

# Best Practice in Clinical Trials

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for Research  
Administrators**

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**2020**

**UNC SYMPOSIUM**

*for*

**RESEARCH ADMINISTRATORS**

# Learning Objectives

At the end of this session the participant will be able to:

- Describe ways to avoid common pitfalls encountered during study start up.
- Determine steps to take to ensure successful clinical trial implementation
- Apply best practices to study activities

# Office of Clinical Trials

- The core purpose of the Office of Clinical Trials (OCT) to ensure compliance with federal, state and institutional requirements.
- Serving as the point of contact for questions or issues related to clinical trials
- Developing and implementing programs and initiatives to enhance the quality of clinical research and support regulatory compliance, through the implementation of the OnCore clinical trials management system enterprise wide.
- Our office is available for education, consultation and guidance on the conduct of clinical trials.

# Office of Clinical Trials



Clinical Trial  
Quality Assurance  
program (CTQA)



Research Billing  
Compliance  
program



ClinicalTrials.gov  
registration and  
results reporting



Support of the  
Scientific Review  
Committee



Conducts  
compliance  
checks



OnCore  
Implementation –  
Enterprise Wide

## BEST PRACTICES

# Network of Research Professionals Survey

One simple question with multiple answers:

- Please share what pain points you have experienced in the study start-up or study administration process.

## BEST PRACTICES

# Navigating the new COVID policies

Finding answers:

- CRSO website
  - <https://www.med.unc.edu/crso/covid/som-guidelines-and-processes/>
- Office for the Vice Chancellor for Research
  - <https://research.unc.edu/covid-19/>
- Office of Human Research Ethics
  - <https://research.unc.edu/2020/05/26/ohre-irb-covid-19-update-2/>

## BEST PRACTICES

# Most Common Pain Points



- Redundancy among the various systems



- Lack of a transparent system to track study start up, coupled with the lack of a clear outline on what needs to be done for study start up



- Lack of communication among the study team, regulatory, finance and contracting

