



THE UNIVERSITY  
of NORTH CAROLINA  
at CHAPEL HILL

August 3, 2017

# Clinical Trials at UNC

UNC Symposium for Research Administrators

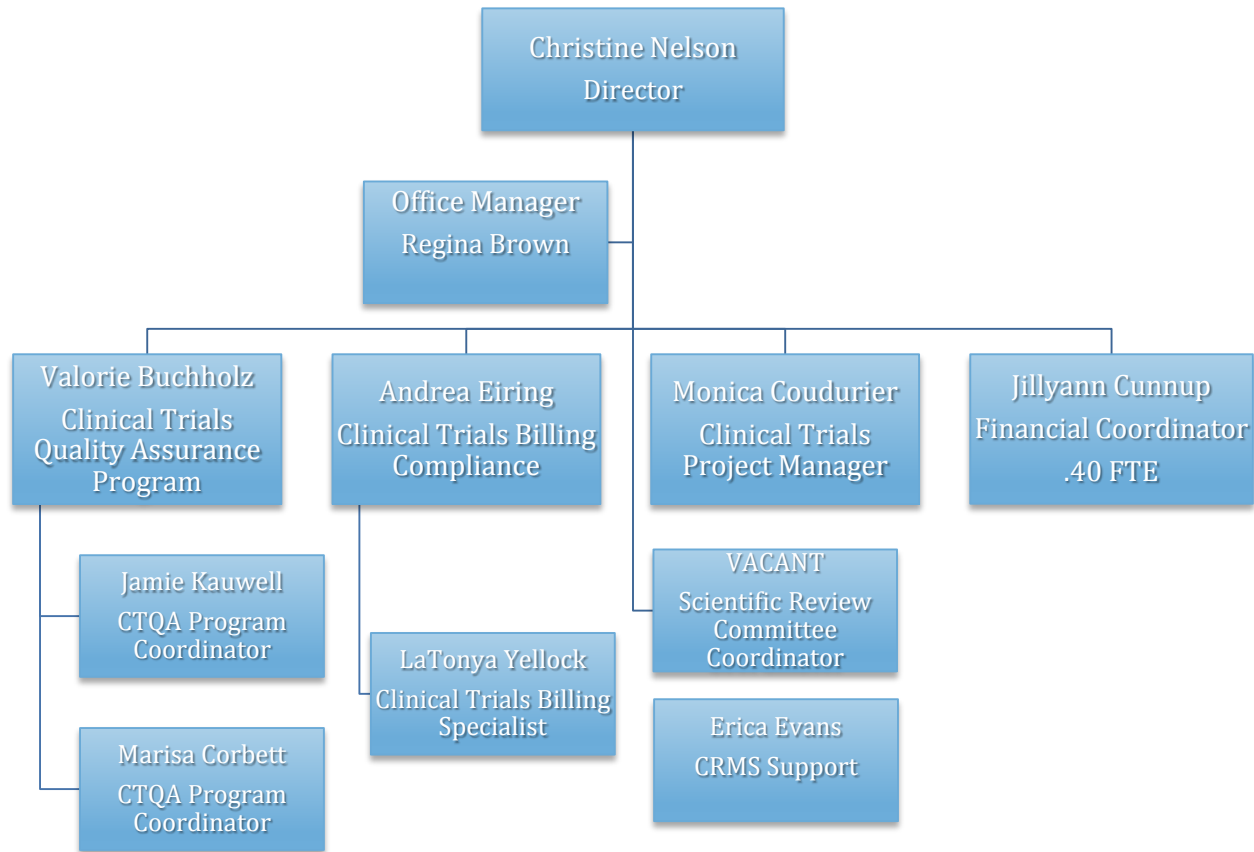
# UNC Symposium for Research Administrators

*Presenter*

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# Office of Clinical Trials



# The Office of Clinical Trials

OCT serves as a central resource for UNC faculty, staff and departments involved in clinical trials research and for sponsors seeking to conduct clinical trials at UNC, serving as an expert resource for information on the issues and requirements for the conduct of clinical trials.



