

Guide to Human Subject Research (HSR) Face-to-Face (F2F) Interaction

Before Meeting with HSR Participants

- A plan including the following must be submitted and approved before contacting human subjects' research (HSR) participants. The plan must include;
 - A justification for work that cannot be done remotely
 - A description of how social/physical distancing (6 feet or greater) will be established during HSR activities/assessments/interventions
 - If six feet of physical distance cannot be maintained, a description of activities that require close contact, direct physical contact (touching) and how exposure will be minimized. If touching of participants is necessary minimize contact to very brief interactions (<30 seconds) if possible
 - If applicable, a description of HSR activity in a community setting and risk mitigation plan that includes how exposure will be minimized for HSR participants and research staff (see Important Considerations "mode of transportation" below). F2F interactions in a participants personal home must be well justified.
 - Consideration of the risk/benefit ratio for HSR participants. Consider if there is additional risk by coming to campus and interacting with research staff or in the community for field research.
 - A description of the use of Personal Protective Equipment (PPE) by research staff and HSR participants
 - A description of decontamination of equipment and surfaces that will come into contact with participant
 - An enrollment strategy; will only participants currently enrolled in the study be contacted? Justify why the recruitment of new participants is necessary. Indicate an approximate number of all participants (current or new) that will be asked to come to campus or meet off campus within a specific timeframe (e.g. 2-week increments). **NOTE: Minors are allowed** to come to campus or be contacted in a community setting for studies only where the IRB has determined there is a direct benefit or the potential of a direct benefit to the minor study participants. See "Important Considerations" below for more guidance.
 - Exercise restraint in the number of participants contacted. Only schedule appointments for the minimum number of people necessary for the study to remain sustainable
 - Signed Research Leader and Staff Responsibilities/Commitment Forms
- Obtain IRB approval for protocol changes
 - Note that the use of PPE to mitigate risk **does not** require IRB approval.
 - Changes to risk level assessment, intervention, and collection of data or samples during HSR activity that are not in current approved protocol **may require** IRB approval. Contact the IRB office to discuss
- Create a COVID-19 Pre-screening guide for research staff (self-assessment) and HSR participants. The guide **does not** require IRB approval as it is not part of the study procedures.
 - Minimum questions that must be asked of staff and HSR participants
 - ✓ Have you had any cold or flu-like symptoms in the last 21 days?
 - ✓ Have you had a fever (100°F (38°C) or above), cough, sore throat, or shortness of breath or other respiratory symptoms in the last 21 days?
 - ✓ Have you had any muscle pain, chills or severe headache in the last 21 days?
 - ✓ Have you had a loss of taste or smell in the last 21 days?
 - ✓ Have you had any close contact with anyone with a lab-confirmed positive test result for COVID-19?
- If activity is conducted at SDSU, create a calendar to schedule activities and use shared equipment. Shared workspace/equipment calendars must be accessible by **all** potential users so that there is no overlap when using space and equipment.

Day of HSR F2F Activity

- Contact the participant 1-3 hours before arrival for their appointment and ask the COVID-19 pre-screening questions. If there is an indication of COVID-19 symptoms, cancel the appointment and reschedule when symptoms clear. The **minimum** recall time is at least 14 days after the clearance of symptoms.
- Research Staff must perform a COVID-19 self-assessment and must not come to campus or meet in a community setting if symptoms are indicated. Staff can only resume work after a self-quarantine time of a minimum 14 days after the clearance of symptoms.
- If activity is at SDSU, research staff must decontaminate surfaces/equipment that may have participant contact, wipe down before first participant arrives and between each appointment. It may be difficult to do this in a community setting, sanitizing wipes or hand sanitizer should be available for research staff and participants.
- If meeting at SDSU, there must be no overlapping HSR appointments to allow time for decontamination between participants
- At SDSU, research staff must wear gloves and face covering/mask when interacting with participants. Face covering/mask (gloves optional) is required if meeting in a community setting.
- Provide participants with a face covering/mask if they do not have any. Provide the option of wearing gloves during the interaction.
- Wash hands frequently
- All names (or codes) of participants, even anonymous participants (i.e. anonymous for the research study not for COVID contact tracing, for research anonymous participants only the minimum information is to be collected so they can be alerted, if necessary, to COVID related issues, name/phone # or name/email) and research staff must be retained in case of contact tracing. The key to the code allowing the PI to de-identify the data must not be broken. The information collected from research anonymous persons must be destroyed after the contact tracing period has ended (e.g. 4 weeks after appointment)

Important Considerations

- Remember HSR participants are volunteers. If they choose not to come to campus or meet in a community setting, respect the decision and do not pressure them. Ask when/if they would like to be contacted again
- Do not offer more incentive to come to campus or community setting for HSR activity. This would be considered non-compliance with the approved IRB protocol.
- Determine the mode of transportation for HSR participants, research staff and investigators, especially travelling to sites outside of the SDSU campus. If public transportation will be used to get to an appointment and there is a potential for an increased risk of exposure (e.g. cross border studies) these F2F activities should stay paused
- Continue to conduct data analysis and research staff meetings remotely
- Research not conducted at SDSU must follow the organization/location specific protocols where participants will report. If not available SDSU requirements described in the plan will apply.
- Consider not asking participants who may be at higher risk of COVID-19 infection to come to campus or meet in a community setting. If persons with risk factors are necessary for F2F interaction, justification is required about why this must happen in phase 2. Risk factors considered to put an individual at higher risk are (not an exhaustive list): <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html>
 - Adults aged 65 and over
 - Asthma
 - Chronic lung disease
 - Diabetes
 - Serious heart condition
 - Immunocompromised
 - Kidney disease requiring dialysis
 - Liver disease