

Campus Human Subjects Research Guidelines

*Campus IRB research
Guidance version August 21, 2020*

Overview: The following guidelines describe the practical application of research strategies to minimize COVID-19 exposure for our research participants, faculty, and staff as we return to in-person research activities. Remote activities should be considered as long as is practical. Duke faculty and staff should refer to the "[Duke Guide for Returning to the Workplace](#)" document for additional guidance.

Retaining Virtual Activities

Throughout the pandemic, we have learned to efficiently operate virtually in a number of ways. We encourage the use of virtual and remote activities when and where possible. Specific guidance will be found in multiple sections below.

Assessing and Routing Participants Who Report Symptoms

- Establish multiple screening points** to assess participants for COVID symptoms and exposure. Use the [symptom and exposure screener](#):
 - *At scheduling* (on phone or online);
 - *On pre-visit calls* (described below);
 - *Upon arrival* (of the participant at a location where the visit is happening, or when study staff arrive at a participant's home, in which case this final screen is best done by phone before entering the home)
- If participant screens positive at scheduling or during a pre-visit call, the participant should be instructed to call their PCP office or local health department. If they screen positive upon arrival, they should be given a face mask, isolated, and instructed to call their PCP office or local health department. In either case, the research visit should be deferred. Provide the participants with a listing of local testing sites and health departments (e.g., [Durham County Public Health](#)). If this is a home visit and the participant screens positive on arrival the research staff should not enter the home and should provide instructions for seeking care/testing by phone.

General Social Distancing

- Complete as many parts of a research visit via **video visit or telephone encounter** as possible.
- In person research visits should be time limited.**
- Encourage participants to attend research visits alone** whenever possible

- ❑ **Spread out research visit start times** to avoid large volumes of participants waiting in the same spaces at the same time.
- ❑ During screening calls study team also should [screen for symptoms](#) of household members; a home visit should not occur if any household member has had symptoms that are consistent with COVID-19 or has tested positive.
- ❑ If conducting a **home visit**, identify the immune status/risk of household members; those who have a weakened immune system, over the age of 60 years, have chronic health conditions (e.g. heart disease, lung disease, diabetes), or other COVID-19 risk factors. If there are high-risk household members, reconsider the face to face visit and consider an alternative method to complete the visit.

PPE, Labs, Study Supply Delivery and Sample Collection

- ❑ Study Investigators and research teams should create processes in compliance with Duke University COVID-19 safety standards. This may include designating a single person on your team who will work with a lab, core or service, e.g., delivering collection supplies and/or bringing in participants.
- ❑ Follow appropriate PPE guidelines
 - **Wear a face mask at all times while at work.**
 - Research participants may wear their own cloth mask and should be instructed to wear one when they arrive on campus. Research teams should have additional masks on hand to provide to participants and family members/visitors who do not have their own masks. If you need PPE for your research participants, please contact **Marnie Rhoads** (marnie.rhoads@duke.edu).
- ❑ If your research involves delivering study supplies, reduce contact with participants by placing the package at the participant's doorstep and stepping back. Study teams should document departure time, delivery and pick up addresses.
- ❑ COVID testing is not required for staff or participants

Consent and In-Person Study Visits

As we return to in-person human research activities, we should initially function assuming every research participant could be COVID positive. All staff should follow best practices for infection prevention for each participant. There are several key approaches that will be critical to reduce risk in non-Duke premises research locations:

- ❑ Whenever possible, conduct remote consent and study visits
- ❑ When it is not possible to conduct entire study visits remotely, remotely conduct as many aspects of the visit or data collection as possible
- ❑ Consider using outdoor spaces (e.g., front porch, back deck or yard) for in-person activities.

- Educate participants to notify the research team if symptoms develop or a known exposure occurs prior to the research visit
- Ensure adequate PPE and disinfecting supplies for the situation, including for the employee and the participant/household/location
- Practice frequent handwashing and carry hand sanitizer at all times.
- If the study involves visiting a participant's home:
 - Limit what part of the home you are in. For example, stay in the room closest to the door instead of moving to other rooms if possible.
 - Request additional household members to wait in other areas of the home when possible to minimize potential exposure for them and for staff.
 - Limit the time spent in a home due to risk of heavily contaminated environment
 - When agreeing to come in for a research visit or having a visit in their home, participants must acknowledge an understanding of these risks and planned compliance with Duke's safety measures.
 - Additional cleaning precautions are needed for home visits:
 - When checking a valid picture ID, the participant should hold their ID while staff views it.
 - Face masks should be worn by the study team and all members of the household during the visit (unless instructed to remove the mask for research activities). Whenever possible other household members should not be in the same room as the study staff and participant. Study team should bring additional face masks to the visits to supply participant or household members if needed.
 - The environment inside a home could be heavily contaminated if someone living in the home is infected, including all surfaces and floors; thus shoes and clothing can be contaminated.
 - Maintain a distance of at least 6 feet between the study staff and participant and family members during a visit.
 - Sanitize hands frequently during the visit if you perform tasks where you are touching things that other people have touched, and sanitize hands as soon as you leave. Use hand sanitizer that you bring into the home.
 - Minimize contact with frequently-touched surfaces at the home.
 - Avoid touching things in the home and do not touch your eyes, nose, mouth, or face during your home visiting time. Wearing a face shield will decrease this risk. Face shields should be decontaminated upon exit from the home.
 - Always cover your coughs and sneezes, and ask others to do the same. Take tissues with you. If you use a tissue, throw it away right after use and then wash or sanitize your hands.

- Disinfect all equipment before and after use.

Guidance to share with research participants

- Prior to their visit, participants should be made aware of both the risk of COVID exposure they may encounter during their in-person study visits, and the safety precautions taken to keep them safe. This should can done by including elements of the [Research Participation During COVID-19 Guide](#) to participants before their visit.
- Study coordinators and investigators should be prepared to discuss safety precautions and participation options, including continuation as planned, visit deferral, and withdrawing from the study.
- Participants should be given ample time (days or weeks) to consider the risks and precautions prior to their scheduled visit.
- Participants who are able to but unwilling to comply with safety standards including screening and PPE, should have their study visit deferred until either they are willing to comply, or such safety standards are no longer necessary or required by Duke.