Department: **UAMS Institutional Review Board**
Policy Number: **1.1**
Section: **Principles and Authority**
Effective Date: **July 31, 2002**
Revision Date: **November 18, 2002; March 5, 2004; February 8, 2005; January 24, 2011; August 6, 2015; February 15, 2016; June 5, 2020; November 17, 2020**

SUBJECT: Principles Governing the Committee

POLICY
All human subject research conducted by the University of Arkansas for Medical Sciences (UAMS), its staff, employees, faculty, students and any institution or individual using the UAMS IRB, is guided by the ethical principles set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the "Belmont Report") .

The three basic principles relevant to the protection of human subjects in biomedical and behavioral research as set forth in the Belmont Report are:

- Respect for Persons: recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy;
- Beneficence: obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm; and
- Justice: fairness in the distribution of research benefits and burdens.

Clinical trials subject to the ICH-GCP(E6) guidelines should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with good clinical practice and the applicable regulatory requirements.

PROCEDURE
A. The IRB operates under a Federalwide Assurance (FWA) in which it agrees to uphold the ethical principles of the Belmont Report and to apply 45 CFR 46 and its Subparts to all federally funded, supported or regulated human subject research. Equivalent protections shall apply to all human subject research that is not federally funded, supported, or regulated. In addition, the IRB operates according to state and institutional regulations and policies.

B. The IRB has and will follow written policies and procedures for:

1. Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution
2. Determining which projects require review more than annually and which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review.
3. Ensuring prompt reporting to the IRB of changes in research activity
4. Ensuring changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except to eliminate apparent immediate hazards to the human subjects.

C. The IRB's written policies and procedures shall be posted on the IRB's publicly available website.

D. For the IRB to meet its ethical obligations for review and to remain free from undue influence, all IRB proceedings must remain confidential.

1. Access to the IRB e-system , protocols provided for review or consultation, and attendance at IRB

meetings will potentially provide information concerning research ideas, confidential information of companies, pre-marketing data and many other kinds of confidential and sensitive personal and business materials.

2. Access to this information is for IRB decision making purposes only, and use of such information for any other purpose would be a violation of the confidentiality agreement previously signed and the legal and ethical principles by which the University of Arkansas is bound.

3. Information about IRB discussions, meetings, documents and decisions shall not be shared outside approved forms of communication (e.g. IRB letters documenting decisions; communications from the IRB chair or staff, reports to the institution or federal agencies in accordance with relevant policies and regulations.)

4. The IRB Director, IRB Chair, and the Vice Chancellor for Research and Innovation is to be notified of any individual (i.e. colleague, media representative) attempting to obtain information about specific IRB proceedings.

5. Any media-related queries shall be directed to the UAMS Office of Communications and Marketing.

REFERENCES

AAHRPP Elements I.1.D and III.2.A
The Belmont Report
45 CFR 46.108(a)(3) and (a)(4)
21 CFR 56.108(a) and (b)
UAMS Human Research Protection Program Plan