Updated 3/23/2022

As we make decisions on how to respond to the COVID-19 outbreak we want to begin by stating that our primary concern is the safety of our research participants and the research team members who work for the University and UC Health. Our secondary goal is to preserve the scientific integrity of the research protocols.

As the need for social distancing increases, the number of UC faculty and staff on site is decreasing even in the clinical areas. Research participants may be less willing and facing even greater risks to come to our facilities. Demands for remaining clinical care resources continue to increase, making it more difficult to safely complete research. We must prioritize safe clinical care and practices that minimize spread of COVID-19. Informed advice about how long clinical research activities will be reduced is difficult to give, as the situation is changing rapidly. As you plan for what to do with your own research protocols, our current advice is to assume there will be no decrease in restrictions for at least two months. We will continue to reevaluate this timeframe.

COVID-19 research is a priority because of societal need for information. All COVID-19 protocols must still have IRB review and approval before starting enrollment. Please contact Dr. Linke before submitting a study involving COVID-19 linkemj@uc.edu

The latest guidance and information will always be available at the UC Coronavirus website and the Office of Research site.

Per the memo *Research Priorities during a Civil Emergency or Regional Crisis* from the Vice President for Research, the following criteria describe which UC research projects will be given priority for ongoing access to facilities during a university-wide emergency. For purposes of this determination, UC research projects are divided into three categories:

Level I Research: **Critical Research** efforts that are directed at responding to or mitigating the crisis that has caused the University closure, and which holds the potential for significant contribution in resolving the crisis;

Level II Research: **Essential Research** efforts that involve a significant investment of University resources, agency sponsorship, or contractual obligation, or effort on the part of researchers and staff that cannot be interrupted without jeopardizing those investments or the research results and overall project outcomes;

Level III Research: **Routine Research** that is in the initial stages, does not require completion of imminent, critical milestones, or may be continued at an alternate site by reprioritizing or resequencing the research structure. Though there may be a loss of data, efficiency or early investment, current efforts can be recreated or resumed after minimal disruption, with little loss of investment.

These criteria are incorporated into the following guidance.

# What should I do about human-subject research?

The Human Research Protection Program (HRPP) staff are working remotely but are operating on our normal schedule. The UC IRB will continue to hold weekly meetings using remote access technology. Please contact the HRPP office at irb@uc.edu or 513-558-5259 with any questions.

## Some Human Participant Research Studies or Activities Must Be Paused.

1. **Why must some human participant research studies or specific activities be paused?**

   The real or perceived risk of viral transmission, the risk/benefit ratio for in-person contact associated with research activities must be assessed for each protocol. Ethical principles of research and federal regulations for the protection of human research participants require an acceptable risk/benefit ratio.

2. **Which studies or study procedures must be paused?** (updated 3/30/2020)

All human subjects research studies with in-person interactions must cease enrollment. UC IRB approval is required to continue enrollment in these studies. IRB approval is also required for currently enrolled subjects to continue participation in these studies. This is effective for all human subjects research conducted at UC, regardless of reviewing IRB. Cancer Clinical trials must be approved by the Chair of the UC Cancer Center Protocol Review and Monitoring Committee (PRMC).

Please carefully evaluate your studies to determine if it is in the best interest of patients and staff to continue enrollment in light of the COVID 19 pandemic. Studies must also be evaluated to determine if it is in the best interest of currently enrolled subjects to continue participation in a study.

To continue enrolling patients and/or participation of currently enrolled subjects, please send a request to Dr. Linke linkemj@uc.edu (if you have not already done so). This requirement is in addition to the College of Medicine approvals. The IRB must now consider how the risk of COVID 19 exposure and infection affects the risk:benefit determination for a study.

Please address the following concerns in your request.

1. Keep patients out of the hospital
   - Most studies that require participants to stay in the hospital or the Schubert Research Center should not continue to enroll.

2. Risk and benefits of study participation. The risk of COVID 19 exposure and infection must be considered in the risk:benefit determination for the study
   - What would happen to the potential participants if they were not in the study?
   - What advantages does the study offer to participants that they would not have outside the study?
   - What are the potential direct benefits to participants?

3. Describe your plans to minimize participant and study staff COVID 19 exposure, transmission, and infection. These plans should address,
   - Screening individuals for COVID 19 symptoms prior to study visits.
   - Screen individuals for COVID 19 exposure prior to study visits.
   - Potential transmission by asymptomatic infected individuals must be considered.
   - The same precautions that are taken with patients being seen for the clinical care should be used for research visits.
   - Could any in-person study visits be switched to remote visits?

