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, and loss of time at work. Research participants 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 their better judgment.

The IRB will review proposed compensation to determine that:

- The amount of compensation 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 participants 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 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 may also be required to provide their social security number 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
See the POLICY AND GUIDELINES FOR ADVERTISING available on the IRB website.

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 monetary compensation, 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 or reimbursement 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 Compensation Payments to Subjects
The following statement should be included in consent forms when payment to an individual will be made.

> Payment for participation in research is considered taxable income and Duke University is required in many cases to report this information to the Internal Revenue Service (IRS).
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> Duke University requires that you provide your name, mailing address, and social security number for this tax reporting purpose before payment can be issued. If you do not want to provide this information, you cannot be paid but you can still take part in the research study.
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> 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.

For studies enrolling Duke Employees, add the following: Research participant compensation made to a Duke University employee at any time during the calendar year will result in a 1099 (Miscellaneous Income) form being issued to the employee and a copy sent to the IRS regardless of the total amount paid.

REFERENCES

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

45 CFR 46.116

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