UNC THE NORTH CAROLINA TRANSLATIONAL & CLINICAL SCIENCES INSTITUTE

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL
NRP Network for Research Professionals

UNC OFFICE OF CLINICAL TRIALS

ORIENTATION FOR NEW CLINICAL RESEARCH PERSONNEL

MODULE 1

Presented by

NC TraCS Institute
UNC Office of Clinical Trials
UNC Network for Research Professionals

Online Logistics

- I will be monitoring the chat window for questions and will ask those questions to the presenter at the end of each talk, or during breaks in the conversation when the presenter invites questions.

- Slides will be emailed to everyone after the presentation, along with the evaluation link and any announcements.

- If you would like a certificate for ACRP/SOCRA credit, please complete the evaluation at the end of the presentation and send me an email – marie_rape@med.unc.edu

- Feel free to reach out to me either in the chat window or by email, I'm happy to help with anything you need.

Overall Agenda for Orientation

- **Module 1:** Introduction, NRP/ Education, and Office of Clinical Trials
- **Module 2:** IRB Processes, Conflict of Interest
- **Module 3:** GCP, Documentation, Informed Consent, Research Monitor Access
- **Module 4:** Contracts, Clinical Trial Agreements, Planning/Accounting of Funds, NIH Budgets, Billing Coverage Analysis
- **Module 5:** Recruitment, Study Start-up, Roles of Research Personnel, UNC Investigational Drug Services, UNC Device Policy
- **Module 6:** Introduction to RedCap, Investigator-Initiated Study Process, ClinicalTrials.gov, Documenting AEs & SAEs, IND and IDE studies

Overall Objectives

- Understand Training Opportunities, Institutional Resources
- Define Good Clinical Practices, Study Documentation
- Review UNC IRB processes, Human Subject Protections
- Review Finances: Contracts, Budgeting, Billing Coverage Analysis
- Understand Investigational Pharmacy Processes, Device Policies
- Review Regulations Relevant to Investigator-Initiated Studies
- Understand Study Start-up, Compliance, Conflict of Interest
- Review Appropriate Informed Consent, Subject Enrollment
- Describe Research Personnel Roles and Responsibilities

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Knowing the Resources Available

Topic	Unit/Office	Website	Telephone
Clinical Research Management System	CRMS	https://irbis.research.unc.edu/crms/	919-843-1629
Clinical research support	NC TraCS Institute	http://tracs.unc.edu/	919-966-6022
Clinical Research Unit	CTRC	http://tracs.unc.edu/index.php/services/ctrc	919-843-1070
Clinical Trials, QI Program, CT.gov	Office of Clinical Trials	http://research.unc.edu/offices/clinical-trials/	919-843-2698
COI & Research Compliance	Research Compliance Program	http://research.unc.edu/offices/research-compliance-program/index.htm	919-843-9953
Conflict of Interest Training	COI Office	https://apps.research.unc.edu/coi-training/	919-843-9953
Contracting for Clinical Trials, BCA, DUAs	Office of Industry Contracting	http://research.unc.edu/offices/oic/	(919) 962-3630
Data and Safety Monitoring Boards	NC TraCS DSMB	http://tracs.unc.edu/index.php/services/regulatory/data-and-safety-monitoring-board	919-966-6844
Hazardous Material Shipping, Safety Training	Environmental Health and Safety	http://ehs.unc.edu/workplace-safety/	919-962-5507
HIPAA Policies, Training	HIPAA online Training	http://www.med.unc.edu/security/hipaa	n/a
Human subjects	Office of Human Research Ethics (OHRE)	http://research.unc.edu/offices/human-research-ethics/	919-966-3113
Human subjects, GCP, and RCR training	CITI on-line program	https://www.citiprogram.org/	n/a
IND/IDE Guidance	TraCS IND/IDE Program	http://tracs.unc.edu/index.php/services/regulatory/ind-and-ide-application-support	n/a
Investigational Drugs	Investigational Drug Service (IDS)	http://pharmacy.intranet.unchealthcare.org/services/investdrugs	919-843-9919
Laboratory Assays for research	UNC Core Labs	http://www.med.unc.edu/corefacilities	n/a
Clinical Research Support	SOM CRSO	https://www.med.unc.edu/crso/	n/a

Who should attend Orientation?

- Personnel involved in clinical research
  - Study coordinator
  - Social / Clinical research assistant
  - Research nurse
  - Research associate
  - Regulatory personnel
  - Investigators

- Involved in any type of clinical research
  - Clinical trials
  - Investigator initiated research
  - Federal grants
  - Social / behavioral research

Training, Training, Training

Well educated study personnel are key to conducting quality research!

- Knowledge of research best practices, good clinical practices, regulatory requirements
- Keeping abreast of current rules, policies, requirements is key to conducting quality research.
- You need to take responsibility for staying informed and educated

Recommended / Required Trainings

- CITI Good Clinical Practice (GCP) Training, www.citiprogram.org
  - required if working with clinical trials (including NIH trials)
  - renewed every 3 years
- CITI Ethics Online Course (IRB modules), www.citiprogram.org
  - required if involved in human subject research, renew every 3 years
- Epic / BCA training (Research Admin 100) – via Hospital LMS system

Additional Resources

- Additional education and training opportunities available through the CITI Training Program:
  - Clinical Research Coordinator (CRC) – Foundations
  - Clinical Research Coordinator (CRC) – Advanced
  - Research Study Design
  - Clinical Trial Agreements
  - https://research.unc.edu/human-research-ethics/getting-started/training/

- UNC SOM Clinical Research Support Office:
  - Mission is to reduce administrative burden, enhance compliance, and help remove barriers to enable efficiency, collaboration, financial productivity, and growth of clinical research at UNC.
  - Website has SOPs, resources, training information
  - https://www.med.unc.edu/crso/

STUDY COORDINATOR EDUCATION

Emily Olsson, CCRP

Program Manager, Recruitment and Retention

Chair, Network for Research Professionals

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Study Coordinator Education

HHS OHRP – Office of Human Research Protection

Responsibilities of UNC

- Before any human subjects research can be conducted, the institution must provide the department or agency a **written Assurance** that it will comply with the requirements of the Policy

  www.hhs.gov/orhp/
  Via UNC OHRE

- The HHS regulations are intended to implement the basic ethical principals governing the conduct of human subject research

General Responsibilities

All parties involved, institution, investigator, and IRB must actively engage in ensuring human subject protection and this is only achieved through proper training/education of all research professionals

Required Trainings vs.
Role-Specific Trainings vs.
Professional Development

Licensure/Certification vs
Documentation of Training

Why Coordinator Education?