4. Verify that the study,
   - Will not utilize resources that are needed to take care of COVID 19 infected patients.
   - Study procedures would not interfere with clinical procedures put in place to treat COVID 19 patients
   - Would not use limited resources such as PPE
   - Research staff will be used for the studies so that clinical staff are not taken away from clinical responsibilities that may be needed to respond to COVID 19.

**3. May new enrollment into existing studies continue? (New Information 03/30/2020)**

- All human subjects research studies with in-person interactions must cease enrollment (as described above)
- Studies with no in-person participant interaction may continue to enroll participants.
- Level I IRB approved studies on COVID 19 may enroll participants.

**4. Which studies may continue? (updated 3/30/2020)**

- Studies that do not involve face-to-face interactions with participants may continue.
- Studies conducted electronically or via telephone or involving secondary data analysis may continue.
- IRB approved studies on COVID 19
- Studies approved by the IRB as described in #2

**5. How should research interactions go forward? (New Information 03/23/2020)**

- For research interactions that cannot be done remotely, opportunities for exposure should be reduced as much as possible without reducing the efficacy of the treatment or increasing risk to the participant. Examples of exposure reduction may include: reducing non-essential visits, reducing the number of blood draws, eliminating non-essential visit time, or maximizing the use of remote technologies in lieu of "face-to-face" interactions.
- For cancer-related studies, interim guidance from the National Cancer Institute for clinical trials supported by the NCI, such as delegation of visits or procedures to local providers or mailing of oral study drugs, see https://ncicirb.org/announcements/memorandum-interim-guidance-patients-clinical-trials-supported-nci-cancer-therapy .
- For FDA-regulated clinical trials, refer to FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic. https://www.fda.gov/regulatory-

information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic

- Limit study staff to be utilized to conduct visits to limit contact for study personnel, study participants and other individuals. Supervisory research personnel should discuss upcoming schedules in the next 6-8 weeks and how to limit the number of study personnel required to conduct visits that must be completed.
- Limit 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.
- Essential research visits that cannot be performed remotely may be performed in person, with the following additional guidance:
    - 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.
    - 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.
    - 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.

**6. What if my study is reviewed by an external IRB? (New Information 03/23/2020)**

This COVID-19 guidance is effective immediately for all human subjects research conducted at UC, regardless of reviewing IRB. If you need to make changes to your research, follow the reviewing IRB's procedures for submitting amendments or deviations.

**7. What if a human research study needs to be modified in response to COVID-19? (updated 3/23/20)**

Per UC SOP HRP-029 Review of Study Modifications "Modifications in approved research may not be initiated without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards". If protocols must be modified to address immediate safety concerns to participants or study staff related to the COVID-19 epidemic, the UC IRB has determined that these modifications meet this exception. Any modifications made per this exception should be subsequently submitted for IRB notification using the Reportable New Information (RNI) function in RAP as an Unreviewed

change: *Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.*

Protocol modifications to eliminate immediate hazards may include;

- Actions taken to reduce potential exposure to COVID-19
- Suspension of all or some research activities
- Decreasing the number of in-person study visits
- Replacing protocol-mandated visits to healthcare facilities with home visits or telemedicine
- Allowing blood draws at remote or commercial laboratories
- Shipping investigational products directly to research participants

Protocol modifications that are not made to eliminate immediate hazards must continue to be approved by the IRB prior to implementation.

Please contact the HRPP office at irb@uc.edu or 513-558-5259 with any questions.

**8. Can I submit new studies for IRB review during the COVID-19 outbreak? (New Information – 03/23/2020)**

- Yes, you may submit new studies in RAP. New studies will be screened and forwarded for expedited or convened IRB review in accordance with standard UC HRPP procedures and timelines; however, enrollment of new participants must adhere to the following:
- Any research studies involving COVID-19 should include COVID-19 in both the Title and Short Title of the protocol submission. Please contact Dr. Linke before submitting a study involving COVID-19 linkemj@uc.edu
- Level I COVID-19 studies may commence after receiving appropriate approvals.
- Clinical trials approved the UC Cancer Center PRMC may initiate enrollment.
- Other studies with in-person interactions may not commence enrollment until further notice.
- Studies with no in-person participant interaction may commence after receiving IRB approval.