

Section Clinical Research Center

Date Created: November 1, 2010 replace SOP 22

Title: Subject Compensation

Date Reviewed/Modified: August 1, 2019

SOP Number: SOP-61

Version Number: 2

**PURPOSE:** This standard operating procedure (SOP) to describe the Clinical Research Center (CRC) process for review and approval of payments to human research participants.

**SCOPE:** This SOP applies to all site personnel involved in the implementation and coordination of clinical research.

**PERSONNEL RESPONSIBLE:** Principal Investigator and when delegated by the principal investigator, sub-investigators, study coordinator and/or other pertinent staff.

**DEFINITIONS:**

**Institutional Review Board (IRB)**--An independent group made up of medical, scientific and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by reviewing and approving the clinical protocol, informed consent form and the methods and materials used in the trial.

**PROCEDURES:**

- Compensation in any form is not considered a benefit to be weighed against risks in the IRB's assessment of the risk/benefit relationship of the research, and that compensation shall not be presented to the potential subject as a benefit in either the process of consent, or the potential benefits section of the consent form.
- An explanation of the visit payment schedule, amounts, etc must be included in the Institutional Review Board (IRB) application and consent form, to be reviewed and approved by the IRB.
- Per University of Nebraska Medical Center (UNMC), if research stipends (excluding travel reimbursements) to an individual will exceed \$600 in a calendar year, the Reward Visa Card program cannot be utilized.
- If the total disbursement (excluding travel reimbursements) by a department to an individual exceeds \$600 in a calendar year, the department must submit a W9 form and report the amount paid to Accounts Payable for IRS form 1099 reporting.

Once the study is active, if a study participant meets the requirements for reimbursement, the following must be completed to ensure the subject is reimbursed:

**Reimbursement via IRB Direct Payment System**

1. The study coordinator is responsible for instructing participants on the reimbursement process and turning in completed visit. The coordinator will confirm the participant's correct address.

Section Clinical Research Center

Date Created: November 1, 2010 replace SOP 22

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2. Coordinator will email the CRC Office Associate or appropriate department staff the following information so a stipend (see below for gift cards) can be issued when a compensated visit is completed:
  - a. study name
  - b. IRB#
  - c. patient's name and MRN#
  - d. date of service
  - e. visit number
  - f. Amount of the stipend to be distributed
3. CRC administrative personnel will process the requests for reimbursement via the IRB Direct Payment System via Management Resources. Participants will receive a check by US mail in approximately 4-6 weeks.

#### **Reimbursement via Gift Card System**

1. The study coordinator is responsible for instructing participants on the reimbursement process.
2. When the study participant is being paid with a gift card (\$10 minimum), it will be dispensed at the study visit by completing the following process in collaboration with the CRC Office Associate per [UNMC Reward Visa Card](#) procedures:

#### **Department Responsibilities:**

- a. Each Department shall have a designated responsible person (Custodian), who is responsible for the tracking, custody, and accounting of the reward cards to ensure this procedure is followed.
- b. Reward cards must be kept in a secure location (locked in drawer or safe) and accessible only by the Custodian.
- c. Departments shall only keep on hand approximately 3 months of estimated use.
- d. Departments must maintain a log on a tracking spreadsheet that is saved on the network (not on a computer hard drive). The detailed procedure for Log Documentation is set forth in Section VI.
- e. If the reward card expense is charged to a grant or contract, a physical count needs to be performed during the project close out process. Departments shall post a journal entry to transfer any remaining inventories from the closed WBS to a departmental account.
- f. Monthly physical inventory count of the reward cards must be performed by an individual other than the Custodian.

