

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	May 2010
Section 7.7	Clinical Research	Revised:	July 2016
Policy 7.7.2	Management of Research Participant Payments	Responsibility:	Vice President for Research

MANAGEMENT OF RESEARCH PARTICIPANT PAYMENTS

Policy

The policy of the UT Health Science Center requires that researchers providing payments to research participants follow uniform processes in the management of cash and cash substitutes. Uniform methods for documenting, tracking, and approval are needed in four key areas:

- 1) identifying approved payments;
- 2) tracking payments to participants;
- 3) tracking transfers of payment inventory and
- 4) reconciling inventories.

Failure to adequately manage these operations jeopardizes the financial and ethical integrity of research at the Health Science Center. Training on this policy and its required documentation is mandatory for anyone who assumes a role or responsibility defined in the policy. Exceptions to this policy must be submitted for prior approval by the Clinical Trials Office (CTO).

Before participant payments can be made they must be approved by the Clinical Trials Office (CTO). When total study payments exceed \$1,000 (USD) per subject per study, approval by the Principal Investigator's Dean (or designee) is required. The Custodian and the Payor (or a Witness), are the two parties validating payments to subjects. Inventory integrity is authenticated by reconciliations conducted by the Department Representative and witnessed by the Custodian. The preferred method of payment is the Health Science Center (HSC) debit card. Debit cards may not be issued to study participants prior to completing an event or milestone in which a payment is to be disbursed. Studies that were CTO approved prior to May 12, 2014, the effective date of the Health Science Center debit card, may continue to use the payment method approved per the studies approved [Subject Payments Schedule](#). The Office of Sponsored Programs (OSP) will ensure that a full cost estimate for each study is provided when reviewing a grant or contract and that the participant payment costs are an allowable expense. All suspected incidents of fraud or misuse must be reported to the Custodian, The Principal Investigator (PI), the CTO, the Bursar, the

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OSP, the Dean (or designee) and the UT Police department.

The [Research Team Process Guide](#) documents the Health Science Center processes and procedural compliance requirements for participant payments. The CTO requires a [Participant Payment Workbook](#) to document the payment plan for a study.

Definitions

CUSTODIAN: The person designated to guard and manages the payment account or inventory (i.e., Health Science Center debit cards, petty cash, gifts or local/state vouchers) or Sponsor provided items (i.e. debit cards, gift cards, gifts). Disburses and approves payments for participants in accordance with the [Subject Payments Schedule](#); distributes payment inventory through the use of the [Payor Distribution Form](#); prepares and provides unique ID numbers to [Subject Payment Form](#); collects and manages all required documentation for the participant payments. The Custodian is responsible for witnessing reconciliations completed by the Department Representative using the [Reconciliation Log](#); and is responsible for shortages or overages; and the reporting of shortages and overages to their supervisor, the Principal Investigator (PI), the CTO, the Bursar, the OSP, the Dean (or designee) and the UT Police department.

DEPARTMENT REPRESENTATIVE: A responsible person who is independent of the business operations of a study. The Department Representative conducts required inventory reconciliations using the [Reconciliation Log](#). Collects and maintains completed Reconciliation Logs. Responsible for reporting shortages and overages to their supervisor, the Principal Investigator (PI), the CTO, the Bursar, the OSP, the Dean (or designee) and the UT Police department.

RESEARCH PARTICIPANT: The individual who is receiving payment for participating in the given research study.

PAYMENT: Research Participant compensation via Health Science Center debit cards, cash, check by local/state voucher, or gifts e.g., mugs, duffle bags, logoed items. Any items provided by the Sponsor for subjects (i.e. debit cards, gift cards, gifts)

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PAYOR: A member of the research team (typically a study coordinator) who works with the Custodian to provide payments to subjects. The Payor obtains signed [Subject Payment Form](#) from Payee(s) as proof of payment for the Custodian. They also request electronic payments for subjects with HSC debit cards. Payors are financially responsible for all payment inventory entrusted to them and are responsible for reporting all payment shortages and overages to the Custodian.