Responsibility of the investigator to ensure that any individual to whom a task is **delegated** is **qualified** by education, training and experience (and state licensure where relevant) to perform the delegated task.

Documentation of training is essential for meeting the guidelines put forth by regulatory agencies for the conduct of Human Subject Research.

Study Coordinator Education

Documentation of coordinator education may be part of the investigator/ department/division/center processes. This may include (dependent on type of research being conducted):

- Completion of Human Research Ethics Training
- Completion of Good Clinical Practices Training
- CV and/or state licensure
- Job Skill Training (such as conducting an EKG)
- Training plan per your specific job title
- Documentation of Training for each protocol (training logs)
- Informed consent training

Example: Training & Education Checklist

DCC Staff Competency Check Off Name: _____

Skill	Observation (initial/date)	Competency (initial/date)	NOTE (study/subject)	Site Director (initial/date)
2. Review sponsor sample informed consent a. Compare AEs and SAEs in IB to risk section in sponsor's ICF b. Review 'research related injury' language c. Confirm that patient payments match study budget d. Indentify required signatures (subject/LAR/assent)				
3. Presenting Informed Consent Form to Subjects a. Give subject Informed Consent Form to take home or read in the office in a private space b. Give subject a highlighter and ask them to highlight any questions they may have throughout the form c. Give the subject ample time to read the form				
4. Reviewing the Informed Consent a. Explain each section of the Informed Consent to the subject paying particular attention to the Risks/Benefits/Study Procedures sections b. Give subject opportunity to ask any questions of the CRC and/or PI				
5. Obtain appropriate signature(s) a. Subject (Consent or Assent) b. Legally Authorized Representative c. Caregiver d. Once all questions are answered, and subject agrees to participate, ask subject to initial, sign, and date the Inform Consent Form accordingly e. Complete any other required signatures for that form (PI, CRC, etc.) f. Review the form to check for accuracy and correct any errors g. Make a copy of the form to give to the subject to take home				
6. Documenting the Informed Consent Process a. Write a detailed clinical note documenting that each part of items 2 and 3 (above) were done b. Include patient specific information such as who was present during the Informed Consent process, questions asked, answers given, etc. c. Always document that the PI was either present or available during the Informed Consent process d. Complete Informed Consent Form and attach to signed ICF in research record				
7. Obtain informed consent from vulnerable subject populations				
C. Scheduling/Screening				

Original: October 11, 2010

Example Matrix of Training

UNC Diabetes Care Center
Delegation of Responsibilities Table

Clinical Trial Activity	MD	PA	NP	RN/LPN	Coordinator per completion of training	Non-medically qualified personnel	
Pre-Screening Activities	X	X	X	X	X	X	
Informed Consent	X	X	X	X	X	NO	
Medical History	X	X	X	NO	NO	NO	
Medical Evaluations	X	X	X	NO	NO	NO	
Venipunctures	X	X	X	X	X- ONLY IF CERTIFIED	NO	
Processes and Shipping Laboratory Samples	X	X	X	X	X	X	
Laboratory value assessments	X	X	X	NO	NO	NO	
IV, SC, IM, PO adminstration of Investigational Product	X	X	X	X	X	NO	
Adverse Event/SAE Causality	X	X	X	NO	NO	NO	
AE/SAE Assessment to Relationship to Drug	X	X	X	NO	NO	NO	
SAE Determination per protocol guidelines	X	X	X	X	X	NO	
SAE/AE Reporting to Sponsor and IRB	X	X	X	X	X	NO	
Height, Weight, Hip Measurement, Waist Measurements	X	X	X	X	X	NO	
Vitals	X	X	X	X	X	NO	

Resources

- UNC-Required Trainings:
  - See NCO introduction slides
- Helpful Trainings:
  - See NCO introduction slides
- Professional Development:
  - https://nrp.tracs.unc.edu
  - https://tracs.unc.edu/index.php/calendar
  - Carolina Talent (via https://connectcarolina.unc.edu)
  - SoCRA (https://socra.org)
  - ACRP (https://acrpnet.org)

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

NRP

Biomedical Behavioral Translational Social

Network for Research Professionals

Mission: To foster a distinguished research community among UNC-Chapel Hill and its affiliates through education, communication, and collaboration

Vision: To engage and empower individual research personnel at UNC-Chapel Hill and its affiliates, creating a collaborative and preeminent research community

NRP Projects

- Monthly educational seminars
- Professional Development Awards
- Networking events with research offices
- Listserv for all individuals involved in human subjects research (unc.crc listserv)
  - Contact Emily Olsson or Erika Hanami to join
- A forum to share your needs and spark change or improvements
- Opportunity for involvement and leadership

Final Points…

- Please make continuing education a priority
- Ensure that the training is documented
- Saves time from creating unnecessary errors or having to re-do work
- Things change (i.e.: job duties, policies, procedures)
- Elevates the quality of your research
- Increased knowledge and skills makes you indispensable to your department
- Wisdom is knowledge applied; must apply what we know.

Who to Contact

- To join the listserv or volunteer, contact Emily Olsson at emolsson@unc.edu

- Information regarding committees and upcoming events can be found on our web site

NRP is here for you!
Please let us know what you need to do your job better!

nrp.tracs.unc.edu

NRP Educational Session

Developing an Appropriate Data and Safety Monitoring Plan:
Speakers: Marie Rape, NC TraCS

Objectives:

- Describe appropriate monitoring of research
- Differentiate between a monitoring plan (DSMP) and a monitoring board (DSMB)
- Identify what to include in a monitoring plan
- Identify roles and responsibilities of a DSMB
- Understand how to complete the monitoring section of the UNC IRB application

Thursday March 18th, 2021

12:00 PM – 1:00 PM

Registration for this event is required - https://tinyurl.com/y7wed9nz

Remote attendance is available. Please mute the line and do NOT put on HOLD.

CLINICAL RESEARCH AT UNC

Panel Members:

Christine Nelson

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UNC OFFICE OF CLINICAL TRIALS

Please Note

I use acronyms through out my presentation

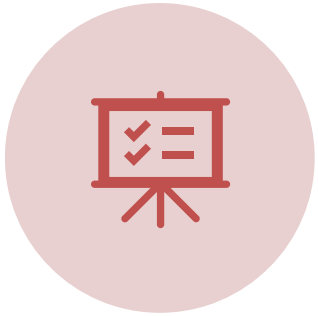
This can be very confusing if you are new to the clinical trial world

Please feel free to stop me at any time and ask me to define the acronym, I try to monitor the chat and answer questions as they come up.

