

Approved by IRB Executive Committee: August 13, 2008
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AAHRPP Element II.5.B.

POLICY

The IRB will evaluate recruitment processes, including advertisements to ensure an equitable selection of participants. Additionally, the IRB considers advertising or soliciting for study participants to be the start of the informed consent process. Therefore, the IRB reviews proposed recruitment processes and advertisements to ensure that they do not violate the regulatory requirements of consent. Advertisements must be included as part of the initial study application.

The Investigator must obtain IRB approval prior to the use of all television, radio, print advertisements, e-mail solicitations, letters, websites, and other recruitment methods and materials intended for the recruitment of prospective research participants.

When advertisements are to be taped for broadcast, the IRB must review the final audio or video advertisement prior to approval. The IRB may review and approve the script of an advertisement prior to taping to preclude re-taping because of inappropriate wording. The review of the final recorded message prepared from the IRB approved script may be conducted via expedited procedures.

The IRB reviews "direct advertising for research participants" which is defined as advertising that is intended to be seen or heard by prospective participants to solicit their participation in a study. This includes any sponsor-provided advertisements or Investigator-drafted advertisements.

Advertisements must be submitted to the IRB in their final form in order to receive IRB final approval for use.

The IRB adheres to the advertising guidelines posted on the IRB website (see Investigator Guidance Series: Recruitment Methods and Advertisements).

PROCEDURES

1. Investigators must describe the plan for recruitment and provide any advertising materials in the new study application.
2. IRB review and approval for additional advertisements or changes in currently approved recruitment methods or advertisements must be submitted in the form of an amendment to the IRB for approval prior to implementation.
3. The IRB Chair or designee may review and approve advertisements or changes to advertisements by expedited means when they are easily compared to the consent document. However, the Chair or designee may refer the advertisement to the full, convened IRB if the IRB reviewer has doubts or other complicating issues are involved.