PETTY CASH FUND: In accordance with [Section 6.4.3](#), “Petty Cash Fund” in the *Handbook of Operating Procedures* (HOP), a research participant petty cash fund is required for cash payments to research participants. Petty cash funds can only be used for direct payments to participants and cannot be used to purchase gift inventory. Custodians must submit a [Petty Cash Fund Request](#) form to the Bursar’s Office to establish an account. The University of Texas System Administration Policy, [UTS166](#), “Cash Management and Cash Handling Policy”, and [Section 6.4.3](#) of the HOP, “Petty Cash Fund,” cover additional issues regarding cash management, handling, and petty cash that are not addressed in this policy.

HEALTH SCIENCE CENTER DEBIT CARD: The preferred method of payment by the Health Science Center, this is a re-loadable Master Card issued to participants for making subject payments. Funds are added to a subject’s debit card by the research team when payment milestones have been met. This process is managed using a Health Science Center approved software application.

PRINCIPAL INVESTIGATOR: Directs and is responsible for a research project, including the scientific, technical and management aspects of the research.

WITNESS: Has first-hand knowledge that a payment has been made to a research participant. The witness cannot be another study participant or a relative of the Payee.

Payment Administration in Research

A given research study may have one or more types of payment, but they must all be funded from only one Project/Grant ID number. Research participants routinely receive approved payment methods in the form of Health Science Center debit card, cash, local/state voucher, or gifts. Health Science Center employees enrolled in research are

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eligible for all participant payments.

The [Subject Payments Schedule](#) (SPS) is a detailed schedule of payment events or milestones, the compensation amount and type. An SPS approved by the CTO is required prior to establishing a payment account, acquiring inventory or making payments to subjects. A copy of the SPS must be kept on file by the Custodian and available for access and review by all other research team members with a role in the participant payment process. Payments must be consistent with the approved version of the SPS; changing the type or amount of payment is not allowed. Proposed changes to the schedule require CTO approval prior to implementing. The CTO will distribute revised copies of the SPS to the PI, Custodian and Bursar. The Custodian must ensure that all payments adhere to the [Subject Payments Schedule](#). Custodians are responsible for managing all required documentation for the subject payment process except for the [Reconciliation Log](#) (RL) which is managed by the Department Representative.

[Reconciliation Logs](#) must be managed and maintained by the Department Representative. The Department Representative establishes a schedule for reconciliations to ensure that all inventories remain secure using the [Reconciliation Log](#) (RL). Reconciliations should be performed based on study activity, but at a minimum should be completed monthly. Reconciliations are also required when opening or closing an account or inventory; when adding new inventory or changing the inventory level; and when changing Custodians or Department Representatives.

**Clinical Trials
Office
Responsibilities**

The Clinical Trials Office (CTO) is responsible for developing institutional policies and business processes for clinical research operations, approving payment methods and inventory levels for studies, approving and distributing the [Subject Payments Schedules](#), administration of the Health Science Center debit card system; and training, and oversight of participant payment operations. Mandatory training required for this policy will be managed by CTO. The CTO will advise research teams on the applicability of this policy.

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Office of the Bursar Responsibilities

The Bursar's Office is responsible for cash and Health Science Center debit card management. To include maintenance of adequate liquidity to fund short-term financial needs, management and coordination of Health Science Center banking services. The Bursar will advise research teams on the applicability of this policy.

Central Accounting Responsibilities

Accounting will determine which study participants, if any, need an IRS Form 1099 at calendar year end. Accounting will request that study coordinators obtain a completed [Vendor/Payee Set-Up Form](#) for any study participants as needed.

Principal Investigator Responsibilities

The Principal Investigator will ensure that standard procedures and staffing for studies are in place in compliance with this policy. Principal Investigators will provide routine oversight of participant payments to verify adherence to this policy.

Types of Participant Payments

Health Science Center Debit Card: (Preferred) The Health Science Center debit card is issued by the Bursar's Office. Debit cards are provided to study participants by researchers who make electronic payments to the debit card when payment milestones have been met.

