

Department: UAMS Institutional Review Board
Policy Number: 2.9
Section: Relationships
Effective Date: September 17, 2026
Revision Dates:

SUBJECT: Unaffiliated Collaborators

POLICY

UAMS or Arkansas Children's (AC)/Arkansas Children's Research Institute (ACRI) investigators may collaborate with researchers not affiliated with either institution to conduct human subject research. When these researchers are from institutions that do not have their own Federalwide assurances (FWAs), they will be considered unaffiliated collaborators.

This policy applies to studies where an Unaffiliated Collaborator Agreement is used to document the relationship between the unaffiliated collaborator and the institution that allows its FWA to cover the unaffiliated collaborator. This agreement will spell out the roles and responsibilities of the unaffiliated collaborator and of the institution.

The UAMS IRB retains the final authority to determine when an unaffiliated collaborator agreement is appropriate. The unaffiliated collaborator will be under the oversight of the UAMS/AC/ACRI study team who retains ultimate responsibility for the conduct of the research, oversight of study activities, human subject protections, regulatory compliance, and reporting obligations.

DEFINITIONS

- A. **Unaffiliated Collaborator** – A person or entity that does not hold its own FWA that will collaborate with a UAMS or AC/ACRI investigator in human subject research. Unaffiliated collaborators may be community partners or other organizations that do not routinely do research.
- B. **Unaffiliated Collaborator Agreement (UCA)** -- An agreement describing the roles and responsibilities of the unaffiliated collaborator and the institution extending its FWA to the unaffiliated collaborator. A template agreement is available from the IRB office.
- C. **Federalwide Assurance (FWA)** – A formal commitment an institution makes to the federal government, through the Office for Human Research Protections, to comply with federal regulations for protecting human subjects in research, including the Common Rule.
- D. **Engagement in Research** - An institution is considered engaged in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects through intervention or interaction with them; (2) identifiable private information about the subjects; or (3) the informed consent of human subjects for the research.
- E. **Study team:** The local site team engaged in the study.

PROCEDURES

A. UAMS Procedure

1. UAMS will consider requests for UAMS/AC/ACRI investigators to work with unaffiliated collaborators.
2. The UAMS IRB retains the final authority to determine whether it will agree to extend the institution's FWA through an Unaffiliated Collaborator Agreement to any non-UAMS institution or individual.
3. Investigators who are not affiliated with another institution may also be unaffiliated collaborators.
4. UAMS Investigators shall work with the UAMS IRB to obtain a signed Unaffiliated Collaborator Agreement.
 - a. The individual signing the agreement on behalf of the unaffiliated collaborator shall be sufficiently authorized to do so.
 - b. On the UAMS side, only the Vice Chancellor for Research and Innovation or their designee may sign unaffiliated collaborator agreements.
 - c. The Unaffiliated Collaborator Agreement must be approved by UAMS Research Legal. A preapproved template agreement is available from the UAMS IRB office. Any changes to this template must be approved by UAMS Research Legal.

B. AC/ACRI Procedure:

1. Unaffiliated collaborators working with AC/ACRI investigators and/or on studies for which AC/ACRI is primarily responsible shall enter into an Unaffiliated Collaborator Agreement or equivalent agreement with AC/ACRI.

C. General Procedures

1. The investigator shall indicate on the IRB e-system submission form that the study involves one or more unaffiliated collaborators. Note that a study may have both relying sites and unaffiliated collaborators; this circumstance is captured in the submission form. Relying sites with their own FWAs will enter into Reliance Agreements with UAMS. See IRB Policy 2.3 for more information about Reliance Agreement arrangements.
2. The study protocol must describe the collaborators' role. The submission form, where appropriate, must also mention the collaborators, such as in descriptions of data sharing and storage.
3. UAMS/AC/ACRI investigators and study teams are responsible for ensuring unaffiliated collaborators have current human subject protection training, such as CITI training or equivalent training approved by the UAMS IRB, disclose any relevant conflicts of interest, and uphold human subject protections while carrying out the protocol as required.
4. Unaffiliated collaborators do not need an IRB e-system account. A description of their role and responsibilities must be included in the study protocol.

5. Unaffiliated collaborators shall be manually entered into the IRB e-system using a New Submission or Modification form in the Unaffiliated Collaborator Staff Section, separate from the local study staff section. A copy of the signed Unaffiliated Collaborator Agreement must be included in the e-system once finalized. Collaborators may not begin working on the study until the unaffiliated collaborator process is completed and approved.
6. Unaffiliated collaborators must promptly notify the UAMS/AC/ACRI Principal Investigator and study team of any event that may require reporting to the IRB, including but not limited to protocol deviations, adverse events, unanticipated problems involving risks to subjects or others (UPIRTSOs), breaches of confidentiality, participant complaints that cannot be resolved by the study team, and potential noncompliance, as per UAMS IRB Policies 10.2, 12.5 and 12.6.
7. Unaffiliated collaborators must maintain study records according to the approved protocol and provide UAMS, AC/ACRI, the IRB, and authorized oversight entities access to those records for monitoring, auditing, compliance review, or regulatory inspection upon request, as per UAMS IRB policies 2.4 and 6.5.
8. Upon completion of their study responsibilities, unaffiliated collaborators shall notify the UAMS/AC/ACRI Principal Investigator and cooperate with all study closure activities, including the retention, transfer, return, or destruction of study records, data, and specimens as required by the approved protocol and institutional policy, as per UAMS IRB policy 8.4.

REFERENCES

UAMS IRB Policies 2.3, 2.4, 6.5, 8.4, 10.2, 12.5, 12.6
OHRP Guidance Extending an FWA to Cover Collaborating Investigators