Department: **UAMS Institutional Review Board**
Policy Number: **1.3**
Section: **Principles and Authority**
Effective Date: **July 31, 2002**
Revision Dates: **February 8, 2005; March 5, 2004; November 18, 2002**

SUBJECT: Federalwide Assurances (FWA)

Purpose: The purpose of this policy and procedure is to provide a basic summary of the assurances UAMS made under its Federalwide Assurance regarding Human Subject Research.

References: All IRB Policies and Charter

Policy: All research reviewed by the UAMS IRB, regardless of funding source, will be governed by the principles outlined in the UAMS Federalwide Assurance

UAMS FWA#: FWA00001119

Summary of Assurances (Complete Assurance Terms and FWA Document available and on file with IRB):

1. **Human Subject Research Must be Guided by Ethical Principles as outlined in the Belmont Report.** 1) Respect for Persons – People are autonomous and those with diminished autonomy are entitled to protection; 2) Beneficience – Protection from harm and Minimize Potential Risks and Maximize Potential Benefits; and 3) Justice – Fairness in distributing benefits and burdens in research. (IRB Policy 1.4)
2. **Applicability. To all research, regardless of funding,** which involves engagement in human subject research or receipt of a direct award to conduct human subject research, even when all activities might be carried out by a subcontractor or collaborator. (IRB Policy 1.4 and 2.7)
3. **Compliance with the Federal Policy for the Protection of Human Subjects.** Also known as the Common Rule, 45 CFR 46 and its Subparts A, B, C and D.
4. **Written Procedures**. Written procedures for the following will be maintained.
   1) ensuring prompt reporting (IRB Policy 2.6) to appropriate officials of any: (i) unanticipated problems involving risks to subjects or others, (IRB Policy 10.2) (ii) serious or continuing noncompliance with the Federal Regulations or IRB requirements (IRB Policy 12.4), and (iii) suspension or termination of IRB approval. (IRB Policy 7.9);
   2) Verification by someone other than the researcher whether proposed human subject research activities qualify for exemption (IRB Policies 1.4 and 7.3);
   3) Conducting IRB initial and continuing review (not less than once per year), approving research, and reporting IRB findings to the investigator and the Institution (IRB Policies 7.4 – 7.6);
   4) Determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB review (IRB Policy 7.6); and

5) Ensuring that changes in approved research protocols are reported promptly and are not initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subject (IRB Policy 8.1).

5. **Responsibilities and Scope of IRB(s).** All human subject research, except as meets the DHHS exempt categories, will be reviewed, prospectively approved, and subject to continuing oversight and review at least annually by the designated IRB(s). The IRB(s) will have authority to approve, require modifications in, or disapprove the covered human subject research. (IRB Policy 1.2)
6. **Informed Consent Requirements.** Except for research exempted or waived in accordance with Sections 101(b) or 101(i) of the Common Rule, informed consent will be: a) sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Section 116 of the Common Rule; b) appropriately documented, in accordance with, and to the extent required by Section 117 of the Common Rule. (IRB Policies 15.1 – 15.4)
7. **Requirement for Assurances for Collaborating Institutions/Investigators.** All institutions and investigators engaged in its human subject research must operate under an appropriate OHRP or other federally-approved Assurance for the protection of human subjects. (IRB Policies 2.3 and 2.7)
8. **Written Agreements with Non-Affiliated Investigators. In**dependent investigators who are not employees will be governed under a formal, written agreement of commitment to relevant human subject protection policies and IRB oversight. (IRB Policies 2.3 and 2.7)
9. **Institutional Support for the IRB(s).** UAMS will provide the IRB(s) that it operates with resources and professional and support staff sufficient to carry out their responsibilities under the Assurance effectively. (Charter and IRB Policy 1.7)
10. **Compliance with the Terms of Assurance.** The Institution will follow items above and will ensure that (a) the IRB(s) designated under the Assurance comply with these terms; and (b) the IRB(s) possesses appropriate knowledge of the local research context for all research covered under the Assurance. (All IRB Policies.)
11. **Assurance Training.** The Institutional officials associated with research have completed the OHRP Assurance Training Modules or comparable training that includes the content of these assurances. (IRB Policies 10.1 and 12.1)
12. **Educational Training** Educational training and oversight mechanisms will be required to ensure that research investigators, IRB members and staff, and other appropriate personnel maintain continuing knowledge of, and comply with, relevant ethical principles, relevant Federal Regulations, OHRP guidance, other applicable guidance, state and local laws, and institutional policies for the protection of human subjects. (IRB Policies 10.1 and 12.1)
13. **Renewal of Assurance** All information provided under this Assurance will be updated at least every 36 months (3 years).