Objectives

DISCUSS THE IMPORTANCE OF CLINICAL RESEARCH AT UNC

DESCRIBE THE CLINICAL STUDY COORDINATOR'S ROLE IN THE SUCCESS OF THE CLINICAL TRIAL



REVIEW THE STEPS FOR SUCCESSFUL CLINICAL TRIAL IMPLEMENTATION FROM STUDY START UP THROUGH STUDY CLOSURE

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 clinical research support systems such as 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

Responsible for compliance reviews prior to study activation

OnCore Implementation – Enterprise Wide

Why is Clinical Research Important?

- **OUR MISSION**
- Cures and treatments for disease. New technologies. New industries for North Carolina and the world. At Carolina, we tackle tough challenges with multidisciplinary teams of top scientists and students whose diverse perspectives deliver creative, unprecedented solutions. As one of America's top research universities, we conduct roughly $1 billion in research annually. We provide dedicated service to our sponsors and unprecedented opportunities for graduate students, postdocs and undergraduates.
- —Terry Magnuson, UNC Vice Chancellor for Research

What does this mean for you?

Your role is **critical** in the success of research studies.

The Association of Clinical Research Professionals (ACRP) describes the 5 “C’s “ of a good clinical research coordinator (CRC)

Coordination
Connection
Commitment
Communication
Collaboration

https://acrpnet.org/2018/08/14/the-anatomy-of-a-great-clinical-research-coordinator/

Coordination

- Organized
- Use of checklists
- Appropriate time management
- Anticipation of problems
- Navigation of strict eligibility requirements
- Find ways to minimize participants burden
- Data accuracy
- Proper use of clinical research systems

Connection

- You are the face of the clinical trial
- First impressions matter
- Help your participants to navigate the system
- Establish rapport
- Be accountable
- Be transparent
- Empower study subjects – shared decision making

Commitment

- Projects have a better chance of success if the coordinator is committed
- Willingness to be challenged
- Seek ways to overcome challenges
- Strive to exceed minimal expectations

Communication

Excellent verbal and written communication skills

Ensure the study subjects understand their role

Develop relationships with the entire research team

Collaboration

Be the leader in building collaborative relationships

Develop partnerships

Become a resource for less experienced

Clinical Research at Carolina

Study start up

Needs to be as efficient as possible

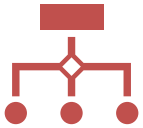
But is complicated

Start by answering a few questions:

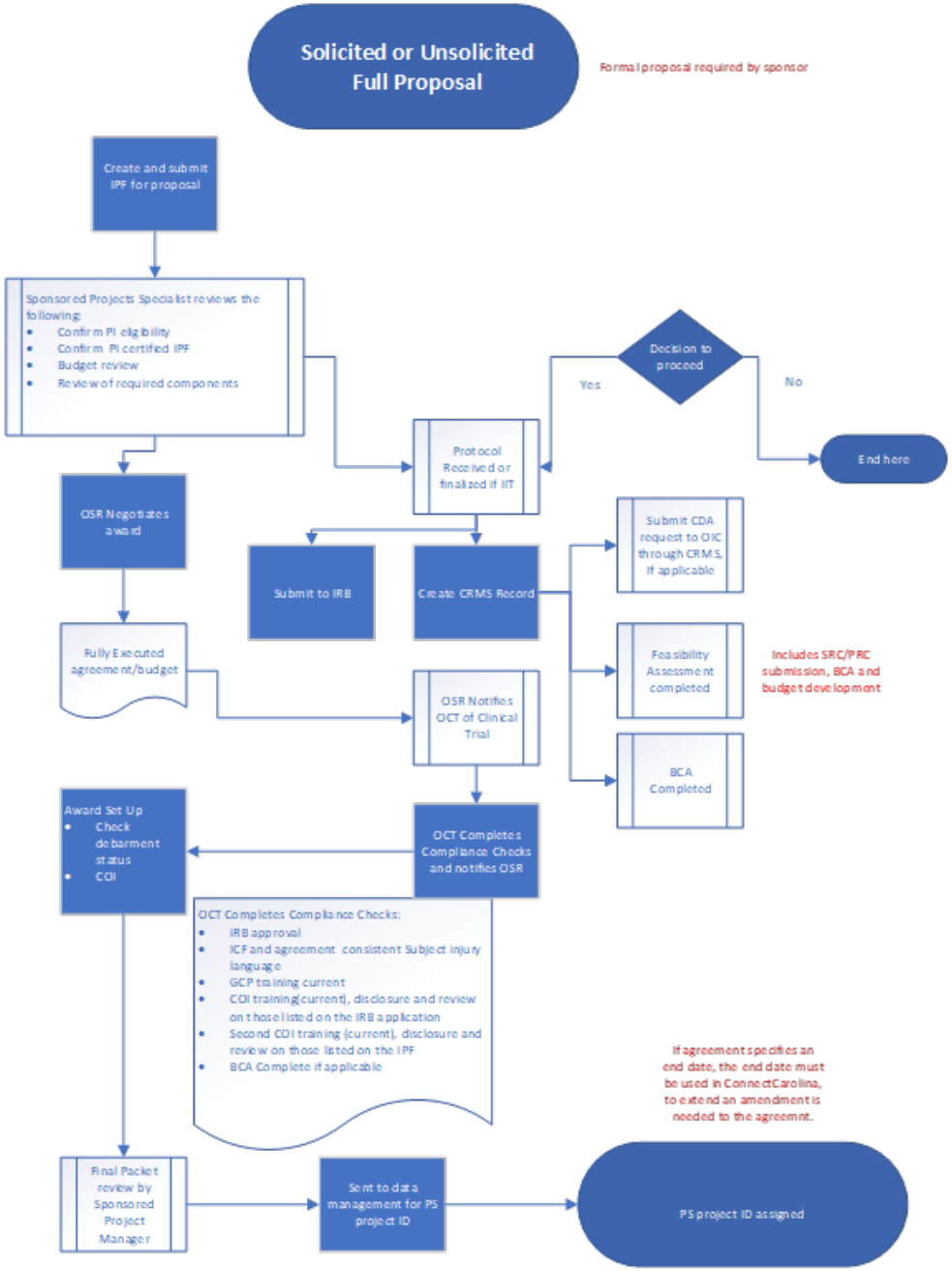
Is this a clinical trial?

