Department:	**UAMS Institutional Review Board**
Policy Number:	**2.3**
Section:	**Relationships**
Effective Date:	**July 31, 2002**
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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, unless the project in question qualifies for exempt status review.

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 a single IRB, 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**: The document signed when an external investigator participates in research overseen by the UAMS IRB, and the external investigator's institution does not formally cede review.

J. Local Context Review: Review of study documents to ensure they meet UAMS and state requirements pertaining to human subject protections and institutional requirements.

K. Relying site: A research-engaged site that relies for review on an external IRB or on the UAMS IRB acting as IRB of record.

Procedures:

A. **Unless covered under a reliance agreement or equivalent agreement with an xIRB, UAMS will be the IRB of Record for all human subject 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.
   c. Research qualifying for exempt status review. Investigators should contact the IRB if a study sponsor, funder, or other party requests the use of a single IRB for a multi-site, exempt status project.
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.
   c. The study is routed correctly.
3. The SMART IRB agreement shall be the preferred reliance agreement to be used to document reliance.
4. If the study is not using the SMART IRB system, a signed IAA between UAMS and the xIRB must be completed 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.
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, including initial submissions and any modifications. The UAMS IRB's role shall be limited to this local context review and it will acknowledge, not approve, materials approved by the reviewing IRB. Documents required at initial submission are the approved protocol, the approved main informed consent and HIPAA authorization templates, site-specific informed consent and HIPAA authorization forms, any other documents requiring local context review, the most recent reviewing IRB full approval letter (either original approval or the most recent continuing review), and the signed reliance agreement, if available.
8. Other UAMS Human Research Protection Program components will retain all of their usual review responsibilities for xIRB studies. The UAMS IRB may consult with other HRPP components as needed during its local context review.

9. Documentation of the signed reliance agreement and the xIRB approval letter will be added to the project's CLARA file with a modification if it is not available at the initial submission.
10. 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.
11. The UAMS investigator and study team 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.
12. 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.
13. The UAMS study team shall submit modification forms to notify the UAMS IRB of the following xIRB determinations.
    a. Approval of protocol modifications that affect the UAMS study site, including a copy of the revised protocol
    b. Approved informed consent form and HIPAA authorization template documents that will be adapted for use at the UAMS study site and including a copy of the revised documents.
    c. Notification of any required continuing review approval.
    d. Determinations of serious or continuing noncompliance or of an unanticipated problem involving subjects or others that affects, or may affect, study performance at the UAMS site.
    e. Any other changes requiring another local context review at the UAMS 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 relying 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. The study does not qualify for exempt status review. Investigators should contact the IRB if a study sponsor, funder, or other party requests the use of a single IRB for a multi-site, exempt status project.

2. Procedure for requesting UAMS IRB central review:
    a. The UAMS investigator or study team is strongly encouraged to consult with the IRB office prior to submission in the IRB e-system or, when applicable, of a request for funding to a funding agency to advise that such a request will be made.

b. The IRB and the UAMS study team will ensure that a signed IAA or equivalent documentation will be available. External investigators may sign an unaffiliated investigator agreement with UAMS if their home institution does not have an IRB and therefore cannot cede review.
c. 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. 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.
e. The study will be submitted in the UAMS IRB e-system, with the questions about UAMS IRB serving as the reviewing IRB for multiple sites answered accurately.
f. The UAMS study team must describe and should document all relying sites' study specific requirements, including the relying site's local context review or consent form requirements. This information may be captured using a local context form that is included with each site's site addition form (see below).
g. 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 site-specific documents relevant to the reviewing IRB's determinations, such as the locally adapted consent form, a completed local context form, the local PI's CV, and any relevant conflict of interest information. The IRB may approve the site addition modification using expedited procedures.
h. If UAMS is both the reviewing IRB and a site engaged in the research, or if ACRI is engaged in such a research study, the study team must submit a separate site addition modification for the UAMS or ACRI site to ensure site counting is correct in CLARA. UAMS-specific document changes approved later through the main submission (due to a need for budget or other institutional review) should be submitted to the site-specific modification after approval. ACRI materials will be based on UAMS IRB-approved templates and shall be submitted to the ACRI site addition form once the templates are approved.
i. Site-specific changes made after initial approval shall be submitted to the UAMS IRB for review by modifying that site's site addition form.
j. 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.
k. The UAMS investigator will be responsible for making any other required UAMS institutional submissions.
l. Study staff at the collaborating sites, in coordination with the study team, will confirm their staff have completed either basic human subject protection through the CITI training program or comparable human subject protection training elsewhere.
m. The UAMS IRB will require any conflicts of interest at the relying sites to be disclosed as part of the site addition process.

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 these submissions 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, 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