As part of the Clinical Trials Transformation Initiative, The Clinical Trials Support Office (CTSO) and Clinical Research Calendar Review & Analysis Office (CRAO) have partnered to document financial best practices, gather resources and develop the tools that will support the following goals:

**Optimize and standardize the process of cost recovery and related negotiation practices in order to support operational excellence throughout the life cycle of clinical trials**

**Address bottlenecks that prevent timely initiation of clinical trials and increase the ability of University of Michigan clinical researchers to compete with peer institutions in trial initiation and recruitment, with the ultimate goal to enhance the culture of clinical research**
Eliminate waste and reduce administrative burden for faculty, finance staff and study coordinators.

Many thanks to Dr. Lok for all of her help in developing and coordinating the many facets of this knowledge base.

This resource would also not be possible without the incredible help of our collaborators from a variety of departments and units. Since re thanks to all of you who shared the examples, documentation and knowledge that are the meat & potatoes of this knowledge base, including Kate Hoffman, Mariella Wells, Amy Oliver, Marilyn Cramer, Linda Beekman and the entire CRAO team.

Navigating the Knowledge Base

Please note that knowledge base access is restricted by default; to request access, report an issue, submit feedback or just say hi, please direct all correspondence to thefunk-admins@umich.edu. Thank you!
Information and resources are grouped into three main categories:

A. Best Practice Presentations

The Basics: Slides and supplemental materials pertaining to the three-part 'Best Practices' training sessions, offered for CTSU Administrators, Financial Personnel and Study Coordinators over the course of the summer (2016); see the brief summaries below for additional details on content covered in each presentation.

B. Justification Guidance and Standard Definitions

A library of standard justifications for common/anticipated budget line-items or expenses, provided as a resource to facilitate the negotiation process. Rate suggestions are given as a jumping-off point for budgeting.

C. Case Studies and Historical Justification Documents

Further reading for those who wish to drill deeper into the nuances of the sponsor negotiation process. Each case study is an email chain beginning with the initial UM-sponsor contact for a specific trial and ending with a successfully negotiated budget. Helpful for anyone interested in the ebb and flow of the negotiation process, how specific rebuttals have been used to push back on sponsors with success, common clarifications requested by sponsors, odd situations that come up, etc.
**Justification Guidance and Standard Definitions**

- **Routine Invoicable Study Conduct Fees**: Various annual fees / etc.
- **Other Invoicable Fees**: Other considerations that will be applicable on a case-by-case basis; includes the ever-important screen failure line-item (beware of screen failure caps!)
- **Study Visit Costs**: Costs that factor into each visit total as well as the overall per-patient amount

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**Activation (Start-Up) Fees**
Case Studies and Historical Justification Documents

Specific Justifications
Requests for Clarification / Specifics
Sponsor Arguments & Rebuttals

Quick Links & FAQs

Roles & Responsibilities: A Comprehensive Overview

A task-list that provides helpful detail to consider when determining specific staff responsibilities, calculating effort or determining study logistics.
Where can I find an internal budget template?

A current (suggested) template can be downloaded from the Budgeting Tools & Tips page.

Resources Galore

A wide selection of links to relevant details housed on other University sites (ORSP, FinOps, MICHRI etc.)

Beware of Screen Failure Caps!

Sponsor insisting on a screen failure cap? This case study illustrates how to work with the sponsor to reach an agreement amenable to everyone.
**Indirect Costs**

ORSP's page on indirects (also known as Facilities & Administrative, F&A, or IDC) features a comprehensive overview as well as current rate information.

**Budget Tools, Tips & Templates**

Resources for effort calculation, CPT selection and more.

**Account Reconciliation Help and Charge Correction Overview**

Advice from the CRBI (Clinical Research Billing Issues) experts.
Q. How often should a study account be reconciled?

A. On (at least) a monthly basis

Need help getting started / un-stuck? Check out the Clinical Research Billing Issues (CRBI) team's latest reconciliation recommendations and handy tips for navigating MiChart here, or contact the experts directly @ CRBIssues-help@med.umich.edu
su-core-services  eff  ort  erpm  experience  e-canvas  final-four  financials  footnote  financials  footprint  game-plan  gidd  y-up  guidance  hsi  p  ide  ids  ind  internal-allocations  internal-budget  internal-budget-tab  invoicable  in  voicables  irb  irbmed-fee  items-and-services  ices  jira-craoo  cw  jira-crbu  j  ustification  kb-how-to-article  cle  kb-trouble  eleshooting-article  labs  mais  m  bect  mcru  mcru-alc-fee  e  meeting-notes  miap  naming  ni  mblification  nimblify  n  on-clinical-trials  oldie  onc  ore  onco  re-allocations-tab  orsp  p/g
UMMS Office of Research's Research Project Route Map

View the interactive version here, or download the full PDF here