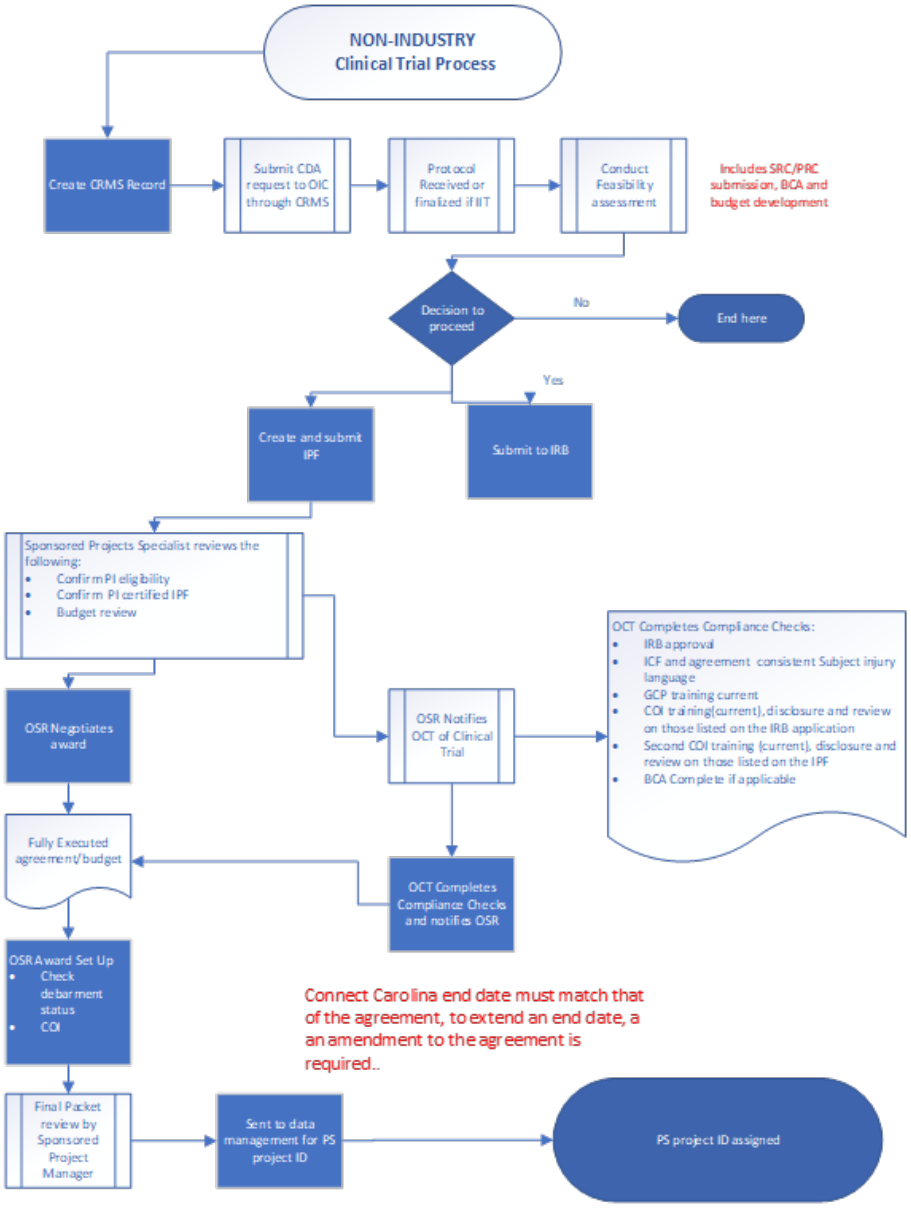
Who is funding the clinical trial?

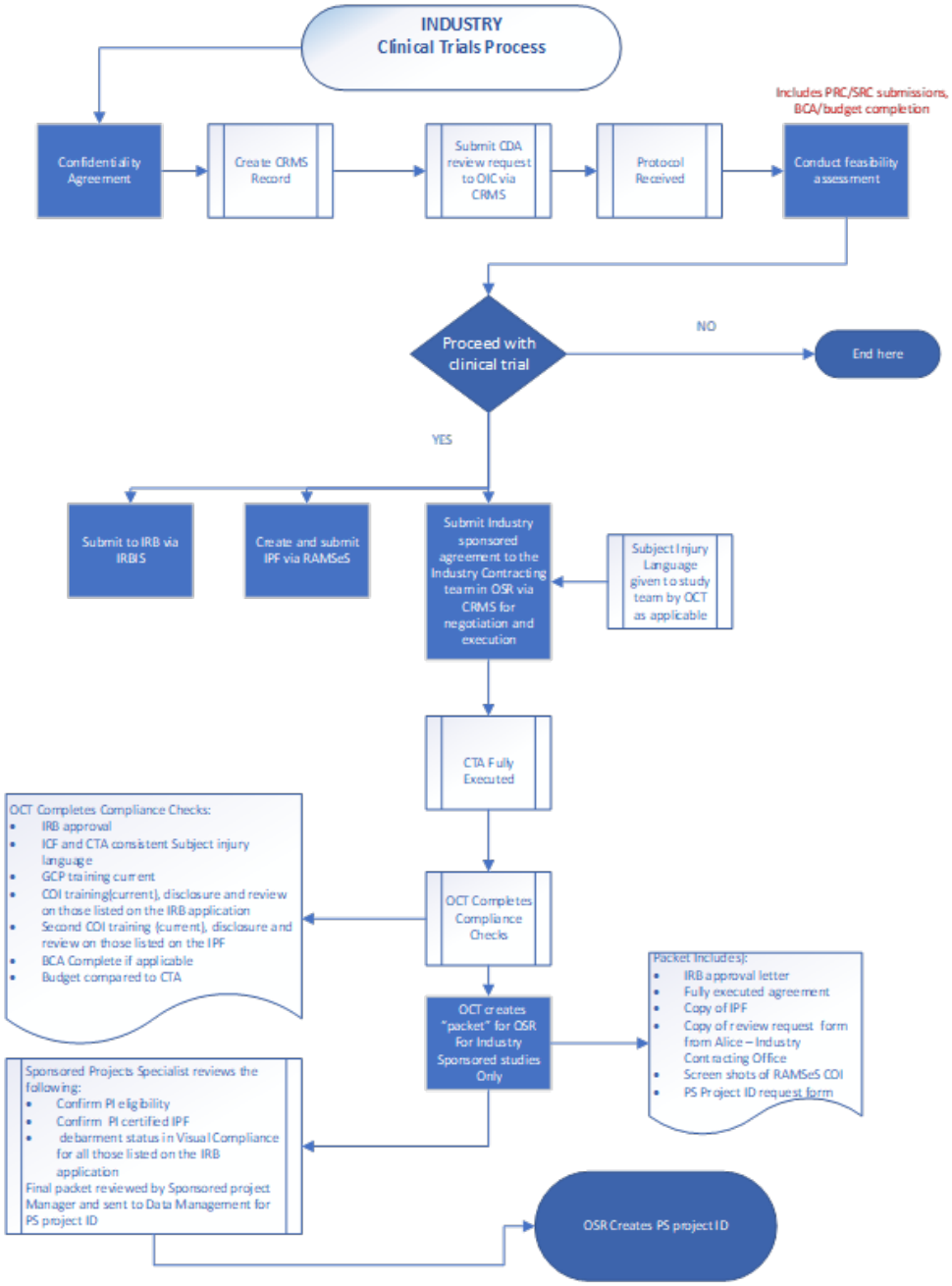
- Full proposal
- Non-industry (federal, non-profit)
- Industry



