

Department: UAMS Human Research Advisory Committee
Policy Number: 5.3
Section: Records
Effective Date: July 31, 2002
Revision Date: November 18, 2002

SUBJECT: Protocols Reviewed

Each Protocol (whether full review, expedited review, or exempt) is assigned a unique number by the HRAC Manager. Numbers are assigned chronologically and each new protocol is maintained in an individual file and then filed numerically.

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 [21CFR56.115(a)(1); 38 CFR16.115(a)(1); 45CFR46.115]
2. Records of continuing review activities [21 45CFR46.115(a)(b)]
3. Emergency use reports [21CFR56.115(a)(4); 45CFR]
4. Adverse reactions reports [21CFR56.115(a)(1) and (4); 45CFR] and documentation that the HRAC reviews such reports
5. Copies of all correspondence between the IRB and the investigators [21CFR56.115(a)(4); 45CFR]
6. Statements of significant new findings provided to subjects, as required by [21CFR50.25; 21CFR56.115(a)(7); 45CFR]