UCHealth Guidelines for Research Involving Human Subjects During COVID-19 Outbreak

Update: May 4, 2020

These updates reflect status as of May 4, 2020. Given slowing of the growth in number of COVID-19 patients in Colorado and relative stability of the number of COVID-19 patients being admitted to UCHealth facilities, UCHealth and the Anschutz Medical Campus are gradually reactivating clinical and research activities. Such reactivation is subject to executive orders from the Governor of the state of Colorado, Public Health Orders from the Colorado Department of Public Health and Environment (CDPHE) and other governmental orders. In addition, the extent of reactivation, or return to more restrictive functioning, is dependent up on changes in COVID-19 incidence. The pace of research reactivation in UCHealth clinical settings will be dependent upon the pace of clinical reactivation within UCHealth.

The safety of research participants and study teams is paramount during the COVID-19 outbreak. Because information and processes involving the outbreak are quickly evolving, please monitor the Source for most up to date information.

Infection Prevention Guidance for COVID-19 Disease
UCHealth Research Administration COVID page
UCHealth's COVID resources webpage

Access and Presence of Research Personnel at UCHealth Locations

General Guidance

1) Investigators should consider placing temporary holds on enrollment or other study activities for current studies, in consultation with the funding agency.

2) For clinical studies providing potential immediate clinical benefit or patient safety assurance, please continue, when possible, for any active participants. Consideration of new enrollment should depend on the degree of potential health benefit to patients and available alternatives.

3) Investigators should consider the appropriateness of substituting phone calls or videoconferencing for study visits. Please see below for FAQs on this topic and others.

4) With new COVID-19 precautions, investigators can choose to have a provider schedule a virtual health visit as part of the research study. Then the provider can send a research staff member the video link via a secure chat. As the same with in-person visits, the participant must agree to the virtual visit and sign all appropriate consents ahead of time. Please see this link for: **FAQs for Virtual Visits for Research.**

5) Research reactivation will be gradual, considering the following:
   a) Critical nature of the research. UCHealth will follow a Phased Approach that is consistent with the Anschutz Medical Campus guidance for clinical research reactivation (https://www.cuanschutz.edu/coronavirus/research-guidance/updates).

   b) Operational considerations:
      a. Anyone who has in-person contact with patients/participants must follow relevant institutional personal protective equipment (PPE) requirements.
      b. All research conducted within UCHealth patient care areas (ambulatory, procedural areas or inpatient) is subject to approval by relevant operational leadership (medical director + manager or director).
      c. On the Anschutz Medical Campus, CTRC resources (outpatient clinic and mobile nursing unit) remain available for investigators. The outpatient CTRC has remained open during the COVID-19 outbreak for support of approved clinical research protocols. The outpatient CTRC plans to gradually expand research support capacity following guidance from UCHealth and CU-AMC leadership. The inpatient CTRC was closed at the start of the COVID-19 outbreak. Decisions regarding opening of the inpatient CTRC at University of Colorado Hospital will be determined by CTRC leadership (Dr. Tom Campbell and Diane Branham) and UCHealth leadership (Jen Zwink, ACNO).

Staffing

1) As of May 4, 2020, research staff (PRAs, Sr PRAs, research coordinators) are still not permitted to conduct face-to-face research activities with patients/subjects, including enrollment, data collection, and sample collection. Investigators may continue to perform these tasks at the present time, and research staff may support activities outside of the clinical space. This limitation will be reconsidered over time based on current status of the COVID-19 outbreak in Colorado, PPE availability and status of the UCHealth clinical reactivation.
2) Given the imperative for PPE conservation, in-person research activities should be limited and be preferentially conducted by individuals who have a need to be in direct contact with the patient for clinical purposes and so will already be using PPE.

3) For research that will be conducted with persons who are under investigation for or have confirmed COVID-19, in-person research activities may *only* be performed by individuals who have documented training in use of proper personal protective equipment (PPE).Requests for clinical research staff (PRAs, Sr PRAs, research coordinators) to perform face-to-face research activities with persons who are under investigation for or have confirmed COVID-19 must be evaluated/approved on a project by project basis by the System Director of Research Administration as well as the facility CMO. Submit such requests to UCH-ResearchAdmin@uchealth.org with your request, IRB #, and a copy of your protocol.
4) Face-to-face research activities with patient/participants who are not confirmed to have COVID-19 including enrollment, data collection, and sample collection will need to be evaluated/approved on a project by project basis with the Regional Director of Research Administration. Further review may be required by the regional CMO. A request should be submitted to UCH-ResearchAdmin@uchealth.org with your request, IRB #, and a copy of your protocol. Please describe the planned face-to-face research activities and plans for minimizing PPE usage.
5) Research staff (PRAs, Sr PRAs, research coordinators) are required to complete the CU Skillsoft training module, entitled CU: COVID-19 Return to Campus, prior to returning to the clinical research environment. Access to this training is available through the My CU portal. After selecting the CU Denver | Anschutz campus icon, then choose the SkillSoft button and enter the CU Denver | Anschutz training menu. The mandatory training will be at the top of the training menu.
6) On the Anschutz Medical Campus, CTRC mobile nursing is also available to support research activities for both COVID-19 and non-COVID-19 approved clinical research protocols. Request for CTRC nursing support should be directed to Diane Branham diane.branham@uchealth.org.

