THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

SOP-19: Payments to Human Subjects

1. Objective

To ensure that the Principal Investigator (PI) and all research team members assisting in the conduct of clinical research are informed about their obligations and responsibilities as they pertain to Good Clinical Practices (GCP), the investigational plan, applicable regulations, guidances, and institutional policies. This Standard Operating Procedure (SOP) applies to the written procedures followed by all members of a clinical research team involved in the conduct of human subjects' research at The Ohio State University Wexner Medical Center (OSUWMC), hereafter called the investigational site. These detailed instructions promote compliance in conducting clinical research.

SOP-19 describes the process for payments to human subjects for clinical research. Attachment templates include:

A: Payment Type Flow Chart
B: Subject Payment Request Form

2. Responsibility

The College of Medicine Center for Clinical Research Management (COM-CCRM) develops, implements, and maintains SOPs. The need to write a new or revise an existing SOP is based upon changes to federal regulations, guidelines, institutional policies, or procedures. These documents will be provided to departments and research teams conducting human subjects' research. Departments or research teams may develop additional research SOPs or a Research Procedure Addendum (RPA) to expand on an existing SOP, however this need should be limited.

The PI is ultimately accountable for all clinical research activities and is responsible for the appropriate delegation of tasks to individuals with adequate training and education to perform such tasks. It is the responsibility of all members of the clinical research team involved in supervising, managing, or conducting study-related activities to follow the SOPs. The clinical research team may include but is not limited to the following members:

Research Team Members

Principal Investigator (PI)	Clinical Research Coordinator (CRC)
Sub-Investigator or Co-I (Sub-I or Co-I)	Clinical Research Assistant (CRA)
Clinical Research Manager (CRM)	Other Research Staff as appropriate
Clinical Research Specialist (CRS)	Administrative and Support Staff

3. Definitions

Please refer to the SOP Glossary document for detailed definitions of commonly used clinical research terminology.

4. Procedures

A. Guidelines for Payments to Human Subjects

The Principal Investigator is responsible for ensuring the subject is eligible to receive payments and for ensuring the payment process is documented and processed appropriately.

The Principal Investigator must document the payment arrangements as part of the research budget and IRB application. Payment type, amount, and timeline must be approved in advance by the IRB before payments may be made to any subjects. This information must be outlined in the informed consent form (ICF) and communicated clearly to subjects during the informed consent process.

Payment for participation in research may not be offered to the subject as a means of undue influence, where it might cause someone to assume risks they would not otherwise assume. Rather, it should be a form of recognition for the investment of the subject's time, travel expenses, or other inconveniences incurred.

Payments should be based on the research subject's time allotted to and reasonable expenses incurred during his/her participation in the research study. Payments should not be contingent on the subject's completion of the study. Payments should be given as set forth in the ICF to avoid the impression that the investigator is coercing the subject to continue in a study or is penalizing the subject for choosing to withdraw.

B. Custodian Responsibilities

Individuals delegated the responsibility of the custodian are specifically responsible to:

- Store the gift cards or other incentives in a locked safe, or, at minimum, in a locked drawer in a locked room.
- Ensure only appropriate personnel have access to gift cards or incentives.
- Document gift card chain of custody.
- Ensure incentives are used only for the project for which they are approved.
- Ensure all aspects of the visit requirements are completed prior to submitting the payment request.
- Be ready to present a reconciliation of signatures and unused cards/incentives to auditors.

C. Taxability

All subject payments, regardless of the amount and form of payment, are taxable income and subjects should be made aware of this during the informed consent process.

D. Purchasing and Payment Guidelines

Vendor Setup Form
For payments processed through the Office of Sponsored Programs (OSP) Accounts Payable, each research subject is required to complete an Ohio State Vendor Setup Form (substitute W-9). The Vendor Setup Form only needs to be completed one time per study for each subject unless any of the subject's contact information changes or if the account is deactivated due to inactivity. University employees do not need to complete this form. A Vendor Setup From should be completed by every subject regardless of payment amount.

There are rare exceptions where the Vendor Setup Form does not need to be completed. A Certificate of Confidentiality may be secured from the Department of Health and Human Services for studies of a highly sensitive nature. After receiving a Certificate of Confidentiality, the PI must obtain approval from their College Associate Dean for Research and from their Senior Fiscal Officer before submitting a formal request to the OSP Manager of Accounts Payable.

Payment Options:
The Payment Type Flow Chart *(See Attachment A: Payment Type Flow Chart)* can be referenced to determine appropriate guidelines for subject payments based on payment amount and U.S. citizenship. Please also refer to the OSP website for additional guidance on how to determine the appropriate payment type for a research study.

Any subject payment refusal should be thoroughly documented and maintained in the subject's research record.

1. OSP Check Request Workday
Subjects must complete the Ohio State Vendor Setup Form (substitute W-9) for reimbursement to be processed and for OSP to remit payments. Prior to processing the first payment request, a vendor account must be created on the OSU Stores website under Vendor Maintenance. Check OSU Financial system to verify if a vendor ID already exists for the subject; a duplicate vendor ID should not be created. Appropriate financial training must be completed to gain access to this system. Information on the Vendor Setup Form is used to create the vendor account and the original form should be destroyed once the account is created, however, an electronic copy will be kept on file. OSP tracks the subject by their vendor ID. The subject's study ID should be used.

