Recruitment and Selection of Participants

Research Advertising Materials Guidelines

It is the policy of both the ETSU IRB and the ETSU/VA IRB that non-coercive methods must be used by investigators to recruit subjects. Procedures for enrolling subjects and compensation for subjects must minimize the possibility of coercion or undue influence. Direct advertising for research participants is considered to be the start of the informed consent and participant selection process.

For VA Studies: Non-veterans may be entered into VA approved research studies only when there are insufficient veterans available to complete the study or when the researcher can present a compelling argument to the IRB for the inclusion (e.g., survey of VA employees; study of active duty military; study involving veterans' family members) and the research is relevant to the care of veterans or active duty military personnel. All regulations pertaining to the participation of veterans as research subjects pertain to non-veterans subjects enrolled in VA-approved research.

In VA studies, during the recruitment process, researchers must make initial contacts with veterans in person and/or by letter prior to any telephone contact, unless there is written documentation that the participant is willing to be contacted by phone about the study in question or a specific kind of research (e.g. if the prospective participant has diabetes, the participant may indicate a desire to be notified of any diabetes-related research studies.) The initial contact must provide a telephone number or other means that veterans can use to verify the study constitutes VA research. (One source of information about clinical trials is http://www.clinicaltrials.gov).

For VA studies, researchers must ensure that in later contact, the research team begins telephone calls to the participant by referring to previous contacts and, when applicable, the information provided in the consent document.

In addition, for VA studies, researchers must ensure that the scope of telephone contacts with the participant is limited to topics outlined in IRB-approved protocols and consent documents. In these contacts, researchers must not request social security numbers.

All advertisements, questionnaires, surveys, testing forms and/or introduction letters associated with the study and intended for subject use or view must be submitted to the IRB for approval.

Advertisements may not include the following:

⇒ The ad cannot state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.

⇒ The ad cannot make claims, either explicitly or implicitly, that the drug, biologic, or device is safe or effective for the purposes under investigation.
⇒ The ad cannot make claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic, or device.

⇒ The ad cannot use terms such as “new treatment,” “new medication,” or “new drug” without explaining that the test article is investigational.

⇒ The ad cannot promise free medical treatment when the intent is only to say participants will not be charged for taking part in the investigation.

⇒ The ad cannot include any exculpatory language

Advertisements to recruit participants should be limited to the information that prospective participants need to determine their eligibility and interest. When appropriately worded, the following items should be included in advertisements:

⇒ name and address of the Investigator;

⇒ purpose of the research;

⇒ criteria to be used to determine eligibility in a summary form;

⇒ location of the research (e.g., Vanderbilt);

⇒ a brief description of the study activities, when appropriate;

⇒ potential benefits, if any; and

⇒ name and phone number of the person to contact for further information.

Advertisements may also include a statement that participants will be paid, but should not emphasize the payment of the amount to be paid, by such means as larger or bold type.

The material should clearly state, “This is a Research Study,” or, when appropriate, “This Research Study involves the use of an Investigational Drug or Device.

IRB Review

The IRB Chair, or his/her designee, may approve advertisements that are easily compared to the approved Informed Consent document through the expedited mechanism. If the reviewer has any doubt or there are any complicating issues involved, the convened board should review the advertising.

The IRB will review the information contained in the advertisement and its method of communication to determine that participants are not coerced.

The IRB must review the final copy of all advertisements, including print advertisements and audio/video tape for broadcast. If an advertisement is to be broadcast, the IRB may
review and approve the wording prior to taping. The approval of the final taped message prepared from the IRB-approved text can be given through expedited review.

**Payment of Participants**

Payment to research participants is not considered a benefit but a recruitment incentive. The amount and schedule of all payments should be described in the IRB application at the time of initial review, including the amount of payment, and the proposed method and timing of disbursement. The IRB must review this information to assure that the amount, method, or timing of payment are not coercive and do not present undue influence. Credit for payment should accrue as the study progresses and not be contingent upon the participant completing the entire study. While the entire payment should not be dependent upon completion of the entire study, payment of a small proportion as an incentive for completion is acceptable, providing that such incentive is not coercive. The IRB should determine that the amount paid as a bonus for completion is reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.

Procedures for prorating payment should the participant withdraw should be considered when submitting the IRB application and informed consent documents. Unless it creates undue inconvenience or a coercive practice, payment to participants who withdraw from the study may be paid at the time the study would have been completed had they not withdrawn. For example, in a study lasting only a few days, it may be permissible to allow a single payment date at the end of the study, even to participants who withdraw before completion.

All information concerning payment, including the amount and schedule of payment(s), should be set forth in the informed consent document and the narrative.

Compensation for participation in a trial offered by a sponsor may not include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

**For VA Studies:** VA policy prohibits paying human subjects to participate in research when the research is integrated with a patient’s medical care and when it makes no special demands on the patient beyond those of usual medical care.

Payment may be permitted, with IRB approval, in specific circumstances outlined in IRB Policies.