1. **Objective**
   To ensure that the Principal Investigator (PI) and all employees 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 the clinical research team involved in the conduct of human subject research.

   This SOP describes the process for Payments to Human Subjects for clinical research conducted at The Ohio State University College of Optometry, hereafter called the investigational site. These detailed, written instructions create uniformity in conducting clinical research at this investigational site to ensure compliance.

2. **Attachments**
   A. Payment Type Flowsheet
   B. Sample Human Subject Payment Receipt
   C. Sample Human Subject Account Reimbursement Form
   D. Sample Cash Custodian Log

3. **Responsibility**
   The Principal Investigator 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.
Individuals delegated the responsibility of the custodian are specifically responsible for:

- Cashing checks. The university has an agreement with the medical center branch of Huntington Bank to cash these checks without a personal account. It is advisable to cash checks with a witness present.
- Storing petty cash, gift cards, parking stickers, or other payments in a locked safe or, at a minimum, in a locked drawer in a locked room.
- Documenting chain of custody.
- Ensuring that payments are used only for the project on which they are drawn (i.e. do not use petty cash from study A to pay subjects on study B).
- Maintaining records for reconciliation of signatures and unused cash/gift cards/payments.

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)
- Co-Investigator (Co-I)
- Sub-Investigator (Sub-I)
- Clinical Research Manager (CRM)
- Clinical Research Specialist (CRS)
- Clinical Research Coordinator (CRC)
- Clinical Research Assistant (CRA)
- Regulatory Manager (RM)
- Clinic Manager
- Regulatory Compliance Officer (RCO)
- Clinical Research Data Manager (CRDM)
- Clinical Research Data Coordinator (CRDC)
- Budgets and Contracts Staff
- Administrative and Support Staff
- Program Manager
- Project Coordinator
- Program Coordinator
- Research Associate/Assistant
- Other Research Staff as appropriate

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

5. **Procedures**

   **A. Guidelines for Payments to Human Subjects**
   The FDA makes a distinction between payments and reimbursements to human subjects. 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, loss of wages, or other inconveniences incurred. Reimbursement for expenses incurred, such as travel expenses to and from the clinical site and associated costs such as airfare, parking, and lodging, are not seen as raising issues regarding undue influence. Like payments to human subjects, information about possible reimbursements should be in the study protocol. Note that reimbursements generally are made after a receipt is provided, whereas payments are provided regardless of the expense incurred by the subject.
Family members of research team members are considered to be part of a vulnerable population, like students and employees. The College of Optometry strongly recommends that family not be enrolled in clinical trials. Most industry sponsors do not allow family members to be enrolled at all. If family members are enrolled, they cannot be paid, per Ohio Ethics Law. Ohio Ethics Law defines “family” as the employee’s parents, grandparents, children of any age, grandchildren, spouse, or siblings. The residence of any of these family members is irrelevant.

The Principal Investigator or designee must document the payment arrangements as part of his/her research protocol 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 document, when applicable, and communicated clearly to subjects during the screening phase and informed consent process.

Payments should be based on the research subject’s time allotted and reasonable expenses incurred during his/her participation in the research study. Payments should not be withheld contingent on the subject’s completion of the study. Payments should be given on a reasonable prorated basis 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. If a subject declines a payment, the PI or designee must document this refusal and obtain the subject’s signature on the documentation.

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

B. Taxability
All subject payments, regardless of the amount or form of payment, are taxable income and subjects should be made aware of this during the informed consent process. Note that the receipt signed by subjects should include information about taxability. If requested by a research subject, a copy of the receipt may be provided. However, all original receipts must be maintained in a study payment binder. Reimbursements for travel for the study are not taxable.

C. Nonresident Aliens
Accounts Payable (either OSP or OSU) must be contacted prior to enrolling nonresident aliens to a protocol that provides payments of more than $100 per calendar year. There are additional requirements guided by the IRS, Homeland Security, and home country laws for nonresident aliens, and these payments must be approved prior to enrollment. A copy of the subject’s visa or immigration stamp, a copy of his/her passport, and a completed Nonresident Alien Payment Request form (https://busfin.osu.edu/document/non-resident-alien-nra-payment-request-form), the appropriate W-8 (see Foreign Entity W-8 form at https://busfin.osu.edu/system/files/w-8statement.pdf), and Compliance Form for Payments to B or W Visa Holders (if applicable) are required. OSP or the Optometry Business Office will notify the PI or designee if the nonresident alien may be paid for study participation.

