



Campus Administrative Policy

Policy Title: Study Subject Payments

Policy Number: 2010 Functional Area: **Finance**

Effective: July 1, 2012
Date Last Amended/Reviewed: July 1, 2012
Date Scheduled for Review: July 1, 2019
Supersedes: Study Subject Payments (February 1, 2010)

Approved by: Associate Vice Chancellor for Administration and Finance

Prepared by: Finance Office
Reviewing Office: Provost and Executive Vice Chancellor for Academic and Student Affairs
Responsible Officer: Controller

Applies to: University of Colorado Denver
University of Colorado Anschutz Medical Campus

A. INTRODUCTION

This policy establishes the procedures and methods of payments to Study Subject participants at the University of Colorado Denver (CU Denver | CU Anschutz), including Internal Revenue Service (IRS) tax reporting requirements.

Each CU Denver | CU Anschutz department head or person responsible for the administration of clinical trials, protocols, or surveys involving Study Subjects shall be responsible for compliance with this policy when providing compensation to participants.

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C. **APPLICABILITY AND DEFINITIONS**

1. **Applicability**

This policy applies to all clinical trials, protocols or surveys that provide compensation to Study Subjects. It is the responsibility of the investigator to take the appropriate steps to maintain the confidentiality of the study subjects when making payments and to comply with IRS and University reporting requirements.

2. **Definitions**

Clinical Trial: A type of research study that uses volunteers to test new methods of screening, prevention, diagnosis, or treatment of a disease. This is also called a clinical study.

COMIRB: Colorado Multiple Institutional Review Board.

HIPAA: Health Insurance Portability and Accountability Act of 1996, which requires protecting the privacy of patients' health information

Investigator: A person who is responsible for the design, conduct, or reporting of research.

Petty Cash: Monies used for small payments to study subjects or for incidental expenses when not otherwise obtainable by procurement card or other convenient means.

Protocol: A detailed plan of a scientific or medical experiment, treatment, or procedure.

Survey: a query of a group in order to collect data for the analysis of some aspect thereof.

Study Subject: is an individual about whom an investigator conducts research and obtains data through intervention or interaction with the individual

D. **POLICY STATEMENT**

1. **Approval**
All clinical trials, protocols or surveys involving Study Subjects require prior approval from COMIRB on the CU Anschutz campus and the Human Research Committee on the CU Denver Campus. If payment is to be made via petty cash, gift certificates/cards, money orders and or non-cash items, approval must also be obtained from the Finance Office prior to making any payments to Study Subjects.
2. **Taxable Income**
All payments to Study Subjects are considered “compensation” for time and inconvenience and are considered taxable income to the recipient per the Internal Revenue Code. The Study Subject must be provided a notification, regardless of the dollar amount to be paid during the calendar year, informing the individual that any cash payments, gift certificates/cards, money orders and or non-cash items that are received in exchange for being a participant in a clinical trial, protocol, or survey, are taxable income.
3. **Tax Reportable**
Tracking of Study Subject payments is required for IRS 1099 reporting purposes for full-board protocols (invasive) that pay each study subject more than \$100.
4. **Not Tax Reportable**
Tracking of Study Subject payments for 1099 reporting purposes is not required for exempt protocols (anonymous) and expedited protocols (minimally invasive). Tracking is not required for full-board protocols that pay each study subject \$100 or less.
5. **HIPAA Compliance**
The CU Denver | CU Anschutz payment process to Study Subjects, whether in cash, gift certificates / cards, money orders and or non-cash items require that Study Subject confidentiality must be maintained at all times pursuant to HIPAA rules and regulations. However, reporting Study Subject payments to the IRS for business purposes does not conflict with HIPAA rules because the information reported to the IRS does not provide any patient identifiable information related to the clinical trial, protocol or survey.
6. **HIPAA Confidentiality**
To prevent the possibility of a breach of confidentiality when payments are made to Study Subjects, a coded link must be created between the Study Subject and a particular clinical trial, protocol or survey so that the nature of the payment is unidentified. Only investigators and designated staff may have access to the codes linking the clinical trial, protocol, or survey to the related Study Subject payment.
7. **Internal Controls**
Internal Controls over Study Subject Payments are required at all times. Each clinical trial, protocol and or survey must have written procedures in place that

provide for the proper safeguarding of petty cash, gift certificates/cards, money orders and or non-cash items. The following internal controls at a minimum must be addressed and in place:

- a. Securing: Petty cash, gift certificates/cards, money orders, and or non-cash items should be secured at all times (e.g. locked box in a locked cabinet or drawer). The department must develop a system of internal controls for tracking study subject payments. Petty cash, gift certificates/cards, money orders, and or non-cash items should be used only for study subject incentives in accordance with the purpose of a specific clinical trial, protocol and or survey and Study Subject payments shall not be commingled.
- b. Custody
 - A single individual must be designated custodian of the petty cash, gift certificate/cards, money orders and or non-cash items. Any change in custodian must be coordinated through the Finance Office.
 - Custody may be transferred temporarily from the primary custodian to other departmental personnel for purposes of dispensing Study Subject payments. A receipt needs to be prepared, signed and dated by both parties acknowledging the transfer and the recipient agreeing to be held accountable for the safeguarding of the Study Subject incentives and dispensing the payment in accordance with the business purpose of the clinical trial, protocol and or survey. This process will ensure that responsibility rests with a single individual at any point in time.
- c. Tracking: Study Subject payments should be documented by a prenumbered receipt book or equivalent method designed to uniquely identify each payment. Standard receipt books are a two-part form available at office supply stores. Information to be included on each receipt shall include at a minimum:
 - Study subject name or ID (the study subject ID is any number assigned by the department to identify the individual in order to protect their confidentiality),
 - Date,
 - Purpose of the payment,
 - Serial number applicable to gift certificate / card and or money order,
 - Payment Amount,
 - Initialed by the study subject.
- d. Voids: Before voiding gift certificates, contact the vendor for related conditions and refund procedures. Any “voided” gift certificates or money orders need to be defaced and sent to the departmental administrator who is not the custodian of the Study Subject incentive payments. This process will independently confirm that voided incentive payments are in fact voided and not converted to unauthorized use by the custodian. Any refund monies received from the vendor shall be deposited immediately to the appropriate university speedtype against the expense.

