

TULANE UNIVERSITY SCHOOL OF MEDICINE CLINCARD COMPENSATION POLICIES AND PROCEDURES

Purpose

The purpose of this policy is to allow ClinCards as a way of compensating participants in research projects at the Tulane University School of Medicine, while ensuring the necessary tracking mechanisms are in place for account reconciliation and tax reporting purposes. This system will be overseen and audited by the Clinical Translational Unit (CTU) and by the SOM Dean. The Principal Investigator (PI) is the individual ultimately responsible for the handling and disbursement of research project funds.

Scope

The use of this ClinCard System is limited to research projects conducted at the **Tulane University School of Medicine**.

Responsibilities

Department

1. The PIs, Program Coordinators, and Administrator in each department/section must read the ClinCard Compensation Policy and Procedures and sign a Receipt and Acknowledgement form (attached).
 - a) Signed Receipt and Acknowledgement forms shall be submitted to the CTU for each new user requesting access to the system.
2. The PI of each study will be ultimately responsible for ensuring that subjects are enrolled and payments are made in a manner which complies with this Policy.
3. The PI is responsible for amending all IRB submissions to state that ClinCard will be the sole means of providing study participant compensation.
4. Departments are responsible for enrolling participants and approving scheduled payments in the ClinCard System; in accordance with the “**Procedures**” section of this Policy.

Clinical Translational Unit

1. Disburses ClinCards to PI or designee.
2. Maintains a central file of W-9s for all participants.
3. Maintains a central file of Policy Receipt and Acknowledgements.
4. Enters new users and studies in the ClinCard System.
5. Monitors system and, on a monthly basis, prepares the department correction form to appropriately charge individual accounts for ClinCard distributions during the previous month.
6. Performs periodic audits of individual project records. (See **Monitoring and Auditing**, below.)

SOM Dean’s Office

1. Reconciles overall ClinCard drawdown to amounts charged to individual accounts and investigates discrepancies.
2. Performs monthly reconciliations of study enrollment forms to information loaded into the ClinCard System and compiles UBIT information to submit to the controller’s office.
3. Performs quarterly reviews of audits performed by the CTU.
4. Ensures that funding is available to allow ClinCard loading.
5. Provides annual 1099 report to Uptown accounting.

Procedures

Study Enrollment

1. The Department/Section Administrator shall complete and sign a study enrollment form (attached) for each new clinical trial/study.
2. The Clinical Translational Unit shall enter new clinical trials/research studies and accompanying preloaded payment schedules (as defined on the study enrollment form) into the ClinCard system, using the completed and signed study enrollment form.

Participant Enrollment

1. The first time an individual enrolls as a Tulane University School of Medicine study/trial participant, the enrolling department must collect a W-9 form.
2. Each time a participant joins a new study, the Program Coordinator must have the participant sign a Study Consent Form and HIPAA acknowledgement, if applicable.
3. Departments shall ensure all participant records and ClinCard receipt logs are kept secure and confidential.

Participant Distribution

1. The Program Coordinator shall enter the required participant's information into the ClinCard system prior to any payments being made.
2. The Program Coordinator may load payments that are listed in the preloaded payment schedule. Manual payments outside of the payment schedule and travel payments must be approved by the Department/Section Administrator.
3. All studies will be charged a one-time issuance fee of \$3.50 for each new ClinCard and a \$1.00 loading fee each time compensation is loaded onto the card. Department/Section Administrators and Program Coordinators should budget these expenses into future studies.
4. Studies shall provide research participants with replacement ClinCards when their card is lost or stolen, however studies will be charged a one-time issuance fee of \$3.50 for each replacement ClinCard. It is up to the discretion of the department to determine whether these charges should be passed on to the research participant at any point.
5. Each Program Coordinator may select one additional coordinator to serve as a designee to load payments if the primary coordinator is not available.
 - a. To select a designee, fill out the Designee Request Form and submit completed form to ctuforms@tulane.edu.
 - b. Department/Section Administrators **may not** serve as designees.
6. Once a month, Program Coordinators must sign the Disbursement Receipt Log listing the ClinCard payments that were made in the previous month. The receipt log must clearly state ClinCard number, research project number, payment date, and compensation amount. A sample receipt log is attached.

Reporting

1. The Dean's office will be responsible for providing the Tulane University Controller's office the following reports:
 - a. A ClinCard System report generated at calendar year end to identify all participants compensated \$600 or more to ensure the proper processing of IRS 1099 forms. The report will be submitted electronically to the Controller no later than January 15th of each following year.
 - b. Quarterly reports of UBIT status on all new clinical trials/research studies.
2. The CTU will be responsible for providing the Dean's Office with the following reports.
 - a. A monthly ClinCard System report identifying participant compensation activity by research account number.
 - b. A monthly general journal charging compensation activity by research account number, and crediting the Dean.
 - c. Quarterly copies of the audit reports prepared by the CTU.
3. Departments shall submit the following forms to the CTU, at ctuforms@tulane.edu, on a monthly basis:
 - a. Completed study enrollment forms and designee request forms for all studies entered during the month.
 - b. Completed W-9s for all new participants enrolled during the month.
 - c. Signed Disbursement Receipt Logs for all payments made during the month.
 - d. Signed Policy Receipt and Acknowledgement form for all new users.

Monitoring and Auditing

1. The ClinCard System will be monitored and audited by the CTU to verify that all required forms are on file to support disbursements.
2. Audits will be performed on a surprise basis. Each Program Coordinator shall be audited at least once per year.
3. If deficiencies or discrepancies are discovered during the course of an audit, the Program Coordinator and the PI will be sent a written request to clarify the concerns.
 - a) Both the Program Coordinator and the P.I. must provide a written response within 15 days.
 - b) Both the request and the responses must be kept with the audit report.
4. Failure to follow the guidelines of this Compensation Policy and Procedures may result in a decision by the CTU or the Dean to terminate the project and may also result in disciplinary action for the individuals involved.
5. Any allegations of misconduct involving the ClinCard System will be investigated and resolved in accordance with relevant Tulane University policies and procedures.

**TULANE UNIVERSITY SCHOOL OF MEDICINE
CLINICARD COMPENSATION
POLICY AND PROCEDURES**

Approved by:



L. Lee Hamm, MD

Senior Vice President & Dean, School of Medicine

Revised: April 24, 2017

RECEIPT AND ACKNOWLEDGMENT

I have received and read a copy of the Tulane University School of Medicine ClinCard Compensation Policy and Procedures. I agree that I will comply with this policy and any future revisions, am bound by the provisions contained therein, and understand that failure to comply with this policy may result in disciplinary action as appropriate.

Signature

Date

Printed Name

Department

Departmental Role

- Department/Section Administrator
- Program Coordinator
- Principal Investigator
- Other (specify)_____



CLINCARD STUDY ENROLLMENT FORM

Please complete this form (**one per study**) and email to the Clinical Translational Unit at ctuforms@tulane.edu. Once your application has been received, you will be contacted by the CTU with further instructions. If you have any questions regarding ClinCard program, please contact Rachel Cruthirds at 504-988-9038 or Jen Huber at 504-988-4645.

User First Name	Last Name	Email Address	Phone Number	Role on Project (e.g. Coordinator, PI, Dept. Administrator)

Note: If you have more than three users to add, please continue the list on an attachment or add additional lines.

Target enrollment: _____ x _____ number of projected visits per patient = _____

Department Name	Sponsor Name (if any)	Study Name*(short title)	Study Description	Patient ID Required?	SSN Required?
				Yes	Required

Payment Description (e.g. "Visit 1," "Screening," etc.)	Payment Amount (\$)

Payment Description (e.g. "Visit 1," "Screening," etc.)	Payment Amount (\$)

Note: If there are more than 20 visits with compensation, please continue the list on an attachment or add additional lines.

Provide Billing Information for the Above Study:

Study Name*(short title)	School	Org #	Project (Grant) #
	School of Medicine		

Provide UBIT Exempt Taxable Status Information for the Above Study:

Study Name*(short title)	IRB #	IRS RR 68-373 IS THE PURPOSE OF THE TRIAL testing of an already-approved FDA drug for "public safety"? EXEMPT – Very Common	IRS PLR 8230002 IS THE PURPOSE OF THE TRIAL "for benefit" testing on patients who already have the target disease, for a drug or device that does not yet have FDA approval? EXEMPT – Very Common	IRS PLR 8230002 IS THE PURPOSE OF THE TRIAL "not for benefit" testing on participants who do not have the target disease, for a drug that does not yet have FDA approval? PROBABLY NOT EXEMPT

*These names should match

Signature: _____ Date: _____

of cards requested



**CLINCARD DESIGNEE REQUEST
FORM**

Each Program Coordinator may select one additional coordinator to serve as a designee to approve ClinCard payments if the primary coordinator is not available. Please complete the following information to assign a designee and send the complete form to ctuforms@tulane.edu. Please note that department/section administrators **may not** serve as designees.

Study Name (Short Title): _____

Department Name: _____

Sponsor Name: _____

Study Description: _____

Program Coordinator Name: _____

Program Coordinator Email Address: _____

Program Coordinator Phone Number: _____

Designee Name: _____

Designee Email Address: _____

Designee Phone Number: _____

I request that the individual named above has designated authority to approve ClinCard payments on the above referenced study in the event of my absence or nonavailability.

Program Coordinator Signature

Date

Designee Signature

Date

