

From the Office of the Vice Chancellor for Research: *Revised Interim University of Arkansas for Medical Sciences (UAMS) Requirements on Human Subjects Research Studies during COVID-19 Outbreak*

In the context of the recent COVID-19 outbreak, UAMS has updated the requirements to facilitate a phased approach in reopening human subjects research activities for non-oncology studies. These revised requirements are being implemented to continue to protect research participants, research personnel, and the larger UAMS community from risk of infection with COVID-19, as well as allow limited research activities to resume. These requirements will be reviewed and revised when appropriate based on new information.

The Winthrop P. Rockefeller Cancer Institute is following separate guidelines. Researchers and staff conducting cancer-related human subject research should contact Dr. Kristin Zorn (KKZorn@uams.edu) or Sandy Annis (AMAnnis@uams.edu) for further information.

Interim Requirements

NEW PARTICIPANTS

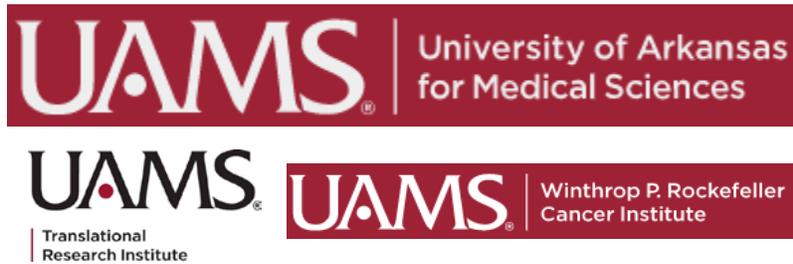
Enrollment of **new participants** on a clinical trial or other human subject-related research is currently allowable for research: 1) directly related to COVID-19; 2) where participation in the trial is essential to a participant's health and/or well-being, as determined by the principal investigator (PI); or 3) where the enrollment and longitudinal participant management can be conducted either remotely or without requiring any additional in-person visits beyond those required for essential clinical care purposes for the duration of the COVID-19 outbreak.

Beginning **June 1, 2020**, new enrollment may begin in studies indirectly related to clinical care where participants are seen in a UAMS facility. An example is a study where the PI reasonably anticipates a health-related benefit to participants, but the study requires one or more in-person visits for research or data collection purposes that are not essential to the participants' health and/or well-being.

Beginning **June 15, 2020**, new enrollment may begin in studies unrelated to clinical care, where participants are seen in a UAMS facility. An example is a study that requires in-person visits but no direct health-related benefits to participants are anticipated.

Research activities taking place in a community setting will remain restricted until further notice.

The above timelines may be extended depending on the viral burden in the state.



ESTABLISHED RESEARCH PARTICIPANTS

Research visits should continue to be performed remotely whenever possible.

If a research visit cannot be performed remotely, onsite visits for participants already enrolled in a trial may resume on **June 1, 2020** according to the following guidance:

- Study teams will contact participants prior to any in-person visit to screen for COVID-19 symptoms using CDC guidance (<https://www.cdc.gov/coronavirus/2019-ncov/index.html>). Any participants experiencing symptoms will be referred to UAMS Health (<https://uamshealth.com/coronavirus/>) and the research visit will be postponed.
- Study teams will provide participants with information regarding the current COVID-19 pandemic and how best to reduce their risk of infection (see CDC Guidance above). If possible, this information will be shared before the research visit.
- All research participants arriving on campus will undergo screening for COVID-19 symptoms at a UAMS screening station in accordance with UAMS protocol.

This timeline may be extended depending on the viral burden in the state.

Research visits in the community setting are postponed until further notice.

Study Sponsors

PI's or their designees will contact study sponsors to notify them of these requirements and make appropriate arrangements. All in-person sponsor visits for clinical trials or other human subject-related research, whether for site qualification, site initiation, or monitoring visits, are not permitted. Visits should be conducted remotely or postponed until further notice.

External visitors who are required at essential study visits (i.e., for medical devices), as determined above, are permitted.

- All such visitors will be screened for COVID-19 symptoms at a UAMS screening station in accordance with UAMS protocol.
- External visitors will be provided with information regarding the current COVID-19 pandemic and how best to reduce their risk of infection. If possible, this information will be shared before the research visit. See the following CDC COVID-19 link for reference and materials: <https://www.cdc.gov/coronavirus/2019-ncov/index.html>.