Research Administration for the Non-Administrators

How to navigate the complex world of clinical trial administration.

Cassandra Barnhart, MPH

Senior Research Administration Manager, UNC Institute for Global Health and Infectious Diseases

Objectives

- Learn the different types of clinical trials
- Learn the administrative life cycle of a clinical trial
- Learn how to navigate the systems to make start-up more efficient

Expectations

- What this presentation will NOT do: Make you an expert on research administration systems
- What this presentation WILL do: Give you a basic, high level overview of the research administration process

Administrative Systems/Offices

- ALICE – UNC's system for processing contracts
- CRMS – UNC's clinical research management system
- IRB – Investigational Review Board (office for human subjects protection)
- OSP – Office of Sponsored Programs
- OVCR – Office of the Vice Chancellor for Research
- Ramses – UNC's system for processing awards

Research Acronyms

- BCA – Billing Coverage Analysis
- CDA – Confidentiality Disclosure
- COI – Conflict of Interest Disclosure
- CTA – Clinical Trial Agreement
- IDS – Investigational Drug Services
- IPF – Internal processing form that is created in Ramses
- SIL – Subject Injury Language

How many types of clinical trials are there?

- Federal – Network (under a Master Agreement)
- Federal – Standalone Protocol
- Non-Profit
- Industry

Types of Payments: Fixed Price

- Fixed Price is a milestone or per subject payment.
- At the end of study, the site is allowed to keep any funds received by the sponsor (in general).
- MOST clinical trials are Fixed Price.
- Ledger 3 for federal or Ledger 4 for industry

https://www.research.ucf.edu/documents/PDF/2021/FixedPrice_vs_CostReimbursableDetermination.pdf

Types of Payments: Cost Reimbursable

- Cost reimbursable agreements are based on a detailed, maximum budget, paid as costs are incurred and invoiced (typically monthly or quarterly).
- In a cost reimbursable agreement, any funds remaining at the end of the project have to be return to the sponsor.
- Ledger 5 for federal or non-profit

https://www.research.ucf.edu/documents/PDF/2021/FixedPrice_vs_CostReimbursableDetermination.pdf

Federal – Network (under a Master Agreement)

These types of studies have multiple protocols housed under a Master Agreement.

- Master is negotiated by the sponsor and Contracting
  - This USUALLY begins in Ramses
- Master Agreement is assigned a Ledger 3 project ID
- Master Agreement is housed in Ramses
- Master Agreement does not have an IRB number

Federal – Network (under a Master Agreement)

Each new protocol has an Addendum to the Master

- Does not require a new IPF in Ramses
- Does not require a detailed budget for each new protocol
- DOES require a unique IRB number (added to the Master Ramses IPF)
- DOES require a unique account for IDS, labs, etc.
- Uses the same Project ID as the Master

Federal – Standalone Protocol

Each new protocol has a unique CTA

- Requires a new IPF in Ramses
- Requires a detailed budget
- Requires IRB approval to be linked in Ramses
- Receives a unique Project ID
  - Ledger 3 if milestone based/fixed price
  - Ledger 5 if cost reimbursable (in general)

Non-Profit

Each new protocol has a unique CTA

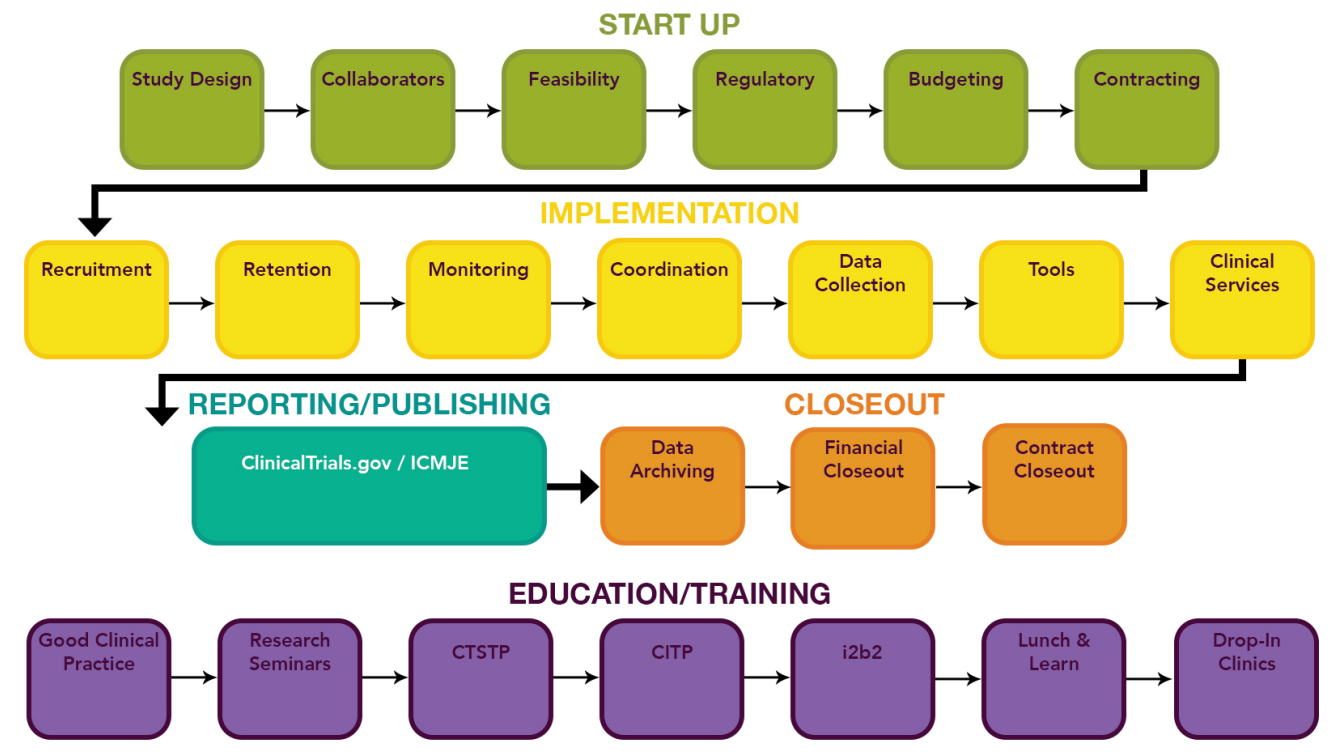
- Requires a new IPF in Ramses
- Requires a detailed budget
- Requires IRB approval to be linked in Ramses
- Receives a unique Project ID
  - Cost Reimbursable Ledger 5 (in general)