Nonresident aliens who are students who work at the university are limited further. They cannot be paid for more than for 20 hours per week of work, including payment of stipends for participation in research. The College of Optometry strongly recommends that nonresident alien students who work 20 hour per week not be paid to avoid potentially subjecting the student to severe consequences. Consequences depend on the scope of the violation(s), and could include not being allowed to return to U.S. for years.
It is strongly recommended that subjects be asked about citizenship/residency at the pre-screening stage for studies where payments will exceed $100 per subject, per protocol, per calendar year and if nonresident alien student workers may be participants.

D. Purchasing and Payment Guidelines

Human subjects may be paid with cash, a check written by the research staff out of a human subject checking account (OSP funds only), gift card (physical or electronic), non-cash gifts, ClinCard, parking stickers, and/or check from Accounts Payable. The method chosen is determined by business requirements, the protocol design, PI and research staff needs, and the needs of the subjects. Please see the Payment Type Flowsheet (Attachment A) for guidance with regard to total payments per year, citizenship status, and the source of funds.

Business procedures for paying subjects using each of the methods are outlined in the Human Subject Payment Procedure, available as a companion document to this SOP.

Human Subject Checking Accounts and Petty Cash:

When using funds from a sponsored research project (OSP funding), human subject checking accounts and petty cash accounts may be established if the amount is:

- \( \leq \$500.00 \) per subject, per protocol, per calendar year for U.S. Citizens and resident aliens (“green card” holders)
- \( \leq \$100.00 \) per subject, per protocol, per calendar year for nonresident aliens

When using funds from a non-OSP account, petty cash accounts may be established if the amount is \( \leq \$100.00 \) per subject, per protocol, per calendar year, regardless of citizenship status.

For both situations, the value is calculated by calendar year, not project year or by 365 days, because this need is driven by IRS requirements.

Regardless of the funding source, the Human Subjects Petty Cash Fund Information Sheet (PR-HS1) (http://osp.osu.edu/forms/) must be completed to establish a human subject checking account or petty cash account. This form establishes the total amount of cash that may be on hand at any given point in time. The PI and the College of Optometry Dean sign the form. The signed form must be attached to the eRequest and a copy of the completed form maintained with relevant human subject payment documents.

When funds are provided to subjects, the Human Subjects Payment Receipt form (or a form substantially similar) must be completed for each payment. (Please refer to Attachment B: Sample Human Subject Payment Receipt or http://osp.osu.edu/files/2013/10/HSPaymentReceipt.pdf) This form requires subject signature and should be retained in a study payment binder. Note that it is not appropriate to use the same form for multiple visits or to use a log (such as the Human Subject Account Reimbursement Form) to collect signatures from multiple subjects or multiple visits on the same sheet of paper.

When more funds are needed to replenish the cash on hand or in the checking account, the PI or designee completes an eRequest. The value of the request will be equal to the difference between the amount authorized by Form PR-HS1 and the cash remaining on hand. To document spending to date, a completed Human Subject Account Reimbursement Form (or a log substantially similar for non-OSP...
funding) must be attached to the eRequest. The log should remain de-identified; no PHI, including subject names, may be included on this log. (Please refer to Attachment C: Sample Human Subject Account Reimbursement Form or http://osp.osu.edu/forms/.)

The study team should maintain a list of all payments and deposits into the checking or petty cash account for overall tracking and account reconciliation and to ensure funds are available as needed for subject payment.

Chain of custody should be documented between the cash custodian and the staff disbursing the funds to the subjects, if applicable. (Please refer to Attachment D: Sample Cash Custodian Log)

The College of Optometry strongly discourages the use of personal funds to pay human subjects before the receipt of petty cash funds from the university or OSP. It is inappropriate for a PI or staff member to pay a subject out of personal funds, then reimburse him/herself when the petty cash from university or OSP funds becomes available. If such a payment from personal funds is necessary, the payee must request a personal reimbursement in eRequest, attaching an ATM or bank withdrawal receipt and the Human Subject Account Reimbursement Form as evidence of payment and appropriate usage of the cash as human subject payments. The researcher’s request for reimbursement may be denied, so using personal funds must be a last resort. If a researcher chooses to pay human subjects using his/her own funding and does NOT seek reimbursement for these costs, the subjects must still sign receipts and logs must be kept. If such personal funds are being spent in addition to university or OSP funds, these two sources of funding must be logged separately.

**Gift Cards and Non-Cash Gifts:**
Gift cards and non-cash gifts may be distributed to subjects as long as the value does not exceed $100.00 per subject, per protocol, per year, regardless of funding source.

