Lewis & Clark College CAS Sponsored Research Office Guidelines on Subject Payments to Incentivize Participation in Externally Funded Research, July 2019

Overview

The use and protection of human subjects in research studies is governed by the Department of Health and Human Services, Code of Federal Regulations, Title 45 Part 46 (45CFR46). In accordance with 45 CFR 46 and institutional <u>Policy</u>, all research at Lewis & Clark conducted by faculty, students, or staff that involves human subjects must be reviewed and approved by the <u>Institutional Review Board</u> (IRB) before any research is initiated.

Payments to individuals who participate in a research study are recognized as legitimate and allowable incentives. The guidelines provided herein apply when federally funded research includes subject payments. In these cases, the Principal Investigator (PI) must maintain appropriate financial records that show responsible use of grant funds and provide these upon request in accordance with the following guidelines.

IRB Review and Approval of Subject Payments

The PI must include any proposed subject payments in the application for review by the IRB, which must be approved prior to research initiation. Payment amounts should be reasonable based on the complexities and inconveniences of the study. Information concerning the remuneration of human research subjects, including the amount or nature and the schedule of the disbursement(s), is subject to initial and continuing review by the IRB.

If your study is designed in such a way that an individual might be paid more than \$100 in a calendar year, you must obtain prior approval from the Business Office. Note that additional information may be required from study subjects in order to comply with IRS reporting guidelines.

Subject Payments

All charges must be allowable, allocable, reasonable, and included in the approved grant budget. Subject payments may be offered in a variety of forms (e.g., cash, gift cards, or other appropriate items of value). *The use of personal funds is not appropriate for cash subject payments.* Non-refundable items should be purchased in relatively small quantities to ensure conservative use of grant funds. The PI must securely hold (e.g., under lock and key) cash and all items intended as subject payments; gift cards must be protected as cash.

Disbursement of all subject payments must be tracked as outlined below. If the PI has multiple projects with subject payments, all records and subject payment logs must be maintained separately. All records of subject payments must be retained by the PI for five years after grant close out, or longer as required by the sponsor. If the PI leaves the College, these documents must be transferred to the Department for retention. The custodian of the documents should be prepared to provide records upon request.

Process for Obtaining and Tracking Subject Payments

1. Obtaining Incentives. After IRB approval, the PI should obtain subject payments before the start of the study as follows:

- a. Cash: PI should complete a request for petty cash using the <u>check request form</u> to cover estimated subject payments for a 60-day period with a maximum of \$500 per request Use the correct grant number plus object code 1050 (e.g. 320-12XX-1050) for the advance request. Submit the check request form to the Grant Administrator. Once approved, the Grant Administrator will submit the form to the Business Office to be processed. The funds may only be used to make approved subject payments. The PI assumes responsibility for any loss incurred. The PI must submit a completed Incentive Payment Log to document the disbursement of funds in research. Petty cash may be requested up to 30 days prior to the date needed for research use. In order to receive specific denominations of cash for distribution as subject payments, the petty cash request must be made at least 2 weeks in advance. Funds can be collected from the Student and Departmental Account Services in Templeton (AKA Cashier's Office).
- b. Gift cards: PI should purchase gift cards using standard methods of procurement, in limited quantities. Gift cards for subject payments should be allocated to object code 7650. Gift cards must be protected as cash and tracked by serial number. Any fees must be accounted for when budgeting.
- c. Other items: PI should purchase other appropriate incentives using standard procurement methods, in limited quantities. Allocate incentive items for subject payments to object code 7650.
- 2. Tracking and Reporting.
 - a. Incentive Payment Log: The PI must track the disbursement of all remuneration used as subject payments on an <u>Incentive Payment Log</u>. The log will include transaction date, amount and/or type of remuneration, and the study participant's signature. The Incentive Payment Log requires that each study participant confirm receipt of any type of remuneration by signing and dating the log. With confirmation from the IRB that the study is anonymized, coded data and a signed certification by the PI will be accepted in lieu of each participant's signature.
 - b. The Incentive Payment Log must be used to track each transaction at the point of exchange throughout the course of the study. The log should be reconciled with items on-hand at least every 60 days, and the PI will document and report any discrepancies to the Grant Administrator. The Business Office conducts random audits of petty cash accounts.
 - c. At least every 90 days, the PI should submit reconcile the petty cash account, or else notify the Grant Administrator in writing if there is a project-based need for an extended deadline.
- 3. Reconciling Petty Cash.
 - a. Cash: The PI will deposit any remaining cash on hand at the Cashier's Office into the correct project account (e.g. 320-12XX-1050), then submit the deposit receipt and a copy of the completed Incentive Payment Log to the Grant Administrator for review and approval.
 - b. Gift cards and other non-cash items: The PI will submit a copy of the completed Incentive Payment Log to the Grant Administrator for review and approval.
 - c. Once approved, the Grant Administrator will submit the documents to the Business Office. The Business Office will close out the petty cash by charging the expense to the correct account and object code (7650, subject payments).

