Clinical Trial Process

What Steps Do I Take?

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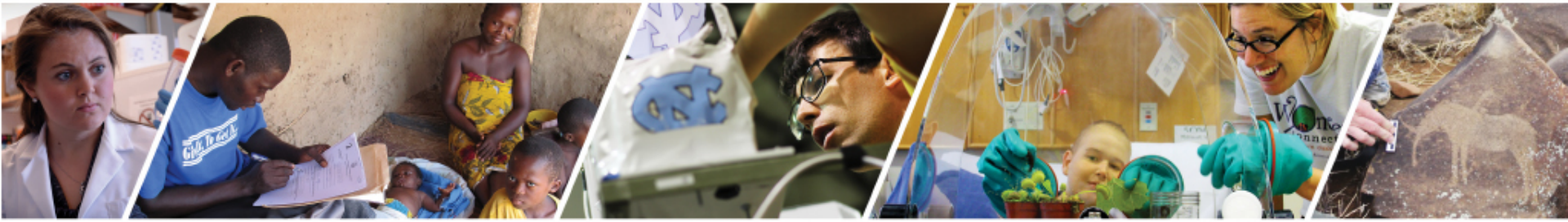

Connect Carolina User Conference

October 18, 2018

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PART ONE

- Funding Proposals
- Obtaining PS Project ID
- Compliance Checks
- Study Start-Up

Where Do I Start?

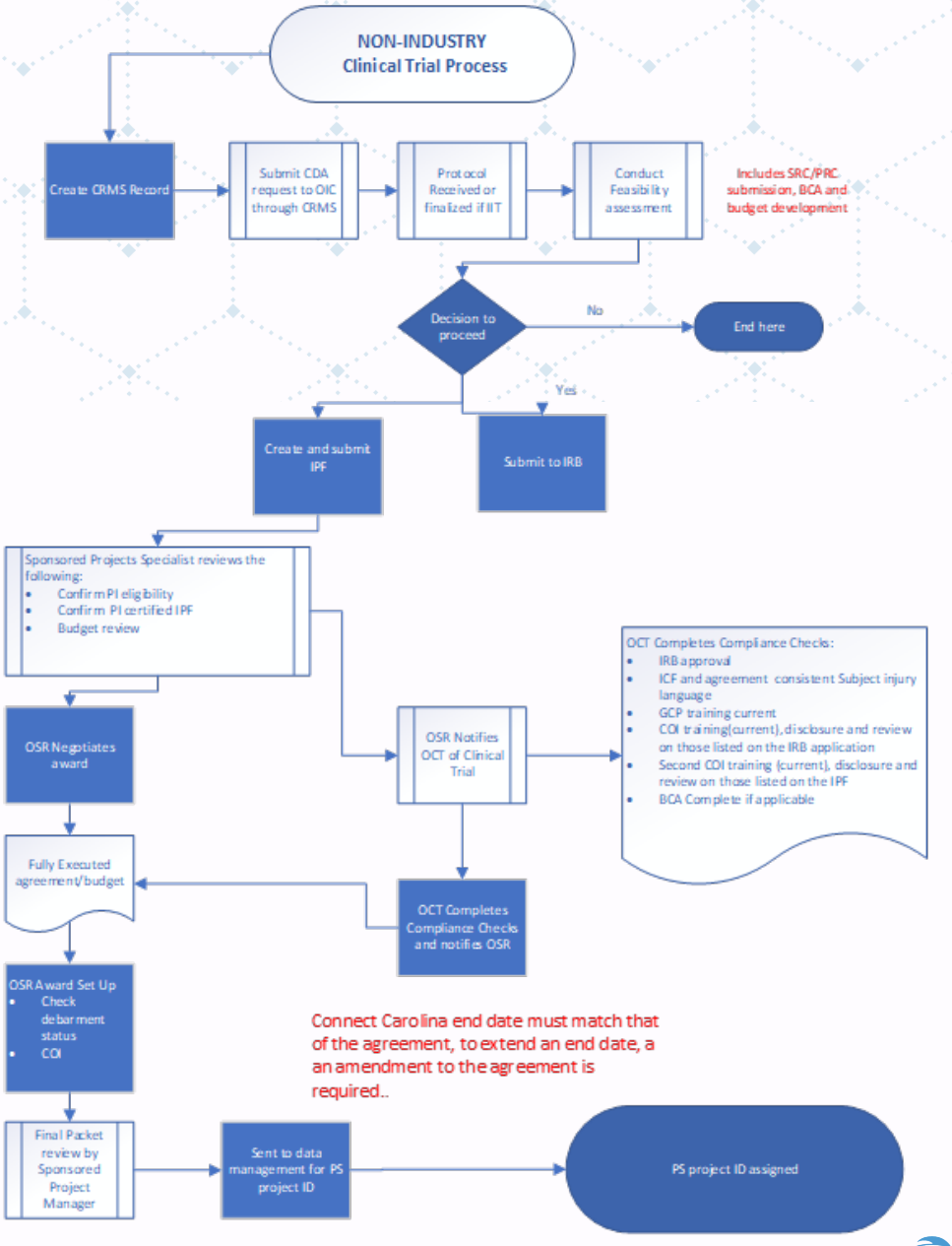
Start by answering a few questions:

