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| **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** |

**SUBJECT: Use of central IRBs**

**Purpose:** The purpose of this policy and procedure is to describe the use of central IRBs, either external to UAMS or when the UAMS IRB serves as the central IRB for multisite research

**Definitions:**

**IRB Authorization Agreement (IAA):** Formal, written agreement documenting the roles and responsibilities of Institution providing the IRB and Institution relying on the IRB.

**IRB of Record:** IRB listed as an approved reviewing body for Institution’s research.

**NCI- CIRB:** Central IRB for National Cancer Institute sponsored research

**Performance Site:** Location where human participant research is being conducted

**External IRB (xIRB):** A non-UAMS IRB serving as IRB of record for UAMS, Arkansas Children’s Hospital (ACH), or Arkansas Children’s Hospital Research Institute (ACHRI)

**Policy:** In order to avoid duplication of effort in research projects with multiple performance sites, UAMS or ACH/ACHRI may enter into IRB Authorization Agreements with other institutions to make the UAMS IRB the IRB of record, or allow an external IRB to be the IRB of record. Each institution remains responsible for safeguarding the rights and welfare of human subjects and for complying with the terms of its Federalwide Assurance. UAMS and ACH/ACHRI will only rely on other IRBs that are operated by AAHRPP accredited organizations or IRBs that operate under equivalent standards.

**Unless covered under an IAA with an xIRB, UAMS serves as the IRB of Record for all of the research conducted at:**

University of Arkansas for Medical Sciences (UAMS) Arkansas Children’s Hospital (ACH)

Arkansas Children's Hospital Research Institute (ACHRI)

**ACH/ACHRI Procedure:**

1. Investigators wishing to submit to an xIRB for ACH based research will contact ACHRI and follow the established ACHRI Central IRB Process.
2. ACHRI will submit a letter to the Vice Chancellor for Research (VCR) requesting the use of an xIRB. The request will include justification for the use of an xIRB. The VCR and IRB Director will review and make a decision.
3. ACHRI 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

**UAMS Procedure:**

1. While the IRB and Vice Chancellor for Research will consider requests individually, the following types of research are generally NOT eligible for submission to an xIRB when UAMS will be a performance site:
2. Research initiated by a UAMS investigator
3. Research in which UAMS holds an IND/IDE
4. Research done only at UAMS (single-site study)
5. Research involving use of recombinant DNA and its derivatives, vectors, or infectious agents and/or requiring UAMS Institutional Biosafety Committee review.
6. New submissions that have been previously submitted to the UAMS IRB for review
7. Investigators wishing to submit to an xIRB, including the NCI-CIRB, must still submit study through the IRB e-system in order to ensure that all UAMS institutional reviews are completed and requirements are met.
8. A signed IAA between UAMS and the xIRB must be in place for the xIRB review to occur. An IAA must be signed by the UAMS authorized official, not by the PI or the study team.
9. 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.
10. For use of all other xIRBs, the Investigator must contact the IRB Director prior to submission of the study in the e-IRB system. The IRB Director and VCR will review the request and justification and grant approval as appropriate. A local context review will be conducted by the IRB Chair, Director and Program Manager. Other individuals may be included in the local context review as needed. The local context review may also involve ensuring all education requirements have been met and that any other required institutional submissions have been made.

The IRB Director and Legal Review Unit will work together to ensure all required consent form changes are consistent.

Given the continued need for institutional involvement for studies reviewed by xIRBs, UAMS will charge an administrative review fee for Industry Sponsored research submitted to an xIRB. This fee must be noted as “UAMS Administrative Review Fee” and listed in the study start up section of the study budget.

**UAMS Acting as the IRB of Record**

1. Conditions under which the UAMS IRB may serve as the IRB of record
2. The UAMS IRB will review such a study only if the external site engaged in the research is part of a multisite study which includes UAMS as one of the sites.
3. The UAMS IRB Office will determine, on a case-by-case basis, whether serving as the central IRB is appropriate. UAMS will NOT review studies that have been previously reviewed and not allowed to proceed by other IRBs.

The following are examples of research where UAMS will typically NOT agree to serve as the IRB of record:

1. UAMS or its agents are not engaged in the research
2. The external site is the coordinating center for a clinical trial
3. The UAMS IRB office determines the IRB cannot adequately oversee the external site or personnel to ensure the protection of human subjects
4. The UAMS IRB will require a signed IAA to be in place before it will review such research.
5. Procedure for requesting UAMS IRB central review
6. The UAMS investigator or study team will consult with the IRB office prior to submission to advise that such a request will be made
7. The IRB and the UAMS study team will ensure that a signed IAA is on file.
8. The study will be submitted in the UAMS IRB e-system.
9. The UAMS study team must submit all external site’s study specific requirements including any issues related to the external site’s local context review or consent form requirements.
10. UAMS institutional reviews will be limited to those pertinent 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.
11. The UAMS investigator will be responsible for making any other required UAMS institutional submissions.
12. 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.