Submit a *Subject Payment Request Form (See Attachment B: Subject Payment Request Form)* through a Workday request at each visit to initiate subject payment. The form should be stored in the subject's research file. When submitting, account number 64610 must be used to ensure subject confidentiality. Hard copies of approved Workday requests must be sent to Accounts Payable at OSP. Checks will be sent directly to the subject.

2. ClinCard/Greenphire
Access to the OSU ClinCard system is restricted to OSP authorized users. Training on accountability, allocation of cards, and reconciliation is required prior to implementation.

If the ClinCards are provided by the sponsor, the study team may defer to the sponsor required process for training on accountability, allocation of cards, and reconciliation.

The subject's ClinCard number should be recorded on each *Subject Payment Request Form (See Attachment B: Subject Payment Request Form)* and should be filed in the subject's research record. This form should be signed by the subject each time there is a visit requiring payment. If the visit is conducted virtually, this should be indicated on the payment request form and the subject signature would not be required.

A Subject Payment Request Form and Vendor Setup Form must be submitted to an authorized ClinCard system user to initiate payment via ClinCard. Payments will be loaded directly to the card assigned to the subject. The card is reusable, so if the subject is receiving payments for multiple visits, they will continue using the same card.

For additional information regarding setting up a ClinCard account for a research study or general questions about the program, contact Senior Director, Financial Management at OSP.

3. Gift Cards (including electronic gift cards) and Non-Cash Gifts
Please refer to the OSP website for guidance on the maximum annual total gift card value per subject per protocol that is allowed. Gift cards may be purchased through OSP Purchasing by submitting a Workday request. Only the quantity needed should be purchased. Gift cards may not be returned. When gift cards or non-cash gifts are dispersed to subjects, the *Subject Payment Request form* (*See Attachment B: Subject Payment Request Form)* is required to be completed. The form requires subject signature and should be retained in the subject's research record. Chain of custody for the gift cards and non-cash gifts should be documented if not distributed directly from the person who submitted the Workday request.

Gift cards should only be mailed to subjects as a last resort. If mailing, the following should be implemented:

a. Notify the subject that the gift card has been mailed and instruct him/her to complete and return a Subject Payment Request Form *(See Attachment B: Subject Payment Request Form)*. Document this conversation in the subject's research record.
b. Send the gift card to the subject via a traceable method – certified mail or UPS/FedEx requiring signature.
c. Enclose a self-addressed stamped envelope and the Subject Payment Request Form for the subject to sign and return *(See Attachment B*: *Subject Payment Request Form)*. If the form is not returned within 30 days, call the subject an additional time to request the form and document this conversation in the subject's research record. The form certifies not only that the subject received the gift card, but the amount received.

At the end of the study, any undistributed gift cards should be turned in to the appropriate department and charges for these unused gift cards must be transferred off the sponsored research project to the department. A final reconciliation of the gift cards on a project should confirm that the value of all human subject payment requests retained in the research files are equal to the total expenses for gift cards charged to the project.

4. Human Subject Cash Accounts and Human Subject Checking Accounts
Please refer to the OSP website for guidance in establishing either a petty cash account or a checking account for the purpose of paying study subjects. If implemented, a custodian is assigned and must maintain strict records including a list of all payments and deposits into the checking or petty cash account for overall tracking and account reconciliation, and must ensure funds are available as needed for subject payment.

5. Payments to Nonresident Aliens
Before enrolling the subject on a research study, contact the Accounts Payable Manager at OSP Accounts Payable. There are additional requirements guided by the IRS and Homeland Security for nonresident aliens and these payments must be approved by OSP. OSP staff will need a copy of the subject's visa or immigration stamp, a copy of his/her passport photo and a completed Vendor Setup Form (substitute W-9). Please refer to the OSP website for guidance on maximum allowable payments made to research subjects who are nonresident aliens.

a. Non-resident aliens cannot be paid via ClinCards.
b. Taxes will automatically be withheld from the payment amount.

E. End of Study

All documents should be maintained and kept on file in accordance with the OSU records management policy or contract requirements, whichever is longer.

5. Applicable Regulations, Guidelines and Policies

Regulation/ Guidance/Policy	Title
21 CFR 50	Protection of Human Subjects
21 CFR 56	Institutional Review Boards
21 CFR 312	Investigational New Drug Application
21 CFR 812	Investigational Device Exemptions
45 CFR 46	Protection of Human Subjects
45 CFR 160	HIPAA Privacy Rule
45 CFR 164 Subparts A and E	HIPAA Privacy Rule
OSU Office of Responsible Research Practices HRPP	Recruiting Methods, Recruitment Materials, and Participant Compensation
OSU Office of Responsible Research Practices HRPP	Responsibilities of Principal Investigators, Co-Investigators, and Key Personnel
OSU Office of Sponsored Programs	Policy on Payments to Research Subjects
ICH GCP E6(R2)	Guideline for Good Clinical Practice: E6 Integrated Addendum
FDA Guidance for Industry	Investigator Responsibilities- Protecting the Rights, Safety, and Welfare of Study Subjects, October 2009
FDA Guidance for Industry	Payment to Research Subjects-Information Sheet
FDA Guidance for Industry	Recruiting Study Subjects-Information Sheet