- Is this a clinical trial?
- Who is funding the clinical trial?
  - Full proposal
  - Non-industry (federal, non-profit)
  - Industry

What is a Clinical Trial?

NIH Definition of a Clinical Trial:

A **research study** in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral



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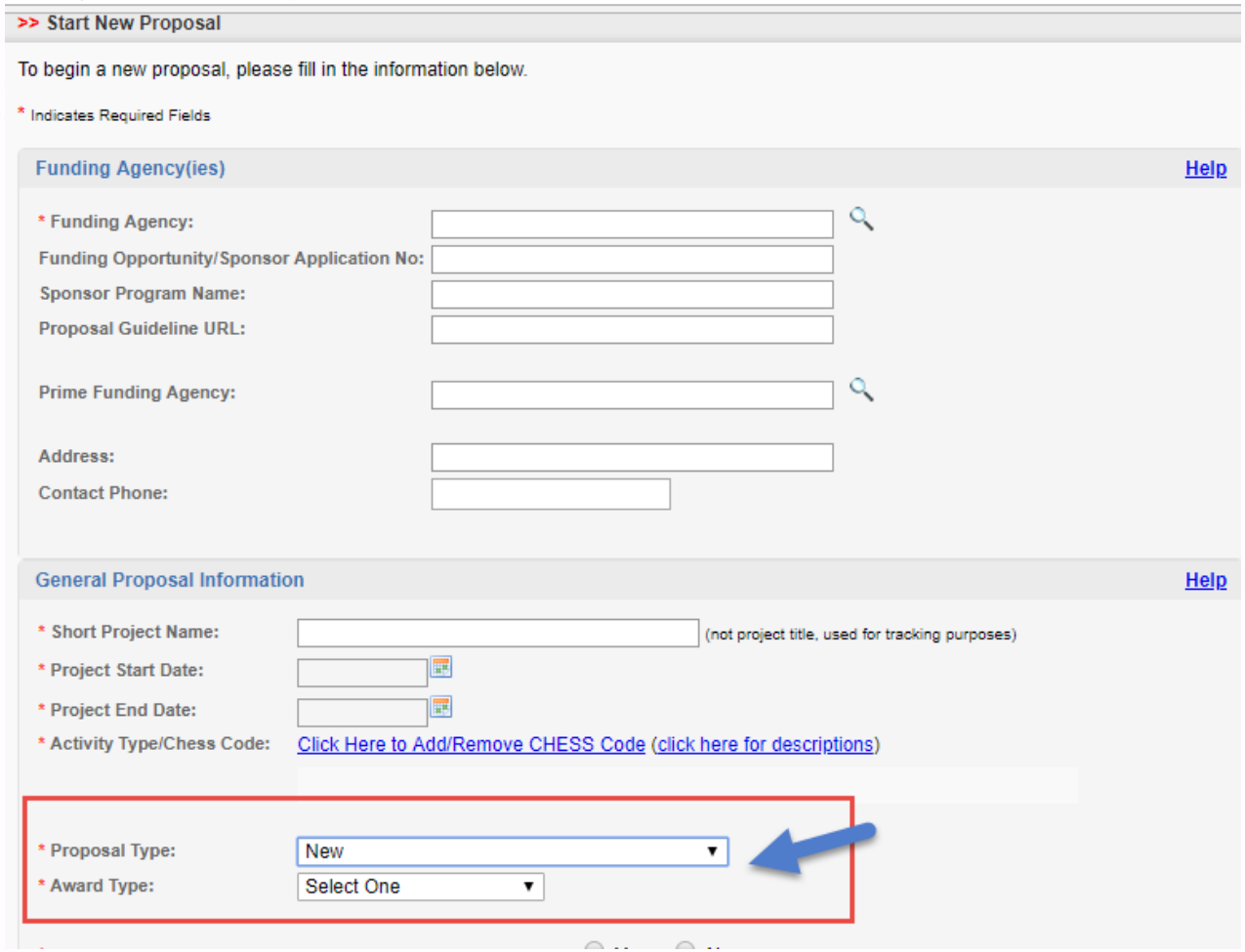
RAMSeS IPF