Gift cards (physical or electronic) or non-cash gifts may be purchased by submitting an eRequest. Only the number needed should be purchased; gift cards may not be returned. When gift cards are disbursed to subjects, the Human Subjects Payment Receipt form (or substantially equivalent form) is required to be completed. This receipt must also be signed when disbursing non-cash gifts of greater than de minimis value (see the Grants and Contracts Administrator for a determination of de minimis value before purchasing gifts). The receipt requires subject signature and should be retained in the study payment binder. When gift cards are emailed to subjects, a copy of the email showing the recipient’s email address and the gift card code must be kept in the payment binder as evidence of appropriate usage. In the rare circumstance where it is not possible or allowable by the IRB to get the recipient’s signature see the Grants and Contracts Administrator for assistance. In these circumstances, two study personnel must complete and sign the Human Subjects Payment Receipt form or a list of cards released with all the same demographic information. The Chief Administrative Officer must also sign the form/list. Chain of custody for the gift cards and non-cash gifts should be documented, if applicable.

Gift cards or non-cash gifts provided directly by a sponsor must be stored and their use monitored in the same manner as gift cards purchased using OSP funds. Sponsor-supplied unused cards or non-cash gifts must be returned to the sponsor at the close of the study.
ClinCard:

ClinCard from Greenphire is a reloadable gift card available for use on sponsored research projects. ClinCard can be used by the subject like a pre-paid Visa gift card, but the program is still a pilot at the university. Contact the Grants and Contacts Administrator to determine if ClinCard use will be allowed by the Office of Sponsored Programs for a particular study. Payment via ClinCard is an acceptable option for payments:

- of any amount for U.S. Citizens and resident aliens
- totaling ≤$100.00 per subject, per protocol, per calendar year for nonresident aliens. (This is an Optometry-specific restriction to protect non-resident alien subjects from endangering their visa status.)

There is a charge to establish a card with a subject, as well as an additional charge for each subsequent payment. Until the ClinCard is loaded with cash electronically, the physical card is blank, reducing the risk of having valuable items on hand.

To issue a ClinCard to a subject, the subject must complete a Vendor Setup Form and sign a ClinCard Participant Receipt (provided upon request by OSP Financial Services). Both forms must be kept with the study documentation; neither is ever provided to OSP. Note that the Vendor Setup form contains restricted (S4) information and must be appropriately secured (a completed form may not be emailed). Subjects do not sign human subject payment receipts after receiving a ClinCard, and no documentation of payments is submitted to OSP. Study staff must enter subject information into the online ClinCard system using the completed Vendor Setup Form, and Greenphire will issue the tax documentation to subjects when appropriate. OSP will provide the system link at the set-up stage.

Parking Stickers:
Subjects’ parking costs may be covered by giving them quarters for the parking meters in front of Fry Hall or a parking sticker for use in a parking garage. Quarters for parking meters are petty cash. Both types of parking payments require a signature from the subject receiving the payment; the same receipt form may be used to document one visit’s parking sticker disbursement and the stipend. The receipts signed by the subjects should be similar to those used for other payments. Parking stickers are purchased from CampusParc via an eRequest, and they expire each July.

OSP Accounts Payable Disbursement:
When using funds from a sponsored research project, payment via OSP Accounts Payable or ClinCard is required for payments totaling more than $500.00 per subject, per protocol, per calendar year for U.S. Citizens and resident aliens.

When using funds from a non-OSP source or when paying a non-resident alien, payment via OSU Accounts Payable is required when payments totaling >$100.00 per subject, per protocol, per calendar year are anticipated.

To initiate a payment via Accounts Payable, the PI or designee will use eRequest. However, to ensure subject confidentiality, the eRequest should include only the vendor ID number for a non-employee subject and the employee ID number for an employee subject. To obtain a vendor ID number for a subject, subjects who are not university employees must complete a Vendor Setup Form. The staff member submits the form to the Optometry Business Office for processing and assignment of the
vendor ID number. The Vendor Setup Form needs to be submitted one time, unless the subject’s contact information changes. Note that the process for paying non-resident aliens using accounts payable differs. See the section in this SOP on non-resident aliens for the list of documents required for payment. Those documents must be submitted with each request for payment, even during the same study and for the same individual.