Industry

Each new protocol has a unique CTA

- Requires a new IPF in Ramses
- Requires a detailed budget
- Requires IRB approval to be linked in Ramses
- Receives a unique Project ID
  - Fixed Price Ledger 4 (in general)

Lifecycle of a Clinical Trial



L

JUST
KIDDING

Administrative Lifecyle of a Clinical Trial

Pre-Award

- CRMS record is created for new study
- Confidentiality Disclosure (CDA) is submitted through CRMS
- Sponsor sends protocol and site feasibility questionnaire
- If selected, site will receive a draft budget and Clinical Trial Agreement (CTA)

Lifecycle of a

Pre-Award

- Master agreement ted in Ramses
- The following are
  - Draft CTA
  - Draft Budget
  - Sponsor Protocol
  - Sponsors ICF Temp

If any of these docu

Lifecycle of a Clinical Trial

Pre-Award

- When approvals for BCA, IRB, COI, SIL, and contract are finalized, a Project ID is issued (Yay!)

Post Award

- Cash advances are needed to order pre-paid cards for study participants
- Invoiceables must be tracked and submitted to sponsor (if you're in OnCore, this is done by indicating that one has occurred; if you're not, you have to manually track and invoice)

Lifecycle of a Clinical Trial

Post Award

- When payments are received, they need to be deposited to OSP
- All invoices must be sent and payment received/deposited before closing a study out
- If you're participating in a cost reimbursable clinical trial, you may have to provide a final technical and financial report to the sponsor

What do each type of clinical trial have in common?

- Contract needs to be approved
- Budget needs to be finalized
- IRB approval is needed
- IDS protocol is needed (if applicable)
- CRMS record is needed

How do they differ?

	Federal	Industry	Non-Profit
Budget Negotiations?	Not usually	Always	Not usually, but it depends
Salaries (usually for PIs)	Salary Cap	Actual Salary	It depends, but usually Actual Salary
Reporting Due	Yes	Not usually	Yes

How to Navigate the Systems

- IRB, budget and CTA negotiation, and BCA can be done at the same time
  - IRBIS will ask for a Ramses number, but it's okay if you don't have one yet.
  - CRMS and ALICE will ask for an IRB number, but it's okay if you don't have one yet.
- Once a BCA is received, use it to negotiate the budget
  - OVCR now has a Finance office to help (Thanks, Bill and Nicole!)

How to Navigate the Systems

- When you have a final budget and contract, create a Ramses IPF
  - Link the IRB number if you have one
  - For a ledger 3 or 4 study, a very basic budget is sufficient, but must include the following:
    - At least 1% effort for the PI
    - A general idea of the total budget expected (try to match the contract as much as possible)
  - For a ledger 5 study, a detailed budget is needed. Most contracts will not allow rebudgeting between categories (personnel, supplies, participant stipends, etc.) without sponsor approval, so try to be as accurate as possible.

How to Navigate the Systems

- A Project ID cannot be issued until all of the following are finalized:
  - Completed BCA, approved by PI
  - UNC-approved Subject Injury Language in consent and contract
  - IRB Approval
  - Conflict of Interest for all personnel listed in IRBIS OR in Ramses
  - Signed, fully executed contract

If you have questions…

Resources and Links

Office of Sponsored Programs: https://research.unc.edu/sponsored-programs/

Industry Contracting: https://research.unc.edu/sponsored-programs/resources/industry-contracting/

CRMS: https://apps1.research.unc.edu/crms/

ALICE: https://apps2.research.unc.edu/alice/index.cfm

One UNC Clinical Research Office: **OneUNCClinicalResearch@unchealth.unc.edu**

ONE UNC Clinical Research Hotline: **984-974-8110**

Thank You! Any questions?