Section Clinical Research Center

Date Created: November 1, 2010 replace SOP 22

Title: Subject Compensation

Date Reviewed/Modified: August 1, 2019

SOP Number: SOP-61

Version Number: 2

- g. Departments are responsible for lost or stolen cards. The Custodian may be held personally liable for the value of any missing cards.
- h. If cards are lost or stolen, Departments must contact Campus Security and the Controller's Office for immediate action.
- i. If there are unused cards, contact the Controller's Office.
- j. The department must retain all reward card distribution records in its files according to the University record retention policy.
- k. If the total disbursement (excluding travel reimbursements) by a department to an individual exceeds \$600 in a calendar year, the department must submit a W9 form and report the amount paid to Accounts Payable for IRS form 1099 reporting.

#### **Cashiering Office Responsibilities:**

- a. Cashiering Office is responsible for processing, receiving, and distributing reward cards to Departments.
- b. Cashiering Office posts journal entries to charge the reward card expenses to the WBS or Cost Center provided on the Reward Card Application Form with GL 526902 – Research Study Participant or GL 526001 – Contracted Service – Travel Expense.
- c. Cashiering Office creates an initial log on a spreadsheet to track the receipt and distribution of reward cards and provides the log to department custodians to maintain and collect additional information while the department distributes cards to research participants.
- d. Cashiering Office performs reward card audits and test counts on a quarterly basis. Any findings of the audit or test counts will be communicated to the Controller's Office.

#### **Log Documentation:**

- a. Cashiering Office compiles an initial log on a spreadsheet to track the receipt and distribution of reward cards. The spreadsheet shall include the following information:
  - Date of distribution to department
  - Name of the department
  - Name of the custodian
  - Card serial number
  - Dollar amount of card

Section Clinical Research Center

Date Created: November 1, 2010 replace SOP 22

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SOP Number: SOP-61

Version Number: 2

- IRB#
  - WBS or Cost Center
  - Type of the disbursement (T - Travel Reimbursement, S - Stipend, O – Other)
- b. Cashiering Office provides the Excel Log to Department Custodian to maintain and collect additional information while distributing cards to research participants.
- c. Department Custodian shall collect the following information:
- Date of distribution to research participant (recipient)
  - Name of recipient or subject ID if a study is confidential
  - Name of staff member giving out reward card
  - Signature of recipient to acknowledge receipt of the reward card
- d. A copy of the log must be sent monthly to the Controller's Office until all gift cards are distributed or returned to the Controller's Office.

## Reimbursement for Study Related Travel

### A. Study Reimbursed Travel

1. The study coordinator is responsible for instructing participants on the reimbursement process and turning in receipts. The coordinator will confirm the participant's correct address.
2. The route from the participant's home to the site must be outlined by online mapping service to document mileage
3. Coordinator will email the designated administrative staff the following information so a stipend can be issued:
  - a. study name
  - b. IRB#
  - c. patient's name
  - d. MRN#
  - e. date of service
  - f. dollar amount
  - g. Receipts
  - h. Mileage
4. CRC administrative personnel will process the requests for reimbursement. Participants will receive a check by US mail in approximately 4-6 weeks.
5. When the study participant is being paid with a gift card, it will be dispensed at the study visit by completing the following process in collaboration with the CRC Office

Section Clinical Research Center

Date Created: November 1, 2010 replace SOP 22

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SOP Number: SOP-61

Version Number: 2

Staff per [UNMC Reward Visa Card](#) procedures. See Section [Reimbursement via Gift Card System](#) of this SOP for details.

## **B. Study Related Travel is NOT Reimbursed**

1. In special circumstances, if an individual participant lacks transportation or funds to complete study visits, the study coordinator will:
  - a. Consult Investigator and advise CRC Director of Clinical Research Operations of the situation.
  - b. The CRC Director of Clinical Research Operations or Start-up Manager will review contract services with the Investigator and sponsor and authorize coordinator if mileage expense can be covered.
2. Because travel reimbursement will most likely not be IRB approved, a protocol deviation must be submitted and approved by the IRB in order to reimburse a subject.

### **ASSOCIATED FORMS:**

#### **SOP-61 Rewards-Card-Procedure**

SOP-61  
Rewards-Card-Proce

#### **SOP-61 Gift Card request form**

SOP-61  
Rewards-Card-Requ

#### **SOP-61 Stipend Receipt for Receiving Gift Card**

SOP-61 Stipend  
Receipt for receiving

#### **SOP-61 Stipend Record for Gift Card**

SOP-61 Stipend  
Record for gift card.

