

From the Office of the Vice Chancellor for Research: *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 revised its requirements related to human subjects-related research. These requirements are being implemented to protect research participants, research personnel, and the larger UAMS community from risk of infection with COVID-19, as well as to ensure ongoing access to research which may provide essential support and care to participants. These requirements will be revised when appropriate based on new information.

The Winthrop P. Rockefeller Cancer Institute has implemented additional clinical research restrictions applicable to cancer-related studies. 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 only allowable if: 1) participation in the trial is essential to a participant's health and/or well-being, as determined by the principal investigator (PI); or 2) 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.

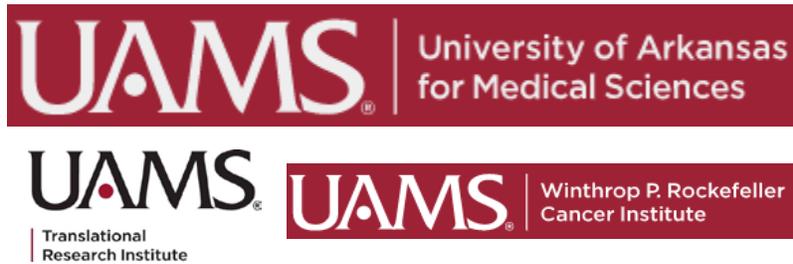
ESTABLISHED RESEARCH PARTICIPANTS

Research visits will be performed remotely whenever possible.

If a research visit cannot be performed remotely, the principal investigator (PI) will determine if the visit is essential or not essential to the participant's health and/or well-being.

Research visits that cannot be performed remotely and *are* essential to a participant's health and/or well-being may be performed in person, 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.



Research visits that cannot be performed remotely and are *not* essential to a participant's health and/or well-being will be postponed until further notice.

Research Personnel

All research personnel (faculty and staff) will receive appropriate training regarding proper research participant screening and participant triage should a research participant be deemed at risk for COVID-19 infection during an in-person research visit screening.

Guidance from the UAMS IRB on how to proceed with necessary protocol amendments (e.g., changing to remote visits) can be found here: <https://irb.uams.edu/2020/03/12/human-subject-research-in-the-time-of-coronavirus-covid-19/>. For studies under the oversight of an external IRB, the policies of the IRB of record will govern such changes.

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>.