

Department: UAMS Institutional Review Board
Policy Number: 2.3
Section: Relationships
Effective Date: July 31, 2002
Revision Dates: February 8, 2005; March 5, 2004; November 18, 2002;
August 6, 2015, February 15, 2016; April 27, 2017, November 8,
2019; May 11, 2020; August 26, 2020; August 15, 2022

SUBJECT: Use of single/central IRBs

POLICY

UAMS or AC/ACRI may enter into IAAs or reliance agreements with other institutions to make the UAMS IRB the IRB of record, or to allow an external IRB to be the IRB of record, for multisite projects.

Reliance Agreements or IAAs will typically apply only to a single study, specified on the agreement.

Each institution named in the Reliance Agreement remains responsible for safeguarding the rights and welfare of human subjects at its site and for complying with the terms of its Federalwide Assurance.

UAMS and AC/ACRI will only rely on xIRBs operated by AAHRPP-accredited organizations or IRBs that operate under appropriate standards for the research reviewed.

As of Jan. 19, 2020, all multisite research subject to the Common Rule and supported, funded, or regulated by a federal agency is required to use one IRB for review for the part of the research done in the United States, unless one of the exceptions at section 114 of the 2018 Common Rule applies. NIH-supported studies have been required to undergo sIRB review since January 2018. Other multisite studies may also undergo review by an xIRB, as appropriate or required.

Roles and responsibilities of both the relying and the reviewing institution will be spelled out in a written agreement between the two institutions.

Definitions

- A. **IRB Authorization Agreement (IAA) or Reliance Agreement:** Formal agreement documenting the roles and responsibilities of Institution providing the IRB and Institution relying on the IRB.
- B. **IRB of Record:** IRB acting as the reviewing body for multisite research.
- C. **NCI- CIRB:** Central IRB for National Cancer Institute sponsored research
- D. **Performance Site or Local Site:** Location where human subject research is being conducted

- E. **External IRB (xIRB):** A non-UAMS IRB serving as IRB of record for UAMS, Arkansas Children's Hospital (AC), or Arkansas Children's Research Institute (ACRI)
- F. **External Investigator:** An investigator not affiliated with UAMS, AC, or another institution whose research the UAMS IRB routinely oversees.
- G. **SMART IRB:** An online platform designed to facilitate creation of reliance agreements between member institutions. UAMS is a SMART IRB member.
- H. **Study team:** The local site team engaged in the study. The study team may actual be involved in direct human subject research, or may be a coordinating center.
- I. **Unaffiliated Investigator Agreement:** A document extending the FWA of one institution to another investigator or institution not otherwise covered by an FWA.

Procedures:

A. Unless covered under a reliance agreement or equivalent agreement with an xIRB, UAMS will be the IRB of Record for all of the research conducted at:

- University of Arkansas for Medical Sciences
- (UAMS) Arkansas Children's (AC)
- Arkansas Children's Research Institute (ACRI)

B. AC/ACRI Procedure:

1. Investigators wishing to submit to an xIRB for AC based research will contact ACRI and follow the established ACRI Central IRB Process.
2. The study team and ACRI will use the IRB's e-system to notify the UAMS IRB about the request to use an xIRB and to request approval of the request.
3. ACRI will enter into an IAA with the xIRB and will be responsible for the conduct and oversight of the research per the terms of the IAA.

C. UAMS Procedure for relying on an xIRB:

1. While requests will be considered individually, the following types of research are generally NOT eligible for submission to an xIRB when UAMS will be a performance site, unless a specific regulatory requirement to use an xIRB applies:
 - a. Research in which UAMS holds an IND/IDE
 - b. Research done entirely at UAMS (single-site study) with no other sites involved.
2. Studies to be reviewed by an xIRB, including the NCI-CIRB, will be submitted prior to initiation at UAMS through the UAMS IRB e-system, with questions about using an xIRB answered correctly, to ensure:

