

## Ramping up Human Subjects Research

### On Campus Research

- No group-based activities, including data collection (e.g., focus groups) and/or intervention, for groups of 10 or more. For groups of less than 10, physical distancing must be maintained at all times; spaces must be large enough to accommodate physical distancing, and all participants must wear a protective face covering consistently and correctly for the duration of the visit.
- Participants need to answer the four questions used by UHealth to assess COVID-related symptomology and exposure. Questions should be asked at time appointment is confirmed, ideally 24 hours before the appointment time, and then again day of, before accessing UM facilities.
  - Are you currently in isolation or quarantine due to COVID-19 symptoms or exposure?
  - Do you plan to be on campus today?
  - How do you feel physically today?
  - Have you had close contact with anyone in the last 48-72 hours who has COVID-19 symptoms or is under investigation for COVID-19 (someone with a positive test result but without symptoms)? The CDC defines a close contact as someone with whom you have spent more than 15 minutes of time in less than 6 feet of space.
- Attention should be given to scheduling visits when building density is lower, such as after most common class hours.
- Appointments should be scheduled with sufficient time in between participants to avoid congregating or clustering of participants. If a waiting room must be employed, care must be taken to ensure that seats are marked to promote physical distancing.
- When possible, participants should enter the UM building using a separate entrance from faculty/staff/students. If not possible, building “rules” about COVID-capacity in elevators, stairwells, halls, and rooms must be followed.
- Like clinical facilities, participants cannot be accompanied by someone, unless the participant is a minor and/or requires accompaniment given extenuating health conditions. Exceptions such as these must be approved in advance by Principal Investigator, and in these cases only one person will be allowed to accompany the individual.

- Participants are expected to proceed directly to the meeting/research location and limit all activity to the assigned/approved areas.
- Effort should be made to minimize the number of in-person visits required, as well as visit length. When possible, informed consent and data collection should be performed over ZOOM or another comparable, IRB-approved platform to limit the amount of time allocated to face-to-face encounters.
- For procedural activities (i.e. phlebotomy, etc.), the amount of close interaction with participants should be minimized and limited to the time it takes for the procedure to be completed.
- Measures of pulmonary function and breath sampling require special approval.
- All participants must wear a protective face covering consistently and correctly for the duration of the visit. Surgical masks should be available for participants who arrive without a mask and/or wearing a mask that is not permitted in UM buildings (e.g., exhaust valve mask).
- Faculty/staff/graduate students must wear masks consistently and correctly and potentially other PPE as appropriate given the nature of interaction.
- Existing protocols for reducing exposure during biospecimen collection/storage must be followed.
- If equipment of any kind is used, including furniture, it must be cleaned between participants using standardized protocols and EPA-approved disinfectants.
  - Hygienic cleaning/sanitation actions must be regularly performed on hard surfaces commonly touched by staff (countertops, commonly used computer keyboards) and equipment.
  - Surfaces utilized by staff will be cleaned with soap and water (where compatible) and wiped regularly with an appropriate EPA-approved sanitizing wipe at least once every 4 hours for commonly used surfaces during business hours.
  - Patient contact surfaces (e.g. exam tables, etc.) will be wiped with an appropriate EPA-approved sanitizing wipes after each patient.
- Participants should be asked to let the Investigator/lead faculty know if they become COVID positive and/or develop COVID-like symptoms in the 48-72 hours after the appointment.
- Similarly, the research team should have a protocol for advising any participants if/when close contact occurred during a research encounter. Per the CDC, a close contact is someone who has spent more than 15 minutes in less than 6 feet of space with a positive individual. If a research team member tests positive for COVID, any

close contact who is part of the research team and/or participants must be notified promptly and provided with instructions about quarantine (14 days post-exposure), as well as, resources for testing.

