Financial and Administrative Support of Clinical Trials

This document is intended to clarify the Roles & Responsibility Work Guides on the division of financial and administrative support for faculty involved in clinical trials projects.

Since the original issuance of the work guides, we have recognized that the department and CTSU individual strengths to support faculty should be more clearly outlined. Some may read these guidelines and note that this is already happening. For others, the CTSUs will be working with the departments to realign services.

- Projects that are Clinical Trial Site Activity (defined as class code 31200) will be maintained fully by the CTSUs.

- In cases where there is both a research and clinical trial component, the department will maintain the overall project management. The CTSU will support the department by financially managing and providing information about the trial component.

Common traits of research projects where the department maintains overall project management:
When there are scientific or programmatic reporting requirements, the project will be maintained in the department with support from the CTSU on the clinical trial/human subjects component.

What does that mean for providing faculty service?
Generally, the department will manage the project and maintain compliance with sponsor required items. This would include generating typical interim and final progress reporting, submitting revised budgets, managing prior approvals, or requesting project changes like no cost time extensions. The CTSU will still develop and negotiate, as needed, the components of budget for patient/participant costs, reconcile patient charges against billing calendars, and inform the department of protocol amendments or other changes that will affect the project management, budget, or reporting. The CTSU would provide consistent financial reporting on the trial component and information on recruitment / accrual to the department and investigators.

Specific example: under an award from NIH that requires yearly progress reports, the department will manage the overall project and set up a subaccount to the CTSU to manage the human subjects portion. The department would lead completion and filing of the progress report (RPPR) with the CTSU providing (1) financial information on the trial component to inform the budget and (2) if a CTSU clinical coordinator supports the project, recruitment and accrual information to complete the human subjects/trial responses.

In all cases, as soon as the project is identified as a clinical trial, an intake form should be completed. This will allow for early conversations about project support plans and provide an opportunity for the CTSU to detail services that will be beneficial to the project and investigator.

We also recognize there will be specific cases where no financial or project activity will be directly managed in the CTSU. In these cases (characteristics listed below), the CTSU will still maintain information on the trial in OnCore, the study team will track summary accrual information, and the department will financially manage the project.
The specific circumstances must have **ALL** the following characteristics:

- No billing calendar
- No patient care* (no MiChart entry, billable items or services, or patient account reconciliation)
- Summary accrual or enrollment only
- Cost reimbursable; no milestone payments/invoicing
- Department- or PI-based study coordinator
- Recruiting primarily outside of the U-M clinical system, although recruitment may take place in our health system
- HSIP is the only clinical trials “transactional” activity

*An exception may be considered by CRAO if all items and services are provided exclusively by research personnel, in research space.*

In these cases, the CTSU will interface with the department-based team to register and create a record of the trial in OnCore. The study team (PI/study coordinator) will still be required to enter information in OnCore. The CTSU staff will work with individual project teams in these cases.

If issues or interpretations under this guidance is needed, please consult with the Administrative Lead of the CTSU unit for clarification.
Department / CTSU Roles & Responsibilities

Management of the Clinical Trial Component

- Complete Intake Form

Research with Trial Component (eg Federal, line item)

- Incorporate Trial Budget, Complete Form Pages, submission
- Review Award Terms

Cost Reimbursable

Manage Overall Award (Monthly Reconciliation, Forecasting of Project)
- Handle Project Finances, Sponsor Reporting
- HR Changes

Fixed Price

Clinical Trial Site Activity (eg Industry, Per Patient)

- Complete Internal Budget for Clinical Trial Component
- Negotiate Fixed Price Financials
- Review Award Terms
- Manage Clinical Trial Component (Monthly Reconciliation, Forecasting of Trial)

- Provide Trial-Specific Reporting
- Handle Invoicing, Collection

Department/PI

CTSU