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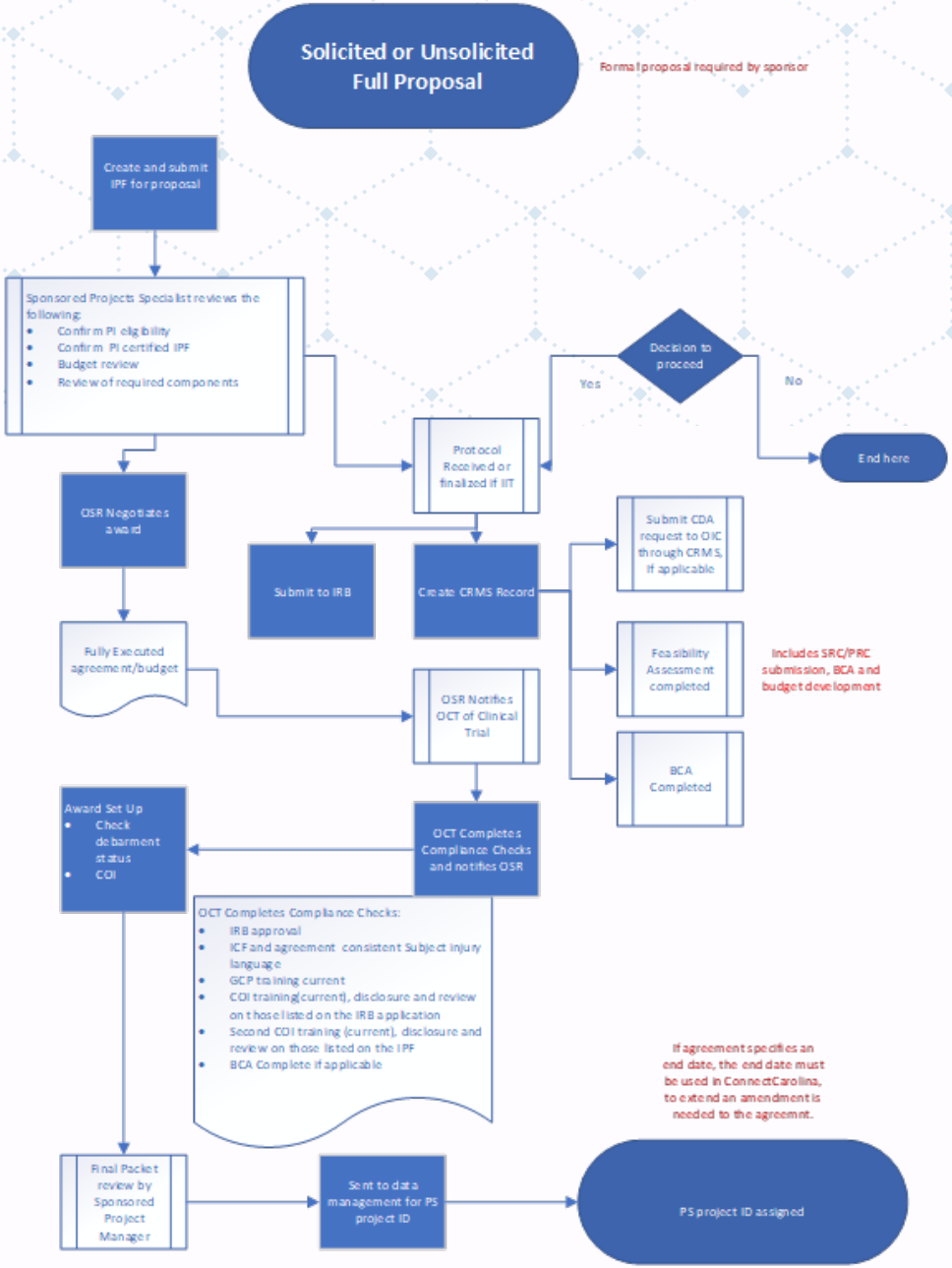
Checklist for Non-Industry Sponsored Clinical Trials

