

Title:	Recruitment and Compensation
Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Karen Hansen, IRO Director
	<i>Signature/date</i>
Effective Date:	August 1, 2007
Policy:	2.0

POLICY STATEMENT

It is the policy of Fred Hutchinson Cancer Research Center (FHCR) that all study recruitment materials that will be used to recruit potential research participants and method of compensation must first receive IRB review and approval prior to use of the material. IRB review is required to ensure that the information contained in the materials is factual and objective

DEFINITIONS

None.

REFERENCES

21 CFR 312.7(a)
21 CFR 812.7(d)
21 CFR 56.110(b)(2)
OHRP Guidance on Institutional Review Board Review of Clinical Trial Websites
45 CFR 46.109(b)
FDA Information Sheets: Guidance for Institutional Review Boards and Clinical Investigators:
Recruiting

PRINCIPLES/OVERVIEW

The FHCR IRB follows policies and procedures to review and approve materials used to recruit and compensate, if applicable, research participants.

INDIVIDUALS AFFECTED BY THIS POLICY

The contents of this policy apply to Institutional Review Office (IRO) staff, IRB members, employees of FHCR and investigators from other institutions who submit research studies to the FHCR IRB for review and approval.

RECRUITMENT METHODS

1. Doctor to Doctor Letters

Letters providing basic information to physicians affiliated with outside clinics or institutions regarding an FHCRC investigator's research study do not require IRB approval.

2. Advertisements/Flyers/Posters

a. Federal regulations require IRBs to review the information contained in advertisements to determine that the procedures for recruiting research participants is not unduly coercive and does not promise a certainty of cure beyond what is outlined in the consent and the protocol. IRB review is necessary to ensure that the information is not misleading to research participants, especially when the study may involve research participants considered vulnerable (e.g. children, pregnant women).

b. Advertisement for research participant includes, but is not limited to:

- Newspaper
- Radio
- Television
- Bulletin boards
- Posters
- Flyers that are intended for potential research participants

It does not include communications intended for health professionals, such as doctor-to-doctor letters (see Item 1 above).

c. Advertisements used to recruit research participants should be limited to the information the potential research participants need to determine their eligibility and interest.

- the name and address of the PI and research facility (if applicable)
- the purpose of the research
- the criteria that will be used to determine eligibility for the study
- a brief summary of participation benefits, if appropriate
- time or other commitment required of the research participant
- location of the research and the person to contact for additional information

The Food and Drug Administration (FDA) does not require inclusion of all the listed items.

d. The advertisement should not include any claims, either explicitly or implicitly, that are misleading. The advertisement should not, for example, state that an FDA regulated investigational drug, biologic or device is safe or effective for the purposes under investigation, or that the drug, biologic or device is known to be equivalent or superior to any other drug, biologic or device. Such claims would not only be misleading to the research participants but would violate FDA regulations [21CFR312.7(a) and 21CFR812.7(d)].

e. Advertisements for investigational drug, biologic or device should not use terms such as "new treatment", "new medication", or "new drug" without explaining that the test article is "investigational". For example, using the phrase "receive new treatments" may lead research participants to believe that they will be receiving newly improved products of proven worth.

- f. Advertisements should not state “free medical treatment” when the protocol states that research participants will not be charged for taking part in the protocol. Advertisements may state that research participants will be paid but should not emphasize the payment amount.
- g. The IRB should review the final copy of printed advertisements to evaluate the relative size of type used and other visual effects.
- h. When advertisements are to be taped for broadcast, the IRB must review the final audio/video tape. The IRB may review and approve the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording. The review of the final taped message prepared from IRB-approved text may be accomplished through expedited procedures.
- i. Type of Review: For written advertisements, posters, newspaper, print ad, etc., the IRB Chair or designee, may review and approve the advertisement by expedited means if the advertisement can be easily compared to the approved consent and protocol.
- j. However, the IRB Chair or designee may request full review at a convened IRB meeting if the information in the advertisement may appear coercive, for example.
- k. All approved advertisement/flyer/posters, must include the date of approval in the footer of the document.

3. Approach letters

- a. Approach letters are generally seen as the first step of the informed consent and subject selection process.
- b. Approach letters should include similar information to those required for advertisements/flyers/posters:
 - the name and address of the PI and research facility (if applicable)
 - the purpose of the research
 - the criteria that will be used to determine eligibility for the study
 - a brief summary of participation benefits, if appropriate
 - time or other commitment required of the research participant
 - location of the research and the person to contact for additional information
 - how the study obtained the research participants’ names/information
 - a toll-free contact number, if applicable
 - the hours when research participants can contact the study
 - a statement that participation is voluntary
- c. The approach letter should be printed on FHCRC or the study’s letterhead.
- d. If the targeted research participants were recruited from another study, the PI who initially enrolled the targeted research participants must sign the approach letter introducing the PI of the new study.

4. Website Recruitment

- a. OHRP’s *Guidance on Institutional Review Board Review of Clinical Trial Websites* states that when a study recruitment material (e.g. website) includes only the basic descriptive information, IRB review and approval is not required.
 - study title

- purpose of the study
 - protocol summary
 - basic eligibility criteria
 - study site location(s)
 - study contact information
- b. Risks and potential benefits and requesting identifiable information are two examples of information that go beyond the basic descriptive information.
- c. All web-based sites and forms (e.g. surveys, questionnaires, etc.) used in a research study to collect personal information that may be considered confidential and privileged are reviewed by the Voice/Data Operations Manager or his designee. This review is documented in the IRB application and provides assurance to the IRB that a study's website/forms are fully in compliance with security standards so that research participants' information is protected.

COMPENSATION METHODS

1. Compensation Methods Allowed For Research Participants

The following methods of compensation are permitted:

- a. Monetary compensation is allowed as a form of recognition for the investment of the research participant's time, loss of wages, or other inconvenience. Monetary compensation should be relevant to the cultural context in which the research participant resides. It should be appropriate to the time and procedures involved.
- b. Other compensation might include:
- School supplies
 - Gift certificates
 - Parking reimbursement
 - Meal coupons

The IRB will evaluate the compensation method proposed on a study by study basis.

2. Compensation Methods That Are Not Allowed For Investigators Or Research Participants

Investigators may not receive payment for referrals (i.e. finder's fees)

Research participants may not receive escalated payments for the purpose of accelerating recruitment (i.e. bonus payments)

SUPPORTING DOCUMENTS

Application for Review