ADMINISTRATION AND UTILIZATION OF CLINCARD SYSTEM	Research Policy # 4-70402 June 2026

PURPOSE:
This policy establishes the ClinCard system as a centralized system of record for administering participant payments associated with research and approved engagement activities at OSU Center for Health Sciences (OSU-CHS). This policy establishes a comprehensive internal control framework, including defined roles, approval structures, monitoring activities, and enforcement mechanisms to ensure consistency with institutional policy standards.

SCOPE:
This policy applies to all OSU-CHS personnel utilizing the ClinCard system for:
- Payments to human subjects participating in research
- Participant support costs (as defined by Uniform Guidance)
- Advisory panel participation or similar approved activities
- Participant travel service arrangements (e.g., Lyft or similar transportation services)

POLICY:
ClinCard must be used in accordance with approved study protocols, IRB determinations, and institutional financial controls. Payment structures must prioritize milestone-based disbursements. Exception-based (miscellaneous) payments are considered higher risk and are subject to enhanced justification, approval, and monitoring controls. All users and administrators are responsible for ensuring adherence to internal control expectations and regulatory requirements governing participant compensation and financial stewardship.

All ClinCard transactions must be compliant, allowable, fully auditable, and appropriately documented in accordance with the Common Rule (45 CFR 46), FDA regulations (21 CFR Parts 50, 54, 312, and 812), Uniform Guidance (2 CFR 200), Office of Inspector General (OIG) expectations, and applicable OSU-CHS financial, research compliance, and institutional policies.

DEFINITIONS:
ClinCard System: A third-party prepaid card and payment management platform administered and implemented by OSU-CHS as the official system of record for participant payments and approved engagement-related disbursements
Milestone Payments: Pre-approved payments tied to specific project activities or visits.
Miscellaneous Payments: Non-standard payments not tied to predefined milestones, requiring additional review and justification.
Requestor: Study team member initiating payment transactions.
Approver: Individual authorized to approve payments based on designated thresholds.
Principal Investigator (PI): Individual responsible for the conduct and oversight of the project.

ROLES AND RESPONSIBILITIES

OSU-CHS Office of Research

- Administers the ClinCard system and maintains system integrity; provides first-line support
- Establishes and manages user access and role assignments
- Builds project setup in system, including payment structures, assigned Requestors and Approvers
- Monitors ClinCard transactions for anomalies and compliance risks
- Investigates potential noncompliance and reports findings
- Coordinates with Post-Award Administration on financial oversight
- Maintains a log of all projects allowed by Vice President for Research to use miscellaneous and travel services payment structures

Principal Investigator (PI)

- Retains ultimate responsibility and accountability for all ClinCard transactions conducted under their project, regardless of delegation. The PI may designate qualified study personnel as Requestors and/or Approvers but remains responsible for oversight and compliance.
- Ensures all payments align with the sponsor funding budget and IRB-approved protocol and informed consent
- Ensures Requestors are aware of ClinCard policy and procedures
- Reviews and approves applicable payment transactions per designated thresholds
- Reviews monthly miscellaneous payment reports
- Promptly respond to queries, monitoring findings, or audit requests.
- Reports concerns or discrepancies to the Office of Research

Approver

- Ensures all payments align with the sponsor funding budget and IRB-approved protocol and informed consent
- Ensures Requestors are aware of ClinCard policy and procedures
- Reviews and approves applicable payment transactions per designated thresholds
- Reports concerns or discrepancies to the Office of Research

Study Team (Requestors/Designees)

- Submit a formal access request form to Office of Research
- Request project setup with milestone payment schedule consistent with project budget, contract/protocol, and consent
- Initiate payment requests in compliance with policy
- Enter required justification for miscellaneous payments

Post-Award Administration

- Reviews and approves high-value transactions for financial compliance and cost allowability and alignment with sponsor and institutional requirements
- Reviews and reconciles vendor invoices (e.g., ClinCard billing statements) against system transaction records to verify accuracy, completeness, and allowability of charges

- Ensures costs are properly allocated to the appropriate funding source and comply with Uniform Guidance (2 CFR 200) and applicable sponsor terms
- Identifies and escalates discrepancies, unallowable costs, or compliance concerns to the Office of Research and appropriate institutional stakeholders

