

Human Research Protection Program Policies & Procedures

Payments to Research Participants

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Research Integrity Office
Mail code L106-RI
Portland, Oregon 97239-3098
Phone: 503-494-7887
Fax: 503-346-6808

Background

Payments to research subjects raise ethical issues regarding voluntary participation and the individual's need to make informed choices about research that are based on the risks and benefits of participation, not on financial incentives. HHS regulations on informed consent require that the circumstances under which a prospective subject is asked to participate in research minimize the possibility of coercion or undue influence.

Guidance from the Office for Human Research Protections explains undue influence as "an excessive or inappropriate reward or other overture in order to obtain compliance." The Food and Drug Administration cautions against payments to participants that are "...coercive or present undue influence." The National Institutes of Health similarly warns IRB's about payments that cause "undue inducement."

Payment to research subjects may be appropriate in some circumstances, such as reimbursing subjects for their time and travel expenses or covering costs associated with research-related injury, but such payments must not be made in a manner that creates undue influence. Federal regulations and commentaries offer guidance about such incentives, but set no strict limits, leaving Principal Investigators and local Institutional Review Boards to decide how much payment is appropriate.

I. Scope

This policy applies to all research at OHSU involving human subjects who may receive any type of payment or reimbursement in connection with their participation, including payment as a participation incentive, reimbursement for expenses, and payment for research-related injury.

II. Responsible Parties

- A. Investigators
- B. IRB

III. Policy

- A. Payment to subjects for participation in research is permissible as long as the amount is not coercive or excessive relative to the nature of the project.
- B. The OHSU IRB allows reasonable reimbursement to participants in all research studies for research-related expenses, such as the cost of transportation, parking, and travel.

- C. The reasonableness of a particular sum of money or other form of payment may be based upon:
 - 1. the time involved;
 - 2. the inconvenience to the subject;
 - 3. the risk to the subject; and/or
 - 4. expenses incurred while participating.
- D. Payment to subjects for participating in a study is not considered a “benefit” in determining whether the risks to subjects are reasonable in relation to the anticipated benefits.
- E. Research subjects may receive a reasonable payment as an incentive for recruiting other subjects as long as the amount is not coercive to the current subject and is not likely to cause the current subject to place undue influence on the potential subject to participate.
- F. OHSU generally requires that industry sponsors provide reimbursement for injuries to subjects caused by the research procedures or test article(s). See the [OHSU Position Statement](#) on this issue for more information.
- G. All information concerning payment to research participants, including the amount, form, and schedule of payment(s), or a description of how such elements are determined, must be clearly presented to the subject in writing (usually in the informed consent document).

IV. Procedure

- A. *IRB Review*
 - 1. The amount and schedule of all payments to study subjects should be presented to the OHSU IRB at the time of initial review of a study protocol.
 - 2. During the initial review, the IRB will review the amount of payment and the proposed method and timing of disbursement to ensure that they neither are coercive nor present undue influence.
 - 3. The IRB will also review the description of potential payment for subject injury in the informed consent form to ensure that it satisfies regulatory and OHSU policy requirements.
 - a. The consent form must include the correct OHSU-approved liability statement for the funding source of the study. Current liability language is available on the [IRB website](#).
 - b. Consent forms may not ask subjects to agree to follow a list of study-related instructions. Such language implies that subjects have no right to seek compensation for research-related injuries if they do not follow the instructions to the letter. This is exculpatory language and is prohibited under federal law (45 CFR 46.116 and 21 CFR 50.20). Consent forms may, however, list or summarize actions that are expected of the subject and may state that the subject will be removed from the study if he/she does not follow instructions.

B. *Payments for Study Participation*

1. Any payment received by the research participant should accrue as the study progresses; compensation should not be contingent upon the research participant completing the entire study. However, payment of a small portion as a bonus or incentive for completing the study is an acceptable practice so long as the amount is not coercive.
2. Payment to subjects who withdraw from the study can be made at the time they would have completed the study (or completed a phase of the study) had they not withdrawn, unless it creates undue inconvenience or a coercive practice.
3. Payment for participation is often not provided for therapeutic research studies.

C. *Reimbursement of Participation-Related Expenses*

1. This generally includes parking, gas, and travel reimbursements, and may include per diem (meals).
2. Reimbursing volunteers for parking is standard.
3. Gas reimbursement does not need to be calculated at the University rate.
4. All types of reasonable transportation costs are reimbursable.

D. *IRS Reporting*

1. In compliance with Internal Revenue Service (IRS) requirements, OHSU reports payments made to human subjects that total \$600 or more in a calendar year. This amount is the total from all payments regardless of form (e.g. cash, gift cards, etc.), including payments received across more than one research project. However, reimbursements for travel and similar expenses are not included in this total.
2. Subjects must be informed of this in the consent form where appropriate.

E. Forms of Payment

1. The following is a list of examples of acceptable forms of payment:
 - a. University Check
 - Payment by University check is preferred, but may only be used when participants are not anonymous.
 - Participants must be informed that checks can take as much as 6 weeks to issue.
 - b. Cash
 - It may be inappropriate to give some populations cash, for example children and drug-users.
 - Cash distribution must meet petty cash policies.
 - c. Gift Cards
 - d. Drawing
 - The consent form and recruitment materials (as applicable) must state the chances of winning.
 - In order to avoid confusion with state-regulated gambling activities, the drawing may not be called a "raffle" or "lottery."
 - e. Other Items of Value – depending on the nature of the study, other items of value may be appropriate.

2. For studies that have a research sponsor, it is NOT appropriate to include, as compensation, a coupon good for a discount on the purchase price of the sponsor's product once it has been approved for marketing.

V. Authority

Federal Regulations:

21 CFR 50.20 and 45 CFR 46.116 state that an investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

45 CFR 46.111 states that risks to subjects must be minimized and reasonable in relation to the anticipated benefits.

Guidance:

Food and Drug Administration: [Payment to Research Subjects – Information Sheet \(1998\)](#).

[Office for Human Research Protections: Informed Consent FAQs](#)

VI. Definitions

Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance.

Undue Influence occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable. (Belmont Report)