Department: **UAMS Institutional Review Board**
Policy Number: **5.1**
Section: **Records**
Effective Date: **July 31, 2002**
Revision Date: **August 25, 2004**

SUBJECT: IRB Records

Storage. The IRB support staff is housed in an office suite that contains all active protocols. Access to this office is restricted to designated personnel and is secured when the IRB staff is not physically present. FDA regulations require that for all applications approved and the research initiated, the records are retained for at least three (3) years after completion of the research. The records shall be accessible for inspection and copying by authorized representatives of the sponsoring Department or Agency at reasonable times and in a reasonable manner.

The IRB office maintains the following records:

- A current list of HRAC membership and qualifications.
- Agenda and minutes of meetings, including information regarding member attendance, discussions held, decisions made, and voting results.
- 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.

All paper records submitted prior to the implementation of ARIA are retained in hard copy until the study is no longer collecting data and the investigator requests closure. Closed/terminated studies of this nature are scanned and retained electronically for an indefinite period of time.

All records submitted after the implementation of ARIA are retained electronically in the system indefinitely.