

Financial Management of Clinical Trials

1. Overview

As a recipient of sponsored funds that support clinical trial activities, the University must ensure that all activities are implemented in compliance with applicable local, state and federal regulations, as well as sponsor specific requirements.

Research Financial Services (RFS) is responsible for preparing and submitting all invoices associated with Federally funded clinical trials in compliance with the terms and conditions of the award. RFS will setup the project for the entire amount of the contract to ensure timely recognition of revenue. Departmental personnel are responsible for preparing and submitting invoices and/or confirmation of completion of milestones or other activities associated with non-Federally funded clinical trials, ensuring that such invoices and/or confirmations comply with the terms and conditions of the clinical trial contract or sponsored program, and for submitting copies of invoices and/or confirmations to RFS to support the effective and timely collection of clinical trial funds and the official University record. Principal Investigators (PIs) are responsible for ensuring that all clinical trial activities comply with all applicable regulations, and for confirming completion of deliverables or milestones associated with clinical trial activities.

2. Purpose

To ensure the University submits accurate and timely clinical trial invoices and/or confirmation of completion of milestones or other activities in compliance with Federal regulations (2CFR 200.343) and other sponsors requirements.

3. Who Must Comply

Department Personnel
Research Financial Services
Principal Investigators

4. Definitions

Cost Reimbursable: Invoices are based on actual expenditures recorded in Oracle on a monthly basis or predetermined time interval, quarterly, semi-annually, etc.

Invoice/Payment in Advance: Invoices/payments are based on a predetermined invoicing schedule with a final invoice reconciliation based on actual costs. If the sponsored program is cost reimbursable, the final invoice will be based on actual expenditures recorded in Oracle and will either reflect a refund back to the sponsor for surplus funds or a balance due. If the sponsored program is fixed price, the final invoice will reflect the final payment as noted in the award terms and conditions and will not reflect actual expenditures recorded in Oracle.

Fixed Price: invoices are based on payment arrangements such as milestone completion, performance deliverables, or predetermined time interval, monthly, quarterly, etc. Invoices are not based on actual expenditures as recorded in Oracle and any unexpended balances at project end are retained by the University.

Milestone: The achievement of a specific activity or submission of a specific deliverable, such as the accrual of a certain number of patients.

5. Procedures

Once a clinical trial contract or sponsored program is in place, the PI will work with the relevant University regulatory offices, including the Institutional Review Board (IRB) and school or college's clinical trial management office (CTMO) or equivalent, to obtain all required approvals. The PI, with support from department personnel, will then implement the clinical trial activities in compliance with the protocol and all other applicable regulations.

It is the responsibility of the University, supported by RFS, PIs and department personnel, to submit timely and accurate invoices and/or confirmation of completion of milestones or other activities to clinical trial sponsors that result in sponsor payment. The invoice and/or confirmation should meet the following requirements:

- Aligns with terms and conditions of the award;
- Accurately reflects project expenses as captured in Oracle for cost reimbursable agreements;
- Represents the progress of the clinical trial activities and aligns with milestones or scheduled payments based on the agreed upon invoicing schedule.

Department personnel will prepare and submit all invoices and/or confirmation of completion of milestone or other activity, including care reports, associated with clinical trials. Department personnel will prepare the data and/or invoice, obtain PI approval, and submit to the sponsor.

Once invoices and/or confirmation of completion of milestones or other activities are submitted, the department personnel will email a copy of the invoice or otherwise notify RFS of the completion of the milestone or activity with the associated requested payment amount to ensure that the University records are accurate and complete. This will enable RFS to create the appropriate Accounts Receivable entry in Oracle in a timely manner and to accurately recognize revenue.

6. Roles and Responsibilities

Department Personnel	<ul style="list-style-type: none"> • Confirm completion of milestones/performance deliverables • Prepare and submit invoices for clinical trials, when applicable, that are accurate and timely • Provide RFS with copies of clinical trial invoices and other information that support effective and timely collection of clinical trial funds to RFS to support the official University record
Research Financial Services	<ul style="list-style-type: none"> • Collaborate with the Principal Investigator and department personnel to confirm milestone completion • Ensure that all invoices accurately reflect the sponsored agreement payment terms • Ensure that all clinical trial invoices are accurately reflected in the financial system • Maintain complete and accurate records of clinical trial invoices on behalf of the University
Principal Investigators	<ul style="list-style-type: none"> • Ensure all clinical trial activities comply with applicable regulations and requirements • Confirm completion of milestones/performance deliverables • Collaborate with RFS and departmental personnel to ensure invoices are accurate and submitted timely to sponsor

7. Resources

Related Procedures

 Sponsored Projects Invoicing

Federal Regulations

 Uniform Guidance 200.327 Financial Reporting