- e. **Lost:** Employees are held responsible for any petty cash, gift certificates/cards, money orders and or non-monetary items in their possession that are lost or misplaced. Any shortage must be reported immediately to the Finance Office and the campus police department.
- f. **Inventory:** A periodic inventory of unused petty cash, gift certificates/cards, money orders, and or non-monetary items should be conducted. A physical inventory needs to be performed on a periodic basis (at irregular intervals) and the results reconciled to the custodian's incentive payment records. The inventory needs to be performed by an individual who is not responsible for the issuance or custody of the incentive payments while in the presence of the custodian.
- g. **Data Security:** All personally identifiable information must be secured appropriately. This includes paper and electronic records including but not limited to social security numbers, W-9 forms, and patient data. Paper records should be locked in a file cabinet. Electronic records should be secured in conformity to the campus IT Security policy.

8. Methods of Payment

- a. Petty Cash
- b. Money Orders
- c. Gift Certificates/Cards
- d. Non-Cash Items (Note – Gift Certificates are considered cash)
- e. Payment Voucher (PV)
 - i. No departmental tracking of PV payments for IRS 1099 reporting is necessary as the PSC will capture tax reporting information.
 - ii. Submit W-9 to PSC with first payment for given individual.
 - iii. All checks must be mailed to the payee; they may not be delivered to the department.

9. Non-Resident Aliens

Tax reporting for nonresident aliens is different than the 1099 reporting rules stated above. The following tax reporting requirements for nonresident aliens need not be applied to anonymous studies. Study Subjects may not be international visitors on an F-1 or J-1 visa (students and faculty) as these individuals may not work as independent contractors. Study subject payments for nonresident aliens must be made by payment voucher, and cannot be made by petty cash, gift certificate / card, money order, or non-monetary items. To make payments to non- resident aliens:

- a. Use the Payment Voucher form (PV),
- b. Withholding is required at 30% (and there is no minimum amount subject to this withholding percentage),
- c. Complete IRS form W-8 BEN,
- d. Submit the PV with W-8 BEN to the International

E. PROCEDURES

Performed By:	Action:
Request Approval to make compensation pmts to Study Subjects	
Departments	1. Request approval from the Finance Office to issue Study Subject payments via petty cash, gift certificates / card, money orders, and or non-cash items. If payment is being made by payment voucher, prior approval from Finance is not required.
Review Request to issue Study Subject pmts	
Finance Office	2. Review request to issue Study Subject payments, including verifying allowability under the terms of the sponsored project, if applicable. 3. Send authorization memo to the department for review and implementation. 4. Assist department in determining whether payments must be tracked for IRS reporting.
Tracking of Study Subject Payments	
Departments	5. Review Study Subject Payments policy and the Petty Cash and Gift Card policies, as necessary, for familiarization with internal control and IRS reporting rules. 6. Implement internal controls to safeguard study subject incentive payments (e.g. petty cash, gift certificates / cards, money orders, and or non-cash items). 7. Collect W-9 data for IRS reporting, as necessary. This data must be kept secure at all time. Campus or departmental computers and networks are <i>not</i> considered secure unless the storage methodology has been certified as secure by the campus Information Technology Services Department. 8. Issue prenumbered receipts to study subjects.
Reporting of Study Subject Payments to the PSC	
Departments	9. Report IRS 1099 Study Subject payments (defined above under section D-3) by petty cash, gift certificates / cards, money order, and or non-monetary items to the Procurement Service Center by January 5th via secure method as directed by the Finance Office.

Notes

1. Dates of official enactment and amendments:
February 1, 2010: Adopted by Associate Vice Chancellor for Administration and Finance
July 1, 2012: Updated
January 23, 2019: Formatting Updated
2. History:

January 23, 2019: Modified to reflect a Campus-wide effort to recast and revitalize Campus policy sites into a standardized and more coherent set of chaptered policy statement organized around the several operational divisions of the university. University branding, article links, and formatting updated by the Provosts office.

3. Initial Policy Effective Date: February 1, 2010

4. Cross References/Appendix:

- IRS 1099 Reporting
- Administrative Policy Statement 4015, [Propriety of Expense](#)
- Procurement Service Center Procedural Statement – [Petty Cash & Change Funds](#)
- Procurement Service Center Procedural Statement – [Recognition and Training](#)
- Procurement Service Center Procedural Statement - [Study Subject Payments](#)
- [CU Denver | CU Anschutz HIPAA Policies](#)