The UHCL Committee for the Protection of Human Subjects (CPHS), at the request of the Division of Academic Affairs, has provided updated guidance for human subjects research. Please keep in mind that this guidance is subject to change as the national, state, and regional/local/UH system responses change. The Centers for Disease Control and Prevention (CDC) web site (www.cdc.gov) is the best source of the most current information.

This guidance addresses the risks that COVID-19 (coronavirus) may present to human subjects or to researchers interacting with human subjects. It applies to all research, for which CPHS has reviewed and approved a protocol. It will also apply to new or renewed protocol applications until the Office of Environmental Health and Safety determines that the virus is no longer a threat to the health of students, faculty, or staff.

At this time, we recommend:

- Delaying all face-to-face data collection in any form or group size, in which social distancing cannot be maintained. The CDC defines social distancing as a minimum of 6 feet between the researcher and research subjects, and between the research subjects themselves.
- Offering an alternative format to research subjects if the study needs to proceed without interruption.
- Reminding human subjects that they are volunteers and should not participate in face-to-face if they are uncomfortable or if they are required to comply with county or city mandates.
- Submitting a protocol modification to the protocol to sponsoredprograms@uhcl.edu for review if research will be adapted to collect data in formats not involving face-to-face contact. Please note that for HIPAA-compliant research, modifications must receive approval prior to implementation.

If the investigator determines that face-to-face interaction is essential for the study, we require:

- Verbal pre-screening of all subjects prior to coming to campus. The researcher must ensure that the research subject:
  1. has not received a positive COVID-19 test in the past 14 days;
  2. does not exhibit any of the COVID-19 symptoms (cough, shortness of breath or difficulty breathing, chills, repeated shaking with chills, muscle pain, headache, sore throat, loss of taste or smell, diarrhea, a measured temperature greater than or equal to 100.0°F); and
  3. has not come in close contact with a person who has tested positive for COVID-19 in the past 14 days.
- No face-to-face research involving subjects in high-risk groups:
  1. Persons over the age of 65 or under the age of 18
2. Anyone with an underlying medical condition that the CDC has determined puts them at high risk for severe illness from COVID-19:
   - Asthma
   - Hemoglobin disorders
   - Chronic lung disease
   - Diabetes
   - Kidney disease being treated with dialysis
   - Immunocompromised conditions
   - Liver disease
   - Serious heart condition
   - Severe obesity
   - Resident of a nursing home or long-term care facility

   • Strict adherence to all safety precautions to prevent person-to-person transmission:
     1. Schedule appointments to not overlap with those of other subjects
     2. Thoroughly sanitize research area and equipment between subjects
     3. Frequently sanitize hands during visits
     4. All subjects and research personnel must wear masks
     5. Maintain a list of all subjects who come to the lab and those who interact with them, for contact tracing purposes.

Note that the required sanitization, verbal COVID-19 screening, research subject exclusion, use of personal protective equipment, and other safety precautions do not have to be added to the CPHS protocol. It is understood and expected that these processes are in place as long as they apply to all human subjects research conducted on in a face-to-face format by UHCL investigators.

If faculty, students, or staff encounter Human Subjects research activities that cause concern and that lie outside these guidelines, they should contact the Office of Sponsored Programs (sponsoredprograms@uhcl.edu) as soon as possible. A policy modification or revocation of CPHS approval for the study be required in order to be responsive to these concerns.