- Create CRMS record
- Submit CDA to OSR's Industry Contracting Office through CRMS
  Note: CRMS still has OCT listed and not Industry Contracting
- Industry Contracting Office notifies of fully executed CDA
- Conduct Feasibility Assessment
- Submit to the Scientific Review or Protocol Review Committees, as applicable
- Submit to IRB
- Create IPF
- PI certifies IPF
- OSR confirms PI eligibility, reviews budget, notifies OCT for Compliance checks
- Compliance checks completed and Agreement executed

→ **PS PROJECT ID ASSIGNED**



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Formal Proposal Required

Proceed as with any other grant proposal:

- Create Proposal record (IPF) in RAMSeS
- Attach the call for proposal, if applicable
- Attach internal budget
- Attach full application or note where it is found (Cayuse, Workspace)
- Attach all subaward commitment documents, if applicable

Note: Include in Personnel list everyone at UNC to be paid from grant

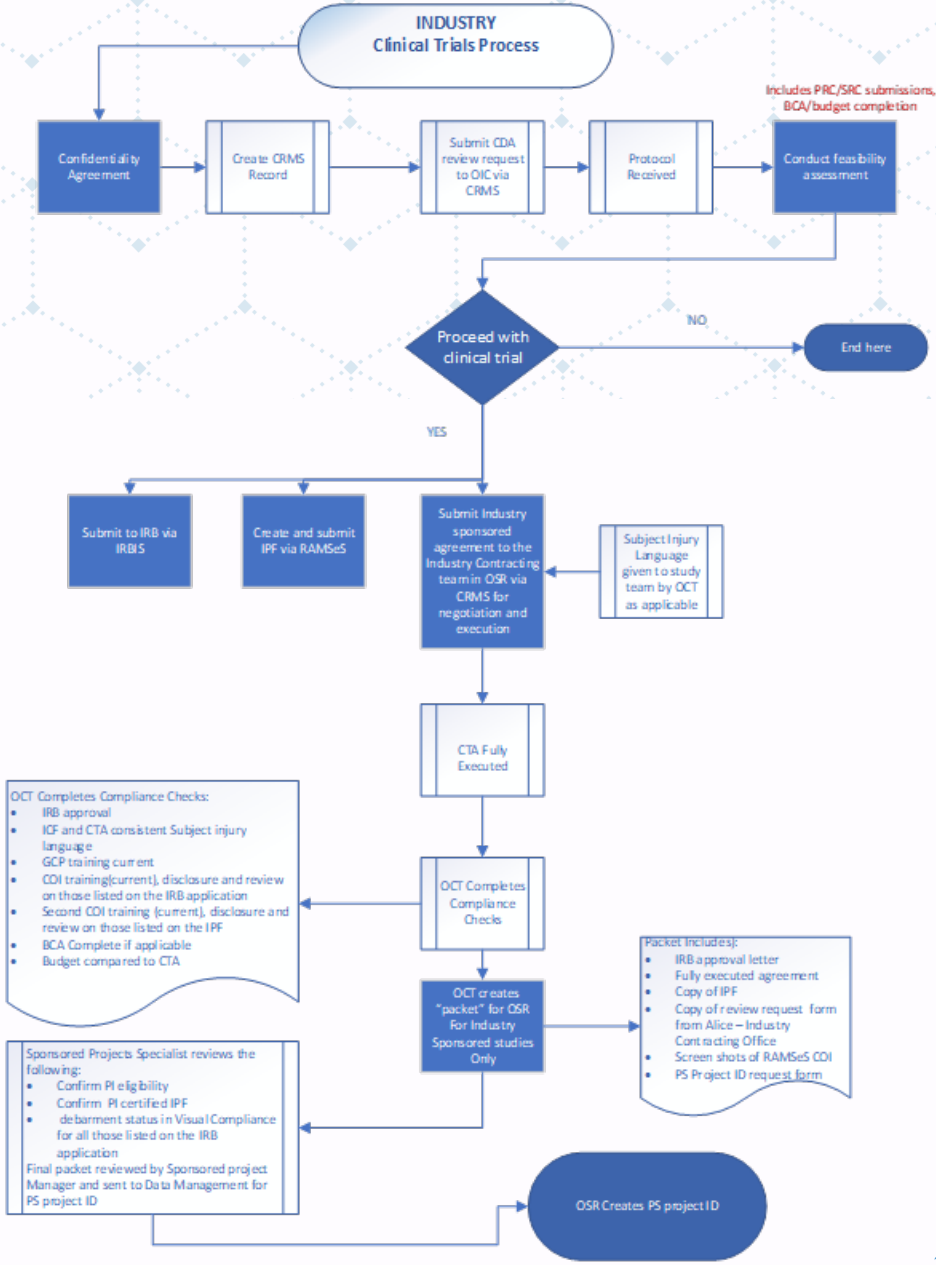
Proposal routed to either OSR or SPO (School of Medicine)