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## RESOURCES:

### UNMC:

- [IRB Policy #3.8 Research Subject Compensation](#)
- Reward Visa Cards at <https://info.unmc.edu/management/finance/controller/Reward-Visa-Card.html>

### Staff Accountability:

Developed By: Director of Clinical Research Operations, Clinical Research Center  
Medical Director, Clinical Research Center

Reviewed By: Office Associate, Clinical Research Center

### Department Approval

Signed   
Director of Clinical Research Operations

Signed   
Medical Director of Clinical Research Center





## REWARDS CARD PROCEDURE

### I. Overview:

Effective on May 1, 2019, the Reward Visa Cards will replace the gift card program which is currently in place. UNMC departments shall use the Reward Card Application Form to request prepaid cards for the disbursement of research study - stipends if the amount to any participant is less than \$600 within a calendar year. Departments can also use reward cards to disburse research study – travel reimbursement or other payments with prior approval from the Controller’s Office.

If research stipends (excluding travel reimbursements) to an individual will exceed \$600 in a calendar year, the Reward Visa Card program cannot be utilized. The disbursement request shall initiate through the IRB Direct Payment System. The information regarding the IRB Direct Payment System is set forth in Section VII.

### II. Purpose of Procedure:

To set forth the requirements of reward cards related to use, approval, purchase, safeguarding, and accounting. Reward cards are cash-like instruments and it is important they are carefully controlled and documented.

### III. Request and Approval Process:

- a. Departments must submit the [Reward Card Application Form](#) to the Controller's Office ([controller@unmc.edu](mailto:controller@unmc.edu)) for approval.
  - o Employees should not use personal funds to directly purchase similar cards and seek reimbursement. Failure to follow these procedures could lead to a denied reimbursement request.
- b. Other payment solutions besides reward cards will be a part of the review (such as, use of IRB Direct Payment).
- c. Reward Card is limited for approved IRB Programs or other programs with written prior approval.
- d. The quantities of reward cards shall be ordered not to exceed the distribution over a three-month period.
  - o Departments are not allowed to order a large quantity simply because it is in the project budget.
- e. Upon approval from the Controller’s Office, it will take 6-8 business days for the Cashiering Office to process orders and receive reward cards from US Bank.
- f. Upon receiving reward cards, Cashiering will contact Departments for pickup.



#### **IV. Department Responsibilities:**

- a. Each Department shall have a designated responsible person (Custodian), who is responsible for the tracking, custody, and accounting of the reward cards to ensure this procedure is followed.
- b. Reward cards must be kept in a secure location (locked in drawer or safe) and accessible only by the Custodian.
- c. Departments shall only keep on hand approximately 3 months of estimated use.
- d. Departments must maintain a log on a tracking spreadsheet that is saved on the network (not on a computer hard drive). The detailed procedure for Log Documentation is set forth in Section VI.
- e. If the reward card expense is charged to a grant or contract, a physical count needs to be performed during the project close out process. Departments shall post a journal entry to transfer any remaining inventories from the closed WBS to a departmental account.
- f. Monthly physical inventory count of the reward cards must be performed by an individual other than the Custodian.
- g. Departments are responsible for lost or stolen cards. The Custodian may be held personally liable for the value of any missing cards.
- h. If cards are lost or stolen, Departments must contact Campus Security and the Controller's Office for immediate action.
- i. If there are unused cards, contact the Controller's Office.
- j. The department must retain all reward card distribution records in its files according to the University record retention policy.
- k. If the total disbursement (excluding travel reimbursements) by a department to an individual exceeds \$600 in a calendar year, the department must submit a W9 form and report the amount paid to Accounts Payable for IRS form 1099 reporting.

