Department:	**UAMS Institutional Review Board**
Policy Number:	**6.5**
Section:	**Documentation**
Effective Date:	**July 31, 2002**
Revision Date:	**November 18, 2002; August 25, 2004; February 8, 2005; January 24, 2011; March 11, 2011; August 7, 2015; February 15, 2016; July 16, 2020; November 17, 2020; October 15, 2024**

SUBJECT: 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. This includes items sent for exempt, expedited, or convened IRB review; items related to studies reviewed by external IRBs, and records related to IRB operations. Access to records, whether paper or electronic, shall be limited to authorized personnel to maintain the confidentiality of this material. Each study will be assigned a unique IRB study number and maintained in a separate electronic file.

PROCEDURE

A. IRB Staff shall maintain the following records:
   1. A current list of IRB membership and qualifications
   2. Agenda and minutes of meetings
      a. Any notes or worksheets created by reviewers outside of the IRB's e-system are considered working papers and do not have to be retained.
      b. Checklists completed by the reviewer or the convened board, notes and records entered into the IRB's e-system, approval letters and meetings minutes, shall be considered documentation of the resolution of any controversial issues and part of the meeting minutes.
      c. All materials submitted to the IRB for review and related IRB responses. These materials include, but are not limited to: IRB applications; protocols; consent and HIPAA authorization forms; investigator brochures; recruitment materials; reportable new information reports; audit reports and responses; reports to regulatory agencies; and correspondence between the IRB and the investigators.
   3. At reasonable times and in a reasonable manner, the IRB will provide access to the e-system for inspection and copying by authorized personnel. Authorized personnel shall specifically include OHRP, the FDA, and the Association for the Accreditation of Human Research Protection Programs. Institutions which rely on UAMS as their primary IRB of record, to include but not be limited to AC and ACRI, shall also be provided access. Other components of the UAMS Human Research Protection Program shall also be provided the access needed to carry out their responsibilities.
   4. External sites engaged in research for which the UAMS IRB is the IRB of record will normally not have access to the e-system.
   5. Consult with the IRB director, associate director, IRB chair, and/or the Institutional Official before giving anyone not previously authorized access to the e-system.

B. All records submitted are retained in the e-system indefinitely. There are no plans to purge the e-system of any study records.

REFERENCES

45 CFR 46.115
21 CFR 56.115
AAHRRP Elements II.5.A and II.5.B
OHRP/FDA Guidance *Institutional Review Boards Written Procedures: Guidance for Institutions and IRBs*
FDA Information Sheet *Institutional Review Board Frequently Asked Questions*