Research Subject Remuneration

Purpose

This policy defines the types of payments made to subjects, acceptable methods and tracking, and partial payment guidance.

Policy

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 neither has 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.) be used.
As each protocol differs, there are no established policies as to the amount and type of payments that may be offered to research subjects and families. The IRB will consider the time commitment and the proposed procedures, when determining if the planned amount is appropriate.

Renumeration requirements:
The protocol application and informed consent should describe in detail:

- When the subject will receive the remuneration
- Specification of the type of payments to be offered and what will be provided (toys, gift card, cash, voucher, check, etc.)
- Who will be provided with remuneration parent and/or child
- Any other appropriate details

Remuneration may *not*:

- Be sizeable enough to induce subjects to participate, regardless of how minimal the risk.
- Require that a subject complete the research in order to receive compensation.

The IRB recognizes four types of payments:

1. Reimbursement
2. Compensation
3. Tokens of appreciation
4. Incentives

In addition to approving specific amounts and types of payments, the IRB may also require changes in the amount and/or type. Any change or modification to approved amounts and/or types of payment must be submitted to the IRB as an amendment.

Taxable Income: 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 must be reported to the Internal Revenue Service as taxable income.

- *Requirement*: The informed consent must address this fact. For suggested wording, see: ***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 with the amount of compensation paid.

Partial Payment: If a subject withdraws from a study, he or she must be offered payment for the completed portion of the study.

Procedures

Types of Payment

The IRB requires investigators to identify the amounts and types of payments offered to research subjects. Investigators are encouraged to consider what on average is reasonable.

1. **Reimbursements:** Direct, research-related expenses incurred by the family as a result of their participation in the research study. Examples: transportation, parking, meals, and childcare.

2. **Compensation**: Payment to families, children, and adolescents for the time and inconvenience of research participation. Compensation is intended to negate the burdens and inconveniences that research participation adds to families' lives. Example: A parent or adolescent is away from work in order to participate.

3. **Tokens of appreciation** are small payments, gifts, gift certificates, or savings bonds given to the family to thank them for their efforts or participation.

4. **Incentives**: 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. Incentives are generally discouraged in pediatric research; however, the IRB 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. Examples include "completion bonuses," additional payments above and beyond expense reimbursements, and compensation that are made as the study progresses.

Renumeration Methods and Tracking Guidance

Once the remuneration for the protocol has been approved, the IRB recommends the following processes depending on the method. This guidance is an effort to encourage the streamlining of

the renumeration process, while improving the tracking of research funds and simultaneously reducing research staff liability.

ClinCard Information

Research Finance provides the option to use ClinCard system to distribute and track participation renumeration. Participants can use ClinCards in the following ways:

- In-store purchases (as a Credit or Debit Card)
- Online purchases
- ATM withdrawals
- Cash advances

See: ***Research Finance: ClinCard Information***

Gift Cards/Vouchers

1. Gift Cards/Vouchers should be purchased by the study team.
2. A log should be created and stored in the research binder to account for the cards. The log template should include the following:
    1. Unique ID on the gift card
    2. The location of the card
    3. The date the gift card was purchased.
3. Once the card has been distributed to the subject, the log should be updated to indicate:
    1. Date of distribution
    2. Study ID
    3. Recipient of the card/voucher: If the card was provided to the subject or the parent
    4. Research Staff member who distributed the gif card/voucher
4. Whenever possible, study staff should obtain a signed receipt from the subject 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.

Cash

1. Study staff may request that a local petty cash fund be established.
2. The amount requested should be based on anticipated visits and approved subject payments.
3. 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.
4. **Petty Cash Policy**: This policy is to account for funds and to limit the amount of cash that is being stored for subject remuneration.
    i) It is the responsibility of the study staff to ensure that undisbursed cash is properly safeguarded. This would include keeping the cash in a locked location and limiting access.

ii) Investigators should consider how to best organize within their clinical research organizational structures to request the $500.

iii) If you have any questions regarding this policy please contact Lina Tollis at 857-218-4378 or lina.tollis@childrens.harvard.edu

5. To request a local fund, study staff will complete a ***Clinical Trial Subject Remuneration Voucher***.

   i) The principal investigator will approve the request by signing the voucher.

   ii) Once signed by the PI the voucher will be submitted to the Research Finance office for review.

   iii) If approved, Research Finance will sign the voucher and return it to the study staff.

   iv) The signed voucher can be taken to the hospital cashier's office for payment.

   v) The study project will not be charged until payments are distributed to subjects.

   vi) **Renumeration Log**: As individual payments are provided to parents/study subjects out of this fund, they must be recorded on a Remuneration Log.

      (1) A separate log will be maintained for each study.

      (2) The log will indicate: 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.

   vii) Remuneration logs will be submitted to the Research Finance department on a monthly basis.

      (1) Monthly submission ensures that local petty cash fund can be replenished, and the study project can be charged for the payments distributed.

      (2) Logs may be submitted as frequently as necessary to maintain sufficient cash in the fund.

      (3) Researchers should allow three business days for replenishment to occur.

Check

1. A requisition for payment for an individual subject should be sent to Accounts Payable for the appropriate amount.
2. 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.
3. Accounts payable will send the check directly to the research subject.
4. A copy of the Accounts Payable requisition request should be maintained in the study binder.
5. Only the protocol number or fund number should be noted on the requisition (not the protocol title).

Partial Payment

If there are multiple visits, 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 Withholding payment until the end of the study may make the subject feel that they are required to complete all the visits, 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.

When designing the remuneration policy for the protocol, time consuming practices should be minimized and avoided where possible.

- **Example**: Indicating that travel expenses will be reimbursed based on actual miles traveled, which require the payment to be calculated for each subject is very time consuming.
- **Recommendation**: 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.).

Related Content

BCH Website

Research Finance: ClinCard Information

BCH/IRB Forms

Consent Form Template.

Clinical Trial Subject Remuneration Voucher

Document Attributes

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