PAYMENT STRUCTURE REQUIREMENTS

Milestone Payments (Preferred Method)

- Milestone payments are required where feasible
- Must align with IRB-approved compensation and schedule
- Considered low risk due to pre-approval and structured automation

Miscellaneous Payments (Restricted Use)

- Allowed only when milestone payments are not feasible
- Requires approval by the OSU-CHS Vice President for Research to use payment function due to their higher risk classification
- Requestor must provide documented justification for each payment transaction
- **Approval Thresholds for Miscellaneous Payments**

Payment Transaction Amount	Approval Required
< $200	Auto-approved
$200–$500	PI or authorized designee approval
≥ $501	PI AND Post-Award Administration approval

Participant Travel Services (e.g., Lyft)

Use of ClinCard-enabled travel services must comply with all institutional and regulatory requirements and are subject to the following controls:

- Must be explicitly approved within the IRB-approved protocol and receive prior approval from the OSU-CHS Vice President for Research
- Must be limited to same-day transportation for scheduled study visits or project-required activities (i.e., travel occurring on the day of the visit)
- Must not constitute undue influence or inducement beyond what is described in the informed consent
- Must be documented and linked to specific project visits or activities
- Must be reasonable in scope (e.g., appropriate origin/destination and frequency consistent with protocol schedule)

COMPLIANCE CRITERIA FOR PAYMENTS

All transaction payments must meet the following criteria, as applicable:

- Consistent with the Common Rule
- Consistent with FDA regulations
- Costs must be allocable, allowable, and reasonable consistent with Uniform Guidance
- Aligned with the IRB-approved protocol and informed consent document
- Meet OIG expectations for fraud prevention and stewardship

Transactions not meeting compliance criteria will be rejected. If funds have already been disbursed for non-compliant transactions, charges will be transferred to non-sponsored funds. The PI's department bears financial responsibility for non-compliant transactions.

MONITORING AND INTERNAL CONTROLS

- Office of Research will perform routine monitoring of all ClinCard transactions
- PI or their designee must review and verify accuracy of payments
- Payment initiation, approval, and oversight roles must be separated where feasible
- All transactions must be documented within the system
- Justifications and approvals must be retained in accordance with institutional financial policies and sponsor requirements, where applicable
- Office of Research will document and report findings of noncompliance

CONSEQUENCES OF NONCOMPLIANCE

Depending on the severity, frequency, and risk associated with noncompliance, one or more of the following actions may be taken by the Office of Research or OSU-CHS administration:

- Targeted or department-wide internal audit; formal audits will be coordinated with the Office of Internal Audit when applicable
- Required corrective action plan and mandatory retraining
- Increased transaction monitoring or pre-approval requirements
- Temporary or permanent suspension of ClinCard system access
- Financial reassignment of unallowable costs to departmental funds
- Reporting to the Institutional Review Board (IRB), sponsors, or regulatory agencies, as applicable
- Referral to Department Chair, Dean, or institutional leadership for administrative review
- Repeated, intentional, or high-risk violations may result in escalated compliance actions, including restrictions on project activity or institutional disciplinary measures.

REPORTING

- Suspected fraud, waste, or abuse must be reported immediately to the Office of Research. Office of Research will escalate issues in accordance with institutional policy and OIG expectations.

TRAINING REQUIREMENTS

Users must attest that they have reviewed this policy and associated procedures and agree to exercise appropriate fiscal responsibility when requesting access to the ClinCard platform and initiating project set up.

REFERENCES

- 45 CFR 46 - Protection of Human Subjects (Common Rule)
- FDA regulations - 21 CFR Parts 50, 54, 312, and 812
- 2 CFR 200 - Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (Uniform Guidance)
- HHS Office of Inspector General (OIG) Compliance Program Guidance
- OSU-CHS Compensation for Human Subjects Research Policy
- OSU financial management policies and procedures
- Institutional Review Board (IRB) Policies and Procedures

DOCUMENT HISTORY:

Initial Approval, OSU-CHS Vice President for Research, version 1 (6/24/2026)