

Request for Continuation of In-Person Research Activities and/or New Enrollment

The risk of COVID 19 exposure and infection must be considered in the risk:benefit determination for the study. Please reassess the benefits of having in-person research activities to ensure that these outweigh the risks of COVID-19 exposure for research participants, study team members, and the risks of strain on the health care system when diverting clinical resources to research visits.

In responding to the items below, you must consider the impact on individual participants or participant groups in your study. For example, if your study consists of a placebo or control arm in which participants do not derive benefit from participation, you should indicate whether they are specifically included in or excluded from your request. The plan should also follow the relevant conditions in the Ohio Department of Health Director's Stay Safe Ohio Order in Section 9. Medical Care.

1. Risk and benefits of study participation.

- What advantages does the study offer to participants that they would not have outside the study?
- What are the potential direct benefits to participants?
- What are the risks of the research to the participants?
- Please provide a compelling justification as to why the requested research activities are in the best interest of the participants. Please consider whether the risks of exposure to COVID-19 impacts this assessment.

2. How will your team ensure the in-person research activities are conducted in a safe manner that protects subjects, researchers and the community? 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 absolutely necessary to ensure the safety of the study participant and ensure the integrity of the research.

The following are examples of criteria procedures that should be addressed in your plan.

- Screening individuals for COVID 19 symptoms prior to study visits.
- Screen individuals for COVID 19 exposure prior to study visits.
- All study participants should be contacted by telephone and asked about any respiratory symptoms or fever prior to their visits on the day prior to the scheduled visit. If study participants have any respiratory symptoms or fever they should be referred for appropriate testing before coming to a study visit.
- Upon arrival to UC Health or UC Medical Center, study participants should be asked again about respiratory symptoms or fever, and, if they report any, should be immediately moved to an isolated room and asked to put on a mask.
- Study personnel should wear appropriate personal protective equipment when conducting a study visit with a participant who is having respiratory symptoms or fever and refer the study participant for appropriate testing for infectious diseases.

- Potential transmission by asymptomatic infected individuals must be considered.
- Participants should be provided with information regarding the current COVID-19 pandemic and how best to reduce their risk of infection. This information may be provided in multiple forms suited to the type of contact, including a website link, a telephone script and an in-person handout. If possible, this information should be shared before the research visit.
- The same precautions that are taken with patients being seen for the clinical care should be used for research visits.

3. Please describe whether the research protocol requires effort and/or resources that may need to be re-directed to high demand areas to support clinical care related to COVID-19 (e.g., research protocols that require beds and/or clinical personnel who care for patients with severe respiratory distress)

Verify that the study,

- 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
- Does not take clinical staff away from clinical responsibilities that may be needed to respond to COVID 19.
- 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

Send your responses to these questions in an email to IRB Chair, [Dr. Mike Linke](#). If the study is currently approved include the protocol number.

NOTE: You will still need approval from your college AND from the research site(s). Consider shortages of personal protective equipment (PPE) which may impact your ability to do research at clinical sites.