



COMPENSATION AND PAYMENTS TO RESEARCH PARTICIPANTS AND RESEARCH PERSONNEL

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This document describes:

- the investigator's responsibility to explain proposed plans for compensation of research participants,
- the DUHS IRB's policy for reviewing and approving proposals for such compensation, and
- restrictions placed on investigators and key personnel regarding payment to them for conducting the research.

Compensation and Payments to Research Participants

Payment to research participants in studies is not considered a benefit; rather, it should be considered compensation for time and inconvenience associated with participation in research activities, or a recruitment incentive. Payments may be in the form of cash or non-cash.

The IRB recognizes that there are monetary costs involved with participation in clinical research, for example, parking, gasoline expense, childcare services, loss of time at work. Research subjects should not be disadvantaged by their participation in research, and therefore appropriate compensation for time/expenses may be approved by the IRB. However, undue inducement is to be avoided. "**Undue inducement**" may be seen as inducement so high that *were it not for the amount of the inducement*, the participant would not enter the study, or the participant would withdraw from the study early, given his or her better judgment.

The IRB will review proposed payments to determine that:

- The amount of payment and the proposed method and timing of disbursement are neither coercive nor do they present an undue influence.
- Credit for payment accrues as the study progresses and is not contingent upon the participant completing the entire study.

Investigator Responsibilities

The investigator will provide a detailed description of proposed compensation as requested in the iRIS Application Standard Research Summary and the Subject Procedures and Costs section of the application. If subjects are to be compensated, the investigator will provide specific prorated amounts to be paid for expenses such as travel and/or lost wages, and/or for inducement to participate.

As mentioned above, credit for payment should accrue as the study progresses. For example, payments should coincide with scheduled clinic visits, and not be contingent upon the participant completing the entire study. Participants should be

paid in proportion to their time and inconvenience as a result of their participation in the research study.

The compensation for participation in a trial offered by a commercial sponsor may **not** include a coupon good for a discount on the purchase price of the product once it has been approved for marketing (FDA Information Sheet, IRBs Frequently Asked Questions, 1/98 Update).

Disclosure of Payments

The investigator will disclose all information concerning compensation, including the amount and schedule of payments, in the informed consent document. Study participants will also be required to complete a Personal Data Disclosure Form for Research Participants as compensation is considered taxable income.

Alterations in Payments

If there are alterations in payments to research participants, that information is to be submitted as an amendment to the IRB prior to implementation.

Completion Bonus

The use of a completion bonus is ordinarily discouraged. When a completion bonus is proposed, the IRB will determine whether the amount paid as a bonus for completion is reasonable and not large enough to unduly influence participants to remain as a study participant when they would otherwise have withdrawn.

Advertisement of Payments

Advertisements may state that participants will be compensated or paid, but should not emphasize the payment or the amount to be paid, by such means as larger or bolded type, or prominent placement in the ad itself.

Compensation for Minors

As a rule, the IRB will not approve cash payments to children. Children receive, if anything, non-cash gift certificates of a small amount, or something else non-cash, such as movie theater passes or tickets to a children's musical event. The parents may receive cash, to help defray expenses such as parking, gasoline or meals associated with their child's participation in the research study. If the study involves a complicated or uncomfortable procedure or if the child will be at Duke for a long day, a gift certificate in a larger amount may be proposed for the child, and the IRB will consider its justification. For studies requiring an overnight stay, hotel costs and meal coupons (such as for the Duke Hospital cafeteria) may be provided for the family.

Assistance may also be offered to cover child-care costs if necessary for siblings of the study participant. The IRB will review, on a protocol-by-protocol basis, the appropriateness of compensation proposed for studies involving minor participants.

Reimbursement

FDA does not consider reimbursement for reasonable travel expenses to and from the research site and associated costs such as airfare, parking, and lodging to raise issues regarding undue influence. The study application and consent form should clearly state what costs will be reimbursed and how these reimbursements will be

made (i.e., payable based upon receipts provided).

Payments to Research Personnel

Payments to non-study personnel in exchange for referrals of potential participants (finder's fees) are not allowed, nor are payments to study personnel designed to accelerate recruitment that will be tied to the rate or timing of enrollment (bonus payments).

Standard Language for Payments to Subjects over \$600

The following statement should be included in consent forms when payment to an individual exceeds \$600 in any one calendar year.

“Payment received as compensation for participation in research is considered taxable income to the research subject. If payment to an individual totals \$600 or more in one calendar year, Duke University is required to report this information to the Internal Revenue Service (IRS). Research subject payments to a non-employee of Duke University adding up to \$600 or more during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the individual and a copy sent to the IRS.”

REFERENCES

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/payment-and-reimbursement-research-subjects>

45 CFR 46.116

Previous Version Date(s): 5/20/2008, 2/15/2016