

Research Guidance Document

COMPENSATION OF RESEARCH SUBJECTS

Definitions

The University of Illinois Urbana-Champaign 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 exceptions may be approved on a caseby-case basis.
- While the total compensation should not be contingent upon completion of the entire study, payment of a small portion 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is reasonable and not so great as to unduly induce participants to stay in the study when they might otherwise have withdrawn.
- 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the study may be made at the time they would have completed the study (or completed a phase of the study) had they not withdrawn.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.



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Compensation must be paid to University of Illinois Urbana-Champaign participants according to the policies and guidelines set forth by the Office of Business and Financial Services. The guidance is meant to ensure the proper handling of confidential information and to reasonably ensure compliance with reporting requirements. Investigators should review and be familiar with the policy if research participants are compensated for participating in University of Illinois Urbana-Champaign research projects. Depending on the amount of compensation and the method used to make the payment (e.g., check), the investigator may need to collect tax information using an IRS W-9 form and forward it to Accounts Payable. If the collection of social security numbers is required to pay participants, the consent must disclosure such a requirement.

https://www.obfs.uillinois.edu/bfpp/section-8-payments-reimbursements/payments-human-subjects

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 <u>not</u> 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. Question 10.5, 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

Please contact the OPRS Office at (217) 333-2670 or $\underline{\text{irb@illinois.edu}} \text{ for additional guidance.}$



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a participant does not complete the study. If a Social Security Number

is required for payment, please state this.

Advertisements: 1. **Compensation**: It is preferred that advertisements not list a specific

compensation amount. Instead, you may state, "You will be

compensated for your participation in this study," or, "Compensation

will be offered." Additional information can be found in RGD -

Advertisements.

References & Links

Payments to Human https://www.obfs.uillinois.edu/bfpp/section-8-payments-subjects reimbursements/payments-human-subjects

RGD – Advertisements <a href="https://oprs.research.illinois.edu/forms-templates/guidance/guidance-gui

advertisements