| Title: | Cash Control and Accountability for Payments to Human Subjects for Participation in Research | |
|--------------------------|--|---|
| Department: | Finance | |
| Policy Type: | ☑ Partners System-wide☐ Partners Corporate☐ Entity | □ Partners System-wide Template□ Partners Corporate Departmental |
| Applies to: | All Partners HealthCare Entities, Employees and Agents | |
| Approved by: | Peter K. Markell, Executive Vice President of Administration and Finance | |
| Approval Date: | September 2010 | |
| Effective Date: | September 2010 | |
| Revision Date(s): | April 2012 | |
| Next Review Date: | April 2015 | |
| Contact Person: | Controller | |

KEYWORDS:

IRB: Institutional Review Board IRS: Internal Revenue Service

PHRC: Partners Human Research Committee (same as IRB)

Partners AP: Partners Accounts Payable department

PI: Principal Investigator RC: Research Compliance

PURPOSE:

The purpose of this policy is to detail the procedures applicable to researchers and their staff for obtaining, making, and maintaining accountability for payments to human subjects participating in research projects. The policy is intended to ensure appropriate institutional and investigator control over cash, cash equivalents, and other items provided in research studies consistent with the institutions' standards for financial accounting and responsibility

POLICY STATEMENT:

In order to ensure financial controls and accountability for cash, cash equivalents, and other items provided as payment to human subjects, investigators must follow the procedures described in this Policy. Research Compliance has a central role in this Policy as part of its responsibility for monitoring clinical research financial operations at the institutions. Working with institutional Controllers and Partners Accounts Payable (AP) or other groups within Partners as necessary, local Research Compliance will provide an oversight function for the Policy that may include procedures such as auditing/monitoring of required documentation,

collection of additional documentation or information, or additional institutional review and approval of specific payments, processes, or requests.

This Policy does not address taxation issues related to the various kinds of payments that may be made to research subjects or the required documentation and reporting of taxable payments. These issues are addressed in the Partners Human Research Committee's (PHRC) policy on Payments to Human Subjects for Participation in Research

http://library.partners.org/PartProd/trove.asp?FI=Research-

Human+Subject&DI=Payments+to+Human+Subjects+for+Participation+in+Research&HU=EmptyURL

The Policy also does not address the PHRC's (IRB's) consideration of fair and appropriateness of payments from a human subjects perspective, which is governed by the PHRC (IRB)'s related general policy on *Remuneration for Research Subjects*

http://healthcare.partners.org/phsirb/remun.htm. Investigators must abide by all of these policies and the requirements and procedures described therein.

PROCEDURES:

The following are the specific procedures and other considerations applicable to payments in the form of remuneration, reimbursement, and tangible items, respectively.

Remuneration

Remuneration includes cash or cash equivalents (e.g., checks, gift cards) provided to research subjects as compensation for the time and effort they spend participating in a clinical research study. (**Remuneration** is sometimes referred to as **compensation**, **stipend**, or **payment**.)

- 1. Limit on Cash Payments (Cash vs. Check)
 Payments greater than \$50 must be made by Partners AP check.
- Payments Using a Partners Procurement Card
 Using a Partners Procurement Card to purchase gift cards or gift certificates as payment (up
 to and including \$50) for subjects is **not** allowed, unless approved in advance by the
 Partners' Research Controller.
- 3. Gift Cards/Gift Certificates

Gift cards and gift certificates should be treated like cash from both accountability and reporting perspectives. Investigators are responsible for their safekeeping and appropriate documentation (see 4b below) of their distribution to subjects. It is important for researchers to avoid over-purchasing these items.

4. Procedures for Receiving Cash

The following procedures outline the requirements for obtaining cash for disbursement of payments to research subjects, for the safeguarding and documentation of such payments, and for appropriate reconciliation of cash balances. Questions or requests for exceptions to these procedures should be addressed to local Research Compliance after approval of the study protocol by the PHRC (IRB).

