



COMPENSATION OF RESEARCH SUBJECTS

Definitions

The University of Utah IRB uses the term “compensation” for payments made to research participants for participation in a study. Compensation may be provided to reimburse participants for their time, effort or for other expenses. Compensation includes any monetary compensation, gift certificates or vouchers, mileage reimbursement, movie tickets, promotional items, etc.

Description

The IRB reviews payment arrangements to research participants (compensation) to ensure an equitable selection of subjects by only approving payment methods that are not coercive and do not present undue influence. Additionally, compensation must be described in the consent document. Therefore, the IRB will review the description of compensation in the consent document to prevent any violation of the regulatory requirements of consent.

If compensation will be offered to participants, the IRB will adhere to the following guidelines:

- The amount of compensation should be appropriate for the time and effort put forth by study participants.
- Credit for payment should accrue as the study progresses and not be contingent upon the participant completing the entire study. Investigators should provide a plan for pro-rating compensation should a participant withdraw from a study. Pro-rating compensation may not be feasible in all studies that offer compensation and may be approved on a case-by-case basis.
- While the total compensation 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, providing that such incentive is not coercive. The IRB should determine that the amount paid as a bonus for completion (if applicable) is reasonable and not so great as to unduly induce participants to stay in the study when they might otherwise have withdrawn.
- Unless it creates undue inconvenience or a coercive practice, compensation to participants who withdraw from the study may be made at the time they would have completed the study (or completed a phase of the study) had they not withdrawn. For example, in a study lasting only a few days, an IRB may find it permissible to allow a single payment date at the end of the study, even to participants who had to withdraw before that date.
- All information concerning payment, including the total amount, schedule of payment(s), and any plan for prorating payments if a participant does not complete the study should be described in the informed consent document.

Compensation must be paid to University of Utah participants according to the guidelines set forth by Accounts Payable. The guidance is meant to ensure the proper handling of confidential information and to reasonably ensure compliance with reporting requirements. The guidance,

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.



[“Human Subject Payment Procedure”](#), is found the Accounts Payable website. Investigators should review and be familiar with the policy if research participants are compensated for participating in University of Utah research projects.

What are the additional considerations for compensation to participants in Clinical Trials subject to FDA regulations?

- FDA does not consider reimbursement for travel expenses to and from the clinical trial site and associated costs such as airfare, parking, and lodging to raise issues regarding undue influence.
- Compensation for participation in a clinical trial offered by a sponsor may not include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

What are the additional considerations for compensation to participants for Department of Defense studies?

- Participants may be compensated for research participation as long as the participant is involved in the research when not on duty. Enrolled individuals may not receive payment of compensation for research participation during duty hours.
- Federal employees while on duty and non-Federally employed individuals may be compensated for blood draws for research up to \$50 for each blood draw.
- Non-Federally employed individuals may be compensated for research participation other than blood draws in a reasonable amount as approved by the IRB.

Points to Address

New Study Application: 1. **Section 6.4, Compensation:** Complete this section.

Consent Document:

1. **Benefits:** Payment to research participants for participation in studies is **not** considered a benefit. Do not mention compensation in this section.
2. **Costs and Compensation Section:** Explain whether participants will be compensated for participation. If no compensation is provided, please clearly state this. If compensation is provided, specify the total amount, schedule of payment(s) and any plan for prorating payments if a participant does not complete the study. If a Social Security Number is required for payment, please state this. (Note: if participants will be receiving a check from the University of Utah, a SSN will be required.)

Advertisements:

1. **Compensation:** Do not list a specific compensation amount on any advertisements. Instead, you may state, *“You will be compensated for your participation in this study,”* or, *“Compensation will be offered.”*

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References & Links

*U of U Consent
Template*

<http://irb.utah.edu/forms/>

*Payments to Human
Research Participants
(Accounts Payable
Guideline)*

<http://fbs.admin.utah.edu/download/AP/ResearchPartPayments.pdf>

FDA Guidance

[Payment and Reimbursement to Research Subjects – Information Sheet](#)

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