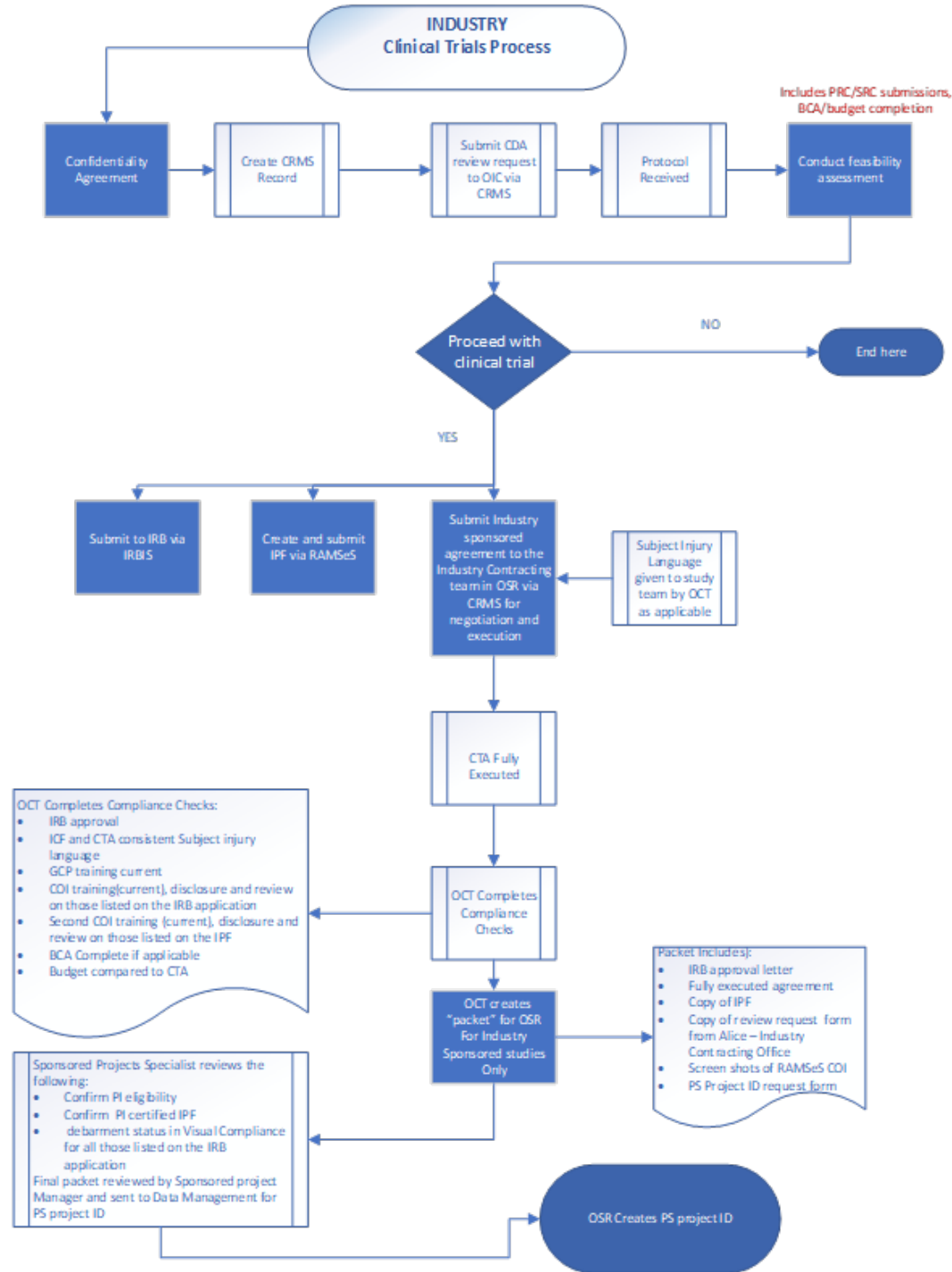
## BEST PRACTICES

# Lack of transparent system to track study start up

- Multiple systems

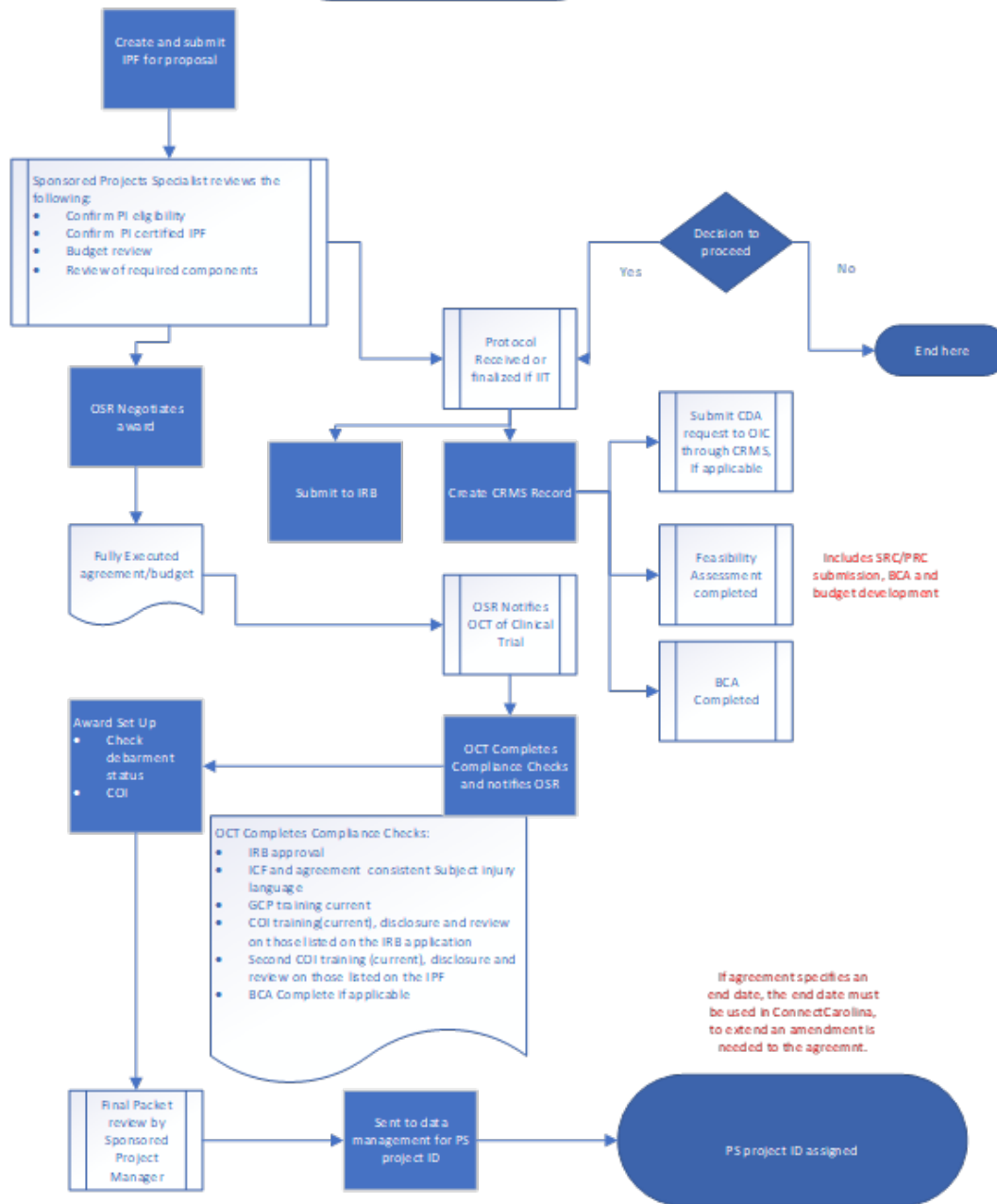
- CRMS – Clinical Research Management System
- ALICE – A Look Into Contract Execution
- RAMSeS – Research Administration Management System and eSubmission
- IDS – Investigational Pharmacy Services (Vestigo)
- OnCore – Clinical Trials Management System for Oncology only (for now)
- IRBIS – Institutional Review Board Information System

