Department: **UAMS Institutional Review Board**
Policy Number: **14.3**
Section: **Recruitment Practices**
Effective Date: **July 31, 2002;**
Revision Date: **October 10, 2002; June 24, 2004; February 8, 2005; January 24, 2011; August 19, 2015; February 15, 2016; July 21, 2020**

SUBJECT: Subject Recruitment Materials

POLICY
As part of its responsibility to ensure equitable research subject selection with appropriate safeguards to protect participants' rights and welfare, the UAMS IRB will review the methods and materials that investigators use to recruit subjects.

DEFINITION
Advertisements – For the purpose of this policy, advertisements encompasses any publicly accessible recruitment material, including but not limited to newspaper, television, or radio ads; posted flyers; brochures; social media postings, and online clinical trial listings.

PROCEDURE

A. Investigators and the IRB shall be aware that advertisements are an extension of the informed consent and subject selection processes.

B. All advertisements must be submitted to the IRB for review before use.

    1. A posting on a federally mandated website that contains only the basic descriptive information required by that website shall not be considered advertising, and such a posting does not require separate IRB review.

C. In its review, the IRB will verify the information is not misleading to subjects, especially when a study will involve persons with acute or severe physical or mental illness, persons who are economically or educationally disadvantaged, or other potentially vulnerable populations.

D. Advertisements may also be subject to communication and marketing policies and practices of an Institution. If changes are requested under those policies, the revised advertisement may not be used until the IRB has approved the modification.

E. Investigators wishing to use advertisements as part of their recruitment processes must submit the following items/information to the IRB for review:

    1. The information contained in the advertisement.
    2. The advertisement method
    3. Copies of printed advertisements. Draft copies may be submitted with initial submission. However, the IRB may require a copy of the final product before use, if the final version differs significantly from the draft reviewed.
    4. The final transcript for audio or video advertisements.

F. Advertisement content should be limited to:

1. The researcher's or research team's name and contact information
2. The purpose of the research, specifically stating that it is research
3. The eligibility criteria, in summary form, that will be used to admit subjects to the study
4. A brief description of possible benefits 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
7. Payment or compensation may be mentioned, but must not be overly emphasized.

G. Advertisements may not:

1. Be misleading or coercive, either in wording or visual effects
2. Promise a favorable outcome
3. Promise "free medical treatment" to indicate there is no extra cost associated with study participation
4. Imply any benefits beyond what is outlined in the consent and protocol
5. Use terms such as "New Treatment," "New Drug," or "New Medication" without explaining that the test article is investigational
6. Emphasize amount of payment for participation
7. Make claims, 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.
8. Provide coupons for discounts on purchase price of product, or other inducements to purchase product, once it has been approved for marketing.

H. The IRB shall review advertisements for compliance with this policy to ensure subject selection is equitable and that advertisements are accurate and do not unduly influence a decision about participation.

REFERENCES

AAHRPP Elements II.3.C, III.1.E
OHRP *Guidance on Institutional Review Board Review of Clinical Trial Websites*
FDA Information Sheet *Recruiting Study Subjects*