#### **V. Cashiering Office Responsibilities:**

- a. Cashiering Office is responsible for processing, receiving, and distributing reward cards to Departments.
- b. Cashiering Office posts journal entries to charge the reward card expenses to the WBS or Cost Center provided on the Reward Card Application Form with GL 526902 – Research Study Participant or GL 526001 – Contracted Service – Travel Expense.
- c. Cashiering Office creates an initial log on a spreadsheet to track the receipt and distribution of reward cards and provides the log to department custodians to maintain and collect additional information while the department distributes cards to research participants.
- d. Cashiering Office performs reward card audits and test counts on a quarterly basis. Any findings of the audit or test counts will be communicated to the Controller's Office.





**VI. Log Documentation:**

- a. Cashiering Office compiles an initial log on a spreadsheet to track the receipt and distribution of reward cards. The spreadsheet shall include the following information:
  - Date of distribution to department
  - Name of the department
  - Name of the custodian
  - Card serial number
  - Dollar amount of card
  - IRB#
  - WBS or Cost Center
  - Type of the disbursement (T - Travel Reimbursement, S - Stipend, O – Other)
- b. Cashiering Office provides the Excel Log to Department Custodian to maintain and collect additional information while distributing cards to research participants.
- c. Department Custodian shall collect the following information:
  - Date of distribution to research participant (recipient)
  - Name of recipient or subject ID if a study is confidential
  - Name of staff member giving out reward card
  - Signature of recipient to acknowledge receipt of the reward card
- d. A copy of the log must be sent monthly to the Controller's Office until all gift cards are distributed or returned to the Controller's Office.

**VII. IRB Direct Payment System:**

- a. **IRB Direct Payment System:** Departments can initiate disbursement requests through the IRB Direct Payment System for research study stipends and associated travel reimbursements to research participants.
- b. **Access to IRB Direct Payment System:** Departments access the IRB Direct Payment System via Management Resources. Accounts Payable grants access of IRB Direct Payment System to Departments upon request.
- c. Contact Information: [unmcaccountspayable@unmc.edu](mailto:unmcaccountspayable@unmc.edu)



# REWARDS CARD APPLICATION FORM

Departments must submit the Form to the Controller's Office ([controller@unmc.edu](mailto:controller@unmc.edu)) for approval.

Will the Research Study – Stipend for this project (excluding travel reimbursements) to any individual exceed \$600 in a calendar year?

- If “Yes”, stop and initiate the disbursement request through IRB Direct Payment System.
- If “No”, continue and complete this Reward Card Application Form

Date: \_\_\_\_\_ Department: \_\_\_\_\_

Requestor: \_\_\_\_\_ Custodian: \_\_\_\_\_

Phone: \_\_\_\_\_ Zip: \_\_\_\_\_ Phone: \_\_\_\_\_ Zip: \_\_\_\_\_

Principal Investigator: \_\_\_\_\_ IRB#: \_\_\_\_\_

Cost Center or WBS: \_\_\_\_\_

### Reason for Request

*(A copy of IRB needs to be submitted along with the application)*

- Research Study – Travel Reimbursement (Code “T”)
- Research Study – Stipend (Code “S”)
- Other (Code “O” – Provide explanation)

### Request Amount (\$10 minimum)

Reason for Request	QUANTITY	DOLLAR AMOUNT	TOTAL
			0.00
			0.00
			0.00
			0.00
			0.00
			0.00
<b>TOTAL:</b>			0.00

Requestor Signature

Date

Controller Office Approval

Date

Dept. Pickup

Date

Cashiering Process

Date

I, patients name: \_\_\_\_\_ received a \_\_\_\_ \$-- gift card for Visit # \_\_\_\_\_ in the  
*Patient's name*

\_\_\_\_\_ Study.

Date: \_\_\_\_\_

Patient signature indicates card received \_\_\_\_\_

Card #	Date Purchased	Date Issued	Study ID/IRB #	Serial #	Amount #	Issued By	Comments
1							
2							
3							
4							
5							
6							
7							
8							
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