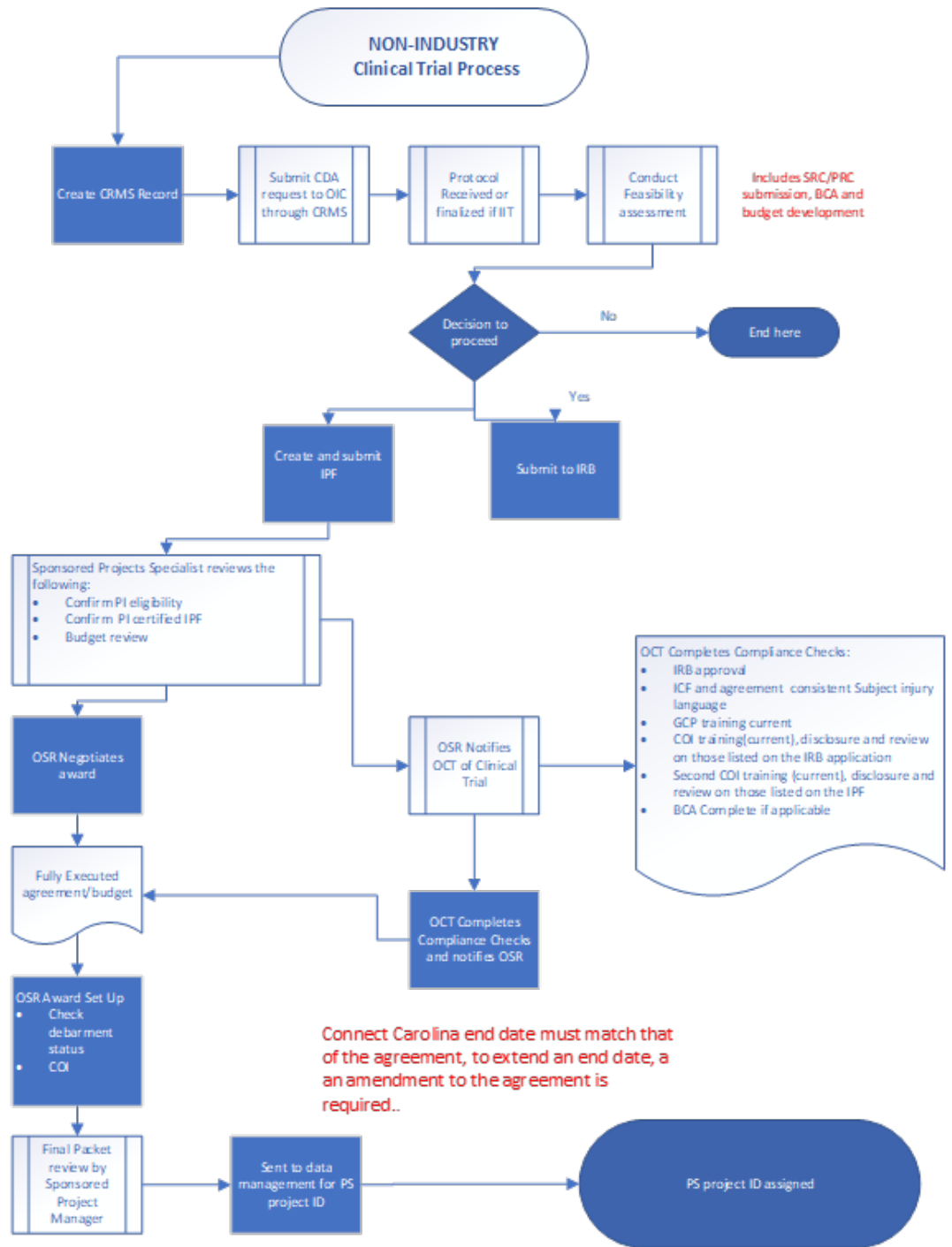




# Solicited or Unsolicited Full Proposal

Forms/proposal required by sponsor





# Checklist for Clinical Trials

- Create CRMS record
- Submit CDA to in the Industry Contracting Office through CRMS. (note: CRMS still has the OCT listed and not the Industry Contracting.)
- Industry Office notifies of fully executed CDA.
- Regulatory packet received from sponsor.
- Conduct feasibility assessment.
- Submit CTA to the Industry Contracting Office for negotiation, PI certifies submission
- Create BCA
- Submit to the Scientific Review Committee or Protocol Review committee as applicable.
- Request Subject Injury Language – currently email [Christine\\_nelson@unc.edu](mailto:Christine_nelson@unc.edu)
- Submit to IRB.
- Create IPF.
- PI certifies IPF.
- OSR will confirm PI Eligibility
- Once all compliance checks completed and agreement executed, PS project ID assigned.

# Subject Injury Language in the Informed Consent

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As of April 2018 the UNC has approved standard subject injury language

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The Industry Contracting Team is required to obtain certain subject injury language in the CTA with industry sponsors

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Language will be different for PI initiated and Federally or non-profit funded clinical trials

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Current OHRE SOP requires an “official” email to be included in your submission to an external commercial IRB

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Please email [Christine\\_nelson@unc.edu](mailto:Christine_nelson@unc.edu) with the draft ICF with the standard subject injury language

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I will review and send the “official” email

# Those pesky compliance checks

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## OCT Completes Compliance Checks:

IRB approval

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ICF and CTA consistent Subject injury language

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GCP training current

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Conflict of Interest (COI) training(current), disclosure and review on those listed on the IRB application

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Second COI training (current), disclosure and review on those listed on the IPF

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BCA Complete if applicable

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Budget compared to CTA

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# What can you do to help?



Work with the study staff to ensure their COI and GCP training are current. Keep your own spreadsheet



Read the approved ICF and check for errors as soon as it is received.



Check the ICF against the subject injury language you were given, if the IRB made a clerical error, notify ASAP to get it corrected.



Check the approved ICF against the fully executed CTA and budget



If using an external IRB upload load your approval documents to IRBIS ASAP



Make sure your IPF has been submitted in RAMSeS



Those listed in the IPF will need second COI disclosure



If you have questions call OCT 919-843-2698

# CONTACT US

## ***Presenter or Office Name***

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