



Texas A&M University Human Subjects Research Guidance for Conducting In-Person Study Visits During COVID-19

Introduction

The plan below covers the university's guidance as it relates to in-person human subjects research. This plan has the predominant goal of keeping everyone as safe as possible while allowing in-person study visits. The plan requires processes for COVID-19 screening and exposure assessments as well as cleaning and disinfecting procedures.

If you have an infection control plan in place that was previously approved by the Vice President for Research's (VPR) Clinical Research, Education, and Service Advisory Committee, you may continue to follow the plan except for requiring face coverings. If you do not have a previously approved infection control plan or if the approved plan is longer viable you are asked to follow the guidance below.

The guidance below and other public health activities implemented to minimize the risk of contracting or spreading COVID-19 are not research procedures that require IRB review and approval. However, the IRB may ask for a copy of your plan to be included with your study application.

Any changes to the currently approved research protocol including any changes to the consent and recruitment process will require IRB review and approval prior to implementation. If you are not sure if changes to your research require IRB approval, contact the IRB at 979.458.4067 or IRB@tamu.edu. You may also contact your department's assigned IRB coordinator found at [My IRB Contact — Research Compliance and Biosafety \(tamu.edu\)](#).

The Principal Investigator remains responsible for implementing and monitoring changes to COVID-19 control strategies and assuring that the research team has appropriate staffing, resources, and training to support in-person interactions with research participants. Whenever possible, conducting research procedures remotely is highly recommended.

Procedures Prior to Participant Arrival:

Notify all participants that they must complete the CDC Coronavirus Self-Checker for COVID-19 symptoms or known COVID-19 exposure within 24 hours of coming to campus ([Symptoms of COVID-19 | CDC](#)). If any questions are answered with "yes," and the symptom is not related to a pre-existing medical condition, they may not come to campus.

Provide details about how the study visit will be conducted, include additional information related to any protective measures that may be utilized to prevent the spread of COVID-19. Inform the participants that face coverings are recommended but are not required, and that research personnel also have a choice about wearing a mask.

When the participant is a minor, ideally only one accompanying adult will be present. Both the child and the caregiver must pass the COVID-19 screenings. If the participant is not a minor, an accompanying person is not recommended unless the participant requires a caregiver for transportation or care.

Procedures on Day of Study Visit:

Verify that the participant was negative for the [COVID-19 Screening](#) and [Exposure Assessment](#) questions. If the participant exhibits any of the listed symptoms and those are not related to a pre-existing medical condition, the participant should be asked to leave campus and reschedule the study visit.



Time of entry, duration of visit, confirmation of screening, and contact information for potential contact tracing should be entered into the [contact tracing log](#).

All research personnel must pass the same screening when study participants are scheduled for the day. The number of research personnel in the lab/testing area should be limited to as few as necessary to conduct the required study procedures.

Schedule appointments so that they do not overlap with those of other participants and whenever possible keep participants 6 feet or more apart in waiting areas. Allow sufficient time between participants in the research lab or testing area to clean applicable surfaces with an EPA-approved cleaner, for the required contact time.

Research staff, participant, and any accompanying adult must wash their hands with soap and water or use hand sanitizer before and after each appointment, including when first entering the research area. Hand washing or hand sanitizer use should be available throughout the visit.

The participant must be given the participant acknowledgement letter to sign, in addition to the consent form for the study. Ensure the participant retains a copy. Keep a signed copy of the acknowledgement in the participant's research file. If the participant is not comfortable with the COVID precautions listed, they may reschedule or choose to withdraw from the study.

Maintain social distancing between individuals whenever possible throughout the visit.

If the participant chooses to wear a mask and the research calls for the participant to *not* wear a mask for a particular procedure, this will be discussed with the participant. If the participant is not comfortable removing the mask, they may reschedule or choose to withdraw from the study.

When the study involves the collection of biological samples (i.e., blood, saliva), study personnel should follow standard biosafety procedures. Gloves may also be worn by study personnel for any direct contact with human participants. If gloves are used, [CDC guidelines for removing gloves](#) should be followed.

All equipment and surfaces must be thoroughly cleaned after each participant with a disinfectant that meets CDC and [EPA guidelines](#) with disinfectant-specific contact times as follows:

Applicable surfaces include, at a minimum: keyboards, chairs, instrumentation, touchpoints, and any items that come in contact with the participant or investigator/study personnel.

If disinfectant is used, research data collection sessions should be scheduled to allow sufficient time for proper cleaning and disinfection of the area and equipment between participants.

To make sure disinfectant is effective, follow all disinfectant-specific instructions, including ensuring the item/surface is left wet with disinfectant for the required contact time.

These cleaning standards are recommended for any space or research lab in which human participants are seen.

Single-use or disposable supplies are encouraged when possible. In the event that sensitive equipment cannot be cleaned, appropriate protective equipment may be applied to the equipment (such as a



disposable/cleanable cover) or to the participant (gloves or finger cots). Participants are to remove gloves following the CDC guidelines for removing gloves.

The guidelines above serve as a minimum recommended standard. Given unique requirements for each different research protocol or the inclusion of populations more vulnerable to COVID-19, each PI may evaluate how to effectively perform safe and responsible research beyond the requirements listed above, bearing in mind that neither participants nor research team members may be required to wear face coverings or provide vaccination status.

Fully explain any deviations from the guidelines above that are essential to carry out the study procedures and/or list any additional measures needed to minimize the risk of contracting or spreading COVID-19:

Principal Investigator Acknowledgement

I have read the information provided above and acknowledge that I have been informed of and understand the precautions that Texas A&M University is requiring to safeguard potential research subjects from contracting COVID-19.

Principal Investigator Printed Name

Principal Investigator Signature

Date

Departmental Supervisor's Printed Name

Departmental Supervisor's Signature

Date