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| **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** |

**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, 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 file.

**PROCEDURE**

A. IRB Staff shall:
   1. Maintain the following records:
      a. A current list of IRB membership and qualifications.
      b. Agenda and minutes of meetings, including information regarding member attendance, discussions held, determinations and decisions made, and voting results.
         i. Any notes or worksheets created by reviewers during their review and prior to making final determinations are considered internal working papers and are not be required to be retained.
         ii. The checklists completed by the reviewer or convened IRB documenting determinations, along with approval letters and meeting minutes, shall be considered documentation of the reconciliation of any controverted issues.
      c. All materials submitted to the IRB for review. These materials include, but are not limited to: IRB applications, protocols, submitted and final consent forms, investigator brochures, recruitment materials, reports of Unanticipated Problems Involving Risk to Subjects or Others, audits, new findings, serious adverse event and death reports, reports of injuries or complaints, proposed amendments, progress reports, data and safety monitoring reports, correspondence between the committee and the investigators, and, where applicable, correspondence from sponsoring agencies.
   2. At reasonable times and in a reasonable manner, provide access to 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. Access should be limited to site specific records or records in which their employees are involved. For entities not specifically mentioned here, the IRB Director or Chair should be contacted prior to providing access.
   3. Consult with the IRB director, associate director, or chair before releasing records to anyone not previously authorized to view the specific records in question.

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
AAHRPP Elements II.5.A and II.5.B
OHRP/FDA Guidance *Institutional Review Board Written Procedures: Guidance for Institutions and IRBs*
FDA Information Sheet *Institutional Review Board Frequently Asked Questions*