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Hospital**

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Owner Susan Kornetsky:
Manager
Department Research
Applicability Boston Children's
Hospital- Policies
& Procedures

Research Subject Remuneration Policy/Procedure

Internal Approval

SVP, Research Administration

EVP, Chief Scientific Officer

Scope

This policy defines the types of payments made to subjects, the process by which remuneration should be tracked and distributed to research subjects, and to provide guidance as to acceptable practices.

Policy Statements

1. The Institutional Review Board (IRB) must review and approve any payment, monetary or otherwise, offered to a subject or family as part of a research protocol. The IRB will consider the details of remuneration when evaluating the protocol.
2. There are no established policies as to the amount and type of payments that may be offered to research subjects and families, as each protocol differs. The IRB recognizes four types of payments:
 - a. reimbursement
 - b. compensation
 - c. tokens of appreciation
 - d. incentives
3. The protocol application and informed consent should describe in detail when the subject will receive the remuneration, what will be provided (toys, gift card, cash, voucher, check), and other appropriate details.

4. Investigators are to specify the types of payments to be offered and provide specific information regarding each category. The IRB will consider the protocol, including the time commitment and the proposed procedures, when determining if the planned amount is appropriate. The IRB does not have a set list of recommended remuneration amounts for specific tests or length of visits, nor does it require that one method (gift cards, cash, etc.) must be used. The IRB recognizes that varying amounts and methods of remuneration may be appropriate depending on the particular circumstances of a protocol and the participant.
5. The informed consent should provide details regarding remuneration, including the amount and schedule of payment(s). The consent should provide details regarding who will receive the remuneration (parents/guardians, the child/ adolescent), and the type provided (toys, gift card, cash, voucher, check, clincard).
6. Remuneration cannot be so great that it entices participants to engage in any activity to which they are averse, or to act against their better judgment.
7. Remuneration to research participants for participation in studies is not considered a benefit.

Procedures

Payments to Subjects

1. It is sometimes desirable to provide payments to subjects and their families for their participation in research projects. Such payments may take the form of reimbursement for taxi fare or other travel expenses, babysitting fees, compensation for time, small gifts, or gift cards. Remuneration may not be sizeable enough to induce subjects to participate, regardless of how minimal the risk.
2. Investigators may not require that a subject complete the research in order to receive compensation. If a subject withdraws from a study, he or she must be offered payment for the completed portion of the study. The amount and type of any payments are to be specified in the consent form. The IRB reserves the right and has the obligation to review and approve all types of remuneration.
3. In addition to approving specific amounts and types of payments, the IRB may also require changes in the amount and/or type, if deemed appropriate. Any change or modification to approved amounts and/or types of payment must be submitted to the IRB as an amendment.
4. The IRB requires investigators to identify the amounts and types of payments offered to research subjects. The four types of payments are as follows:
 - a. **Reimbursements** are direct, research-related expenses incurred by the family as a result of their participation in the research study. Examples include transportation, parking, meals, and childcare. The IRB realizes that the amounts and types of reimbursement are specific to a family's situation; however, investigators are encouraged to consider what, on average, is reasonable.
 - b. **Compensation** is payment to families, children, and adolescents for the time and inconvenience of research participation. For example, compensation may be made for the time a parent is away from work in order to participate, or for the time an adolescent could be working. Compensation is intended to negate the burdens and inconveniences that research participation adds to families' lives. The IRB realizes

that the amounts and types of compensation are specific to a family's situation; however, investigators are encouraged to consider what, on average, is reasonable.

- c. **Tokens of appreciation** are small payments, gifts, gift certificates, or savings bonds given to the family to thank them for their efforts or participation. Incentives are payments, gifts, or gift certificates intended to intentionally encourage a subject's enrollment and/or continued participation in a research protocol.
 - d. **Incentives** are intended to exceed the value of reimbursement for actual costs, compensation for time and the value of tokens of appreciation. Examples include "completion bonuses," or additional payments above and beyond expense reimbursements and compensation that are made as the study progresses. Incentives are generally discouraged in pediatric research; however, The IRB will carefully consider whether an incentive unduly influences a child and/or family to participate when reviewing and approving this type of payment. Any bonus payment for completion of the trial must be reasonable and not so large as to induce participants to stay in the trial.
5. If the amount of compensation per year (including the value of gift cards and excluding payments offered to reimburse for expenses) is equal to or greater than \$600, the compensation it must be reported to the Internal Revenue Service as taxable income. The informed consent must address this fact; suggested wording may be found in the consent form template.

Guidelines for Distributing Remuneration

1. As part of their review, the IRB will note and approve the method for providing remuneration to participants. This may include gift cards/vouchers, cash, checks, bank reimbursement cards (Clincard), and other methods proposed by the research team. The research team is responsible for following any institutional policies regarding the method of remuneration including the method of disbursement and any record keeping requirements. Once the remuneration for the protocol has been approved, investigators are responsible for following institutional policies and processes for the approved, method for distributing the remuneration to subjects.
2. If payments will be provided per visit, every effort should be made to provide the subject with remuneration after each visit, instead of waiting until the subject completes all, or a group, of the study requirements and then issuing payment for the entire study. The subject may feel that they must complete all visits to receive the payment, when in fact, the study likely does not require completion of all visits to receive remuneration. The IRB recognizes that there may be circumstances in which it is appropriate to distribute remuneration for multiple study visits at one time. If provided with sufficient rationale, the IRB will approve grouped payments as appropriate.
3. When designing the remuneration plan for the protocol, time consuming practices should be minimized and avoided where possible. For example, parking vouchers should be provided whenever possible, so participants do not need to be reimbursed at a later time or be concerned about having enough cash on hand to pay hourly parking rates.

Informed Consent and Assent

1. When reviewing the consent form, the IRB will ensure that the following conditions are met:
 - a. The consent form does not include payment as a benefit,
 - b. The purpose, timing, form, and amount of payments have been specified,
 - c. Payments to subjects, are listed separately from payments to parents/guardians,
 - d. When payment or reimbursement will be made with reimbursement bankcards, the consent form will include information that the bank will have access to identifiable information but not to any medical information,
 - e. Payment to subjects and families are not conditioned upon completion of the research; if a subject withdraws from a study, they must be offered payment for the portion of the study completed,
 - f. When payment to an individual could exceed \$600 in a calendar year, the study team must disclose to subjects that BCH will be required to issue IRS Form 1099 to the parent and child.



Approval Signatures

Step Description	Approver	Date
Co-chair Approval	David Davis	3/1/2025
Site Administrator: Education/ Training Requirement	Dwight Mayfield	2/26/2025
Steering Committee	Dwight Mayfield	2/26/2025
Required Departmental Review/Approval	August Cervini	2/6/2025
Committee Chair(s)	Susan Kornetsky: Manager	2/6/2025
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Applicability

Boston Children's Hospital- Policies & Procedures