Department: UAMS Institutional Review Board

Policy Number: 1.2

Section: Principles and Authority

Effective Date: July 31, 2002

Revision Date: November 18, 2002; March 5, 2004; February 8, 2005;

January 24, 2011; August 7, 2015; February 15, 2016;

June 5, 2020; September 15, 2023

SUBJECT: Authority of the UAMS Institutional Review Board

POLICY

As outlined in the UAMS Human Research Protection Program Plan, all human subject research must undergo review by an organizationally designated IRB. Unless the UAMS IRB cedes its oversight of research to another IRB in accordance with UAMS IRB Policy 2.3, the UAMS IRB shall be the IRB of record for research under its purview.

PROCEDURE

- A. As outlined in the UAMS Human Research Protections Program Plan, the organizationally designated IRB overseeing research has the authority to:
 - 1. Approve, disapprove, or require modifications of all Human Subject Research activities;
 - 2. Require progress reports from the investigators and oversee the conduct of the studies;
 - 3. Suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that had been associated with unexpected serious harm to subjects.
 - 4. Reopen terminated/closed protocols;
 - 5. Observe or have a third party observe the consent process and the conduct of research
- B. In order to approve non-exempt Human Subject Research, the IRB shall determine that all of requirements outlined in IRB Policy 7.1 are satisfied.
- C. Exempt status research also must be submitted to and reviewed by the UAMS IRB, as described in UAMS IRB policy 7.3.
- D. No Human Research project may begin until IRB approval has been received. Human Research approved by the IRB may be subject to further review by other institutional committees or officials. The institution where the research will be conducted retains the right to disapprove any research covered by these policies. However, an institution may not approve any Human Subject Research that the UAMS IRB has disapproved or declined.

REFERENCES

45 CFR 46 21 CFR 56

AAHRPP Element I.1.C

AAHRPP Tip Sheet 12, IRB or EC Authority or Independence

UAMS IRB Policy 2.3, Use of Central IRBs

UAMS IRB Policy 7.1, Criteria for Institutional Review Board Approval of Research

UAMS IRB Policy 7.3, Exempt Categories of Research