

IRB Guidance – Research Ramp-Up (6/16/20)

Human subjects research (HSR) activities must be phased in gradually so that population densities and safe practices can be monitored to minimize risk and to ensure the health and safety of the faculty investigator, staff and research participant. Please see the [Guidelines for UCM Research Ramp-Up](#) for more details on the ramp-up plan and phases. In addition to COVID-related HSR requirements established by the Institutional Review Board, all general UCM health guiding principles and general policies must be adhered to. Throughout the phased expansion of HSR activities, risk and potential benefit to participants must be balanced, while implementing appropriate risk mitigation strategies. Any resumption and/or expansion of work from the current ramped-down phase will necessarily occur slowly and will be a balancing act between ensuring access to human subject research with the potential for direct benefit to participants and ensuring the health and safety of all involved.

Risk Mitigation Form Submission

Researchers must submit the COVID-19 [Risk Mitigation Plan Form](#) prior to resumption of in-person research visits. This form should be submitted as a modification to existing protocols or in initial protocols in the Additional Information Section as an attachment. The approved protocol must be submitted with the [COVID-19 Campus Research Operation Plan](#). An approved copy of the protocol can be downloaded from Cayuse IRB on the Study Details page.

Pre-Screening

All subjects attending a scheduled appointment for research-related purposes must be pre-screened via telephone prior to their in-person visit. Using the pre-screening checklist below, if the subject has not had or been ordered to any of the listed conditions, the in-person visit may proceed. However, the study participant will be required to have additional in-person screening upon arrival and all risk mitigation protocols must be adhered to. If the subject has had or been ordered to any of the listed conditions, the research must terminate the in-person visit. Study personnel are responsible for maintaining a record of completed pre-screening checklists for all study participants. Audits to ensure compliance may occur. Adult participants should answer pre-screening questions for themselves. Parents/legal guardians should answer pre-screening questions for minors.

All UCM faculty, staff and students must complete UCM Health Check self-screening each day before conducting research.

Pre-Screening Checklist for Research Subjects by phone prior to AND at the time of arrival on campus – For each individual subject

The subject may participate in a research visit only if they have not:

Had a positive COVID-19 test in the past 30 days.

Had contact with a person with a positive COVID-19 test in the past 14 days.

Had a fever, cough, headache, diarrhea, shortness of breath, difficulty breathing, chills, repeated shaking with chills, muscle pain, sore throat, loss of smell or taste in the past 14 days.

Been ordered to quarantine or self-isolate by physician or government

If the subject has not had or been ordered to any of the above the subject is eligible for the in-person visit.

If the subject has had or been ordered to any of the above, the researcher must terminate the in-person visit.

Research Visits

Goal: To transition to a hybrid model for the conduct of human subjects research, including a combination of in-person and virtual visits, that allows appropriate adherence to study specific requirements for all study subjects regardless of the type of study, while at the same time adhering to recommended physical distancing guidelines and considering the necessity of face coverings. This applies to all research space. Study teams must be aware of, and comply with, policies

and strategies for physical distancing and PPE utilization. Please see the UC interim policy [Universal Requirements for Physical Mitigation and Reduction of the Transmission of COVID-19](#) for UC Merced specific information.

1. Scheduling

- Appointments should be scheduled to ensure adequate time in between in-person visits for cleaning/disinfection of the study space and any applicable equipment.

2. Face Coverings and other Personal Protective Equipment (PPE)

- Use of face coverings should follow all guidance/policies provided by [UC Merced](#), the Merced County Department of Public Health, and the CDC.
- Face coverings will be provided to UC Merced personnel should they not have their own personal face coverings.
- Masks or cloth face coverings should be changed whenever soiled, wet, or damaged.
- Use of other PPE (e.g., face shields, safety goggles/glasses, gowns, gloves) should be in accordance with policies in effect for specific research procedures.

3. Physical Distancing

- Ensure that physical distance (6 feet or more) between individuals is maintained for the entirety of the visit. At this time, UCM policy allows one person per 250 square feet of lab or research space, one person per bay, and a minimum of six feet of distance maintained between individuals at any given time, including in public/shared/common spaces. Specific space capacities for campus buildings can be found at the [infoReady COVID-19 Campus Research Operational Plan page](#).

4. Check-in/Waiting

- Ask subjects to check in via phone call to the study team who will coordinate the subjects' entry into the facility.
- When subjects call to check in, let them know that they have the option of waiting in their car until the study space is available. Study team will call the subject when the room is ready.
- Continue symptom screening upon arrival.
 - Every subject (> 2 yrs old) will be asked to wear a face covering upon arrival, and will be provided one if needed.
- Hand sanitizer needs to be available, and soap and water, if possible.
- Arrange waiting room seating/study space to allow for proper physical distancing.
- Utilize separate entrances and exits as possible.

Cleaning/Disinfection of Study Areas

Once the subject has left the study space/lab, the space/lab must be immediately disinfected following standard precautions. Surfaces and equipment should be cleaned/disinfected as stated in [Appendix 1 of the Guidelines for UCM Research Ramp Up](#).

Consideration for Field Studies

Due to travel restrictions and greater potential for exposure to risks, the timing for the resumption of field research may be different from that of the other phases of research ramp-up. The policies and practical considerations in Appendix 7 of the [Guidelines for UCM Research Ramp-Up](#) are meant to serve as guidelines for researchers. A copy of the research operational plan should also be submitted to the UCM EH&S as necessary.

COVID-19 Information Sheet

The IRB has developed an [information sheet for COVID-19](#) to provide subjects. The information sheet addresses the risk reducing efforts implemented by UC Merced.