

Department: UAMS Institutional Review Board
Policy Number: 5.1
Section: Records
Effective Date: July 31, 2002
Revision Dates: February 8, 2005; August 25, 2004; November 18, 2002

SUBJECT: IRB Records

Purpose: The purpose of this policy is to describe the maintenance of IRB records

Policy: The IRB shall retain all documents submitted to it or created by it in accordance with federal, state and local law, and any applicable sponsor or organizational requirements. In order to maintain the confidentiality of such records, access to records, whether paper or electronic, is restricted to authorized personnel.

1. The IRB Staff will:

1.1. Maintain the following records:

1.1.1 A current list of IRB membership and qualifications.

1.1.2 Agenda and minutes of meetings, including information regarding member attendance, discussions held, decisions made, and voting results.

1.1.3 All materials submitted to the committee for initial and continued review of each study including: IRB applications, protocols, submitted and final consent forms, serious adverse event and death reports, proposed amendments, progress reports, correspondence generated between the committee and the investigators, and, where applicable, correspondence from sponsoring agencies.

1.2 At reasonable times and in a reasonable manner, provide access to ARIA or paper records for inspection and copying by authorized personnel. Authorized personnel shall specifically include OHRP and the FDA. Institutions which rely on UAMS as their IRB of record, to include but not be limited to CAVHS, ACH and ACHRI, shall be provided access for inspection and copying of site specific records or records in which their employees are involved. For entities not specifically mentioned here, the Director or Chair should be contacted prior to providing access.

1.3 Upon closure of any study submitted prior to the implementation of ARIA, scan all paper records into a History document in the ARIA record for that study. All records submitted after the implementation of ARIA, or scanned into ARIA upon closure, are retained electronically in the system indefinitely.

2. The IRB Director or Chair will determine the appropriateness of providing access to parties other than those listed in Section 1.2.