

**Department:** UAMS Human Research Advisory Committee  
**Policy Number:** 5.1  
**Section:** Records  
**Effective Date:** July 31, 2002  
**Revision Date:** November 18, 2002

**SUBJECT: HRAC Records**

**Storage.** The HRAC 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 HRAC 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 [21CFR 56.115(b); 38CFR16.115(b); 45CFR46.115.7 (b)].

Records regarding an approved application are retained in hard copy until the study is no longer collecting data and the investigator requests closure or the study is terminated. Closed and terminated records are scanned and stored electronically for an indefinite period of time. Records regarding an application that was not approved are retained for one year. At the end of one year, the HRAC Manager sends the investigator a letter asking if they plan to resubmit their protocol. If the investigator replies no or does not send a reply, the database records are shown closed and the record is scanned.