Process flow is different based on the funder


Solicited or Unsolicited Full Proposal
Formal proposal required by sponsor
Create and submit IPF for proposal
Sponsored Projects Specialist reviews the following:
Confirm PI eligibility
Confirm PI certified IPF
Budget review
Review of required components
Decision to proceed
Yes
No
End here
Protocol Received or finalized if IIT
OSR Negotiates award
Submit to IRB
Create CRMS Record
Submit CDA request to CIC through CRMS, if applicable
Feasibility Assessment completed
Includes SRC/PRC submission, BCA and budget development
BCA Completed
Fully Executed agreement/budget
OSR Notifies OCT of Clinical Trial
Award Set Up
Check debarment status
COI
OCT Completes Compliance Checks and notifies OSR
OCT Completes Compliance Checks:
IRB approval
ICF and agreement 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 Complete if applicable
If agreement specifies an end date, the end date must be used in ConnectCarolina, to extend an amendment is needed to the agreemnt.
Final Packet review by Sponsored Project Manager
Sent to data management for PS project ID
PS project ID assigned


NON-INDUSTRY
Clinical Trial Process
Create CRMS Record
Submit CDA request to OIC through CRMS
Protocol Received or finalized if IIT
Conduct Feasibility assessment
Includes SRC/PRC submission, BCA and budget development
Decision to proceed
No
End here
Yes
Create and submit IPF
Submit to IRB
Sponsored Projects Specialist reviews the following:
Confirm PI eligibility
Confirm PI certified IPF
Budget review
OSR Negotiates award
OSR Notifies OCT of Clinical Trial
OCT Completes Compliance Checks:
IRB approval
ICF and agreement 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 Complete if applicable
Fully Executed agreement/budget
OCT Completes Compliance Checks and notifies OSR
OSR Award Set Up
Check debarment status
COI
Connect Carolina end date must match that of the agreement, to extend an end date, a an amendment to the agreement is required..
Final Packet review by Sponsored Project Manager
Sent to data management for PS project ID
PS project ID assigned


INDUSTRY
Clinical Trials Process
Confidentiality Agreement
Create CRMS Record
Submit CDA review request to OIC via CRMS
Protocol Received
Includes PRC/SRC submissions, BCA/budget completion
Conduct feasibility assessment
Proceed with clinical trial
NO
End here
YES
Submit to IRB via IRBIS
Create and submit IPF via RAMSeS
Submit Industry sponsored agreement to the Industry Contracting team in OSR via CRMS for negotiation and execution
Subject Injury Language given to study team by OCT as applicable
CTA Fully Executed
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 Complete if applicable
Budget compared to CTA
OCT Completes Compliance Checks
OCT creates "packet" for OSR For Industry Sponsored studies Only
Packet Includes):
IRB approval letter
Fully executed agreement
Copy of IPF
Copy of review request form from Alice – Industry Contracting Office
Screen shots of RAMSeS COI
PS Project ID request form
Sponsored Projects Specialist reviews the following:
Confirm PI eligibility
Confirm PI certified IPF
debarment status in Visual Compliance for all those listed on the IRB application
Final packet reviewed by Sponsored project Manager and sent to Data Management for PS project ID
OSR Creates PS project ID

Industry sponsored – process

Sponsor or Clinical Research Organization (CRO)

- Contacts the site
- Site information form (SIF)
- Protocol synopsis
- Confidentiality Agreement (CDA)
- Non-Disclosure Agreement (NDA)

Principal Investigator (PI) determines interest

CDA negotiated and fully executed by the Industry Contracting (OIC) within the Office of Sponsored Research (OSR)