- a. Procedure for the establishment of a petty cash fund
 - 1) After protocol approval by the PHRC (IRB) and coordination with Research Compliance, if necessary, an online Check Request ("eCheck") must be submitted to Partners' Accounts Payable for the total amount required, payable to the Petty Cash Custodian of the department and authorized by the Principal Investigator (PI). When

establishing the petty cash fund, account 919700 Petty Cash should be charged to avoid any tax reporting issues for the petty cash custodian. In addition, the following documentation must be attached to the eCheck submission via a file upload or scanning to a dedicated fax line:

- a) A copy of the PHRC (IRB) approval letter
- b) An estimated payment schedule consistent with the payment provisions approved by the IRB including anticipated dates, numbers of subjects, and amounts to be paid. The schedule is for planning purposes only.
- 2) The eCheck request will be routed to the PI for approval through electronic work-flow before submission to AP for payment. Within 10 business days after receipt of the eCheck submission, AP will issue a check.
- b. Procedure for safeguarding and documenting cash payments to subjects
 - 1) Checks received for subject payment may not be deposited into investigators' personal bank accounts. They must be cashed and the funds safeguarded in a secure and appropriate manner. This includes storing the cash in a secure lock box with limited and controlled access by the Principal Investigator or designee. The PI is ultimately in control of the funds and responsible for the distribution and reconciliation of the cash.
 - 2) During the conduct of the research, the preferred practice is to record the date, amount of payment, and signature of the recipient. The name of the individual disbursing the payment must be indicated in the record.
- c. Reconciliation of petty cash balances for replenishment
 - 1) If the study is to continue and additional funding is needed, an eCheck must be submitted (with appropriate documentation attached) to Accounts Payable.
 - 2) Once the subject payments have been made, or prior to the draw-down of additional funds to continue the study, the Petty Cash balance must be reconciled.
 - 3) In order to obtain additional cash, the "Cash Payment Log" (for Replenishment of Petty Cash) worksheet is required. The document is an Excel file and is the required mechanism to record and track payments to subjects. The Cash Payment Log must include the following data:

Research Fund Number

Date cash was given to Subject

Coded subject number or subject name

Cash reimbursement and cash remuneration provided

Name of the individual disbursing the payment

- d. Study Closeout
 - If the study has ended and all of the allocated funds have <u>not been paid</u> to subjects, the balance must be returned for re-deposit into the study fund at the Cashier's Office and credit the Petty Cash account, 919700.

Reimbursement

Reimbursement includes re-payments to research subjects to cover expenses they incur while participating in clinical research, e.g., reimbursement for travel expenses such as taxi fare or parking. It also includes direct payments of such expenses that subjects would otherwise have to incur to participate in the research, e.g., direct booking and payment for a flight or hotel room for a subject to travel or stay here for a study visit, or provision of a parking sticker or meal voucher.

1. Receipts

Reimbursement may be made only if a receipt is provided by the subject. In the event of a direct payment of expenses by the investigator, the investigator must retain the receipt or maintain equivalent documentation of the payment.

- 2. Limit on Cash Reimbursements (Cash vs. Check)
 Reimbursements greater than \$50 must be made by Partners AP check.
- 3. Meal Vouchers / Parking Stickers and Other Direct Payments Investigators should be aware that meal vouchers and parking stickers are available and may be more efficient than providing reimbursement for small or numerous such expenses, as they eliminate the need for cash or an eCheck. Other direct payment of significant expenses, such as flights and hotel rooms are encouraged when possible to avoid complicated subject reimbursement requests.
- 4. Procedures for Receiving Cash
 The same procedures for receiving cash described above under "Remuneration" apply to
 receiving cash for reimbursements as well.

Tangible Gifts

Tangible Gift includes items of nominal value (\$100 or less) that are given to a research subject

- 1. Grant Requirements
 - The use of tangible gifts as payments must be consistent with the terms of the grant or other source of funds.
- 2. Payments Using a Partners Procurement Card
 Using a Partners Procurement Card to purchase tangible gifts as payment for subjects is **not** allowed.
- 3. Accountability

Although tangible gift items may be considered expendable, care should be taken not to over-purchase them. Investigators are responsible for the safekeeping of the distribution of these items to subjects. Researchers anticipating the use of such items for subject payment should contact their local Research Compliance office with any questions prior to purchasing such items.

OTHER APPLICABLE PARTNERS HEALTHCARE POLICIES:

See the PHRC (IRB)'s related general policy on *Remuneration for Research Subjects*, which governs consideration of fair and appropriate payments to research subjects: http://healthcare.partners.org/phsirb/remun.htm

See also the PHRC's policy on *Payments to Human Subjects for Participation in Research*, which addresses taxation issues related to the various kinds of payments that may be made to research subjects or the required documentation and reporting of taxable payments: http://library.partners.org/PartProd/trove.asp?Fl=Research-

Human+Subject&DI=Payments+to+Human+Subjects+for+Participation+in+Research&HU=EmptyURL

ATTACHMENTS: Cash Payment Log

DEVELOPMENT AND CONSULTATION

| Reviewed by: | Original Review Date: | Revision Approval Dates: |
|-------------------------------|-----------------------|--------------------------|
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| Office of the General Counsel | September 2010 | April 2012 |
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