

Department: UAMS Human Research Advisory Committee
Policy Number: 2.3
Section: Relationships
Effective Date: July 31, 2002
Revision Dates: February 8, 2005; March 5, 2004; November 18, 2002

SUBJECT: To Other Institutions

Purpose: The purpose of this policy and procedure is to describe the relationship that the UAMS IRBs have to other Institutions.

Definitions:

IRB Authorization Agreement: 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.

Performance Site: Location where human participant research is being conducted either under the direction of or in direct collaboration with PI utilizing UAMS IRB.

Policy: In order to avoid duplication of effort in research projects with performance sites, UAMS may enter into IRB Authorization Agreements with other institutions to review research for the site, or to have research reviewed for UAMS. Each institution remains responsible for safeguarding the rights and welfare of human subjects and for complying with the terms of the Federalwide Assurance. UAMS will only rely on other IRBs that are operated by AAHRPP accredited organizations.

References: IRB Policies 1.3 and 2.7

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)
Central Arkansas Veteran's Healthcare System (CAVHS)

UAMS serves as the IRB of Record for certain research at:

Arkansas Department of Health (ADH) – All research involving ADH employees conducted at or in conjunction with UAMS, ACH, ACHRI or CAVHS

National Center for Toxicological Research (NCTR) – All research involving NCTR employees conducted at or in conjunction with UAMS, ACH, ACHRI or CAVHS, provided that the FDA IRB retains initial review requirements.

University of Arkansas at Little Rock (UALR) – All research involving UALR students or employees conducted on the UAMS, ACH, ACHRI or CAVHS campus.

Procedure:

1. Investigator will:

- 1.1 Identify All Performance Sites in ARIA Application for New Submission or in ARIA Modification if needing to add a new Performance Site after Initiation.
- 1.2 For any Performance Site that has its own FWA and IRB:

- 1.2.1 Provide FWA# and IRB approval from that Performance Site before initiation of research at that site. OR
- 1.2.2 If Performance Site is AAHRPP accredited and wishes to assume IRB responsibilities for any individual subject to the UAMS IRB oversight or name the UAMS IRB as its IRB of record for a limited study, contact the IRB Director for assistance, preferably prior to ARIA submission, to see if allowable and to arrange IRB authorization agreement.
- 1.3 For any Performance Site that has a FWA but no IRB: Contact the IRB Director for assistance. UAMS will serve as the IRB of record under an IRB authorization agreement for many local organizations working with UAMS investigators.
- 1.4 For any Performance Site that does not have a FWA or an IRB: Each site engaged in research must operate under appropriate assurances. Contact the IRB Director in order to assist the Site with obtaining a FWA and putting in place an IRB Authorization agreement if allowable.

2. IRB Director or Designee will:

- 2.1 For all Performance Sites:
 - 2.1.1 Check the OHRP website for approved assurances to see if Performance Site has a current FWA and IRB of Record.
 - 2.1.2 Review the planned research and roles of the investigator, in conjunction with IRB Chair or Office of Research Compliance as necessary, to determine if it would be most expedient, as applicable, to:
 - 2.1.2.1 Rely on the other Site's IRB for specific research project and enter into an IRB Authorization Agreement delegating IRB review responsibilities for specific study to other Site, provided other Site's IRB is operated by an AAHRPP accredited organization;
 - 2.1.2.2 Enter into a Dual oversight agreement with Site;
 - 2.1.2.3 Assist Site in obtaining their own FWA through OHRP; and/or
 - 2.1.2.4 Enter into an IRB Authorization where UAMS becomes Site's IRB of record for specific study.
 - 2.1.3 Relay decision either way to Investigator.
 - 2.1.4 Follow-up as needed.