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 the COVID-19 Public Health Emergency***

In the context of the COVID-19 pandemic, UAMS has updated requirements pertaining to human subjects research activities for non-oncology studies. These revised requirements are intended to protect research participants, research personnel, and the larger UAMS community from risk of COVID-19 infection while allowing research activities to continue where risks can be mitigated. These requirements will be reviewed and revised as needed as new information becomes available.

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 has previously been restricted for certain types of clinical research studies requiring in-person participant interaction. At this time, enrollment is allowed for all research study types, including those involving in-person participant interaction.

For research activities occurring on-site at a UAMS facility, all study personnel, participants, and guests must fully comply with all UAMS entrance screening, masking, and other PPE requirements.

For research activities occurring off-campus and in community settings, PPE requirements and precautions should be dictated by the nature of the activities and physical environment with consideration to current state and federal guidance and should fully comply with all precautions required by community partners, including those that may be more restrictive than current guidance.

ESTABLISHED RESEARCH PARTICIPANTS

UAMS investigators should consider performing research visits virtually when possible.

If a research visit will be conducted in-person, investigators should:

- 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.
- Provide participants with information regarding COVID-19 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.

Study Sponsors

Principal Investigators or their designees are responsible to communicate to study sponsors any local restrictions or requirements that may impact the conduct of study activities, including requirements that may restrict on-site sponsor visits for site qualification, training, or monitoring. At this time, it is recommended that sponsor visits be conducted remotely when objectives of the visit can reasonably be completed via virtual methods (e.g., EpicCare Link access for source data verification).

If a sponsor visit cannot reasonably be completed remotely, or if the scope of the research requires a sponsor representative to be in-person at essential study visits (e.g., for medical device programming), on-site visits may proceed with the condition that all sponsor representatives must fully comply with UAMS entrance screening, masking, and other PPE requirements.