Sponsor/CRO sends regulatory packet

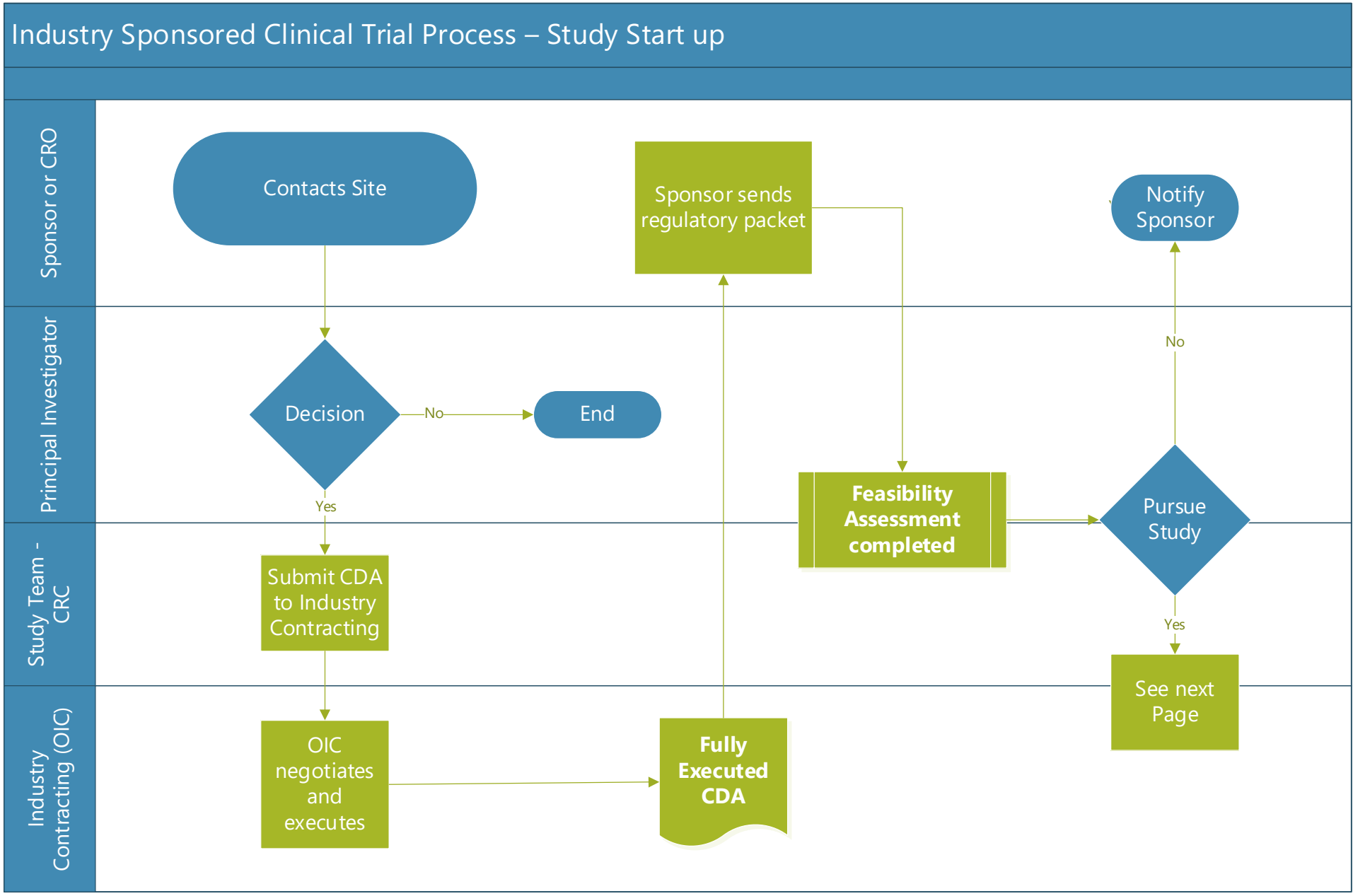
Site Survey

- Site information form
- Site Qualification form
- Site Feasibility form
- Sponsors and CROs track turn around times

Confidentiality Agreement (CDA) or Non-Disclosure Agreement (NDA)

- CDA submitted via Clinical Research Management System (CRMS)
- Can be mutual for PI initiated studies
- Cannot be signed by PI
- Quick turn around
- Not every CDA results in receiving a protocol
- Sponsors and CROs track turn around times

Industry Sponsored Clinical Trial Process – Study Start up



Clinical Research Management System (CRMS)

You will receive training

ALL CLINICAL TRIALS MUST USE CRMS

Feasibility Assessment

- Tools needed to conduct a Feasibility Assessment
  - Protocol – final or draft?
  - Draft ICF
  - Draft CTA
  - Draft Budget
  - Investigator brochure
  - Pharmacy manual
  - Lab manual

Feasibility

- Conduct a preliminary feasibility assessment
  - If PI Initiated work with your PI
  - Read the draft ICF
  - Read the protocol
    - Potential enrollment
    - Study schedule (practical, reasonable)
    - Study duration
    - Non-routine care items
    - Imaging
    - Pharmacy
    - Lab/specimens
    - Resources (study coordinator, data manager, 24/7)
    - Adequate staffing
    - Training requirements
    - Special vendor requirements

Feasibility Assessment

- May include submission to the Scientific Review Committee (SRC) - non-oncology or Protocol review Committee (PRC) - oncology
- Billing Coverage Analysis (BCA) is needed to develop an internal budget
- Feasibility Checklist Available on the Office of Clinical Trials (OCT) https://research.unc.edu/clinical-trials/forms/
- The School of Medicine Clinical Research Support Office (CRSO) will also assist with feasibility assessment

Feasibility Assessment
Create Internal Budget

- Billing Coverage Analysis – required for all clinical trials where tests and/or procedures are performed at UNC Health
  - Spreadsheet from CRMS, Deemed and Qualified;
  - Epic Billing calendar
- Funding source (federal or industry)
- Consistent approach
- Ensure start up fees are sufficient and invoiced
- Standardized fees
- Screen fails
- Monitoring visits
- Monthly invoicing
- Investigational Drug Service Fees
- Clinical and Translational Research Center (CTRC) fees

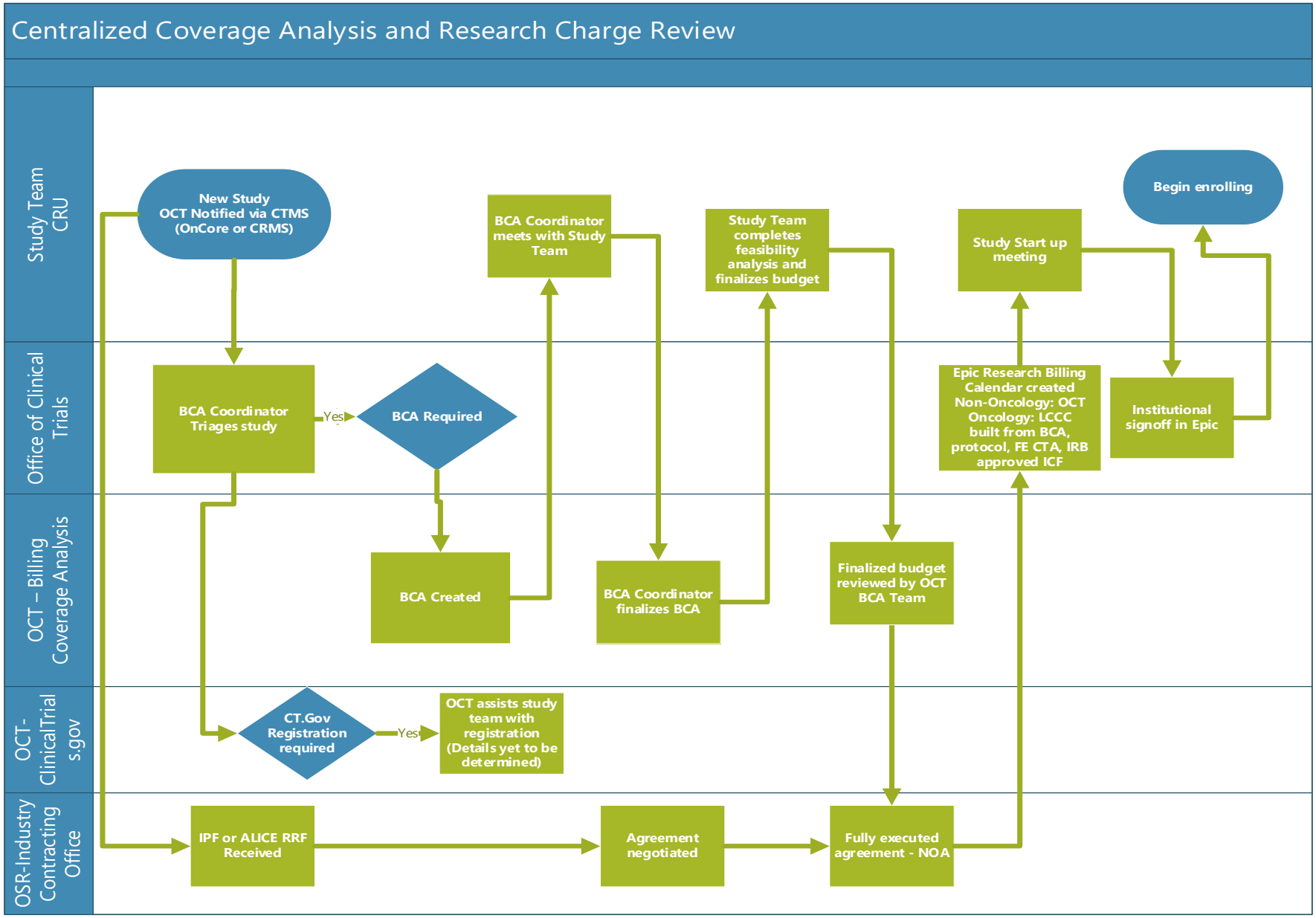
CURRENT PROCESS – **NEW ROCESS April 11, 2021**

