Interim Translational Research Institute (TRI) Requirements on Human Subjects Research Studies during COVID-19 Outbreak

In the context of the recent COVID-19 outbreak, the Translational Research Institute (TRI) has revised its requirements related to human subjects-related research. These requirements are being implemented to protect research participants, researchers, and the larger University of Arkansas for Medical Sciences (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.

Interim Requirements (Effective March 13, 2020)

Research visits should be performed remotely whenever possible.

Research visits that cannot be performed remotely and are *not* essential to a participant's health and/or well-being, at the discretion of the Principal Investigator (PI), should be postponed until further notice.

Research visits that cannot be performed remotely and are *are* essential to a participant's health and/or well-being, as determined by the (PI), may be performed in person, with the following additional guidance:

a. Participants should be provided with information regarding the current COVID-19 epidemic and how best to reduce their risk of infection. If possible, this information should 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](https://www.cdc.gov/coronavirus/2019-ncov/index.html).

b. All research participants should be screened for fever, cough and flu-like symptoms by research staff prior to the research visit if possible, with repeat screening by research staff at the time of an in-person visit. Those who screen positive will require triage as per UAMS protocol before being cleared to participate in an in-person research visit.

c. Enrollment of new patients on a clinical trial or other human subject-related research should be allowed only if: 1) participation in the trial is essential to a participant's health and/or well-being, as determined as above; or 2) the enrollment and longitudinal participant management can be conducted remotely for the duration of the COVID-19 outbreak.

Research Personnel

All research personnel (faculty and staff) should 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/](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.

3/13/2020
Study Sponsors

PI’s or their designees should contact study sponsors to notify them of this policy 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, should be postponed whenever feasible. Study sponsors and/or their representative conducting essential in-person site visits will be subject to UAMS visitor screening protocols. Consideration for remote monitoring should be based on study need and resource availability.