Tips and Considerations for Resuming In-person Human Subjects Research

Planning Stage Considerations

• To reduce interaction time, is it possible for some or all study visit procedures to be completed via telephone or virtually? For example, is it possible to screen and consent individuals prior to coming into the lab, and/or conduct some data collection virtually?

• Is it possible for some study visits or visit activities to occur outdoors?

• Review and modify the timing and scope of specific study visits to account for essential versus non-essential study procedures.

• Create a list of study procedures that may prevent safe distancing or require modified use of PPE by participants (e.g., if there is a need to use equipment that will preclude a participant from wearing a face covering). Document safety precautions and procedures that can be put in place to mitigate risk of infection of participants or research team members.

• Consider the study population and whether the research aims/questions could be sufficiently addressed without recruiting those at greatest risk of COVID-19 infection. It is recognized that some research studies require working with specific populations. See CDC guidelines for a complete listing.

• Consider what adjustments can be made to procedures and locations when study participants may not be able to wear face coverings. For example, this may apply to studies that involve infants and toddlers. Consideration should be given to not only mitigate risk for study team members interacting with the participant but also for the entire time that the participant will be on campus.

• Minimize the use of paper forms.

• 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, fluctuating capacity).

• Be mindful of current federal, state, local, and institutional restrictions and guidelines on the conduct of research and face-to-face contact with human subjects.

• Before the resumption of any human subjects research, each Principal Investigator should develop standard operating procedures (SOP’s) specific to their own research activities (including operations,
equipment, and procedures). This should also include the location of the research and the risk of exposure both due to geographical location and the facility types. (e.g., on campus, hospitals, clinics, schools, community, homes). The locations of work should be evaluated room by room where participants and staff will be present.

- Please also check if your local Division/Department has any specific templates or guidance.
- Develop a plan for cleaning and disinfecting lab space. See “Cleaning and Disinfecting of the Lab” found at the end of the document.
- Determine what additional supplies may be needed: PPE, cleaning supplies, etc.
- Consider implementing disposable items.
- Consider whether any changes require an amendment to any current IRB approvals/exemptions and submit as necessary.

Prior to Interaction with Study Participants

Restrictions

- Restrict study visits to essential individuals and limit interactions.
  - Only those individuals that are necessary to complete the study procedures should be present: study personnel, study subject, guardians, and those that may be there to assist the study subject, if necessary. If possible, designate a single individual to interact with the participant for the entire study visit, with all others at safe distance.
- Limit the number of people present in an area at any given time.
  - This may involve creating a schedule for study team members, using multiple rooms for study visits, waiting areas, etc.
- Consider whether it is possible to move study procedures to conference rooms or classrooms that have greater airflow and greater feasibility of maintaining social distance.
- Consider using video conversations with individuals in different rooms/locations where possible to limit personal interactions.
- Consider approaches to train personnel and/or participants on study procedures virtually, if possible. If this is not possible, researchers requiring to be trained on specific study procedures should only be present at study visits if the training is absolutely necessary—the study team should be conscious of room occupancy and to maintain a safe environment for all.
- Prepare a schedule for visits to ensure sufficient time between visits.
  - It is recommended to plan for sufficient time between visits of different participants to ensure proper sanitation of any materials or equipment as well as sufficient turnover of air where the
study visit is being performed. Groups sharing spaces for human subjects research should have a schedule to enable this to be coordinated across groups and studies. PIs should contact Divisional leadership for any questions related to timing, space, and HVAC systems.

**Screening for COVID-19**
- All study team members that will be present in the lab space and/or that may come in contact with study participants are required to self-screen prior to coming to the lab each day.
- Study participants should be contacted and screened both on the day before the visit if possible (to avoid unnecessary travel/contact if they screen out) and immediately upon arrival.
- If the participant is unable to be reached the day before, the visit screening should be attempted the morning of the study visit in addition to the required screening immediately upon arrival.

**Training for Research Staff**
- All essential personnel should review proper PPE use prior to interaction with participants.
- Be sure any trainings and attestations are current and completed.

**Preparing Study Participants for the Visit**
Research teams should consider communicating the following information to participants before their study visit:
- Depending on the level of information to be shared, consider developing a simple informational sheet that can be provided to all participants describing how the study team is making the environment as safe as possible when they come in for their research visit and so they know what to expect. Be sure to communicate if there are special procedures (e.g., parking, building access, or location changes), limits on who participants can bring with them, etc.
- As part of communication to participants, research teams may want to consider sharing the latest CDC guidelines on risk factor associated with COVID-19.
- Instruct participants to bring water and a snack, if applicable.
- Advise participants that they must wear a face mask, regardless of symptoms.

