CLINICAL RESEARCH COORDINATOR ROLE

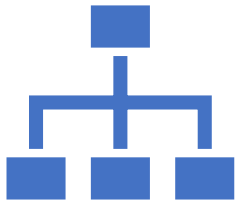
THE STUDY SUPERHERO

UAB SCHOOL OF NURSING
The University of Alabama at Birmingham

OUTLINE

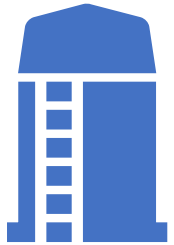
- DESCRIBE HISTORICAL PERSPECTIVE
- REVIEW CURRENT ROLE RESPONSIBILITIES
- WHAT'S WORKING?
- WHAT'S NOT WORKING?
- NEXT STEPS

HISTORICAL PERSPECTIVES



Program Manager I, II, III

Program Manager – SON Programs



Clinical Research “Ladder”

Clinical Research Career Ladder

The Clinical Research Career Ladder was developed by the University to meet four goals:

1. Provide progressive advancement opportunities for staff engaged in the conduction of clinical research

2. Contemporize existing job descriptions for staff

3. Clarify and communicate competencies or proficiencies required for each new description/level

4. Ensure staff are appropriately classified, compensated and are aware of training and proficiency requirements

I. DOMAIN: RESEARCH OPERATION

- Screening
- Subject level documentation
- Prepare and conduct study visits
- Specimen collection and preparation
- Investigational Products
- Study level documentation
- Subject management and retention
- Consent procedures
- Monitoring and Audits
- Adverse Event Data Collection
- Adverse Event Reporting
- Intellectual Property Rights
- Interactions with IRB

II. DOMAIN: ETHICS AND PARTICIPANT SAFETY

- Clinical Activities versus Research Activities
- Implementation of Ethical Conduct of Research
- Safety Plans
- Risk versus Benefit

III. DOMAIN: DATA AND INFORMATICS

- Data Flow
- Data Collection
- Data Security and Provenance
- Data Corrections and Queries
- Quality Assurance
- Data Contracts and Agreements

IV. DOMAIN: SCIENTIFIC CONCEPTS AND RESEARCH DESIGN

Literature Reviews

Scientific Collaborations

Research Design

Study Results

V. DOMAIN: LEADERSHIP AND PROFESSIONALISM

- Apply Principles of Leadership
- Management and Mentorship
- Guidelines and Code of Ethics
- Education and Training
- Professionalism: Cultural Diversity

VI. DOMAIN: SITE AND STUDY MANAGEMENT

- Determining Participation in Trials
- Managing Resources
- Managing Risk
- Site Visits and Sponsor Training
- Operational Plans
- Study Closeout

VII. DOMAIN: COMMUNICATION AND TEAM SCIENCE

Communication with Sponsors, Sites, and CROs

Teamwork

VIII. DOMAIN: PORTFOLIO AND PROGRAM DEVELOPMENT & MANAGEMENT

IX. DOMAIN: CLINICAL SKILLS

Clinical Research Ladder

The Ladder consists of 5 tracks and 5 levels across which clinical research staff may move throughout their career at UAB.

Each level expressing, through its minimum requirements, an expectation of increased expertise through the addition of relevant experience and education.

	Level 1	Level II	Level III	Manager	Director
ADMINISTRATOR	G320/HS	G340	G355	G380	G415
COORDINATOR	G325/HS	G345	G365	G380	
NURSE COORDINATOR	G350/RN	G365	G375	G390	
REGULATORY	G320/HS	G340	G355	G380	
DATA MANAGEMENT	G315/HS	G335	G355	G380	

Promotion ‘Fine Print’

The minimum requirements do not create the business need within a clinical research area (school/department/division/center) by which one is able to promote within the Ladder.

The business need is created by the duties that must be conducted by staff within the area on various protocols.

The process to determine which track and level of the Ladder is most appropriate for an area’s needs is initiated when that area's HR contact emails the Clinical Research Career Ladder Title Review Committee at **CareerLadder@uab.edu**.

What's Working?

- One thing that is working from my perspective is the opportunity to have CRC I and IIs available to work on Projects. If you remember with ENABLE CHF we relied heavily on RRSF for a lot of study activities that these CRCs do now
- And, a significant portion of the grant funds was expended toward the Service Center and NOT to building up research (support) staff in SON. For example, Charis and Brieana are invaluable assets to Peg and I with Cornerstone and CASCADE. In the past, it was just the Project Manager, RRSF and the Coaches. So that is one thing I wanted to share, especially since that slide "What is Working…" was blank at the end of the meeting.

Having ready access to ORS and SON finance is a huge help with Travel, buying and paying for study supplies and services…etc. It was a minefield in previous years and hard to ask or get help.

What's Not Working?

- CRCs w/ multiple projects have competing priorities that interfere w/ each other- e.g., IRB (CRCIII) vs recruiting (CRC I)
- Processing documents is time-consuming and needs to be streamlined; often processes change and it's not till you process it wrong that you learn its' done wrong. Example, contracts, sub-awards. You learn it when it 'bounces back'. GDRM, SON Finance, & CRC need to be on the same page.
- Travel not always paid from Grants & need to work w/ Dept personnel to do this
- Cost transfer forms are time-consuming-object codes are a guessing game and are not common-adobe sign needs to be completed w/ object codes; how to use oracle;
- Getting to Monday money minutes is great; but hard to get to; ppts are helpful but not shared—what order for documents in

What Next?

- Have a CRC I who is dedicated to only recruitment over a number of studies, or to do only data collection, or [pt payment-CRC II]. (this would replace RRSF which is expensive and would keep study $ in house)
  - These are tasks that are tedious and time-consuming but require high degree of accuracy. These are usually not time sensitive and can be put off.
  - Budget issues are time consuming and difficult, e.g. travel processing is ‘fun’
- Need a CRC go-between (manager) to address study issues that don’t necessarily need a PI to address (i.e., sort out effort of CRC on studies, recruitment issues)
- Need a dedicated CRC trainer
- PM - Admin (not CRA)-to do travel, budget, processing supplies, payment requests, cost transfers