There are rare exceptions where the Vendor Setup Form does not need to be submitted for reimbursement via Accounts Payable. 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 the College of Optometry Dean and from the Chief Administrative Officer before submitting a formal request to the OSP Manager of Accounts Payable (when using OSP funds) or Optometry Business Office (when using non-OSP funds). Note that all NIH-funded studies automatically have Certificates of Confidentiality, but a request to eliminate the need for a Vendor Setup Form may only be sought for those studies where it is necessary due to the sensitive nature of the work.

E. End of Study
All documents should be maintained and kept on file in accordance with the OSU records management policy, and all legal and contract requirements, whichever is longest (see SOP-05 Essential Document Management). Receipts signed by subjects are considered payment/financial records for purposes of evaluating OSU record retention requirements. See https://library.osu.edu/osu-records-management/retention-schedules for current Ohio State University records retention schedules.

Reconciliation:
Petty Cash/Checking
The difference between the amount of cash taken from the project and the amount paid to subjects and documented appropriately must be returned to the Office of Sponsored Programs, which will credit the project. OSP will issue a receipt for these returned funds, and that receipt must be kept with the financial records for the study. Any payments not substantiated by signatures or the alternate process described above when physical signatures cannot be obtained are unallowable costs that the department must bear. Unspent cash taken from OSU funding sources must be returned to the college Business Office with a log showing appropriate usage.

Gift Cards
At the end of the study, any undistributed gift cards should be turned into the college business office. The cost of these unused gift cards, as well as the value of any used that are unsubstantiated by signatures, must be transferred off the sponsored research project to the college. A final reconciliation of the gift cards on a project must confirm that the value of all Human Subject Payment Receipts retained in the research files is equal to the total expenses for gift cards charged to the project.

Parking Stickers
At the end of a study, unused parking stickers may be retained with the study documentation and allowed to expire. Unused parking stickers may also be transferred off an OSP project via journal entry for use by the college or other projects.

6. Applicable Regulations, Guidelines and Policies
Please refer to SOP companion document Intro Table of Contents and Glossary for a list of applicable regulations, guidelines and policies, with URLs, listed by SOP.
Revision History Log

<table>
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<th>Effective Date</th>
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<td>11/15/2017</td>
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<td>Receipt requirements clarified.</td>
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<td>3.0</td>
<td>4/15/2019</td>
<td>4/15/2019</td>
<td>Format updated per new SOP Template. SOP title changed to reflect addition of discussion of reimbursements. Payments to family members, using personal funds to pay subjects, and process for appropriately documenting payments when receipts cannot be obtained addressed. Appropriate use of a certificate of confidentiality on NIH studies to avoid gathering Vendor Setup Forms is clarified. Process for returning unspent petty cash explained. Documentation for non-resident alien payments revised to reflect current requirements. Information about payment caps for nonresident alien student workers added.</td>
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## SAMPLE HUMAN SUBJECT PAYMENT RECEIPT

<table>
<thead>
<tr>
<th>Human Subject Protocol Number: ___________________</th>
<th>OSP Project Number: _______________</th>
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<tr>
<th>Date: _______________</th>
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<table>
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<tr>
<th>Paid To: _______________________________________</th>
<th>Subject Number: ____________________</th>
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<tr>
<th>Amount Disbursed: $ ________________</th>
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<table>
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<tr>
<th>Check Number (as applicable): ________________</th>
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<table>
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<tr>
<th>Gift Card Number (as applicable): ________________</th>
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<table>
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<tr>
<th>Parking pass given to subject? ☐Yes ☐No</th>
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<tr>
<th>Payee Signature: __________________________</th>
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<th>Authorized By: ___________________________</th>
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Recipient: Please note that this payment is taxable income and that the recipient is required to report this amount on federal and state tax returns.

Clinical trial staff: This receipt must be maintained confidentially in the project files.
SAMPLE HUMAN SUBJECT ACCOUNT REIMBURSEMENT FORM

Human Subject Protocol #: __________________
OSP Project #: ________________ Non-OSP funding source: ________________________

<table>
<thead>
<tr>
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<th>$ Amount</th>
<th>Subject ID (No names)</th>
<th>Check #, Gift Card #</th>
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Total Petty Cash Disbursed: $___________
Total # Gift Cards Disbursed: __________

I certify that this reimbursement is for funds that were duly authorized and made solely as payments to the recipients for participation as a human subject in an official project of The Ohio State University, and that detailed supporting documentation is maintained in the PI project files for audit purposes.

Signature of Principal Investigator: ____________________________
## SAMPLE CASH CUSTODIAN LOG

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<th>Amount Deducted</th>
<th>Balance</th>
<th>Received By (Initials)</th>
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