Department: UAMS Institutional Review Board

Policy Number: 14.3

Section: Recruitment Practices

Effective Date: July 31, 2002 Revision Date: June 24, 2004

Subject: Advertising for Study Subjects

The UAMS IRB is responsible for ensuring the equitable selection of research subjects [45 CFR 46 111 (a) (3)]. In fulfilling this responsibility, the UAMS IRB will review the methods that investigators use to recruit subjects. One method of recruiting subjects is through advertisements.

Advertising for research subjects is not in and of itself an objectionable practice. However, when advertising is to be used, the UAMS IRB will review the information contained in the advertisement, and the mode of its communication, to determine that the procedure for recruiting subjects affords adequate protection.

Advertisements used to recruit subjects should be seen as an extension of the informed consent and subject selection processes. Therefore, the UAMS IRB will review all advertisements to ensure that the information is not misleading to subjects, especially when a study will involve persons with acute or severe physical or mental illness or persons who are economically or educationally disadvantaged. The UAMS IRB is responsible for assuring that appropriate safeguards exist to protect the rights and welfare of research subjects

Generally, any advertisement; print, electronic or other media, to recruit subjects should be limited to:

- 1. The name and address of the clinical investigator and/or the research facility
- 2. The purpose of the research
- 3. The eligibility criteria that will be used to admit subjects to the study
- 4. A straightforward and truthful description of the benefits or burdens (*e.g.*, reimbursements, no cost treatment, placebo control) to the subject for participating in the study
- 5. The time or other commitment required from the subject
- 6. The location of the research and the person to contact for further information

No claims should be made, either explicitly or implicitly, that a drug or device is safe or effective for the purposes under investigation, or that the drug or device is in any way equivalent or superior to any other drug or device. Such representation would also be a violation of the FDAs regulations concerning the promotion of investigational drugs and of investigational devices.

See FDA information sheets updated 9/98 on Recruiting Study Subjects.