Issuing Department: Human Subjects Protection Office
Policy Number: 2011-015.0
Policy Title: Recruitment of and Payment to Research Subjects

Purpose

The purpose of this policy is to set forth requirements regarding recruitment of subjects into research studies.

Definitions

See policy 2011-007.0 for definitions of:

Informed Consent Form	IRB Approval	Private Information
Treatment Relationship, Direct	Treating Relationship, Indirect	

Policy

Recruitment of subjects into a study may not begin prior to final IRB approval. The IRB must approve all recruitment methods and material prior to use. The content of recruitment materials and the method for communicating it cannot contain misleading language or tactics that create undue influence or coercion. The IRB will evaluate proposed recruitment methods and materials as part of the standard IRB review process.

Subjects are considered enrolled at the time of signing a consent form. If a separate consent form is used for the initial screening phase of the study, subjects must be informed that they may be withdrawn if it is determined that they do not meet inclusion criteria. The principal investigator is to report subjects who signed a screening consent but did not meet the inclusion criteria as withdrawals from the study at the time of continuation.

Principal investigators are responsible for tracking the ethnicity or race of subjects who are recruited into studies. Investigators should ask subjects to self-identify at the time of consent. If a subject declines to declare, the investigators will be asked assign a race/ethnicity at the time of continuation as part of an overall summary report of enrolled subjects.

Investigators may obtain and use identifiable private information for recruitment purposes only if a treatment relationship exists between the principal or co-investigators and the potential subjects. In a group medical practice it is acceptable for any doctor in the practice to have access to the information. However, a recruitment letter must bear the signature of the physician who has the direct relationship or of all physicians in the group practice.

Advertisements: Advertisements should contain only limited information that still provides enough information to the prospective subject to determine his/her interest and potential eligibility. Visual effects that may create undue influence cannot be used, e.g. placing the word PAID in all capital letters while the rest of the ad is in lower case.

Generally, the elements of any advertisement to recruit subjects should be limited to the elements noted below.

- the name of the principal investigator;

- the department conducting the study;
- the title of the study;
- an accurate description of the condition under study and/or the research purpose e.g. if a placebo is to be used in a drug study, the advertisement should describe the study as a comparison of the drug to the placebo; if investigational products are to be used they must be identified as such and not represented as new treatments;
- in summary form, the eligibility criteria that will be used to admit subjects into the study;
- a straightforward and truthful description of the benefits, if any, to the subject from participating in the study;
- if applicable, a statement that compensation is available or a statement of how much compensation is available and how it will be paid, e.g. "Participants may receive up to $100 paid in equal installments over 4 visits"
- the amount / length of time or other commitment required of the subjects;
- the location of the research and contact information for obtaining additional information;
- the IRB number (it is acceptable to insert the IRB number once it is known without seeking approval via a modification), and
- the date the ad was approved (it is acceptable to insert the approval date once it is known without seeking approval via a modification).

Advertisements **cannot** incorporate elements that:

- state or imply a certainty of favorable outcome or other benefit beyond what is in the informed consent form;
- make claims that the drug, device or biologic is safe or effective for the purpose under investigation;
- make claims that the drug, device or biologic is know to be equivalent or superior to any other drug, device or biologic;
- use terms such as new treatment, new medication or new drug without identifying it as investigational;
- promise free medical treatment when the actuality is that subjects will not be charged for partaking in the study.
- appear to release the institution, sponsor, or investigator from liability

If the study involves the use of FDA regulated products (drugs or devices) no claims can be made, either explicitly or implicitly, that the drug or device is safe or effective for the purposes under investigation, or that the drug or device is in any way equivalent or superior to any other drug or device. Such representation would not only be misleading to subjects but would also be a violation of the FDA's regulations concerning the promotion of investigational drugs and of investigational devices

Advertisement may be reviewed through the expedited review process by the Chair if the content of the ad can be easily compared to the informed consent form. The IRB reserves the right to require full board review of any recruitment material.

The IRB must review and approve the final taped version of any radio or t.v. advertisement. Contingent approval for the ad may be granted based on the script but the final product must be submitted for additional review and approval to ensure consistency with the language / tone presented in the script.

The final approval of taped ads may be granted through the expedited review process by the Chair, Vice Chair or designated experienced IRB member.

