UCCS Controller's Office Policy: Study Subject Payments

A. 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.

B. Definitions

Human Research Participant (Human or Study Subject): A living individual from whom an investigator (whether professional or student) conducting research obtains data through the following methods:

- An intervention, interacting with the individual and using, studying, or analyzing the information or biospecimens, or
- Obtaining, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens (adapted from 45 CFR 46.102).

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.

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

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

Nonresident alien (NRA): Any individual who is not a citizen or resident alien of the United States is a nonresident alien individual. An alien individual meeting either the "green card test" or the "substantial presence test" for the calendar year is a resident alien. Any person not meeting either test is a nonresident alien individual. Study subject payments to a nonresident alien must be made by payment voucher only. Withholding is required at 30% and there is no minimum subject to the withholding percentage. Obtain a completed IRS form W-8 BEN.

COMIRB: Colorado Multiple Institutional Review Board

C. Policy Requirements

HIPPA Compliance and IRB Approval

The University of Colorado pays individuals to participate in various types of studies. Some of these studies involve confidential health-related or human subject research, and those payments must be processed in accordance with federal law (the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which requires protecting the privacy of personal health information) and with the rules and regulations established by the federal Office of Human Research (OHRP) for the conduct of studies involving human subjects. For

additional information related to research involving human subjects go to the Office of Sponsored Programs and Research Integrity (OSPRI) website (Link to: <u>Research Involving Human Subjects IRB</u>). These studies must be submitted to the IRB and obtain an approval number.

It is important to select a study subject payment method that will meet the privacy requirements of the research study while still providing sufficient information to the University for Internal Revenue Service reporting. NOTE: There is a confidentiality distinction between study subjects (non-confidential) and health-related/human subjects (confidential). This distinction determines how records are kept and how payments should be processed. The following term "study subject payments" refers to both confidential and non-confidential study subject payments.

Taxable Income and Tax Reporting

All payments to Study Subjects 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.

Departments are responsible for collecting an IRS form W-9 from a study subject participant when a payment is greater than \$100, or their total payments are greater than \$100 for the calendar year. When the payments are made to a nonresident alien in any amount, a W-8BEN must be collected. The forms should be kept on file in the department for 4 years following the date of the most recent payment.

UCCS Office of Information Technology offers <u>Lionshare</u>, a secure and approved method for file sharing with people in and outside of UCCS. Lionshare services may be used to securely transfer W-9s, W-8BENs, and other sensitive information with participants and the PSC, as necessary.

Departments are responsible for reporting all payments greater than \$100 and all payments to a single participant when their total is greater than \$100, to the PSC for year-end 1099 processing. Payments should be reported to the PSC using the Payment Reporting Spreadsheet. The completed spreadsheet should be submitted to <u>PaymentReporting@cu.edu</u> no later than January 5th each year for all reportable payments made in the prior calendar year.

Payments to CU employees, in any amount, must be reported by email to Employee Services.

Payment Processing Methods

Processing study subject payments are accomplished in one of the following payment methods discussed below.

Allowability Chart

	Payment Classification:				
	Employees	Employees	Non-Employees	Non-Employees	NRA
	(up to \$100)	(>\$100)	(up to \$100)	(>\$100)	(any amount)
Payment Method:					
Study Subject	YES (See A)	YES (See A)	YES	YES (See B)	YES
Payment (SSP) Form					
Petty Cash Fund	YES (See A)	YES (See A)	YES (See C)	YES (See B)	NO
Gift Cards	YES (See A)	NO (See C)	YES (See C)	NO (See C)	NO
Cash Advance	YES (See A)	YES (See A)	YES (See C)	YES (See B)	YES, with
					Approval
Online Coordinator	YES (See A)	NO	YES (See C)	NO	NO

NOTE:

A) All payments to employees, in any amount, are reportable to Employee Services.

- B) Payments to non-employees greater than \$100, individually or in aggregate, are reportable to the PSC and require a completed W-9.
- C) Study subject payment(s) totaling <\$100 per calendar year, per person, are exempt from reporting (except employees – see A). However, if at any time it is known that a participant's total payments are greater than \$100 for the calendar year the payments are reportable and require a completed W-9. Gift Card programs involving phases where total payments may be greater than \$100 for a single participant must follow W-9 and reporting requirements.

Controller's Office Approval

If the study subject payment is to be made via petty cash, gift certificates/cards, money orders, and/or non-cash items, approval must be obtained from the Controller's Office prior to making any payments. If payment is being made by payment voucher on the Study Subject Payment (SSP) form, prior approval from the Controller's Office is not required.

To establish a study subject payment program at UCCS the following is required:

- Identify a custodian. The custodian is fiscally responsible for safeguarding the assets (petty cash, gift certificates/cards, money orders, and/or non-cash items).
- Custodian Skillsoft training must be taken and passed by the custodian prior to approval.
- Written procedures for safeguarding the assets, addressing the following:
 - o Custody
 - o Security
 - o Issuance of Receipts
 - o Inventory
 - Audit Log
 - Quarterly Reconciliations (completed by department & forwarded to acctfund@uccs.edu)
 - o Data Security

- Submit your written procedures and your applicable request form to acctfund@uccs.edu for review and approval.
 - Petty Cash/Change Fund Request Form
 - o Gift Card Authorization Form
 - o Study Subject Online Coordinator Form
 - o Non-Cash Items (no form, submit email request)
 - Cash Advance Request Form (submitted through Concur System)

D. Resources

- o PSC Procedural Statement: Study Subject Payments
- o <u>Study Subject Payment form</u>
- o Finance Procedural Statement: Petty Cash and Change Funds
- o Finance Procedural Statement: Gift Cards
- o PSC Procedural Statement: Cash Advances
- o <u>Procurement Card Handbook</u>
- o Information Technology Procurement Handbook
- o OSPRI: <u>Research Involving Human Subjects IRB</u>
- o OSPRI: Guidance for Human Subjects Compensation
- o Employee Services: Imputed Income
- o <u>UCCS OIT: Lionshare Services</u>
- o <u>PSC: Payment Reporting Spreadsheet</u>