Harvard Pilgrim Health Care, Inc.
Harvard Pilgrim Health Care Institute, LLC
Office of Sponsored Programs

Policy and Procedure

TITLE: Equitable Selection of Research Participants

PURPOSE:

To describe the policy and procedure for review by the Institutional Review Board (IRB) of:

- proposed human research subject recruitment methods, advertising materials, and payment arrangements, and
- whether such selection is equitable and such arrangements are fair, accurate, and appropriate.

PERSONS AFFECTED:

This policy & procedure (P/P) applies to all Harvard Pilgrim Health Care, Inc. (HPHC) and Harvard Pilgrim Health Care Institute, LLC (HPHCI) (collectively, HPHC/I) personnel engaged in research, teaching or research administration activities in support of the charitable and educational mission of HPHC.

POLICY:

The investigators must ensure and the IRB shall evaluate that recruitment processes, advertisements, and payment arrangements affect the equitable selection of subjects. In order to ensure that the selection of human subjects is equitable, the IRB considers the purpose of the research, the setting in which the research will be conducted, and is particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. During review, the IRB must determine whether the procedures for recruiting and compensating subjects are fair and equitable and provide safeguards for preventing coercion and undue influence. This criterion must be used to approve research under the expedited procedure and to approve research for initial review, continuing review, and review of modifications or changes.

DEFINITIONS:

Finder's Fee or Referral: a payment from the investigator or sponsor to a person who refers a prospective subject.

Recruitment Bonus: a payment from the sponsor to the investigator or organization based on the rate of timing of recruitment (e.g., additional payment if a certain number of subjects are enrolled after a certain period of time or if the site has the highest enrollment at the end of this period).

PROCEDURE:

1. The investigator must include in the Initial Application and other submission documents the following information which the IRB shall consider in order to assess whether the selection of human subjects is fair and equitable:
    a. the purpose of the research;
    b. the setting in which the research will be conducted;
    c. whether prospective subjects are members of a vulnerable population or may otherwise be susceptible to coercion or undue influence;
    d. inclusion and exclusion criteria;
    e. subject recruitment and enrollment procedures, including advertisement and compensation; and
    f. the amount and timing of payments to subjects.

2. The IRB shall review proposed recruitment methods, advertising materials, and payment arrangements as part of its review of the consent process.

3. When advertising is used, the IRB must review the information contained in the advertisement, the mode of its communication, and the final copy of the printed or audio-taped advertisement in order 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. The IRB has the authority to approve whether compensation information shall be included in the advertisement. Any advertisement to recruit subjects shall be limited to the information the prospective subjects will need to determine their eligibility and interest.

4. Advertising materials shall not include:
    a. claims, either explicit or implicit, that the drug, biologic, device or other type of intervention is safe or effective for the purposes under investigation;
    b. stated or implied statements of favorable outcomes or other benefits beyond what is outlined in the consent documents and the protocol;
    c. claims, either explicit or implicit, that the test article is known to be equivalent or superior to any other drug, biologic, device or intervention;
    d. terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational, meaning non-FDA approved;
    e. exculpatory language;
    f. claims, either explicit or implicit, about the drug, biologic, or device under investigation that are inconsistent with FDA labeling;
    g. promises of 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 has been approved for marketing;
    h. promises of "free medical treatment," when the intent is only to say that subjects will not

be charged for taking part in the investigation; or

i. an emphasis on the payment or the amount to be paid, by such means as larger or bold type.

5. Content of advertisements must be limited to the information prospective subjects need to determine their eligibility and interest, such as:

- the name and address of the investigator or research facility;
- the purpose of the research or the condition under study;
- in summary form, the criteria that will be used to determine eligibility for the study;
- a brief list of benefits to subjects, if any;
- the time and other commitment required of the subjects; and
- the location of the research and the person or office to contact for further information.

6. The IRB shall determine whether the method of advertisement poses any risks to potential subjects. This includes, but is not limited to posting in hard copy fliers and handouts or online. Any issues about the appropriateness of posting on websites shall be referred to the Research Integrity & Compliance Officer for review.

7. Contact by the investigator or any member of the research team by physicians, agencies, or others in order to recruit subjects must also be approved by the IRB prior to implementation.

8. No investigator may give an indication that an employee is required or shall consent to participate as a research subject. No coercion or inference that employment status could be affected with respect to participation in research activities is allowed.

9. Payment to research subjects for participation in studies is considered compensation for time and inconvenience rather than a benefit to subjects. The amount and schedule of all payments must be presented to the IRB at the time of initial review. The IRB shall review both the amount of payment and the proposed method and timing of disbursement to determine that neither are coercive nor present undue influence.

10. Payment(s) shall be made to the subject as the study progresses and shall not be contingent upon the subject completing the entire study. If, for example, payment is made for each appointment attended, the payment must be made after each appointment. A schedule for the amount to be paid for each activity will not suffice; a timetable for the payments themselves must be submitted, approved, and presented to every subject as part of the Informed Consent process.

11. Any amount paid as a bonus for completion must be reasonable and not so large as to unduly induce subjects to stay in the study when they would have otherwise withdrawn.

12. The Informed Consent form must clearly establish how the subject is to be paid, (i.e. cash, check, gift certificate, etc.). A subject must sign a receipt for any cash payment, and this procedure must also be described as part of the Informed Consent process.

13. Any alterations in payment or revisions to the payment schedule must be submitted to the IRB as an amendment prior to implementation. A notice to the subjects informing them of payment changes must be part of this submission.

14. The IRB shall examine payment arrangements to determine that they do not place subjects at risk of coercion or undue influence. In particular, IRBs shall ensure that payment arrangements that include a finders' fee or referral and timing of bonuses are not included. Finders' fees, recruitment bonuses or any form of compensation to individuals (including faculty, staff, students, family members, *etc*.) who identify and/or recruit subjects for participation in a research study is not permitted.

REVISION HISTORY:

Department: OSP - Research Integrity & Compliance	**Title**: Equitable Selection of Research Participants
Effective Date: 01/21/19	**Owner:** Senior Compliance Manager, IRB
Replaces P/P Dated: IRB SOP (02/17)	
Related Documents: Initial Application; Initial Application Data Health Information Only Studies; Reviewer Sheet Initial; Consent and Authorization Checklist and Guidance; Consent Authorization Template	
References: 45 CFR 46.111(a)(3); 45 CFR 46.116; OHRP Guidance on Written Institutional Review Board (IRB) Procedures; 21 CFR 56.111(a)(3); 21 CFR 50.20, 21 CFR 56.111(a)(3); AAHRPP Elements II.3.C. and III.1.E; AAHRPP Tip Sheets 1, 11 and 20	