Relevant Responsibilities

Principal Investigator

- Obtain IRB approval for research including human subject payments prior study initiation.
- Manage cash and other items used to remunerate study subjects and maintain records and logs sufficient to document use of project resources.
- Submit required Incentive Payment Logs in a timely manner.
- Retain documentation in accordance with the policies of the federal sponsor and Lewis & Clark College, and these guidelines.

Institutional Review Board

- Determine whether use of subject payments and related financial records in the study design is protective of human subject in accordance with 45CFR46.
- Confirm whether human subject payments should be anonymized such that study participants are not required to confirm receipt of remuneration, as applicable.

Business Office

- Process requests for petty cash that have been approved by the Grant Administrator in accordance with established processes.
- Process requests to clear petty cash accounts when provided with Incentive Payment Logs that have been approved by the Grant Administrator in accordance with established procedures.
- Review requests for subject payments that are likely to result in payment of \$100 or more to an individual in a calendar year. If such requests are approved, communicate additional subject information gathering requirements to the Grant Administrator and PI.
- Comply with IRS reporting guidelines for payments exceeding IRS thresholds.

Grants Administrator

- Meet with the PI to establish standards and expectations for managing subject payments.
- Review and approve requests for petty cash in a timely manner.
- Review and approve completed Incentive Payment Logs in a timely manner.
- Work with the PI and/or Business Office to solve problems and ensure consistent practices and appropriate documentation are retained in case of an audit.
- Retain documentation in accordance with the policies of the federal sponsor and Lewis & Clark College.



Human Subject Incentive Payment Log

Please complete this log from BOTTOM to TOP.

This approach enables the use of a cover sheet over completed entries/rows in order to maintain confidentiality among participants.

Investigator

Project Title

Method of payment (circle all options that apply): Cash

Gift card

Other (describe)_____

Department

<u>Column A</u>	<u>Column B</u>		<u>Column C</u>	<u>Column D</u>	<u>Column E</u>	<u>Column F</u>	<u>Column G</u>
Date of	Type of Payment		<u>Value</u>	Participant Name	Participant Signature	Participant ID	Gift Card #
Payment						(if anonymized)	(if applicable)
	Cash Gift card	Other	\$				
	Cash Gift card	Other	\$				
	Cash Gift card	Other	\$				
	Cash Gift card	Other	\$				
	Cash Gift card	Other	\$				
	Cash Gift card	Other	\$				
	Cash Gift card	Other	\$				
	Cash Gift card	Other	\$				
	Cash Gift card	Other	\$				
	Cash Gift card	Other	\$				
	Cash Gift card	Other	\$				
	Cash Gift card	Other	\$				
	Cash Gift card	Other	\$				
	Cash Gift card	Other	\$				
	Cash Gift card	Other	\$				

Certification statement for PI: I certify that this log is true and accurate and I understand my obligation to retain a copy of this log with the project files in accordance with the Guidelines on Subject Payments to Incentivize Participation in Externally Funded Research.

PI Signature: _____ Date _____ Grant Administrator Approval: ______

Date

Count of individuals paid: ____Cash ____Gift cards ___Other Total value distributed in: Cash Gift cards Other

Incentive Payment Log Sponsored Research Office, v1 July 2019