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**Boston
Children's
Hospital**

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Owner Theresa Applegate
Department Research
Applicability Boston Children's Hospital- Policies & Procedures

Providing Remuneration to Research Policy/Procedure

Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

Scope

The purpose of this policy is to define 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.

Definitions

CCI: Committee on Clinical Investigation

Policy Statements

1. The Committee on Clinical Investigation (CCI) must review and approve any payment, monetary or otherwise, offered to a subject or family as part of a research protocol. The Committee on Clinical Investigation 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 CCI recognizes four types of payments:
 - a. reimbursement,
 - b. compensation,
 - c. tokens of appreciation,

d. incentives

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.

3. Investigators are to specify the types of payments to be offered, and provide specific information regarding each category. The CCI will consider the protocol, including the time commitment and the proposed procedures, when determining if the planned amount is appropriate. The CCI 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 Committee recognizes that varying amounts and methods of remuneration may be appropriate depending on the particular circumstances of a protocol.

Procedures

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. 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 CCI reserves the right and has the obligation to review and approve all types of remuneration.
2. In addition to approving specific amounts and types of payments, the CCI 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 CCI as an amendment.
3. The CCI 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 CCI 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 CCI 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.
 - d. **Incentives** are payments, gifts, or gift certificates intended to intentionally encourage a subject's enrollment and/or continued participation in a research protocol.

Incentives are intended to exceed the value of reimbursement for actual costs 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 CCI will 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.

4. 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. Investigators are required to track payments. When the threshold of \$600 within a calendar year is reached, the investigator must obtain a W9 form from the subject and send it to Accounts Payable along with the amount of compensation paid.
5. Methods for Providing Remuneration
 - a. Once the remuneration for the protocol has been approved, the Committee recommends the following processes depending on the method approved, for distributing the remuneration to subjects. The CCI has developed these guidelines in an effort to assist research staff with streamlining the remuneration process and to improve the tracking of research funds while simultaneously reducing research staff liability by using a system in which study coordinators can account for the whereabouts and distribution of remuneration funds.
6. Gift Cards/Vouchers
 - a. Gift Cards/Vouchers should be purchased by the study team and a log should be created and stored in the research binder to account for the cards. The log should include the unique ID on the gift card, the location of the card and the date the gift card was purchased. Once the card has been distributed to the subject, the log should be updated to note the date, the study ID # of the subject who received the card, if the card was provided to the subject or the parent, and which study staff member distributed the card. The CCI recommends that the study staff obtain a signed receipt from the subject whenever possible to demonstrate that they received the gift card. The subject can either sign (or initial) the log or a separate receipt can be created for each subject and maintained with the remuneration log. Examples of remuneration receipts and logs maybe found on the EQUiP website.
7. Cash
 - a. Study staff may request that a local petty cash fund be established. The amount requested should be based on anticipated visits and approved subject payments. The maximum amount of cash that a research group can hold at any time for purposes of providing payments to research subjects is \$500.00. The goal of this policy is to provide for better accountability of the funds and to limit the amount of cash that is being stored for subject remuneration. Therefore investigators should consider how to best organize within their clinical research organizational structures to request the \$500. If you have any questions regarding this policy please contact

Karen Renaud at 857-218-3518 or karen.renaud@childrens.harvard.edu. It is the responsibility of the study staff to insure that undisbursed cash is properly safeguarded. This would include keeping the cash in a locked location and limiting access.

- b. To request a local fund, study staff will complete a Clinical Trial Subject Remuneration Voucher. The principal investigator will approve the request by signing the voucher. Once signed by the PI the voucher will be submitted to the research finance office for review. If approved, Research Finance will sign the voucher and return it to the study staff. The signed voucher can be taken to the hospital cashier's office for payment. The study project will not be charged until payments are distributed to subjects. As individual payments are provided to parents/study subjects out of this fund, they must be recorded on a Remuneration Log. A separate log will be maintained for each study. The log will indicate the Principal Investigator, protocol number, date approved by the IRB, amount provided to subject, date, Study ID Number, Parent or Subject initials/signature and the study staff signature. Remuneration logs will be submitted to the Research Finance department on a monthly basis, so that the local petty cash fund can be replenished and the study project can be charged for the payments distributed. Logs may be submitted as frequently as necessary to maintain sufficient cash in the fund. Allow three business days for replenishment to occur.

- c. Examples of Remuneration Logs and Vouchers may be found on the EQUiP website.

8. Check

- a. A requisition for payment for an individual subject should be sent to Accounts Payable for the appropriate amount. The research team should tell subjects that a request will be sent through accounts payable and if they do not receive the check within a couple of weeks, they should contact the research staff. Accounts payable will send the check directly to the research subject. A copy of the AP requisition request should be maintained in the study binder. Only the protocol number or fund number should be noted on the requisition (not the protocol title).

9. Other Guidelines for Distributing Remuneration

- a. 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 have to complete all visits to receive the payment, when in fact, the study likely does not require completion of all visits to receive remuneration. The CCI 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 CCI will approve grouped payments as appropriate.
- b. When designing the remuneration policy for the protocol, time consuming practices should be minimized and avoided where possible. For example, stating that travel expenses will be reimbursed based on actual miles traveled and other expenses, which require the payment to be calculated for each subject is very time consuming. Instead, the Committee recommends standardizing the reimbursement amount and

group it based on the number of miles the family traveled for the research visit (i.e. 1-25, 25-75, 75 and over, etc.). This may reduce the time required by the research staff and allow for more timely distribution of funds.

Approval Signatures

Step Description

Approver

Date

Applicability

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