Department: **UAMS Institutional Review Board**
Policy Number: **1.4**
Section: **Principles and Authority**
Effective Date: **July 31, 2002**
Revision Date: **March 5, 2004**

SUBJECT: Studies Requiring Review

The IRB reviews research involving human subjects, regardless of sponsorship, for, but not limited to, the following institutions:

University of Arkansas for Medical Sciences (UAMS)
Central Arkansas Radiation Therapy Institute (CARTI)
Arkansas Children's Hospital (ACH)
Arkansas Children's Hospital Research Institute (ACHRI)
Central Arkansas Veteran's Healthcare System (CAVHS)
Arkansas Department of Health (ADH)
Arkansas State Hospital (ASH)
National Center for Toxicological Research (NCTR)

Research is considered associated with an institution if one or more of the following apply:

1. The research is sponsored by any of the above institutions or;

2. The research is conducted by or under the direction of any employee, faculty, staff, student or agent of the above institutions;

3. The research involves the use of non-public information maintained by one of the above institutions to identify or contact human research subjects or prospective subjects; or

4. The research is conducted in accordance with an assurance filed with the Office for Human Research Protections in which the UAMS IRB is designated as the IRB of record.

Normally, the IRB will agree to serve as the institutional review board for other institutions only if a staff member or faculty appointee of UAMS, ACH, CAVHS, ADH, or ASH is involved as a principal investigator or sub-investigator. However, the IRB will serve any state agency for a specific protocol by written request. Appropriate agreements between the UAMS and the requesting institution will be required. If the study involves the engagement of the institution's staff, then the institution must file a Federalwide Assurance (FWA) with the Federal Office of Human Research Protections and establish an agreement with the IRB for the specific project (45CFR46.103).

All research or clinical investigations involving human subjects, and all other activities that even in part involve such research, regardless of sponsorship, must be reviewed and approved by the IRB. No intervention or interaction with human subjects in research, including recruitment, may begin until the IRB has reviewed and approved the research protocol [45CFR46.101; 21CFR56.103(a); 45CFR].

Specific determinations as to the definition of "research," "clinical investigation," or "human subjects," and their implications for the jurisdiction of the IRB under the University of Arkansas for Medical Sciences policy are made by the IRB.

Research. Research is a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalized knowledge [45CFR46.102(d)]. Examples of research activity include clinical trials, surveys, interviews, behavioral investigations, retrospective reviews of medical information, experiments with blood and tissue, and demonstration or service programs. The Food and Drug

Administration (FDA) includes under the definition of reviewable research, the use of an FDA regulated product outside of its marketed use in the practice of medicine for the purposes of contributing to generalizable knowledge. For example, the use of a cardiac medicine for the treatment of neurogenic pain could be considered experimental and subject to IRB review.

A proposed activity is considered research, if any one of the criteria listed below is met:

1. Is the proposed activity intended for release to the scientific community as a contribution to knowledge?

2. Does the proposed activity involve an interaction or intervention with a living person that occurs solely for the purpose of the project?

3. Will the proposed activity collect identifiable, private data/information in a form that can be associated with the individual?

4. Is the proposed activity portrayed (explicitly or implicitly) by university students, faculty, or staff as “research” or “experimental” investigation?

5. Is the proposed activity intended to fulfill requirements for a master’s thesis, doctoral dissertation, or other research requirement?

Human subject. A human subject is defined as a living individual about whom a professional or student investigator conducting research obtains data through intervention or interaction with the individual or collects identifiable private information [45CFR46.102(f)]. A human subject is also defined as an individual who is or becomes a participant in research, either as a recipient of a test article or as a control. A subject may be a healthy human or a patient [21CFR56.102(e); 45CFR].

Clinical investigation. The Food and Drug Administration (FDA) regulates clinical investigations that use a test articles on one or more human subjects. The FDA also regulates clinical investigations that support applications for research or marketing permits for products. Products regulated include food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products.