Fred Hutch Cancer Center

Institutional Review Board

Policy/Procedure

Title:	Recruitment and Compensation
Version:	1.00
Effective Date:	February 3, 2025
Responsible Office:	Institutional Review Office (IRO)
Responsible Official / Approved By:	Meghan Scott, IRO Director

POLICY STATEMENT

It is the policy of Fred Hutchinson Cancer Center (Fred Hutch) that all study recruitment materials that will be used to recruit potential research participants and method of compensation must first receive Institutional Review Board (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 and not unduly coercive.

DEFINITIONS

None

PRINCIPLES/OVERVIEW

The Fred Hutch 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 Fred Hutch and investigators from other institutions who submit research studies to the Fred Hutch IRB for review and approval.

PROCEDURES

1. Recruitment Methods

a. Advertisements/Flyers/Posters

i. Federal regulations require IRBs to review the information contained in advertisements and the mode of its communication, to determine that the procedure for recruiting research participants 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. 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).

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

- Newspaper
- Radio
- Television
- Bulletin boards

- Posters
- Flyers that are intended for potential research participants

iii. Advertisements used to recruit research participants should generally 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 condition under study and/or the purpose of the research
- in summary form, the criteria that will be used to determine eligibility for the study
- a brief list of participation benefits, if appropriate (e.g., a no-cost health examination)
- 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.

iv. 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)].

v. Advertisements for investigational drug, biologic or device studies 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.

vi. Advertisements should not include exculpatory language, in which a participant appears to waive their rights.

vii. Advertisements should not state “free medical treatment” when the protocol states that research participants will not be charged for taking part in the protocol.

viii. Advertisements may state that research participants will be paid but should not emphasize the payment amount by such means as larger or bold type.

ix. The IRB should review the final copy of printed advertisements to evaluate the relative size of type used and other visual effects.

x. 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.

xi. Type of Review: For written advertisements, posters, newspaper, print ad, etc., a Designated Reviewer, may review and approve the advertisement by expedited means if the advertisement can be easily compared to the approved consent and protocol.

xii. However, the assigned designated reviewer may request full review at a convened IRB meeting if the information in the advertisement may appear coercive, for example.

b. Approach letters

i. Approach letters are generally seen as the first step of the informed consent and subject selection process.

ii. 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 condition under study and/or the purpose of the research
- in summary form, the criteria that will be used to determine eligibility for the study
- a brief list of participation benefits, if appropriate (e.g., a no-cost health examination)
- 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

iii. The approach letter should be printed on Fred Hutch or the study's letterhead.

iv. 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.

c. Website Recruitment

i. 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

ii. Risks and potential benefits and requesting identifiable information are two examples of information that go beyond the basic descriptive information.

iii. 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 Fred Hutch Governance, Risk, and Compliance (GRC) office. 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.

d. Materials that Do Not Require IRB Review:

i. Doctor to Doctor Letters - communications intended to be seen or heard by health professionals, such as "dear doctor" letters and doctor-to-doctor letters (even when soliciting for study subjects) do not require IRB approval

ii. News stories

iii. Publicity intended for other audiences, such as financial page advertisements directed toward prospective investors.

2. Compensation Methods

a. At the time of initial IRB review, the IRB will evaluate the compensation method proposed on a study-by-study basis to assure the amount of payment and the proposed method and timing of disbursement is not coercive and does not present undue influence.

b. The IRB will consider the following when reviewing the proposed compensation plan:

   i. Payment should accrue as the study progresses and not be contingent upon the participant completing the entire study.

   ii. While the entire payment should not be contingent upon completion of the entire study, payment of a small proportion as an incentive for completion of the study is acceptable, provided the incentive is not coercive.

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

c. Information concerning payment, including the amount and schedule of payments, will be described within the consent document.

d. Compensation Methods Allowed for Research Participants

   The following methods of compensation are permitted:

   i. 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 appropriate to the time and procedures involved.

   ii. Other compensation might include:

   - School supplies
   - Gift certificates
   - Meal coupons

e. Compensation Methods that are Not Allowed for Investigators:

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

   ii. Investigators should not accept payments designed to accelerate recruitment that are tied to the rate or timing of enrollment ("bonus payments").

f. Reimbursement for Travel Expenses

   Reimbursement for travel expenses to and from the clinical trial site and associated costs such as airfare, parking, and lodging does not raise issues regarding undue influence.

SUPPORTING DOCUMENTS

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
FDA Information Sheet: Payment and Reimbursement to Research Subjects

VERSION HISTORY

Version	Effective Date
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