Full Proposal Checklist

Solicited or Unsolicited Full Proposals:

- Create and submit IPF
- PI certifies
- OSR or SPO reviews
- Create CRMS record
- Conduct Feasibility Assessment
- Submit to the Scientific Review or Protocol Review Committee, as applicable
- Submit to IRB
- OSR confirms PI Eligibility, reviews budget, notifies OCT for Compliance checks
- Compliance checks completed and Agreement executed

→ **PS PROJECT ID ASSIGNED**



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Subject Injury Language

Start with UNC template language:

- Send draft template to sponsor for approval
- Sponsor accepts template, proceed to submit to UNC IRB
  - If submitting to external IRB, you will need an "official" email from OCT (we are working with OHRE to update their SOP)
- Sponsor does not accept template, send requested changes to Christine_nelson@unc.edu or OCT@unc.edu

Checklist for Industry Sponsored Clinical Trials

- ❑ Create CRMS record
- ❑ Submit CDA to OSR's Industry Contracting Office through CRMS
  Note: CRMS still has OCT listed and not Industry Contracting
- ❑ Industry Contracting Office notifies of fully executed CDA
- ❑ Regulatory packet received from sponsor
- ❑ Conduct feasibility assessment
- ❑ Submit CTA to Industry Contracting Office for negotiation; PI certifies submission
- ❑ Create BCA
- ❑ Submit to Scientific Review or Protocol Review Committees, as applicable
- ❑ Submit to IRB
- ❑ Create IPF
- ❑ PI certifies IPF
- ❑ OSR will confirm PI Eligibility
- ❑ Compliance checks completed and Agreement executed

