

General Guidelines for Conducting Human Subjects Research

Patients who have tested positive for SARS-CoV-2, regardless of whether they are symptomatic or asymptomatic, should be excluded from face to face research. If the study specifically requires face to face contact with positive SARS-CoV-2 research participants, justification for inclusion of this population will be provided to the IEB, along with a detailed protocol of how universal precautions will be used to reduce the risk of infection to the research team.

Research team members who are considered "high risk for severe illness" if they contracted COVID-19 should be excluded from participation in face to face research.

- High risk, as defined by the Centers for Disease Control and Prevention, are:
- People greater than 65 years of age
- People with chronic lung disease (including mild to moderate asthma)
- People with serious heart conditions
- People who are immunocompromised
- People with BMI of ≥ 40
- People with diabetes
- People with chronic kidney disease undergoing dialysis
- People with liver disease

<https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-higher-risk-old.html>

SARS-CoV-2 is spread through respiratory droplets produced when an infected person coughs, sneezes or talks, and you are at greatest risk of infection when not wearing personal protective equipment and are standing within 6 feet of the infected person.

When possible, direct face to face contact should be avoided with all research participants. However, when approved for face-to-face contact by the IRB, the following precautions should be taken.

Social Distancing Guidelines

- Only personnel essential to the study should be in face to face contact with research participants to minimize the risk of infection
- Use disposable supplies and equipment, when available
- Always clean the area before and after your meeting with 60% ethyl- or 70% isopropyl-alcohol
- Avoid sharing or reusing equipment
- Reduce the duration of the meeting
- Provide all paperwork in advance
- Consider excluding all patients from studies with a positive SARS-CoV-2 diagnosis
- Consider all patients, if not known, potential SARS-CoV-2 positive
- Maintain proper social distancing in all shared spaces, a minimum of 6 feet
- Perform vigorous hand washing with soap for 20 seconds before and after wearing and removing your face covering, and before and after contact with research participants
- Always avoid touching your eyes, hands and mouth while in the presence of research participants, and before washing your hands and leaving the room

IRB's Recommendations for Face to Face Research

- If soap and water are unavailable, use alcohol based sanitizer with at least 60% ethyl- or 70% isopropyl-alcohol
- Do not rinse or wipe off hand sanitizer before it dries
- Wear personal protective equipment when in contact with research participants at all times

What to do if you contract SARS-CoV-2

- Stay at home and contact your medical provider.
- Report to your immediate supervisor and the Chair of the IRB
- Avoid all public transportation, ride sharing, or taxis
- Isolate as much as possible
- Monitor your symptoms
- Follow CDC recommended guidelines for personal hygiene, and management

The resources used for these recommendations can be found on the Center for Disease Control Website, the COVID-19 Back to Campus Citi Training, and SHSU's return to campus information at <https://www.shsu.edu/katsafe/coronavirus>