Office Of Clinical Trials

Christine Nelson, RN, BSN, MBA, CCRC

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 Trial Quality Assurance Program

- Routine Reviews
  - Post Approval Reviews
- Directed Reviews
  - OHRE
  - Department head
  - Vice Chancellor for Research
- Preparation for External Reviews
  - FDA
  - Sponsor Audits
- Assist with external audits/inspections

Clinical Trial Quality Assurance Program

- Conducted 57 post approval reviews
- Assisted with 5 FDA inspection
- Conducted 3 root cause analyses (RCA) with departments to assist with the development of Corrective and preventative Action Plans (CAPA)
- Assisted with draft communications with the FDA
- Collaborated with two prominent Clinical Research Organizations to improve the quality of the clinical trials conducted at UNC

Clinical Trial Quality Assurance Program

- Forms and checklists available on our website
- Track GCP training
- Will begin tracking and trending sponsor monitor follow up reports
- Draft policies

PS Project ID Set up

Conduct compliance review prior to PS project ID set up by OSR

- GCP training completed and current
- IRB approval
- IPF submission with internal budget
- COI training, disclosure and review complete
- Congruency of BCA, CTA and ICF

Clinical Trial Billing Compliance

- Review and assistance with the Billing Coverage Analysis
- Ensures consistency of BCA, CTA and ICF prior to account set up
- Research 100 classes, monthly
- Now available – CITI training on Clinical Trial Billing Compliance
- Clinical Trial Billing reviews to start soon

ClinicalTrials.gov

- Support with registration and results reporting for ClinicalTrials.gov
- Alerts investigators when trials appear on the “problem report” for late results reporting

ClinicalTrials.gov

- Final rule announced September 16, 2016
- Effective date January 18, 2017, 90 days to come into compliance – April 18, 2017
- Clarification and expansion of the definition of an applicable clinical trial
- Clarified responsible party
- Clarified and increased the results reporting
- Need full protocol, including a statistical Analysis plan
- NIH can withhold funding if there is failure to report results

CRMS Support

- Provide customer and technical support for CRMS
- Proactively troubleshoot issues
- Perform Quality Assurance/Quality Control of the CRMS System and development measures.
- Training
  - Research 100
  - One on one

Scientific Review Committee

- Need for the separation of the scientific review from the IRB review
- Administrative support
- Require full protocol with statistical analysis plan
  - In line with new NIH and CT.gov final rule
- Goal to improve turn around times for IRB review
- Improve the quality of protocols
- SRC will no longer review industry sponsored protocols

Support New research Opportunities

- Clinical research staffing is key to the success of the investigator and the study
- Investigators may have a desire to lead clinical trials but lack the required study support resources due to difficulty in recruiting, retaining and efficiently onboarding staff.
- UNC has launched a pilot program with a commercial partner to offer site-management services to investigators and departments with limited infrastructure.

Future

- Prepaid card for study subject payments
- IND/IDE registration with OCT
- Policy on delegation of tasks
- Enterprise wide clinical trials management system

Last thought…

Questions