### **Community-based Research**

- No group-based activities, including data collection (e.g., focus groups) and/or intervention, for groups of 10 or more. For groups of less than 10, physical distancing must be maintained at all times; spaces must be large enough to accommodate physical distancing, and all participants must wear a protective face covering consistently and correctly for the duration of the visit.
- Participants need to answer the four questions, used by UHealth, to assess COVID-related symptomology and exposure. Questions should be asked at time appointment is confirmed, ideally 24 hours before the appointment time, and then again day of, before accessing UM facilities.
  - Are you currently in isolation or quarantine due to COVID-19 symptoms or exposure?
  - Do you plan to be on campus today?
  - How do you feel physically today?
  - Have you had close contact with anyone in the last 48-72 hours who has COVID-19 symptoms or is under investigation for COVID-19 (someone with a positive test result but without symptoms)? The CDC defines a close contact as someone with whom you have spent more than 15 minutes of time in less than 6 feet of space.
- If home-based visit, questions must be extended to include family members who may or may not be present during the visit but live in the house. Given that the home environment is less predictable, research team members may need to take additional precautions, including wearing more robust PPE, to prevent unnecessary exposures.
- Physical distancing must be maintained at all times; if this cannot be accomplished, the visit may have to be outside or scheduled at a neutral community site.
- All participants need to be wearing a protective face covering consistently and correctly for the duration of the visit. Surgical masks should be available for participants who do not have a mask and/or are wearing a mask that is not allowed in UM buildings (e.g., exhaust valve mask).
- Faculty/staff/graduate students need to wear masks consistently and correctly and potentially other PPE as is appropriate given the nature of interaction.
- Existing protocols for reducing exposure during biospecimen collection/storage must be followed.

- Effort should be made to minimize the number of in-person visits required, as well as visit length. When possible, informed consent and data collection should be performed over ZOOM or another comparable, IRB-approved platform to limit the amount of time allocated to face-to-face encounters.
- Participants should be asked to let the Investigator/lead faculty know if something in their personal COVID-status changes (e.g., tests positive) within 48-72 hours after the appointment;
  - If the research participant tests positive, anyone on the research team who was in close contact with this individual will need to quarantine for 14 days. Per the CDC, a close contact is someone who has spent more than 15 minutes in less than 6 feet of space with a positive individual. At five days post-exposure, close contacts from the research team can reach out to 305-243-ONE-U to schedule testing. If negative, the research team member will complete the duration of quarantine. If positive, the research team member will start isolation, which is 10 plus one days from the receipt of the positive test result. If the number of close contacts on the research team affects capacity, the work may need to be delayed temporarily.
  - Additionally, Facilities and Operations should be contacted to implement environmental decontamination procedures.
- Similarly, the research team should have a protocol for advising any participants if/when close contact occurred during a research encounter. Positive employees must participate in contact tracing provided through the University. This would identify whether any other research team members were close contacts. Any research participants who fit the definition of close contact would also need to be notified, informed about the recommendation to quarantine for 14 days, and provided information about local testing resources. If the number of close contacts on the research team affects capacity, the work may need to be delayed temporarily. Facilities and Operations should be notified immediately to implement environmental decontamination procedures.

### **Field research, ethnography, participant observation**

- All COVID-related practices and procedures in the research site/setting must be followed, in accordance with the approved SOP, emphasizing low population density, physical distancing, personal safety, and environmental hygiene.
- No group-based activities, including data collection (e.g., focus groups) and/or intervention, for groups of 10 or more. For groups of less than 10, physical

distancing must be maintained at all times; spaces must be large enough to accommodate the 1 person/200 square foot requirement, and all participants must wear a protective face covering consistently and correctly for the duration of the visit.

- In indoor and/or outdoor scenarios, team members must maintain physical distancing and wear masks or other PPE as appropriate consistently and correctly.
- If local travel is involved, team members should take separate cars, when possible, and ensure adequate physical distancing during lunch or other breaks. If group travel is involved, Environmental Health & Safety may need to approve associated proposals on an individual basis.
- In exceptional circumstances, where large groups will be traveling together and staying overnight in shared living quarters, quarantine for a week before and testing a day or two prior to leaving is encouraged to avoid unnecessary risk of transmission. Re-testing upon return is also strongly encouraged.