DukeHealth

Institutional Review Board

Compensation and Payments to Research Participants and Research Personnel			
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1. Overview

1.1 Purpose

The purpose of this policy is to establish clear institutional standards for compensating individuals who participate in IRB-approved research conducted under the auspices of the Duke University Health System (DUHS) Institutional Review Board (IRB). This policy is designed to ensure that compensation for research participation is administered ethically and transparently, that it appropriately recognizes participants' time, inconvenience, and expenses without exerting undue influence on their decision to participate or continue in a study, and that all proposed compensation plans comply with applicable federal regulations, IRB review requirements, and tax reporting obligations.

The policy also describes restrictions on payments to investigators and study personnel to ensure ethical, compliant, and appropriate conduct of human participant research.

2. Definitions

Please note that definitions can be found throughout DUHS's IRB's policies and procedures, as applicable

3. Compensation to Research Participants

Compensation or renumeration to research participants are not considered a benefit of participation intended as payment for pain, discomfort, or research-related risk. Rather, they are intended to compensate participants for the time and inconvenience associated with research activities. Compensation may be provided in either cash or non-cash forms, as approved by the IRB.

When determining the appropriateness of compensation for research participants, the IRB carefully evaluates multiple factors to ensure that payments are ethical, fair, and do not constitute undue inducement. Undue inducement occurs when the amount, nature, or timing of payment is so influential that it could compromise a prospective participant's ability to make a voluntary and informed decision about study participation or continuation. The IRB will review all proposed participant payments to ensure that:

- The amount, method, and timing of payment are reasonable relative to the participant's time and inconvenience,
- Compensation accrues proportionally or prorated as the study progresses and is not contingent upon completion of the entire study,
- Appropriate special considerations are included for vulnerable populations as applicable, and
- Payments or compensation do not create a conflict of interest or otherwise compromise research integrity or participant safety.

3.1 Disclosure of Payments

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

3.2 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, refer to DUHS IRB's additional guidance and policies for all advertising requirements.

3.3 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.

3.4 Coupons or Discounted Products

Per FDA guidance, compensation for participation in a clinical trial sponsored by a commercial entity may not include coupons or discounts for the future purchase of the investigational product once it is approved for marketing. Offering such incentives is prohibited because it may inappropriately suggest to participants that the study will have a favorable outcome or that the product will be promptly approved. Additionally, once the product is marketed, such coupons could create financial pressure for participants to use the product, even when it may not be the most medically appropriate option.

3.5 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.

3.6 Compensation for Minors

As a general rule, the IRB will not approve cash payments to children participating in research. Instead, children may receive small-value non-cash items, such as gift certificates, movie passes, or tickets to age-appropriate events. Parents or guardians may receive cash reimbursement to offset expenses incurred due to their child's participation, such as parking, transportation, or meals as outlined in Section 4.0-Reimbursement of Expenses or Out-of-Pocket Costs.

The appropriateness of all compensation for minor participants will be reviewed by the IRB on a protocol-by-protocol basis, considering the age of the child and the criteria outlined in Section 3-Compensation to Research Participants

3.7 Tax Reporting Language

Payments to research participants that meet or exceed the IRS reporting threshold of $2,000 per calendar year (effective 01/01/2026) are considered taxable and must be reported. This includes cash and cash-equivalent forms, such as gift cards. Such payments will be reported to participants and the IRS using Form 1099. For studies in which participants are expected to receive $2,000 or more (excluding reimbursements for expenses as described in Section 4.0 – Reimbursement of Expenses or Out-of-Pocket Costs), consent documents must include the tax reporting language provided in the DUHS IRB consent templates.

4. Reimbursement of Expenses or Out-of-Pocket Costs

Participation in research may result in out-of-pocket costs or burdens, including but not limited to transportation, lodging, parking fees, and childcare. Participants should not be financially disadvantaged because of research participation. Accordingly, reasonable compensation for expenses may be approved by the IRB.

Federal oversight agencies, including the Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), and other applicable regulatory bodies, generally view reimbursement of participants for reasonable out-of-pocket expenses as ethically acceptable and distinct from compensation or incentives for research participation. Such reimbursement is not considered coercive or an undue influence on participation when limited to reasonable expenses. The reimbursement plans should be transparent, proportionate, and are subject to IRB review and approval, with clear disclosure in study applications and informed consent documents regarding which expenses will be reimbursed and how reimbursement will be provided.

5. Payments for Referrals or to Research Personnel

Payments to individuals in exchange for referrals of potential research participants (finder's fees) are prohibited, as they may create conflicts of interest and compromise the voluntary nature of participation. Similarly, payments to study personnel that are tied to enrollment targets, recruitment speed, or participant study completion are not allowed, as they may inappropriately influence recruitment or study conduct, and threaten the integrity of the research and the protection of human participants.

6. Responsibilities

6.1 Investigator's Responsibilities

Investigators are responsible for ensuring that all participant payments are administered ethically, accurately, timely and in accordance with the IRB-approved application and study materials. This includes accurately describing the amount, form, and schedule of payments in the IRB application and informed consent documents. In addition, investigators are responsible for promptly addressing and resolving any participant questions or complaints regarding payments, in a fair and timely manner, while maintaining compliance with institutional and regulatory requirements.

6.2 DUHS IRB's Responsibilities

The DUHS IRB is responsible for this policy and any related IRB guidance on participant payments, including IRB consent templates, as well as reviewing proposed compensation plans or reimbursement for appropriateness and compliance.

7. Revision

- **Version 2.0: Effective Date 01/01/2026-** Revised to updated DUHS IRB template, revision to tax reporting threshold from $600 to $2000.
- **Previous Versions:** 03/18/2021, 02/15/2016, 05/20/2008