FRIENDS RESEARCH INSTITUTE, INC.
1040 Park Avenue, Suite 103
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Subject: Initial Review Considerations
Division: IRB
Date: September 1, 2012

IRB Policy 107.2: ADVERTISEMENTS

Policy

All direct advertisements (posters, flyers, brochures, etc.), media advertisements (newspaper, tv, radio, etc.), scripts, and letters used for the recruitment of subjects must be reviewed and approved by the IRB prior to their use.

Guidelines

Advertisement to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest. Advertisements should be very clear that research participation is what is being solicited.

Advertisements must not:

- Characterize monetary compensation as a benefit or be emphasized by using bold type or a larger font.
- State or imply a certainty of a favorable outcome or other benefits beyond what is outlined in the consent documents and protocol.
- Include any exculpatory language that appears to waive any rights of the prospective subjects or indicate that the investigator cannot be held liable or at fault for any research-related event.
- Make any claims, either explicitly or implicitly that the drug, biologic, device or other research procedures are safe or effective for the purposes under investigation, or that the test article or other research procedures are known to be equivalent or superior to any other drug, biologic, device, or procedure.
- Use terms such as “new treatment,” “new medication” or “new drug”
- Promise “free medical treatment” when the intent is only to say subjects would not charged for taking part in the study
- Mislead individuals in the purpose of the research

Suggested Elements

The following elements are suggested for inclusion in advertisements to aid prospective subjects in determining their eligibility and interest in the study. The IRB does not require that each of these elements be included in the advertisement.

- Name and address of the investigator and/or research facility
- Condition under study and/or the purpose of the research
- In summary form, the criteria that will be used to determine eligibility
- A brief list of procedures involved
- A brief list of significant risks, if any
- A brief list of participation benefits, if any
- Compensation/reimbursement, if any
- Time or other commitment required (number of visits, total duration including follow-up visits, etc.)
- The location of the research
- Contact person for further information
- Whether or not the investigational agent is FDA-approved for the given indication
- Indication that the study subject may receive a placebo

Responsibility

Researchers should provide recruitment materials as part of the initial study submission for IRB review. If recruitment materials will not be used, an explanation of how subjects will be recruited must be provided prior to IRB approval. The IRB will review advertisements at a convened meeting or via expedited review, when appropriate.

Applicable Regulations and Guidelines

FDA Information Sheet, Recruiting Study Subjects (1998)