→ PS PROJECT ID ASSIGNED

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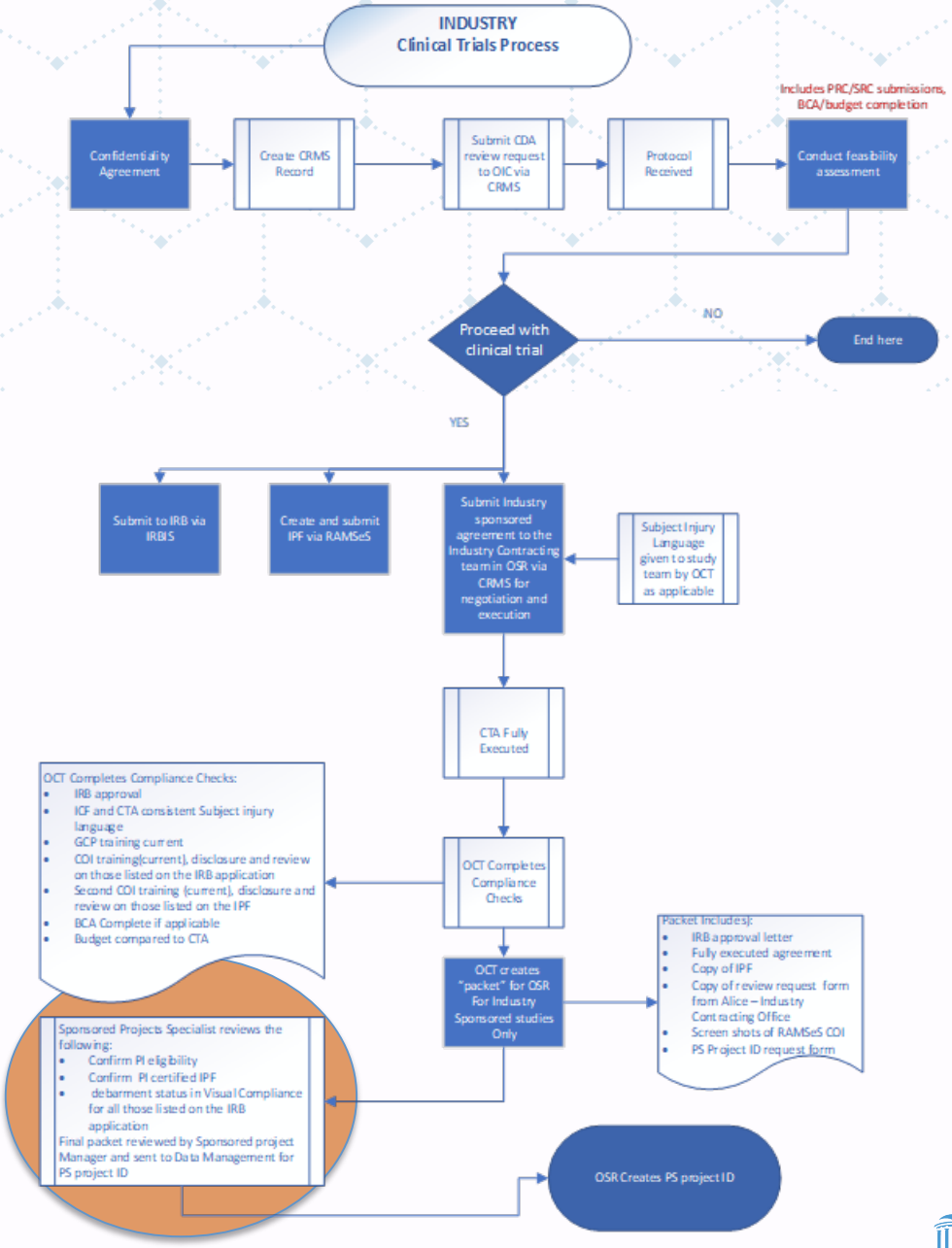

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Those Pesky Compliance Checks

OCT Completes Compliance Checks:

- IRB approval
- ICF and CTA consistent Subject Injury Language
- GCP training current
- COI training(current), disclosure and review on those listed on the IRB application
- Second COI training (current), disclosure and review on those listed on the IPF
- BCA completed, if applicable
- Budget compared to CTA

What You Can Do to Help?

- Work with study staff to ensure their COI, GCP trainings current
- Read approved ICF and check for errors as soon as its received
- Check it against the subject injury language you were given, if the IRB made a clerical error, notify ASAP to get it corrected
- Check approved ICF against the fully executed CTA and budget
- If using an external IRB upload load your approval documents to IRBIS ASAP
- **Questions? contact OCT (919-843-2698 or OCT@unc.edu)**

Further Resources

Full Presentation on Clinical Trials Process:
https://research.unc.edu/files/2018/08/Clinical-Trials-Process-Final.pdf

Office of Clinical Trials:
https://research.unc.edu/clinical-trials/resources/

Office of Clinical Trials Forms & Checklist:
https://research.unc.edu/researchers/forms/clinical-trials/

Office of Sponsored Research Industry Contracting:
https://research.unc.edu/oic/

PART TWO

Clinical Trial Closeout: OSR & Financial/Systems Perspective

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How are Clinical Trial (CT) Closeouts Different from Grants?

Key Differences:

- OSR does not financially report on Clinical Trials (few exceptions: hybrid, federally sponsored) -- *we are working on providing more resources on the Clinical Trial financial/system closeout process*

- Clinical Trial closeouts are generally initiated by the Department/PI

Refer to Operating Standard 700.2 – Project Closeout

What are the Steps for CT Closeout in OSR?