**Preparing the Study Visit Area**
- Clean and disinfect study lab/visit spaces. This may include tables, chairs, equipment such as machines, VR headsets, wearable systems, and other non-disposable equipment or items used during the study visit. See “Cleaning and Disinfecting of the Lab” found at the end of the document as well as [CDC guidance on Cleaning and Disinfecting](https://www.cdc.gov).
• Space utilized for study visits should be cleaned and disinfected daily, in between each participant study visit, and after all visits are completed for the day.
• Designate experiment areas and areas for guardians/other visitors and their belongings.
• Prepare the lab space before the participant arrives (e.g., propping open doors, calibrating all equipment, etc.).
• Consider covering keyboards, mice, tablets, and other devices in plastic (e.g., saran wrap) that can be discarded.
• Have PPE available for study participants (which includes face coverings and hand sanitizer).
• If study procedures prevent being two meters/6 feet apart, consider setting up a plexiglass barrier to separate study staff and participant when possible.

During the Study Visit

• Study staff should be ready for study participant by wearing PPE and having all materials, equipment, and all other items ready for the visit. Study staff should wash or sanitize their hands just before study visit begins, and throughout study visit (i.e., both before and after contacting a study participant or piece of equipment or surfaces in vicinity of participant).
• Screen all study participants and family members, caretakers, legal representatives, etc. before entering the lab/building.
• Provide all study participants and anyone else present (e.g., family members, caretakers, legal representatives) with PPE to wear during the visit in accordance with University guidelines, even if they have their own.
• If and when possible, study staff should maintain distance from participant. Remain six feet apart and use a plexiglass barrier to separate study staff and participant when possible.
• Consider monitoring/communication activities using (non-recording) cameras, tablet, etc., if possible, to create additional physical separation.
• Consenting should be conducted virtually when possible. If the consent process will happen in person, consider a contactless method by which to obtain consent (i.e., not having to use pen and paper), for example, sending the form electronically and having the individual document using their phone or tablet.
• If study protocol prevents safe distancing, seek local institutional guidance to see if additional PPE measures should be taken (e.g., a gown, a face covering, and/or a face shield or goggles). Ensure that PPE is being used by all for the duration of the study visit. Also consider if it is possible to have study team member and participate face in opposite directions.
After the Study Visit

- Clean and disinfect study lab/visit space and space utilized for study visits (consider all spaces, waiting rooms, and areas used by study participants and those accompanying them). These spaces should be cleaned and disinfected daily, in between each participant study visit, and after all visits are completed for the day. This may include tables, chairs, equipment such as machines, VR headsets, wearable systems, and other non-disposable equipment or items used during the study visit. See the “Cleaning and Disinfecting of the Lab” section found at the end of the document as well as CDC Guidance on Cleaning and Disinfecting.
- Ensure that stock of PPE is replenished. This may include face coverings, hand sanitizer, etc.
- Study teams are advised to ask the participant to contact their study coordinator if within 14 days if they or anyone in their living group has any of the above COVID-19 symptoms or a positive COVID-19 test.
- If it is found out that a study team member has contracted COVID-19 following a study visit, follow University guidelines regarding positive test results as well as University guidelines on quarantine and isolation available on the UChicago Forward website.
- Workplace surfaces should be cleaned and disinfected. See the “Cleaning and Disinfecting of the Lab” section found at the end of the document as well as CDC Guidance on Cleaning and Disinfecting.

Cleaning and Disinfecting the Lab Space Where Study Visits Occur

Perform routine environmental cleaning and disinfection of lab areas:

- Routinely clean and disinfect all frequently touched surfaces, such as workstations, keyboards, telephones, handrails, and doorknobs.
- If surfaces are dirty, they should be cleaned using a detergent or soap and water prior to disinfection. For disinfection, most common EPA-registered household disinfectants should be effective. A list of products that are EPA-approved for use against the virus that causes COVID19 is available on the EPA website. Follow the manufacturer’s instructions for all cleaning and disinfection products (e.g., concentration, application method and contact time, etc.).
- Discourage study team members from using shared phones, desks, offices, or other tools and equipment, when possible.
- Provide disposable wipes so that commonly used surfaces (for example, doorknobs, keyboards, remote controls, desks, other work tools and equipment) can be wiped down before each use.
• Examples of equipment that would need to have cleaning protocols developed for would be MRI machines, VR headsets, wearable robots, robot arms, treadmills, wearable sensors, tablets, and other computer input devices.

• If persons suspected/confirmed to have COVID-19 have been in the facility, check with local institutional leadership for appropriate measures. These may be require enhanced cleaning and disinfecting processes or leaving a space vacant for a period of time.