



Stratton VA Medical Center IRB Standard Operating Procedure: Advertising and Recruiting of Subjects

ADVERTISING FOR SUBJECTS

This facility considers direct advertising for study subjects to be the start of the informed consent and subject selection process. All advertisements must be reviewed and approved by the IRB as part of the package for initial review. If, at a later date, the investigator decides to advertise for subjects, the advertisement will be submitted for IRB review.

Once approved, the R&D Office date stamps the advertisement as approved. To recruit subjects, the investigator must use those advertisements that have a stamp of approval.

The IRB reviews the information contained in the final advertisement, whether printed or audio/video taped, to determine that the procedure for recruiting subjects is not coercive and does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.

Advertisements cannot be misleading or contain exculpatory language. No claims should be made, either explicitly or implicitly, that the drug, biologic, or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device. Advertisements should not promise “free medical treatment”, when the intent is only to say that subjects will not be charged for taking part in the investigation.

Any press release related to the research must first be submitted to the Stratton VA Public Relations office for approval. The advertising, with the approval letter from the Public Relations Office, should be submitted to the Research Office for review and approval by the IRB.

Any advertisement to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest. When appropriately worded, the following items may be included:

- (1) The name and address of the clinical investigator and/or research facility

- (2) The condition under study and/or the purpose of the research.
- (3) In summary form, the criteria that will be used to determine eligibility for the study
- (4) The time or other commitment required of the subjects.
- (5) The location of the research and the person or office to contact for further information

(6) Clearly states or illustrates:

1. This is research and not treatment
2. If an investigational drug or device is involved, the advertisement cannot contain statements that are inconsistent with FDA labeling
3. If an investigational drug or device is involved, the advertisement cannot contain statements that include the terms “new treatment,” “new medication,” or “new drug” and without explaining that it is investigational
4. No emphasis placed on amount of payment (e.g. using bold print regarding payment involved)

Recruitment procedures should be designed to assure that informed consent is given freely and to avoid coercion or undue influence. To evaluate this, the IRB should know: from what population the subjects will be drawn; what incentives are being offered; and the conditions under which the offer will be made.

EQUITABLE SELECTION OF SUBJECTS

To approve research, the IRB must determine that the selection of subjects is equitable. This is the concept of “Justice” from the Belmont Report. In making this determination, the IRB should evaluate the purposes of the research, the research setting, and the inclusion/exclusion criteria.

The IRB should be especially cognizant of the problems of research involving vulnerable subject populations (mentally disabled, pregnant women, fetuses, prisoners, economically disadvantages, educationally disadvantaged). Generally, a population that stands no chance of benefiting from the research should not be selected to assume the risk.

In addition, the IRB should be cognizant of the scientific and ethical justification for excluding classes of persons who might benefit from the research.

The IRB should be mindful of the importance of including members of minority groups in research, particularly when the research holds out the prospect of benefit to individual subjects or the groups to which they belong. The IRB should also ensure that subjects are not taken from one group of people because it is convenient.

The IRB should be mindful of the desirability of including both women and men as research subjects and should not arbitrarily exclude the participation of persons of reproductive age. Exclusion of such persons must be fully justified and based on sound scientific rationale.

(Note: With regard to children, it is VA policy that children cannot be included in VA-approved research unless Chief Research and Development Officer has granted a waiver. See VA Directive 2001-028 dated April 27, 2001.)

At the time of initial review and continuing review, the IRB considers subject selection criteria to ensure that subject selection criteria are appropriate to the purposes of research and consistent with VA and DHHS policies.

This facility prohibits compensation to investigators, physicians and other health care providers for identifying/enrolling subjects.

For Department of Defense-sponsored research there are additional safeguards for research conducted with international populations.

The IRB must verify that:

- The organization or researcher has permission to conduct research in that country by certification, or local ethics review.
- The researchers have a plan to assure that all local laws, regulations, customs, and practices will be followed.
- Additional safeguards might not be applicable to social-behavioral research involving no more than minimal risk.

For Department of Defense-sponsored research involving U.S. military personnel:

- The IRB must verify that the following additional protections for military research subjects are stipulated to in a protocol, in order to minimize undue influence,:
 - Officers cannot influence the decision of their subordinates.
 - Officers and senior non-commissioned officers cannot be present at the time of recruitment.
 - Officers and senior non-commissioned officers have a separate opportunity to participate.
 - When recruitment involves a percentage of a unit, an independent ombudsman must be present.

PAYMENT TO SUBJECTS

(Adapted from VA M3, Part 1, Chapter 9.13)

The Stratton VA IRB shall review any proposed payments to research subjects associated with the research that they oversee. Payments to research subjects may not be of such an amount as to result in coercion or undue influence on the subject's decision to participate. Payments may not be provided to subjects on a schedule that results in coercion or undue influence on the subject's decision to continue participation. For example, payment may not be withheld as a condition of the subject completing the research. If the subject withdraws early, payment must be prorated to reflect the time and inconvenience of the subjects participation up to that point.

VA policy prohibits paying patients to participate in research:

- When the research is an integral part of a patient's medical care and when it makes no special demands on the patient beyond those of medical care.
- Compensation for participation in a trial offered by a sponsor to include a coupon good for a discount on the purchase price of the product once it had been approved for marketing.
- Payment in exchange for referrals of prospective participants ("finder's fees").
- Payments to the organization or research staff designed to accelerate recruitment that were tied to the rate or timing of enrollment ("bonus payments").

Payment may be permitted, with the approval of the IRB, in the following circumstances:

- *There is no direct subject benefit* - When the direct intention of the study to be performed is not to enhance the diagnosis or treatment of the medical condition for which the volunteer subject is being treated, and when the standard of practice of affiliated, non-VA institutions is to pay subjects in this situation.
- *Others being paid* - In multi-institution studies, where subjects at a collaborating non-VA institution are to be paid for the same participation in the same study at the same rate proposed.
- *Comparable situations* - In other comparable situations in which in the opinion of the IRB, payment of subject volunteers is appropriate.
- *Payments not coercive* - Payment must not be coercive, in the sense of persuading subjects to take risks they might not otherwise be willing to take.

- For Department of Defense-sponsored research involving U.S. military personnel, there are limitations on dual compensation:
 - This prohibits an individual from receiving pay from more than one position for more than 40 hours of work in one calendar week.
 - This includes temporary, part-time and intermittent appointments.

Procedure

Principal Investigators who wish to pay research subjects must indicate in their proposal the justification for such payment with reference to the criteria listed and, in addition, must:

1. Substantiate that the proposed payments are reasonable and commensurate with the expected contributions of the subject;
2. State the terms of the subject participation agreement and the amount and schedule of payment in the VA informed consent document (Form 10-1086); and
3. Substantiate that subject payments are fair and appropriate, and that they do not constitute (or appear to constitute) undue pressure on the veteran subject to volunteer for the research study; and
4. Any credit for payment should accrue as the study progresses and not be contingent upon the subject completing the entire study.

The IRB will review all proposals involving the payment of subjects (in excess of reimbursement for travel) in light of the above policies. The deliberations will be recorded in the IRB minutes.

COMPENSATION FOR ENROLLING SUBJECTS

The FDA requires a sponsor in a marketing application of any drug, device, or biologic to submit certain information on financial interests and arrangements of clinical investigators conducting studies to FDA. This includes any relationship between the study outcome and the value of the compensation made to the investigator.

This facility requires that Principal Investigators disclose any financial interests or arrangements of concern to the IRB. The Stratton VA "Financial Disclosure Form" serves this purpose, and must be completed by the Principal Investigator and on-site co-investigators and submitted with all initial IRB applications.