Billing Coverage Analysis (BCA) Current process

- Current Process
  - Study teams create CRMS Record
    - Submissions tab
    - Billing Coverage Analysis template
    - Create BCA
    - Send to OCT, review of qualifying clinical trial requirements, supply costs and codes
    - OCT sends back to study team to negotiate budget
    - Study team finalizes
    - Sends to PI for approval certification
    - OCT compliance review of BCA
    - Epic research Billing calendar created

Beginning April 11, 2021
All NEW BCAs will be created by OCT

Centralized Coverage Analysis and Research Charge Review



Negotiate Budget

Internal budgets are used to identify all costs a site will incur to conduct a clinical trial.

Internal budgets should not be sent to the sponsor.

They are used as a tool to develop the sponsor budget.

Include Mandatory fees including overhead or F&A

Budgets are negotiable

Fair Market Value and Justifiable

Information on budgeting coming to the Office of Clinical Trials (OCT) website soon.

Clinical Trial Agreement (CTA)

- Submit draft clinical trial agreement (CTA) to the Industry Contracting Office via CRMS, direct link to ALICE
  - Complete review request form (RRF)
- Contract manager assigned
- Only the assigned contract manager negotiates terms and conditions in the CTA
- Department is responsible for negotiating the payment terms and conditions with the study budget
- Maintain open communication with your contract manager
- The CTA can be negotiated while you negotiate your budget
- Once budget has been finalized with sponsor we can execute the CTA

Institutional Review Board (IRB)

Submit to the IRB Information System (IRBIS) when you are sure the PI wants to participate

UNC local IRB or Central IRB (if the multi center industry sponsored) https://research.unc.edu/2019/09/10/commercial-irb-utilization-and-irbis-update/

Reply to stipulations (if any)

Informed Consent Form and contract must be consistent in respect to subject injury, stipends and what has been promised for free to the subjects

Subject Injury Language in the Informed Consent

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

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

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

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

Please email SIL@unc.edu and include the following:

IRB #, CRMS#, PI full name, Full title, and protocol #

OCT will review and send the “official” Subject Injury Approval memo to include with the IRB Submission

Standard Subject Injury Language

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care.

The Sponsor of the study, [INSERT SPONSOR NAME], has agreed to pay all reasonable medical expenses for the treatment of reactions, illnesses or injuries related to the use of the study drug/device, defects in the manufacture of the study drug/device, [select either drug or device]or as a direct result of properly performed study tests and/or procedures, except to the extent such expenses are due to the negligence of the study staff or due to your current disease or condition unless it is made worse because you are taking part in this study.

Standard Subject Injury Language

The sponsor has no plans to provide additional financial compensation for lost wages or any other loses or expenses. Any costs for medical expenses not paid by the Sponsor will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

If you think you have been injured from taking part in this study, call Dr. (PI Name) at (24 hour phone number). He/she will let you know what you should do.

Standard Subject Injury Language

If required by Sponsor, ONLY the following Medicare Reporting language is acceptable:

To pay these medical expenses, the Sponsor will need to know some information about you like your name, date of birth, and social security number. This is because the Sponsor has to check to see if you have health care insurance through Medicare, and if so, report to Medicare the payment the Sponsor makes toward your medical expenses. We will not collect your social security number for this purpose unless you are injured and a claim is submitted to the Sponsor to pay medical expenses.

Before Starting Enrollment

You need to have the following in place:

- IRB Approval
- Fully executed agreement
- Project account number
  - Requires submission of an Internal Processing Form (IPF) to the Research Administration System and eSubmission (RAMSeS)
- Completed compliance checks

Those pesky compliance checks

IRB approval

ICF and CTA consistent Subject injury language

BCA Complete if applicable

Checklist for Non-Industry Sponsored CTs

- **Non-Industry Sponsored Clinical Trial**
- ☐ Create CRMS record.
- ☐ Submit CDA to in the Industry Contracting Office through CRMS.
- ☐ Industry Office notifies of fully executed CDA.
- ☐ Conduct feasibility assessment.
- ☐ Submit to the Scientific Review Committee or Protocol Review committee as applicable.
- ☐ Create BCA
- ☐ Submit to IRB.
- ☐ Create IPF.
- ☐ PI certifies IPF.
- ☐ OSR will confirm PI Eligibility and review budget, and notify OCT for Compliance checks
- ☐ Once all compliance checks completed and agreement executed, PS project ID assigned

Full Proposal Checklist

- **Solicited or Unsolicited Full Proposals**
- ☐ Create and submit IPF.
- ☐ PI certifies.
- ☐ OSR review.
- ☐ Create CRMS record.
- ☐ Conduct feasibility assessment.
- ☐ Create BCA
- ☐ Submit to the Scientific Review Committee or Protocol Review committee as applicable.
- ☐ Submit to IRB.
- ☐ OSR will confirm PI Eligibility and review budget, and notify OCT for Compliance checks
- ☐ Once all compliance checks completed and agreement executed, PS project ID assigned

Checklist for Industry Sponsored CTs

- **Industry Sponsored Clinical Trial**
- ☐ 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.
- ☐ 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.