When Location Requires Personal Protective Equipment (PPE)

Research personnel must follow relevant institutional PPE requirements. UCHealth PPE requirements are found on The Source COVID-19 page.

When Research Personnel Have Cold or Flu Symptoms or a Fever

1) Research personnel who have cold or flu symptoms or fever should stay at home and consult their supervisor. CU Anschutz based coordinators should follow new information posted here https://www.cuanschutz.edu/coronavirus/research-guidance/updates and the instruction provide in the Skillsoft training.

2) UCHealth Employees should refer to The Source COVID-19 page for the latest updates for Employee Information.
3) CU Anschutz Employees should follow information posted here: https://www.cuanschutz.edu/coronavirus/research-guidance/updates and the instruction provide in the Skillsoft training.

FAQs

1. **Participants from an ongoing research study are coming to my research facility. Are there any precautions that I should take?**

   Research must follow the current guidance for UCHealth Ambulatory settings for screening patients and visitors and for the number of allowable visitors.

2. **I conduct human-subject research in facilities that are shared by participants sequentially. Do I need to change my standard cleaning procedures for equipment?**

    1. Items that are used by participants should be cleaned with standard procedures between each participant use. You need to follow any infection control procedures in the hospital and your joint UCHealth/CU Anschutz approved infection control procedure, if you have an investigational product management plan (IPMP)

3. **Should researchers conduct home, school or other community site visits to collect data?**

    1. Research in home, school or other community site visits must follow State, county and city-level mandates regarding stay at home or safer at home and physical distancing. It is strongly recommended that if a protocol allows for a phone or virtual visit as opposed to an in-person visit, that the research personnel conduct the visit by phone or virtually.

4. **I am the principal investigator of a study that is recruiting participants for a research trial in a health clinic/hospital. Should my research staff be recruiting or interacting with participants who are on COVID-19 precautions?**

    1. No. Research personnel should be instructed to not approach patients on COVID-19 precautions in-person. Recruitment materials may be provided to clinical staff or investigators treating the potential participant for enrollment in a research study when the precautions for that individual have been lifted. Potential participants can also be contacted by phone or may be enrolled in studies where no in-person interaction is required. This will minimally impact recruitment of the majority of clinical trials. If you are conducting a study that specifically enrolls patients who have suspected or confirmed COVID-19, you must contact the infection prevention team at the relevant facility before commencing enrollment.

5. **My study involves surveys of human subjects who fill out information on a study laptop. What cleaning procedures should be in place between study participants?**
    1. Items that are used by participants should be cleaned with standard procedures between each participant use.
6. **What steps should a principal investigator and study team take to prepare for disruptions of study procedures and to safeguard study participants?**
    1. Assess the circumstances and develop a specific plan for each active study based on the criteria below. Continue to submit all associated application materials to the Institutional Review Board with oversight for research unless otherwise instructed by the IRB (including external IRBs):
        1. General procedures include:
            1. Evaluate the need to continue the research in evolving circumstances, including national and regional conditions or restrictions
            2. Consider study team availability, including the ability to recruit participants or administer study procedures
            3. Plan for alternative study locations or facilities and modes of data collection (e.g. phone or electronic interactions rather than face-to face, when possible)
            4. Establish or revise data and biospecimen safety and management plans
            5. Communicate with sponsors about study-specific needs
            6. Students conducting research should consult with faculty advisers about project or deadline changes
        2. Additional considerations for clinical research include:
            1. Consider the need for continuity of the research intervention (behavioral, drug or device) during the study period
            2. Assess clinical staff availability as required per the study protocol
            3. Plan for alternative medical or treatment locations, if needed
            4. Check the availability of Investigational Drug Services (IDS) Pharmacy operations or other pharmacy services
            5. Plan for the orderly withdrawal of participants from the research if indicated or necessary

6. Prepare for substantive delays in the ability of the team or participants to complete study procedures
7. Consider other treatment options for patients not able to access clinical trials (e.g., cancer patients or cardiac patients)
8. Create a plan for continued assessment and reporting of adverse events if the participants are unable to return to the study site

7. **What actions should the principal investigator and/or study coordinator take to prepare for absences of study team members due to the COVID-19 virus?**
    1. Prioritize study activities
    2. Create or update a communications plan for the study team and participants
    3. Identify emergency contacts within the study team
    4. Review procedures for the study team members to work remotely, when possible
    5. Consider travel restrictions and take actions accordingly
8. **What are some considerations for communicating with study sponsors?**
    1. Contact study sponsors/industry for study-specific information on how to continue the study or pause the research
    2. Obtain sponsor guidance for study conduct, including:
        1. Changes in reporting requirements
        2. Sample storage and shipping
        3. Drug shortages or delays in shipping
        4. Alternative safety assessments due to delays
        5. Delayed or missed participant contacts/visits
        6. Changing the study procedures with appropriate IRB approval
9. **Where can I find answers about how to manage my human subjects research protocols and changes amid the COVID-19 situation?**
    1. Please refer to the UCHealth's COVID resources webpage, which includes information regarding changes in workflows and resources. In addition, please see the guidance involving human subjects research amid the COVID-19 situation on the UCHealth Research Administration website.