# OCT Mission Statement

The mission of the Office of Clinical Trials (OCT) is to serve the Carolina research community by improving the quality of support by facilitating and streamlining the startup, conduct and administration of clinical trials.

In support of that mission, the OCT strives to:

1. **Standardize the processes for clinical trials** to ensure consistency, efficiency, and compliance with Federal, State and University requirements;
2. **Provide educational opportunities** to research faculty and staff;
3. **Facilitate regulatory knowledge** and support to investigators and clinical research professionals to enhance compliance with federal and institutional requirements;
4. **Identify and/or support development of new clinical research opportunities** in collaboration with our clinical research teams;
5. **Encourage interdisciplinary collaboration** for clinical research and incorporate available resources throughout the University and UNC Health Care.



# Clinical Trials Quality Assurance Program

- The Clinical Trials Quality Assurance (CTQA) program is designed to support investigators in ensuring their trials are conducted in accordance with federal, state and institutional regulations
- The CTQA staff can assist with setting up systems and processes at the beginning of a trial to validate all the regulatory requirements and essential documents are in place (i.e. documentation of investigators qualifications, confirming Delegation logs are accurately completed, assisting with training documentation).



# Clinical Trials Quality Assurance Program

- Post Approval Reviews
- Direct Reviews
- FDA Inspections
- Response to FDA
- Sponsor Audits
- Requested Reviews



# Research Billing Compliance

In order to comply with federal, state and institutional regulations and standards for clinical trial billing, the University is responsible for establishing effective processes to ensure that all services for a study are billed properly.

- Billing Coverage Analysis support
- Research Billing Audits
- Epic Research Billing Calendars
- Subject injury bill hold





# Scientific Review Committee Coordination

- Scientific Review is a process that evaluates the scientific merit of a clinical trial protocol
- Scientific Review of human subjects protocols is required as there is no acceptable risk to human subjects in the absence of valid scientific merit.
- Risks to participants are minimized by using procedures consistent with sound research design
- SRC review done prior to IRB review



# ClinicalTrials.gov

Monica Coudurier 919-843-2333

- All NIH defined clinical trials must be registered
- Prior to enrollment
- Prior to enrollment is planning to publish results
- Specific requirements for reporting results
- Monetary fines for non-compliance



# Outreach “Pop Ups”

- Collaboration with OCT, OIC and OSR
- Conducted on campus
- Allows research personnel to ask questions specific to their project
- Held twice a month
- Announcements sent NRP and RASG listservs.



# Compliance Review

## *Prior to Account Set Up*

PS Project ID or account number must be established and requires the following compliance checks to be completed by OCT:

- Fully Executed agreement
- IRB Approval
- GCP training complete and current
- Completion of the Billing Coverage Analysis (BCA)
- COI training and disclosures (from the IRB submission)
- Completion of IPF with PI Certification
- Internal budget is compared to FE budget in the CTA
- Congruency check of the BCA, approved ICF and CTA



# Fully Executed Agreement

- Technically you can start a clinical trial with out a fully executed agreement
- It's a risk to start before an agreement is in place
- Risk of consent form and agreement mismatch, requiring revisions to the consent form



# IRB Approval

Any research involving human subjects proposed by faculty, staff, or students must be reviewed and approved by an IRB before research may begin, and before related grants may be funded.



# GCP Training

## *Complete and Current*

- Good Clinical Practice (GCP) is the international ethical and scientific standard expected in the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. Compliance with GCP provides assurance that data are reported, results are credible and accurate, and that the rights, safety, confidentiality, and well-being of trial subjects are protected
- NIH has also issued a policy on Good Clinical Practice Training<sup>1</sup> for NIH Awardees involved in NIH-funded clinical trials. This policy requires that PIs and clinical trial staff involved in all new and ongoing NIH-defined clinical trials<sup>2</sup> complete Good Clinical Practice (GCP) training.
- GCP training is in addition to, and different from, Human Subject Protection training, which is required by the IRB. Renew every 3 years.

