Clinical Trial Setup: Process Flow in ALICE and RAMSeS

Ashwini Roy-Chaudhury, Director of Clinical Research Support and Operations, OVCR
Kimberly Austin, Director of Contracting, OSP
Jennifer Teixeira, Senior Director of Research Administration, OSP

September 28, 2023

2023 SYMPOSIUM
FOR RESEARCH ADMINISTRATORS

How OSP and Clinical Research Ops are Working Together

Open Dialogue

Regular Meetings

Joint Process Improvement Initiatives

Objectives

- What is required to get to a Clinical Trial set-up?
- Where do you start?
  - CTA Contracting Process, Guidance, and Tips & Tricks
  - What you need to know about CTA Budgets?
  - The IRB Approval Process
- Pitfalls & how to improve the process
- Resources
- Q & A

What is Required?

- Submitted ALICE record
- Fully Executed Clinical Trial Agreement
- PI Certified RAMSeS IPF
- Fully Negotiated and Finalized Budget
- Submitted and Approved IRB Protocol

Where to Start?

All of these should be **completed in parallel** but be mindful of *dependencies*....

- CTA Contracts cannot be executed without a fully negotiated and finalized budget
- Congruency Checks cannot be Completed without an Approved IRB and PI Certified RAMSeS IPF that are both linked to the ALICE record
- Project IDs cannot be set up without a Completed Congruency Check

How to Get a CTA Executed?

- Department submits CTA in CRMS
- OSP Coordinator creates ALICE record (if all required documentation is in CRMS)
- OSP Contracting Team Manager assigns ALICE record to OSP Contracting Officer
- OSP Contracting Officer redlines sponsor template (for consistency with UNC policies)
- Redlines go back and forth until terms are finalized
- "Terms Finalized" status in ALICE remains until budget is finalized
- Once budget is finalized, CTA is executed

What helps CTA move quickly?

CTAs usually can be finalized quickly under the following circumstances:

- There is a Master Agreement
  - OSP Contracting Team reviews CTA submission to determine if there is an applicable Master
  - Terms and conditions in Master govern -> little negotiation
  - Some Masters: Gilead, GSK, AstraZeneca

Mirroring Terms

CTAs usually can be finalized quickly under the following circumstances:

- There are other CTAs with the Sponsor and we can mirror terms
- Even though there is not a Master, we have prior agreements with the Sponsor and can agree to use the same terms and conditions

Clinical Trial Agreement

CTAs usually can be finalized quickly under the following circumstances:

- Sponsor agrees to use the Accelerated Clinical Trial Agreement (ACTA)
- Similar to FDP template, "neutral" terms that have been agreed to by industry and University partners

What can slow down a CTA?

New Sponsor

- Both parties are reviewing positions for the first time
- No previous agreements or basic understanding of requirements
- No established relationship

What can slow down a CTA?

Responsiveness

- Lack of response from any of the parties involved in the contracting process, this includes but is not limited to:
  - OSP Contracting Officers
  - Department Contacts
  - Principal Investigators
  - Sponsors
- The longer it takes to get a response the more likely it is that all parties will need to re-review the documentation to become familiar with the issues again.
- If too much time has passed, we may need to revisit the original submission.

What can slow down a CTA?

Inability to come to agreeable terms

- If the sponsor is unable to agree to any of the terms and conditions required of UNC-CH as a Public State institution, it may require abandon negotiation.
- May include more risk to the University and require additional departmental approval (if we can choose to accept the risk).
- Requires extended negotiations and lots of redlines and may require additional coordination with other compliance units on campus.

Budget – When does it go into the CTA?

There is a process to develop the budget…

- Billing Coverage Analysis
- Prices for procedures that will be done at UNC-CH from research fee schedule
- Request prices if not listed in the fee schedule
- Select the appropriate overhead
- Negotiate budget
- Budget has to be fully negotiated with sponsor

Then….. the sponsor will insert budget in the CTA and send it back to OIC for internal and external signature

IRB Approval

- IRB preparation
- Subject Injury language in Informed Consent Form
- IRB submission

IRB approval is needed for congruency checks!