Cash Payments: Cash can be provided to participants using a petty cash fund issued by the Bursar's Office. This petty cash can only be used for participant payments and cannot be used for purchases.

Gifts: Gifts are incentive items provided to participants. Gift inventory must be purchased using local/state vouchers (see below). Health Science Center funds may not be used to purchase gift cards for studies receiving CTO approval after May 12, 2014. The use of sponsor-provided gift cards requires CTO approval and must adhere to applicable requirements of this policy.

Local/State Voucher – Local/state vouchers may be used to make payments by check and to purchase gift inventory. Purchases of gift cards are not allowed for studies receiving CTO approval after May 12, 2014. See local/state voucher instructions.

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Sponsor Payment Methods of Participant Payments: Any items provided by the Sponsor for subjects (i.e. debit cards, gift cards, gifts). Given they are managed in accordance with the policy.

Prohibited Payment Practices

- Research participants are not allowed to give or receive payment or gifts to facilitate enrollment to a study
 - Study personnel are not allowed to give or receive payment or gifts to facilitate enrollment to a study
 - Discount coupons for the test article (to be used after the product has been approved for marketing) are prohibited
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Vendor/Payee Set Up Forms

In accordance with the May 10, 2005, [Business Affairs Bulletin, No. 8 - FY 2005](#), "Refunds, Reimbursements and Patient Study Payments, Local/State Voucher And Travel Voucher Transactions Not Requiring Payee SSN", subject participants must be established as a "Payee" in PeopleSoft if their participant payments are greater than \$500 within one calendar year. If the expected payments are greater than \$500 per calendar year and the participant is not already set-up as a payee in PeopleSoft, the Custodian or Payor must prepare a [Vendor/Payee Set-Up Form](#).

Payments to patients in research studies are excluded from [Section 6.1.4](#), of the HOP, "Payments to Consultants and Non-Employees", and are not subject to the "prior approval" conditions of that policy.

Subject Payments Schedule

For a study to make participant payments it must have a CTO approved [Subject Payments Schedule](#). This schedule is the basis for making participant payments. The SPS documents a detailed schedule of the payment events or milestones, the compensation amount and type. For additional information see the [Research Team Process Guide](#), Subject Payments Schedule Section

Gift Log

If gift items or Health Science Center debit cards are used for payment the Custodian must establish the cumulative inventory on a [Gift Log](#). Only one type of inventory can be entered per [Gift Log](#). For studies

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using multiple gift types, each gift inventory requires a separate [Gift Log](#). For additional information see the [Research Team Process Guide](#), Gift Log Section.

Subject Payment Form

The [Subject Payment Form](#) documents the payment events or milestones, the compensation amount and type being distributed to the study participant. A study participant's signature is required on the form to document their receipt of the study payment(s). These signed forms are receipts for payments made and should be maintained and managed to account for participant payment history. For additional information see the [Research Team Process Guide](#), Subject Payment Form Section.

Payor Distribution Form

A [Payor Distribution Form](#) is used when payment inventory is transferred from the Custodian to a Payor. This form documents the payment type and amount transferred from the Custodian to the Payor. It then documents the payment type and amount plus receipts, returned to the Custodian by the Payor. The amount returned, plus receipt value, must equal the amount originally issued. For additional information see the [Research Team Process Guide](#), Payor Distribution Form Section.

Reconciliation Log

The [Reconciliation Log](#) is completed by the Department Representative to document the mandatory periodic reconciliation of payment inventories. An inventory level is the cumulative inventory total documented on the Gift Log, or the Petty Cash Amount from the Bursar's Office. An inventory is in balance if the inventory on hand, plus the payment Receipts (SPF's), plus the Outstanding Inventory on PDFs equal the inventory level. Reconciliations help reduce the risk to the Custodian and the Institution. For additional information see the [Research Team Process Guide](#), Reconciliation Log Section.

In accordance with [Section 6.4.3](#) of the HOP, "Petty Cash Fund" overages/shortages of \$25 in a single incident or in aggregate during a one month period, by a Custodian must be investigated by the supervisor.
