed by the Harvard Institutional Review Boards (IRB) from the Harvard University Area and the Harvard Longwood Medical Area and to assist the research community with the preparation for research studies that involve in-person interactions with study subjects.

I. Considerations prior to initiating in-person interaction with study subjects

- To reduce interaction time, is it possible for some study visit procedures to be completed via telephone, online, or virtually?
- Is it possible for some study visits to be completed at the subject’s local clinical lab, clinical office, or imaging center? For example, can the procedures occur in the context of a needed clinical care visit and/or through interaction with only the clinical care providers the participant would see even if not participating in the research?
- Modify the timing and scope of specific study visits to account for essential versus non-essential study procedures.
- Consider the study population and whether the research aims/questions could be sufficiently addressed without recruiting those at greatest risk for COVID-19.
- Identify applicable requirements or restrictions that have been or may be put into place at a national, regional, organizational or facility level and how these may impact the research (e.g., travel restrictions, school closings, remote work mandates).
- Be mindful of current federal, state, local, and institutional restrictions and guidelines.
- Familiarize yourself with the prevalence of COVID-19 at the location of the research and the risk of exposure both due to geographical location and the facility types (e.g., hospitals, clinics, schools).

II. Prior to interaction with study subjects

Restrictions
- Restrict study visits to essential individuals.
  - Study visits should be restricted to only those who are essential. This would include legal guardians or legally authorized representatives who must be present with the participant for health care and/or research-related decisions. In addition, only the study team members necessary to carry out the research activities should be present.
  - Consider using video conversations with individuals in different rooms/locations.
- Limit the number of people present in the area at any given time. This may involve creating a schedule for study team members, using multiple rooms for study visits, waiting areas, etc.

Screening
- Study Team: All study team member that will be present in the lab space and/or that may come in contact with study subjects, should be screened (see screening questions below).
- Study Subjects: Study participants should be contacted and screened at least 24 hours prior to of the study visit (see screening questions below).

Preparing Study Subjects for the Visit
- Develop a Script for Participants: Research teams should consider developing a script outlining for research participants:
  - How the institution is making the environment as safe as possible when they come in for their research visit.
To advise patients to check their temperature at home before leaving for their study visit and that they should put on a cloth face covering, regardless of symptoms, before leaving their home.

If there are special procedures for visitors (e.g., parking, building access, or location change).

Preparation for the Study Visit Area
- Clean and disinfect study lab/visit space.
  - Space utilized for study visits should be cleaned and disinfected daily as well as in between each participant study visit and after all visits are completed for the day.
- Have Personal Protective Equipment available for study subjects (which may include university-provided face masks, latex gloves, and hand sanitizer).
- This may include facemasks, latex gloves, and hand sanitizer.

During the Visit
- Screen all study participants upon entry (see screening questions below)
- If study participants are not already wearing a cloth face covering, provide a facemask.
- If possible, study staff and participant should remain at a safe distance. Remain two meters apart or use a glass barrier to separate study staff and participant.
- Use Personal Protective Equipment, especially if the study protocol prevents safe distancing.
  - All present individuals should consider using appropriate face coverings for the duration of the study visit.
  - All present individuals should consider using latex gloves for the duration of the study visit.

After the Study Visit
- Clean and disinfect study lab/visit space.
  - Space utilized for study visits should be cleaned and disinfected daily as well as in between each participant study visit and after all visits are completed for the day.
- Ensure that stock of Personal Protective Equipment is replenished.
  - This may include face masks, latex gloves, and hand sanitizer.

Screening Questions
- In the past 14 days, have you traveled outside of the United States?
- In the past 14 days, have you traveled within the United States?
- In the past 14 days, have you had any of the following symptoms?
  - Fever
  - Cough
  - Shortness of breath
- In the past 14 days, have you lived with, visited, cared for, or been in a room for a prolonged period of time with someone who is under investigation for or has been confirmed for COVID-19?

If the participant answers “yes” to any of the above screening questions, the study staff member should cancel the study visit and request that the individual seek immediate medical assistance.

For more information, contact your Harvard IRB:
- Harvard University Area IRB at https://cuhs.harvard.edu/
- Harvard Longwood Medical Area IRB at https://www.hsph.harvard.edu/ohra/