

**Department:** UAMS Institutional Review Board  
**Policy Number:** 5.3  
**Section:** Records  
**Effective Date:** July 31, 2002  
**Revision Date:** April 9, 2004

**SUBJECT: Protocols Reviewed**

Each Protocol (whether full review, expedited review, or exempt) is assigned a unique number by ARIA. Each new protocol is maintained in an individual file.

Records for each protocol include:

1. Copies of all research protocols reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects [45CFR46.115; 21CFR56.115(a)(1); 38CFR16.115(a)(1)].
2. Records of continuing review activities [45CFR46.115(a)(b); 21CFR56.115(a)(3)].
3. Emergency use reports [45CFR; 21CFR56.115(a)(4)].
4. Adverse reactions reports [45CFR; 21CFR56.115(a)(1) and (4)] and documentation that the IRB reviews and acknowledges such reports.
5. Copies of all correspondence between the IRB and the investigators [45CFR; 21CFR56.115(a)(4)].
6. Statements of significant new findings provided to subjects, as required by [45CFR; 21CFR50.25 §56.115(a)(7)].