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

Study Start Up

When can I enroll! It has been months and I am already tired…

Study Start Up

- Site Initiation Visit (SIV) – Study Start Up Meeting
  - Internal and Sponsor driven
- Study supplies
- CRMS – Clinical Research Management System (OnCore for Oncology studies)
- Epic – UNC Health (electronic health record)
- IDS – Investigational Drug Services at UNC Health
- Subject binders – physical or electronic
- Source documents – Physical or Electronic
- Study visit checklist

Study Conduct

- Enroll your first subject
  - Inclusion/exclusion criteria
  - Informed Consent – ongoing through out the trial
    - Documentation of the informed consent process
  - Review how it went with the first subject and adjust if needed.

- Maintenance of Essential Documents
  - Val Buchholz from the Office of Clinical Trials can work with you on ensuring you have set your study documents correctly.

Ongoing conduct of study

Study visit checklists – may need to be revised as the study progresses
Case report forms
Epic Billing review – to be done by Integrated Billing after 4/11/2021
Investigational product accountability
Serious Adverse Event /Adverse Event reporting
Study Monitor Access
Annual IRB renewal
Protocol and Budget Amendments
Modifications submitted to the IRB
Deviations

STUDY COMPLETION / CLOSE OUT

- ✓ All study subjects complete
- ✓ Data lock / IRB closure
- ✓ Logs
  - ✓ Investigational Product Accountability
  - ✓ Subject Identification Code
- ✓ Final Close-out monitoring report
  - ✓ Includes where site documents will be sto
- ✓ Clinical Study Report
- ✓ Financial closeout
- ✓ Pack up the records
- ✓ Closeout Checklist - https://research.unc.edu/clinical-trials/forms/
- ✓ Pat yourself on the back

Audits –FDA, DEA or Sponsor

Who do you call?

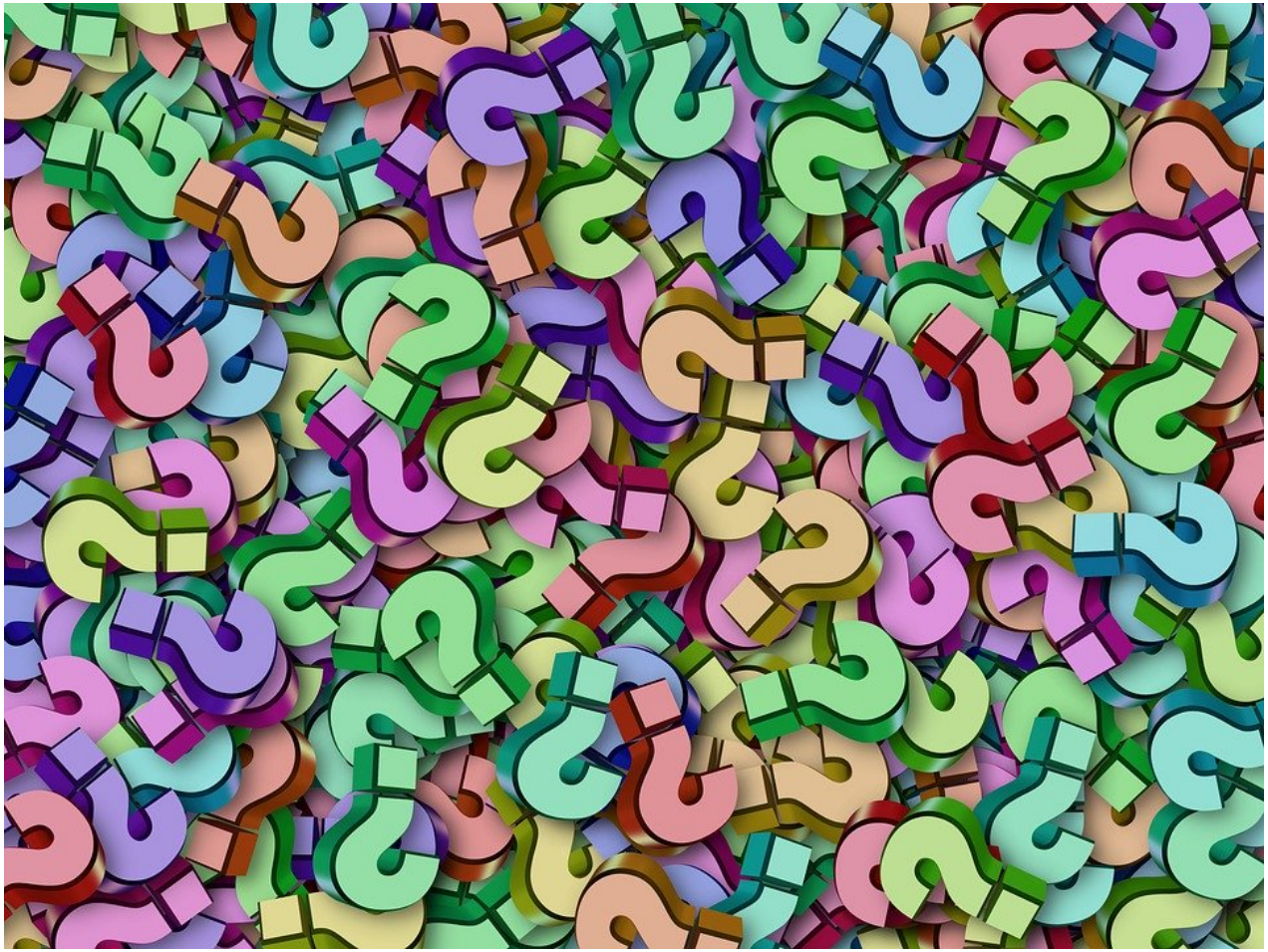
Hint – its not Ghost Busters!

Inspections and Essential Documents

Sponsors and other regulatory agencies look to these documents as part of their processes to confirm the validity of the conduct of the trial and the data collected

Organization is the key to success

Questions?



Week 1
Evaluation Link:
https://go.unc.edu/coordorientwk1

OR

If you need a certificate of attendance, please email marie_rape@med.unc.edu after completing the evaluation survey.