

7.7.2 Management of Research Participant Payments

Chapter 7 - Research and Sponsored Programs	Original Effective Date: May 2010
Section: 7.7 Clinical Research	Date Last Reviewed: September 2021
Responsible Entity: Vice President for Research	Date Last Revised: September 2021

I. Purpose

The purpose of this Policy is to define the roles and responsibilities for administering Payments made from university managed funds to Research Participants.

II. Scope

This policy applies to research involving Payments to participants regardless of the original source of funding (industry-sponsor, institutional, federal grant, foundation grant, or other source).

III. Policy

- A. The policy of UT Health San Antonio (UTHSA) requires that researchers follow uniform processes to manage participant Payments (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 Payment inventories.

Failure to adequately manage these operations jeopardizes the financial and ethical integrity of research at the UTHSA. Training on this policy and its required documentation is mandatory for anyone who assumes a role or responsibility defined in this 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 CTO. When total study Payments exceed \$1,000 (USD) per subject per study, approval by the Principal Investigator's Dean (or designee) is required.

For grants or funding that falls within a restricted fund group, 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 OSP, the Dean (or designee) and the UT Police Department.

The <u>Research Team Process Guide</u> documents UTHSA process and procedural compliance requirements for participant Payments. The CTO requires a Participant Workbook to document the Subject Payment Schedule for a study outlining the payment milestones and the responsible parties. 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.

B. Payment Administration in Research

A given research 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 HSC debit card, cash, local/state voucher, or gifts. UTHSA employees enrolled in research are eligible for all participant Payments.

- 1. Responsibilities
 - a. Clinical Trials Office (CTO)

The 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 Schedule (SPS), administration of the HSC debit card system; and training, and oversight of participant Payment operations. Mandatory training required for this policy will be managed by the CTO. The CTO will advise research teams on the applicability of this policy.

b. Office of the Bursar

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

c. Central Accounting

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.

d. Principal Investigators (PI)

The PI will ensure that standard procedures and staffing for studies are in place in compliance with this policy. PIs will provide routine oversight of participant Payments to verify adherence to this policy.

- 2. Types of Participant Payments
 - a. Health Science Center (HSC) Debit Card (Preferred)

The HSC debit card is issued by the Office of the Bursar. Debit cards are provided to study participants by researchers who make electronic Payments to the debit card when Payment milestones have been met.

b. Cash Payments

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

c. Gifts

Gifts are incentive items provided to participants. Gift inventory must be purchased using local/state vouchers (see below). UTHSA 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.

d. 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.

e. 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.

- 3. Prohibited Payment Practices
 - a. Research Participants are not allowed to give or receive Payment or gifts to facilitate enrollment in a study.
 - b. Study personnel are not allowed to give or receive Payment of gifts to facilitate enrollment to a study.
 - c. Discount coupons for the test article (to be used after the product has been approved for marketing) are prohibited.

C. Vendor/Payee Set Up

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 the requirements of Handbook of Operating Policies (HOP), <u>6.1.4 Payments to Consultants and Non-Employees</u>, and are not subjected to the "prior approval" conditions of that Policy.

D. Subject Payments Schedule (SPS)

For a study to make participant Payments it must have a CTO approved SPS. 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 <u>Research Team Process Guide</u>, Subject Payments Schedule Section.

E. Tracking and Reconciliation of Payment Inventory

The Department Representative is responsible for documenting the mandatory periodic reconciliation of Payment inventories. Payment Inventories include any debit cards, petty cash, gift cards, gifts, or local/state vouchers used to compensate or reimburse subjects for participation in a study. These inventories are study specific and should remain separated from inventories being used for other studies. The Custodian of the Payment inventory maintains the documentation and witnesses the reconciliations. Documentation includes; what inventory has been received, inventory on hand and record of what has been dispensed to subjects. An inventory is in balance if the inventory on hand, plus record of what has been dispensed are equal to the inventory received for the study. Reconciliations help reduce the risk to the Custodian and the Institution. For additional information see the <u>Research Team Process Guide</u>, Reconciliation Log Section.

In accordance with HOP <u>6.4.3 Petty Cash Fund</u>, 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.

IV. Definitions

When used in this document with initial capital letter(s), the following words have the meaning set forth below unless a different meaning is required by context.

 $\underline{Custodian}$ – the person designated to guard and manages the Payment account or inventory (i.e., HSC 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.

<u>Department Representative</u> – 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.

<u>Health Science Center (HSC) Debit Card</u>– the preferred method of Payment by the UTHSA, 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 UTHSA approved software application.

<u>Payment</u> – there are four categories of Payments: 1) reimbursement, 2) compensation, 3) inducements, and 4) appreciation Payments. Payments are exchanged using various methods including HSC debit cards, cash, check by local/state voucher, or non-monetary gifts.

<u>Payor</u> – 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.

<u>Petty Cash Fund</u> – in accordance with HOP <u>6.4.3 Petty Cash Fund</u>, 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 Office of the Bursar to establish an account. The University of Texas System Administration Policy, <u>UTS166</u> (*Cash Management and Cash Handling Policy*), and HOP 6.4.3 (*Petty Cash Fund*), cover additional issues regarding cash management, handling, and petty cash that are not addressed in this policy.

<u>Principal Investigator (PI)</u> – directs and is responsible for a research project, including the scientific, technical and management aspects of the research.

<u>Research Participant</u> – the individual who is receiving Payment for participating in the given research study.

<u>Witness</u>- 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

V. Related References

Business Affairs Bulletin, No.8 - FY 2005, "<u>Refunds, Reimbursements, and Patient</u> Study Payments, Local/State Voucher and Travel Voucher Transactions Not Requiring Payee SSN"

VI. Review and Approval History

- A. The approving authority of this policy is the University Executive Committee.
- B. The review frequency cycle is set for three years following the last review date, a time period that is not mandated by regulatory, accreditation, or other authority.

Effective Date	Action Taken	Approved By	Date Approved
05/2010	Policy Origination		
07/2016	Policy Revision		
09/2021	Policy Revision, discretionary edits		