

Conducting In-person Human Research during the COVID19 Pandemic UC HRPP/IRB Requirements - May 20, 2021

In-person human subjects research activities during the COVID-19 pandemic must meet the criteria described below and be approved by the UC IRB.

For approval to restart in-person activities on approved human research studies, (that have not already been approved) send your request in an email to the UC IRB Chair, Dr. Michael Linke linkemj@uc.edu

Previously approved COVID 19 response plans may be modified per the current requirements without additional IRB approval.

For new studies, please include your plan to address these criteria with your IRB submission.

1. Screen participants for COVID 19 symptoms, exposure, and vaccination status.

If the study participant and all study staff are fully vaccinated, in-person study activities may proceed with no special COVID 19 restrictions.

If the participant is not fully vaccinated, they should be asked about COVID 19 symptoms and exposure upon arrival to the research site.

Screening for symptoms - Ask if they have any [Symptoms of Coronavirus infection](#)

If they have symptoms, the study visit should be delayed and refer them to the [CDC COVID-19 self-assessment tool](#) that can help decide what kind of medical care they might need for COVID-19 For medical research studies, appropriate follow up care should be provided, as needed

Screening for Exposure - Ask if they have been in close contact with someone who has COVID-19.

What counts as close contact?

- You were within 6 feet of someone who has COVID-19 for a total of 15 minutes or more
- You provided care at home to someone who is sick with COVID-19
- You had direct physical contact with the person (hugged or kissed them)
- You shared eating or drinking utensils
- They sneezed, coughed, or somehow got respiratory droplets on you

If they have been in close contact, their visit should be delayed, and they should be referred to [CDC COVID-19 self-assessment tool](#)

2. How will your team ensure the in-person research activities are conducted in a safe manner that protects unvaccinated participants and researchers?

Describe your plans to minimize unvaccinated participant and study staff COVID 19 exposure, transmission, and infection. Study investigators should use their best judgment to limit contact that is not necessary to ensure the safety of the study participant and ensure the integrity of the research. In-person interactions should be switched to remote activities whenever possible. For medical research studies, the same precautions that are taken with patients being seen for the clinical care should be used for research visits.