Key Procedures:

- Ensure all payments (CASH) received from sponsor
- Ensure CASH matches GL balance
  - Process necessary F&A adjustments (OSR)
  - Process Residual Transfers (OSR or Dept)
  - Move Overdrafts to Dept chartfield (OSR or Dept)
  - Process any necessary Refunds (OSR)
- Set CT Project to **CLOSED** status in ConnectCarolina and Frozen/Inactive in RAMSeS

Who in OSR Does CT Closeouts and Which Projects?

- The group currently closing on Clinical Trial closeouts is the "Legacy Closeout Team" within Sponsored Projects Accounting
  - Sponsored Projects Accounting unit in OSR processes financial billing/reporting, cash management, and closeout for all awards
- **Legacy Population** parameters include ONLY awards with an **end date of 6/30/2017 and PRIOR**

All Other Populations?

- For CT Projects outside the Legacy Population, the Dept can still request/process some CT closeout steps:
  - Process necessary F&A adjustments (OSR)
  - **Process Residual Transfers** (OSR or **Dept**)
  - **Move Overdrafts to Dept chartfield** (OSR or **Dept**)
  - Process any necessary Refunds (OSR)
- Project will be placed in **REPORTING** after

Project Status Definitions

- **OPEN:** Status for all on-going and active awards
- **ENDED:** System automatically sets a project to Ended the day after the end date in Connect Carolina
- **REPORTING:** The Sponsored Projects Accountant (SPA) in OSR changes the project to Reporting in order to process interim or final Invoice/Report
- **CLOSED:** SPA Closes the project in the system once cash received matches expenses/transactions posted to GL and all sponsor requirements for closeout are met

What is Allowable by Status?

TRANSACTION TYPE	OPEN	ENDED	REPORTING	CLOSED
Salary	Allows	Allows	Rejects	Rejects
Requisition	Allows	Rejects	Rejects	Rejects
PO	Allows	Rejects	Rejects	Rejects
AP Voucher	Allows	Allows	Rejects	Rejects
Journal Entry	Allows	Allows	Rejects	Rejects
Data Collect Batches (Ex: Recharges)	Allows	Allows	Rejects	Rejects
Budget	Allows	Allows	Error	Rejects

*OSR Help and Sponsored Projects Accountants (SPA) can more easily change project statuses (subject to review/approval) among OPEN, ENDED, and REPORTING.

How to Resolve Common Errors or Stops with ENDED Projects?

- **PERSONNEL Stop:** PAATs will NOT process in Ended after the KK end date. Contact OSRHelp to request KK date extensions (subject to approval)
- **REQUISITION/PO Stop:** Will NOT process in Ended. Contact OSRHelp to Open the project (subject to approval)

  **NOTE: Purchasing must process the Req/PO in the same business day that the project is Opened because the system automatically sets it to Ended again the next day*
- **ERRORS:** Contact OSRHelp for budget error overrides that make transactions "Valid" to process

Common theme? Contact OSRHelp - OSRHelp@unc.edu!

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What You Can Do to Help?

- **Ready to Closeout?** Contact OSRHelp@unc.edu to start the process (*Legacy population has priority)*
- **Projects in the negative?** Be on the forefront of the closeout effort and move expenditures OFF projects that are causing a deficit
- **Encumbrances or Cash Advances?** Liquidate encumbrances and reconcile cash advances as soon as you know you can closeout
  Refer to OSR Operating Standard 500.14 - Cash Advances
- **Residual Funds to Transfer?** In your journal request, include necessary justifications on requests over 25% of awarded amount
  Refer to OSR Operating Standard 700.4 - Residuals

Questions? contact OSR Help (OSRHelp@unc.edu)

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Further Resources

Office of Clinical Trials Study Closeout:
https://research.unc.edu/files/2017/04/close-out-checklist.doc

Full Presentation on OSR Project Closeout:
https://research.unc.edu/files/2018/08/Primer-on-Closeout_Final.pdf

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

CC Info for Research Administrators:
https://ccinfo.unc.edu/research-administrators-2/

THANKS & QUESTIONS?