SPONSORED CLINICAL TRIALS ADMINISTRATION

Louisiana State University Health Sciences Center – New Orleans (LSUHSC-NO) is responsible for complying with the regulations, guidelines, technical and fiscal reporting and billing requirements and management procedures as prescribed by the sponsoring or funding organization. To ensure compliance, controls have been established to mitigate the risk of loss of revenue related to sponsored clinical trials, to ensure that sponsored clinical trial revenue and expenses are allocated and distributed to the appropriate department, and to provide guidance on which departments, sections, or offices hold responsibility for each task.

POLICY STATEMENTS

The principal investigator is primarily responsible for administering the clinical trial. The following areas require the principal investigator's special attention.

1. Administrative Responsibilities.
   a. Performance Regulations. The principal investigator must work closely with the Office of Research Services to draft and negotiate clinical trial agreements and obtain compliance approvals.
   b. University obligations. The principal investigator and departmental business manager must be thoroughly familiar with all obligations assumed by the university for sponsored clinical trials under their administration and see that requirements are met, charges are processed promptly, and required technical reports are submitted on schedule (or that time extensions are obtained when necessary). These personnel are responsible for advanced approval for budget revisions or program plans. They must also ensure that project costs are reasonable, allocable to the clinical trial within the stated time period, allowable, and consistently charged.

2. Fiscal Responsibilities.
   a. Billing and collecting revenue in a timely manner.
   b. ClinCards are administered and monitored appropriately.
   c. Sponsored clinical trial revenues and expenditures are applied to the appropriate project.
   d. Medicare Coverage Analyses (MCAs) are conducted for all sponsored clinical trials.
   e. MCAs and/or billing grids are provided to all 3rd party service providers.
   f. IRB and other fees are listed in the sponsored clinical trial agreement (CTA) and are billed and collected timely.
   g. Maintaining an accurate, comprehensive list of all active University trials and corresponding enrolled participants.
   h. All expenditures are applied to the appropriate project.
   i. Clearing accounts are resolved in a timely basis (please refer to CM-21)

Sponsored Projects Administration (SPA), a section of the Department of Accounting Services, is responsible for maintaining accounting control over all university sponsored clinical trial accounts, including post-award administration of sponsored activities. The primary responsibilities for SPA are:

a. Establishing project numbers for each new sponsored clinical trial.
b. Entering budgets for sponsored clinical trials.
c. Monitoring sponsored clinical trial accounts for deficit balances and their resolution.
d. Loading funds for reimbursement methods for trial participants (ClinCard).
e. Maintaining an accurate and comprehensive list of all extramurally-funded, active sponsored clinical trials.
f. Ensuring that sponsored clinical trial revenues and expenditures are applied to the appropriate project.
g. Ensure that departments follow the closeout process for all completed trials.

DEFINITIONS

Sponsored Clinical Trial: a research study that prospectively assigns human participants or groups of human participants to one or more health-related interventions to evaluate the effects on health outcomes, the costs for which are paid to LSUHSC-NO by a non-LSUHSC-NO entity such as, although not limited to, a pharmaceutical company.

Medicare Coverage Analysis: a review and classification of all costs associated with a sponsored clinical trial, the purpose of which is to ensure that each involved party (LSUHSC-NO, Third-Party Provider, Insurance Company, Medicare, Medicaid, Trial Subjects, etc.) is being accurately and appropriately held responsible for said costs.

Third-Party Provider: a non-LSUHSC-NO entity involved in a sponsored clinical trial, typically as a performance site and/or provider of one or more trial-specific healthcare services.

IRB Fees: one-time and/or recurring expenses charged to most sponsored clinical trials by LSUHSC-NO's Institutional Review Board, which provides review and approval of all research projects involving the use of human subjects, with the purpose of protecting the rights and welfare of individuals participating in those projects.

ClinCards: reloadable debit cards that are used as a method of paying human clinical trial subjects for their trial participation or to reimburse them for participation-related expenses.

PROCEDURES

MCAs:

Departments will prepare, or arrange to have prepared, Medicare Coverage Analyses (MCAs) for all sponsored clinical trials.

Departments will provide copies of all MCAs to third-party providers/participating sponsored clinical trial entities.

IRB Fees:

The Office of Research Services (ORS) will work with Sponsored Projects Administration to prepare journal entries deducting the appropriate Institutional Review Board (IRB) fee amount(s) from each sponsored clinical trial.

ORS will ensure that each clinical trial agreement contains specific mention of the IRB fee as a required financial obligation of the sponsor.

Departments will invoice clinical trial sponsors for IRB fees within 60 days of the IRB fee's being deducted from the sponsored clinical trial's project account.

Receivables:

Departments will invoice sponsors within 90 days of expenses having been incurred, or in accordance with the project's sponsored clinical trial agreement, at which time departments will verify the allowability of project expenses.

Departments will provide copies of all submitted sponsored clinical trial invoices to Sponsored Projects Administration, via the ClinicalTrials@lsuhsc.edu mailbox. Said invoices will indicate the approval/certification of both the Principal Investigator and Business Manager, and will include any receivables that are automatically generated when a patient transaction takes place.

Using the invoices received from departments as described above, Sponsored Projects Administration will enter the receivable into the Accounts Receivable invoicing system.

If a payment is received for which there is any question about to which, if any, sponsored clinical trial it should be applied, Accounts Receivable will work with Sponsored Projects Administration to identify the appropriate project to which it should be applied.

Status:

Sponsored Projects Administration will request, and Departments will provide, on at least a quarterly basis, information on the status ("active" or "concluded"/no additional payments expected) of all sponsored clinical trials.

Departments will submit, and Sponsored Projects Administration will process, closeout request documentation for all concluded sponsored clinical trials.

ClinCards:

Sponsored Projects Administration will ensure, through the use of a standardized ClinCard setup form, during initial setup of or subsequent changes to a sponsored clinical trial's ClinCard account that no single individual is established as both a site coordinator and an approver on a given sponsored clinical trial.

Departments will, on at least a quarterly basis:

- Run a report (suggested: Payments By Study) from the ClinCard system to compare the amounts that sponsored clinical trial patients were paid to the amounts established at the time of ClinCard study setup or at the time of subsequent ClinCard setup changes, and to further compare those payments to the agreed-upon amounts, if any, specified in the CTA.

- Run a report (suggested: Payments By Study) from the ClinCard system indicating which cards were issued, and reconcile them to each trial.
- Ensure that ClinCard transactions are reviewed on at least two levels (business manager reviews clinical trial coordinator's review, or similar).
- Ensure that the signature is collected of each participant who receives a ClinCard payment.
- In accordance with the Policy Regarding Collection of Personal Identifiers for Paid Clinical Trial Participants, collect certain participant identifiers, including full name, valid address and social security number at the time the sponsored clinical trial participant signs the Informed Consent Form (ICF).

FORMS

Closeout1, Closeout2

Invoice Certification Form

ClinCard Setup Form