- a. All UAMS institutional reviews, including but not limited to reviews and approval by pharmacy, budget, coverage and the EPIC beacon treatment and billing process, and the IRB's local context review, are completed and requirements are met.
- b. Local requirements related to the protections of human subjects are met.
3. If the study is not using the SMART IRB system, a signed IAA between UAMS and the xIRB must be in place for the xIRB review to occur. The IAA must be signed by the UAMS authorized official or designee, not by the PI or the study team.
4. If the study involves SMART IRB member institutions, the reliance agreement will be completed through the SMART IRB process when possible.
5. UAMS has an established IAA with NCI for all NCI sponsored studies to be submitted to the NCI-CIRB. An annual local context review is required. The NCI-CIRB approves the UAMS-specific consent form language at the time of the annual institutional signatory review. No other changes may be made to the consent form.
6. Agreements with certain specified xIRBs have been preapproved by legal and require no further legal review prior to signing. The research legal office will be consulted prior to signing agreements with IRBs not on this preapproved list.
7. The UAMS IRB office will be responsible for conducting the local context review of materials in the IRB e-system. The IRB will work with legal counsel as needed to ensure all required consent form changes are consistent with any related contract.
8. Documentation of the signed reliance agreement and the xIRB approval letter will be added to the project's CLARA file.
9. UAMS will charge an administrative review fee for industry sponsored research submitted to an xIRB, to offset the cost of the ongoing required administrative reviews of these studies. This fee must be noted as "UAMS Administrative Review Fee" and listed in the study startup section of the study budget.
10. The UAMS investigator shall become familiar with the reviewing IRB's policies, procedures, and expectations, and shall ensure the reviewing IRB's requirements are met in these areas.
11. Unless specifically stated otherwise in the reliance agreement, each performance site shall remain responsible for ensuring compliance with its FWA and for protecting the rights, safety, and welfare of research subjects at its site.

D. UAMS Acting as the IRB of Record

1. Conditions under which the UAMS IRB may serve as the IRB of record for a multisite study:
 - a. The external site engaged in the research is part of a multisite study in which UAMS or AC is also engaged.
 - b. The IRB Office, after consultation with any other relevant components of the UAMS Human Research Protection program as necessary, has affirmatively determined the UAMS IRB can serve as the IRB of record.
 - c. The study being considered has NOT been previously reviewed and not allowed to proceed by any other IRB.
 - d. A signed IAA or equivalent agreement, e.g. through the SMART IRB system, is in place prior to undertaking the review.
 - e. External investigators may sign an unaffiliated investigator agreement with UAMS if their home institution is not able to cede review to the UAMS IRB.

- f. Unless specifically stated otherwise in the reliance agreement, each performance site shall remain responsible for ensuring compliance with its FWA and for protecting the rights, safety, and welfare of research subjects at its site.
 - g. When relying on the UAMS IRB for review, each performance site and external investigator shall familiarize themselves with the reporting requirements and other responsibilities described in the reliance agreement and UAMS IRB policies, as appropriate.
2. Procedure for requesting UAMS IRB central review:
- a. The UAMS investigator or study team is encouraged to consult with the IRB office prior to submission to advise that such a request will be made. If the investigator is applying for a grant for which the UAMS IRB will be the IRB of record for a multisite study, consultation with the IRB office prior to grant application submission is encouraged.
 - b. The IRB and the UAMS study team will ensure that a signed IAA or equivalent documentation is on file.
 - c. The study will be submitted in the UAMS IRB e-system, with the questions about the use of an xIRB or UAMS serving as the reviewing IRB for multiple sites answered accurately.
 - d. The UAMS study team must describe and should document all external sites' study specific requirements, including any issues related to the external site's local context review or consent form requirements.
 - e. Sites will be added to the study using the site addition modification form. The site addition modification is to include a copy of the signed reliance agreement and any site-specific documents, such as the locally adapted consent form. The IRB may approve the site addition modification using expedited procedures.
 - f. UAMS institutional and local context reviews will relate only to research activities being carried out at UAMS performance sites only. UAMS will not do any institutional reviews for sites not under its institutional control.
 - g. The UAMS investigator will be responsible for making any other required UAMS institutional submissions.
 - h. The UAMS IRB will require that study staff at the collaborating site complete the CITI training modules required by UAMS or provide documentation of having completed comparable training elsewhere.
 - i. The UAMS IRB may require any conflicts of interest at the external sites to be disclosed in the submission.
3. Procedure for study review while the study is ongoing
- a. The UAMS study team shall submit any study modifications, continuing reviews, or other required IRB submissions to the UAMS IRB for review and approval.
 - b. The UAMS IRB will review this submission in accordance with its review policies.
 - c. The UAMS study team will be notified of the IRB's decisions through the IRB e-system, as described in UAMS IRB policy 9.2.
 - d. Unless specifically negotiated otherwise in the reliance agreement, the UAMS study team, and not the UAMS IRB, will be responsible for communicating with other performance sites regarding UAMS IRB determinations and decisions.

References

AAHRPP Elements I-9 and II.2.I

AAHRPP Tip Sheet 24, *Single IRB or EC Review*

45 CFR 46.114