<sup>1</sup> <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html>

<sup>2</sup> <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html>



# Completion of Billing Coverage Analysis

- The purpose of the Billing Coverage Analysis is to determine deemed and qualifying status as well as which routine care costs may be billed to Medicare or other insurers and which costs must be paid by the sponsor. The BCA is required to be performed prior to the initiation of the clinical trial to ensure proper billing of services and financial feasibility.
- Must be reviewed and approved by principal investigator





# Conflict of Interest

- COI review currently done twice
- Upon IRB submission
  - Included all personnel listed in the IRB application
- Upon IPF submission
- OCT only looks at the IRB application
  - Must include current COI training and disclosure
  - Cant move forward until COI committee has reviewed
  - Hard stop for account set in RAMSeS



# Completion of eIPF

- For Industry sponsored clinical trials, done after the agreement and budget complete
- For federally sponsored trials done before agreement
- Must be certified by principal investigator
- Internal budget is compared to the fully executed budget in the agreement



# Congruency Check

- Fully executed agreement, consent form and completed billing coverage analysis
- If discrepancy found – revise consent form or amend contract



# Obstacles to Clinical Research at UNC

- Decentralized
- UNC and UNC Healthcare
- Multiple departments
- Several systems
  - IRB
  - Two Clinical Trials Management Systems
    - CRMS and OnCore
  - RAMSeS
  - ALICE
  - Investigational Drug Service
  - Epic



What can you do to improve  
the process?




# Complete BCA Process through CRMS

- Complete the BCA spreadsheet
- Instructions
  1. Deemed and Qualified
  2. Coverage Analysis
  3. Billing Calendar
- Send to OCT
- If you receive clarifying questions from integrated billing answer them in a timely manner
- When sent back to you, complete budget and finalize
- Send to PI for final approval



**Steps**

	Status	Approver	Date
1	Research Coordinator Saved Initial Budget	Coleman Tew	04/19/2017
2	OCT Coverage Analysis Review	Coleman Tew	05/08/2017
3	Integrated Billing (IB) Coding & Pricing	Andrea Eiring	05/08/2017
4	Research Coordinator Budget Finalization	Lisa Heavlin	05/09/2017
5	Lead Principal Investigator BCA Certification	Coleman Tew	05/11/2017
6	OCT Budget Review and Contract Finalization	Andrea Eiring	05/12/2017
7	Integrated Billing (IB) Creates Calendar	Andrea Eiring	07/11/2017
8	Complete (Calendar Not Needed)		
9	Complete (Calendar Created)		
10	No BCA required	LaTonya Yellock	07/19/2017

*It is important that you read the instructions in order to complete the Billing Coverage Analysis correctly for your study. Please click  to review the instructions.*

The budget process is complete or the file does not exist on sharepoint.

BCA Contact:  Coleman Tew < coleman\_tew@med.unc.edu > Click to open/edit



# Fully Executed Agreement

- Is the subject injury language in the agreement and consent form congruent?
- Do subject payments match?
- Does the BCA spreadsheet and the final approved budget match?





# IRB Approval

- Fully approved
- All COI in the IRBIS application complete



# GCP Training

- Has everyone listed on the IRB application completed GCP training?
- Is the training up to date?



# Internal Budget and eIPF

- Have you submitted the IPF and internal budget?
- Has the PI certified the IPF?
- Is the COI complete in RAMSeS?



# Proposed System Improvements

- One intake form – IPF/RRF
  - Alice and RAMSeS
- One CTMS enterprise wide
  - OnCore
- Continued outreach through Pop Ups and town halls
- Exploring ways to provide assistance to investigators and their staff



# Questions?



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