Web Postings: IRB review and approval is not required for listings of clinical trials on the internet providing that the listing is limited to providing only basic trial information as listed below. Information pertaining to compensation cannot be listed without IRB review and approval.

- PI name;
- IRB number;
- study title;
- study purpose;
- protocol summary;
- basic eligibility criteria;
- study location;
- contact information

Payment or Incentives Related to Subjects: It is acceptable to offer financial payments or other types of incentives, e.g. gift certificates, to research subjects for participation in a study. However, the value of the payment or incentive(s) cannot create undue inducement for subjects to enroll. Furthermore, the payment structure should not be such that a subject cannot withdraw from a study without forfeiting the entire payment. There are no federal regulations that determine what is an acceptable payment or payment structure and it is therefore judged on a case-by-case basis taking into consideration:

- the types and numbers of procedures to be involved
- the time commitment involved
- the expenses incurred by the subject
- the anticipated discomfort or inconvenience
- the level of risk of the study
- the type of populations likely to be enrolled
- the option of using a tiered approach in which subjects receive payment at various stages of the study.

The principal investigator is responsible for ensuring that funds are available to make the payments as presented within the informed consent document. Payment to subjects who withdraw from a study may be held until such time as the payment would have been made had the subject not withdrawn, unless holding the payment will create an undue inconvenience to the subject or a coercive practice. For example, it may be acceptable to hold payment until the end of the study if the study is only a few weeks long, or to hold payment until the first disbursement would have been made if there is only a few weeks difference between the date the subject withdrew and the date the payment was scheduled to be made. The wishes of the subject should be honored when possible. Compensation offered to potential subjects may not include a coupon for discounts on the purchase price of the product once it is approved for marketing.

Financial Reporting Obligations: The confidentiality of a subject must be respected throughout his/her participation in a study. However, in order to make a payment by check payable to the subject certain information may be required to be recorded on financial records and forwarded to accounts payable for

compliance with state and federal requirements for income reporting. The subject may choose to decline receiving payment if s/he does not want the information reported outside of the study.

The subject should also be informed that 1) if cumulative payments to a subject within a year add up to $600 or more a Form 1099 will be issued by the Health Center and the income will be reported to the IRS.

Alternative Option to Financial Reporting Obligations: If a subject does not want his/her name forwarded to accounts payable for the purpose of generating a check for participation, it is possible to have the check made out to cash.

Procedure

General:
The IRB reviewer will use the reviewer sheet provided by IRB staff as a prompt to consider the method of recruitment, recruitment materials, and payments to subjects for enrollment during the IRB review process.

Checks Payable to Subjects:
The subject should be informed by the person obtaining consent of the following:

- that information will be sent to Accounts Payable, e.g. name, social security or taxpayer identification number, mailing address, and amount paid to the subject.
    - subjects should be given the opportunity to decline payment
- the obligation to report to the IRS earnings from participation in research studies that exceed $599 in a calendar year.

Checks Made Payable to Cash:
The subject should be informed by the person obtaining consent of the following:

- that the check must either be picked up in person and that identification must be presented at that time, or the check must be sent through certified mail
- that should the check be lost or stolen another check will not be issued
- of the obligation to report to the IRS earnings from participation in research studies that exceed $599 in a calendar year.

The department must maintain an internal log of the check number, date of issue and to whom it was issued.

Other Incentives:
The subject should be informed by the person obtaining consent about any implications regarding other types of incentives, e.g. that lost gift cards will not be replaced etc.

The department must also track distribution and inventory control of such items.

Related Content

2011-009.2 – Institutional Review Board - Exemptions
2011-009.3 – Institutional Review Board – Expedited Reviews
2011-009.5 – Institutional Review Board – Review by Convened Board
2011-015.1 – Payment to Research Personnel for Subject Recruitment

Basis

21 CFR 312.7(a)
21 CFR 812(7)
Guidance on Institutional Review Board Review of Clinical Trial Websites at http://www.hhs.gov/ohrp/policy/clinicaltrials.html

Document Attributes:

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Replaced Version: Section in HSPO manual dated 11/14/2008

Reviewed and Approved By: **Signed RS 7/21/11** **Date:** _____
Richard Simon, MD
Director Human Subjects Protection Office