Conducting In-person Human Research during the COVID-19 Pandemic
UC HRPP/IRB Requirements - October 2, 2020

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

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

In addition to meting these requirements, UC COVID 19 guidance must be followed when conducting human research. You may still also need approval from your college and from any off-campus research sites.

1. Risk and benefits of study participation

The risk of COVID 19 exposure and infection must be considered in the risk: benefit determination for a study. Please consider the benefits of having in-person research activities to ensure that these outweigh the risks of COVID-19 exposure for research participants and study team members.

Please provide a compelling justification as to why it would be acceptable to conduct the research activities during the COVID-19 pandemic.

2. Screen participants for COVID 19 symptoms and exposure

Contact participants by telephone on the day prior to the scheduled visit to screen for COVID 19 symptoms and exposure.

- Screening for symptoms - Ask if they have any Symptoms of Coronavirus infection
    - Fever or chills
    - Cough
    - Shortness of breath or difficulty breathing
    - Fatigue
    - Muscle or body aches
    - Headache
    - New loss of taste or smell
    - Sore throat
    - Congestion or runny nose
    - Nausea or vomiting
    - Diarrhea

If they have symptoms,

- Their study visit should be cancelled or delayed
- Referred to a Self-checker tool that can help decide what kind of medical care they might need for COVID-19
- Non UC employees or students should be referred to the CDC COVID-19 self-assessment tool
- UC students or employees should be referred to the UC COVID Check app or the web-based REDCap survey
- 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 the Self-Checker tools described above

Upon arrival to the research site, study participants should be asked again about COVID 19 symptoms and exposure. If they have symptoms or an exposure, the study visit should be delayed. The participants should be referred to the UC and CDC websites described above for more information. For medical research studies, appropriate follow up care should be provided, as needed

3. Participants should be provided with information COVID-19 before the research visit.

They should be directed to the UC Novel Coronavirus (COVID-19) and the CDC COVID-19 websites for information on COVID-19 pandemic. This information may also be provided in other forms suited to the participants, such as in-person handout.

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

Describe your plans to minimize 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. Limits the possibility that research staff will be too close to each other and unable to meet the social distancing needed to halt the spread of the COVID-19 virus. For medical research studies, the same precautions that are taken with patients being seen for the clinical care should be used for research visits.

5. The research should not require effort and/or resources that may needed to support clinical care related to COVID-19

Verify that the research:

• Will not utilize resources that are needed to take care of COVID 19 infected patients.
• Would not interfere with clinical procedures put in place to treat COVID 19 patients
• Would not use limited resources such as PPE required for clinical care
• Does not take clinical staff away from clinical responsibilities needed to respond to COVID 19.

Websites
UC Novel Coronavirus (COVID-19) website
CDC Novel Coronavirus (COVID-19)
Google COVID-19 Self-Assessment
UC COVID Check App
UC web-based REDCap survey