***TITLE: Monthly Reporting/Reconciliation***

***SOP*** FM XX.XX

***Approval:***

 ***Approved by Date***

***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

 ***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***Revision Version Effective date Description***

 ***\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

 ***\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

|  |
| --- |
| **Instructions for modifying this template:** 1. This is a template and should be used as such. Please use this in the manner most appropriate for your research unit.
2. Anything in this template can and may be modified as appropriate for your area while accounting for your interpretation of the most current FDA Guidance.
3. After you have modified this SOP template, do not forget to remove the “**Instructions for modifying this template**” table.
4. Number the SOP using you own guidelines for numbering.
 |

**I. SCOPE/PURPOSE** The scope of this SOP is to describe the financial management account reconciliation process related to a clinical trial budget managed by UAB research sites. The purpose of SOPs is to assure consistency and rigor with the design, conduct and implementation of clinical trials at UAB by providing standards and guidelines for the staff. This SOP will describe the development and implementation of SOPs by the CTO Research Group SOP Committee.

**II. ALLOWABLE EXCEPTIONS**

This SOP will be adhered to unless exceptions are required. Exceptions will be noted in a formal note to file.

**III. RELEVANT REGULATIONS/GCPS**

Sunshine Act, UAB F&A Agreement, National Coverage Determination (NCD 310.1), Affordable Care Act

**IV. DEFINITIONS/ACRONYMS**

CTA Clinical Trials Agreement

CTO Clinical Trials Office

CRO Clinical Research Organization

CMS Center for Medicare Services

FAP Fiscal Approval Process

SOP Standard Operating Procedures

**VI. RESPONSIBLE PERSONNEL**

Department Chair/Dean

Department/Division Administrator

Finance Administrator

Coordinator(s)

**VII. DETAILS**

The following is a description of the Monthly Reporting and Reconciliation Process

1. Financial Management & Administrative Responsibilities
2. Principal Investigator (PI) – Monthly review of expenditures; Approve expenses; Allocation of effort
3. Research Coordinator - Enrollment Log(s);Prepare and log participant compensation payments; Reconcile patient care billing to patient enrollment in collaboration with SiteMinder; Maintain Study Binder; Data collection
4. Research Finance Administration - Process salary and expense transactions;

Monthly review of salary & expenditures (Oracle);Make adjustments/corrections based on reports; Update projections; Provide administrative/financial support to PI; Account setup; Monthly reconciliation of patient care charges with Study Team; Approve and process journal entries; Billing to sponsor; Accounts Receivable

1. Research Administration – Reconciling Study Visit Considerations; Reconcile all charges that have been allocated to the clinical trial budget; Confirm that all patients charged to the study are truly part of the study; Check if there are patients that you do not see on your list that you know participated; Check for missing charges, Confirm if there are charges not related to the study.
2. Financial Reporting and Analysis
3. The financial administrator should continuously monitors each project to see how much revenue is outstanding or owed by the sponsor on the study
4. Reporting should illustrate study/project performance based on the revenue earned and expenses (costs) incurred at a point in time. Provides a snapshot of the financial status of a study/project. Strengthens decision making capabilities for future studies and outcomes on an individual study/project.
5. The data reflected on a monthly report/reconciliation; The amount of revenue earned for each project, The expenses incurred (direct and indirect costs), Transfers made in or out of fund codes, The amount of cash still owed by sponsors (accounts receivable).
6. Financial reports can be run for different periods of time;

Inception to Date (ITD) shows the financial activities of a study since its inception.

Fiscal Year to Date (YTD) shows the activities for a particular fiscal year

By Month shows the activity which occurred for a particular month you are reconciling.

Financial reports can be run multiple ways, such as summary or detailed level;

Summary level can show a one line summary of all studies for a PI

Detailed level reporting shows each transaction that has occurred on a study by G/L account.

1. Benefits of Monthly Reports and Reconciliation
	1. Assists in monitoring the portfolio performance at the department, division, or PI

level

* 1. Assists in managing margins (industry) and overdrafts
	2. Assists in preparing operations budgets
	3. Assists in identifying areas of concerns, such as

collection issues

* 1. Assists in identifying trends in monthly expenses
	2. Allows one to reconcile revenues and expenses to ensure the proper activity has been posted to the study
	3. Allows one to confirm the correct effort for faculty and staff has been recorded to the study
	4. Allows one to determine if the proper F&A rate is being assessed to the study
	5. Allows one to determine if the study is in overdraft and what could be the cause of the overdraft
	6. Allows one to measure against the budget to determine progress
1. Questions When Reviewing Monthly Reports
	1. Is there a large accounts receivables balance on the project? If so, is cash coming in on continuous and appropriate basis?
	2. Do salaries look in line with the revenue being generated?
	3. Are the projects generating profit or loss? If so, are transfers playing a role in what is reflected?
	4. Are the transfers in and out appropriate?
	5. Are there major swings in activity from period to period?

**VIII. QA**

 NA

**IX. APPENDICES/RESOURCES**

NA

**X. RELATED SOPS**

NA