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, guidance, 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 LSU Health New Orleans, including the Health Sciences Center (HSC), the Stanley S. Scott Cancer Center (SSSCC) and the Healthcare Network (HN), hereafter called the investigational site. These detailed instructions promote compliance in conducting clinical research.

SOP 2.16 describes the process for payments to human subjects for clinical research.

2. RESPONSIBILITY

The HSC, SSSCC, and HN Clinical Trials Offices develop, implement, and maintain 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 (Sub-I)	Other Research Staff
Clinical Research Nurse Coordinator (CRNC)	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 their 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 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 for:

- Storing stipend cards (i.e., ClinCards or gift cards provided by sponsor) 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 stipend cards or incentives.
- Document stipend card chain of custody.
- Ensuring 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

For payments processed through Sponsored Projects Accounting (SPA), each research subject is required to provide their full name, valid address, and social security number at the time they sign the informed consent.

Payment Options:

1. *ClinCard/Greenphire*

   A ClinCard Spreadsheet used to request setup of a study into the Clin Card System should be completed and emailed to Sponsored Projects Accounting during study start-up. A Request for ClinCard Form should also be sent to Sponsored Projects asking for the number of cards needed for the study.

   One ClinCard will be assigned per subject. The subject's ClinCard number should be recorded on a subject payment/stipend log and should be filed in the subject's research chart. This form should be signed by the subject each time there is a visit requiring payment. The card is reusable, so if the subject is receiving payments for multiple visits, they can continue using the same card. Subjects can receive text or email alerts (standard messaging rates apply) once payments have been loaded to their card. Subjects can also log in to a website to view their balances and track expenditures. OSP currently reconciles payments from research accounts weekly.

Please note:

- There is a fee associated to buy each card ($4.00), along with a fee every time money is loaded to the card ($2.62).
- If a card is lost or stolen, a new card can be issued and a fee will be assessed.
- A charge is applied to the card after 6 months of inactivity. Special consideration should be given for subjects seen less than every six months.
- ClinCards have an expiration date; balances should be transferred to a new card prior to expiration to ensure subjects continue to have access to their study payments.

For additional information regarding setting up a ClinCard account for a research study or general questions about the program, contact Sponsored Projects Accounting.

2. *Gift Cards and Non-Cash Gifts*

   Please contact the departmental business manager for use of gift cards to pay research subjects.

3. *Payments to Nonresident Aliens*

   Before enrolling the subject on a research study, contact the Sponsored Projects Accounting. There are additional requirements guided by the IRS and Homeland Security for nonresident aliens.

E. End of Study

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

5. APPLICABLE REGULATIONS AND GUIDANCE

LSU Health Guidance/Policy	Title
LSUHSC HRP Policies & Procedures	7.03 Subject Payment
LSUHSC Accounting Services	Sponsored Projects
LSUHSC Accounting Services	Clinical Trials/Clin Card
LSUHSC Administration and Finance	VCAF-001 – Collection of Personal Identifiers for Paid Clinical Trial Participants
Federal/International Regulation/Guidance/Policy	**Title**
21 CFR 50	Protection of Human Subjects
45 CFR 46	Protection of Human Subjects
45 CFR 160	HIPAA Privacy Rule
45 CFR 164 Subparts A and E	HIPAA Privacy Rule
ICH E6(R2)	Guideline for Good Clinical Practices E6 Integrated Addendum

FDA Guidance for Industry	Investigator Responsibilities- Protecting the Rights, Safety, and Welfare of Study Subjects
FDA Guidance for Industry	Payment to Research Subjects – Information Sheet
FDA Guidance for Industry	Recruiting Study Subjects – Information Sheet

6. MATERIALS

6.1. Subject Payment/Stipend Log

Approved by:

Jawed Alam, PhD, MBA
Executive Director, Office of Research Services