What can Delay the CTA Project Set-up Process?

- Terms Finalized but there is **no** Negotiated and Approved Budget
- Fully Executed CTA but **no** RAMSeS IPF submitted
- RAMSeS IPF Submitted but **no** PI certification
- Red **X** in RAMSeS on the COI Tab means a Project ID cannot be set up
- IRB Submitted but **no** Approval
- Approved IRB and a Completed/Certified RAMSeS IPF are done but neither are linked to ALICE to complete Congruency Check
  - Congruency Check is required for initiation of Project ID set-up

What can the Study team do to help the process?

Make sure all required documents uploaded in ALICE:

- ✓ Draft Contract (in Word format)
- ✓ Protocol
- ✓ Draft Informed Consent Form
- ✓ Draft Budget

What can the Study team do to help the process?

Ensure the IPF is submitted and certified:

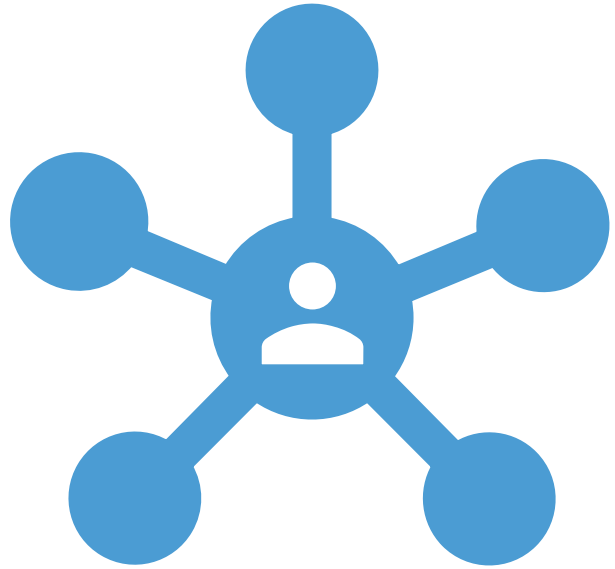
- IPF can be submitted at any time, but is required to initiate Project ID set-up.
- PI must also certify the IPF in RAMSeS.
- To help expedite the process, you can email OSPContracting@unc.edu with the IPF number once it has been certified.

What is OSP doing to Improve the process?

- Auto generated emails to Department and PI as certain ALICE statuses are triggered to help create more transparency around the agreement negotiation process.
- Documented/Updated clear Contract Officer expectations around timelines for when we send out initial redlines, respond to redlines, do follow-ups, respond to departments, etc.
- Created more robust internal reports and metrics to help manage our expectations and identify any concerns.
- Working to streamline negotiation positions, including updates to CTA Checklist.
- Weekly meetings with OCT to address any issues with Project ID set-up.

What can OVCR do to help the process?

- Communication and transparency on the process
- Research teams have a central contact in both OIC and OCT they can reach out to
- The Research Navigation Hub (One UNC Initiative) will be a resource



What We are Working Towards

- Improved & Streamlined Processes
- Better System Integration
- Reducing Duplication of Effort
- More Transparency into the Process
- Clearer Guidance and More Resources

Communication is key

We want to hear from you!

Office of Sponsored Programs

- For general questions or to request an update to an ALICE record please email: OSPContracting@unc.edu
- For specific questions about a Contract that has been assigned please email the assigned Contract Officer. Staff Contacts also available here: https://research.unc.edu/sponsored-programs/about/business-units/research-administration/
- You can always reach out to Jennifer Teixeira (jennifer.teixeira@unc.edu) or Kim Austin (kim.austin@unc.edu)

Office of Clinical Trials

- Email OCT office: oct@unc.edu
- Contact Ashwini Roy-Chaudhury ashwini_roy-chaudhury@med.unc.edu

Resources

Industry Contracting: https://research.unc.edu/sponsored-programs/resources/industry-contracting/
ALICE: https://apps2.research.unc.edu/alice/index.cfm
RAMSeS: https://ramses2.research.unc.edu/ramses/

Questions?

THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL