Department: **UAMS Institutional Review Board**
Policy Number: **5.3**
Section: **Records**
Effective Date: **July 31, 2002**
Revision Dates: **September 22, 2005; February 8, 2005; April 9, 2004; November 18, 2002**

SUBJECT: Individual Protocol Records

Each submission (whether full review, expedited review, exempt, or requests for human research determination) 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; blank Case Reporting Forms (CRFs) or other data research collection forms; progress reports submitted by investigators; and reports of injuries to participants.
2. Records of continuing review activities.
3. Emergency use reports.
4. Adverse reactions reports and documentation that the IRB reviews and acknowledges such reports.
5. Copies of all correspondence between the IRB and the investigators.
6. Copies of all correspondence with other committees relating to the research, including the VA R&D Committee, and institutional specific pharmacies, biosafety and radiation safety committees.
7. Statements of significant new findings provided to participants.