

Clinical Research Support Office (“CRSO”) STANDARD OPERATING PROCEDURE

SOP NUMBER CFI-SOP-4002	TITLE Clinical Trial Management System Financials
EFFECTIVE DATE 08/15/2019	WRITTEN BY CRSO Operations Director
REVIEW/REVISION DATE 10/15/2025	REVISED BY: JESSICA HESKEL

APPROVAL	
SIGNATURE	DATE

1. POLICY STATEMENT

Study Teams are required to use the Clinical Trials Management System (“CTMS”) to support industry-sponsored invoicing activities, and manage study payments/receivables for NIH defined clinical trials, where the study team is responsible for all invoicing and payment activities.

2. PURPOSE

The purpose of this SOP is to standardize financial data entry and invoicing of clinical trials performed within the CTMS as well as provide standard reporting mechanisms for study teams and UK Treasury, as needed.

3. SCOPE

This policy is applicable for all University of Kentucky (“UK”) Industry-sponsored, NIH defined clinical trials that utilized CRSO pre-award services, where the PI or study team is required to invoice the sponsor to receive payment.

4. RESPONSIBILITY

CRSO Financial Manager

- Uses financial reports from CTMS and UK accounting system to identify and resolve issues, monitor account activity, and observe trends;

- Works closely with Research Financial Services (“RFS”) to manage centralized payments;
- Conducts reconciliations between the final CA and the budget to ensure that discrepancies are addressed before release;

Budget Owner

- The Budget Owner is the assigned department-based or CRSO Budget Analyst identified at the study intake meeting, who is responsible for budget development (including budget amendments), sponsor negotiation, and reviews budget entry within CTMS;
- Re-evaluates the budget, considering protocol amendments, and notifies the CRSO as appropriate.

Invoicing Owner

- The Invoicing Owner is the assigned department staff or CRSO Invoicing Analyst identified at the study intake meeting (or subsequently assigned), who is responsible for the creation and modification of study invoices and reconciliation of study payments;
- Works closely with RFS in centralized payment processing

CRSO Central Budget Associate

- Enters initial budget information into the CTMS
- Enters any budget amendments into the CTMS
- Verifies that all required financial documents are uploaded into the CTMS.
- Communicates with Study Teams to resolve any budget build queries
- If any discrepancies are noted during the data entry process related to the CA, the Budget Associate will communicate with the CTASBI Team to address any calendar/CA adjustments as needed.

CTMS Team

- Serve as support and subject matter experts in the use of the CTMS Finance Console.
- Perform the data entry of CTMS budgets previously reviewed by the CRSO Finance Team, and perform the calendar release.

5. PROCEDURE

- 5.1. the CTMS budget data entry may begin, but shall not be finalized until a CA or financial calendar is finalized. See CA SOP for additional details.
- 5.2. Study teams must provide the following documents to the CRSO Central Budget Associate

- 5.2.1. Fully executed Clinical Trial Agreement (CTA)
- 5.2.2. Internal Budget or MCA Budget Version
- 5.2.3. Final Sponsor Budget
- 5.3. CRSO Central Budget Associate will not begin budget entry until the CTA is executed, including a final sponsor approved budget
- 5.4. CRSO Central Budget Associate will;
 - 5.4.1. Finalize data entry of budget parameters;
 - 5.4.2. Enter protocol level items, subject procedure costs, time and effort, milestones, and pass thru items in the CTMS, per the provided budget documents;
 - 5.4.3. Upload final contractual agreement(s) in the Financial Console within the CTMS.
- 5.5. Once the CTMS budget data entry is complete, the Study Team can review and accept the budget build by completing the Specification Finance Signoff.
- 5.6. The CTMS Team will receive notification of the finance signoff and will perform a final technical/quality control review prior to release of the calendar/budget.

Post-Specification Release and Account Generation

- 5.7 Upon receipt of PADR 1, the study team must enter the WBS number into the CTMS. If the study is internally funded, a cost center or N/A must be entered in this field.
- 5.8 Based on the CTMS minimum data footprint, CTMS use is required for sponsor invoicing to generate study receivables and subsequent reconciliation of study payments.
 - 1.1. Sponsor Invoicing and Payment Processing Work Instructions document describes how to create an invoice in OnCore.
 - 1.2. Invoice Owners should:
 - 1.2.1. Review clinical trials and generate an invoice for any activity as indicated by the contract;
 - 1.2.2. Work with study teams to resolve data inconsistencies or errors that impact sponsor invoicing;
 - 1.2.3. Reconcile payments to receivables per the sponsor invoicing and Payment Processing Work Instructions document.
 - 1.2.4. Notify the CTMS Central Budget Associate if any changes are needed to the budget (amendments, issues identified, unexpected sponsor workflow changes, etc.)
 - 2. The CRSO Invoicing Specialist will work with RFS and study teams as part of centralized payment processing.
 - 2.1. All checks should be sent to the RFS central address and bank account.
 - 3. Study Teams must upload the payment remittance documentation into the CTMS Finance Console to serve as back-up documentation for QC and Audits.
 - 4. Modifications to an approved clinical trial contract or payment terms are addressed in

the Amendments SOP.

6. ATTACHMENTS

None

7. REFERENCES

[Office of Sponsored Projects: Clinical Trial Agreements](#)

[Office of Sponsored Projects: Industry Sponsored Agreements](#)

[University Financial Services: Business Procedures Manual](#)

- B-3-2-2 Payment Request Document
- B-3-3-4 Purchase Requisitions Healthcare and Facilities
- E-1-3 Fiscal Roles and Responsibilities
- E-1-4 Internal Control
- E-4 JVs
- E11-1 Penalty for Late Payments to Vendors
- E-17-8 GL accounts
- E-21-5 Collections and Write off policy
- E-50-1 Application for on/off campus F&A rate
- E-50-2 Cost Sharing
- Q-1-6 Electronic signatures
- Appendix 2 Cost transfer for sponsored Projects (JV between two grants)
- Appendix 3 Costing guidelines for Sponsored Projects
- Appendix 4 Service Center and Recharge Operations

[Research Financial Services](#)

- Accounts Receivable and Compliance
- Financial Reporting and Invoicing

Budgeting Work Instructions

Sponsor Invoicing and Payment Processing Work Instructions

CRSO Amendment SOP

CRSO Coverage Analysis SOP

CRSO Data Minimum Footprint