Research Professionals Network

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Duke Office of Clinical Research

Duke University School of Medicine
Research Professionals
Job Classifications

March 2015
Objectives for today

• Review goals and progress of the Clinical Research Professional Working Group (CRPWG)
• Provide overview of proposed clinical research classifications
• Conduct stoplight evaluation
Clinical Research Professional Working Group (CRPWG)

SOM Advisors: Mark Stacy, Billy Newton, David Smithwick, Denise Snyder, Heather Gaudaur, Betsy Hames (May 1)

Members:
- Leigh Burgess (DCI – Oncology CRU)
- Terry Ainsworth (DOCR)
- Angie Cain (Medicine)
- Rebecca Brouwer (DOCR)
- Catee Mullen (Heart Center CRU)
- Debbie Hannah (Dermatology/Pathology CRU)
- Mary Smith (DCRI)

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Goals of the CRPWG

Shape long-term vision for a clinical research workforce by:

• Updating job descriptions so they more accurately reflect responsibilities
• Identifying competencies and performance criteria within the classifications
• Defining career ladder and career progression
• Ensuring staff members performing clinical research functions are appropriately classified
• Mapping currently held positions into reworked job classifications
• Incorporating job classifications across Schools of Medicine and Nursing for new hires in these roles
FIGURE 1. Competency Domains for the Clinical Research Professional

1. Scientific Concepts and Research Design
   - Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials

2. Ethical and Participant Safety Considerations
   - Encompasses care of patients, aspects of human subject protection, and safety in the conduct of a clinical trial

3. Medicines Development and Regulation
   - Encompasses knowledge of how drugs, devices, and biologicals are developed and regulated

4. Clinical Trials Operations (GCPs)
   - Encompasses study management and GCP compliance; safety management (adverse event identification and reporting, postmarket surveillance, and pharmacovigilance), and handling of investigational product

5. Study and Site Management
   - Encompasses content required at the site level to run a study (financial and personnel aspects). Includes site and study operations (not encompassing regulatory/GCPs)

6. Data Management and Informatics
   - Encompasses how data are acquired and managed during a clinical trial, including source data, data entry, queries, quality control, and correction and the concept of a locked database

7. Leadership and Professionalism
   - Encompasses the principles and practice of leadership and professionalism in clinical research

8. Communication and Teamwork
   - Encompasses all elements of communication within the site and between the site and sponsor, CRO, and regulators. Understanding of teamwork skills necessary for conducting a clinical trial

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Competency domains used to describe responsibilities within each job description

2. **Study and site management.** Ensure participant care expenses have appropriate financial routing in a timely manner. Monitor financial study milestones and report appropriately. Coordinate with financial teams, PRMO, etc. and participate in budget development as appropriate. Develop study budgets.
   - Participate in sponsor required training. Coordinate operational plans for multiple research studies. Prepare for and lead site initiation, monitoring, and closeout visits. Coordinate operational plans with other clinical departments. Serve as primary liaison with single sponsor, subcontractor, or vendors.

3. **Scientific concepts and research design.** Understand the basic concepts of study design. Conduct and synthesize literature reviews. Assist investigators with the development of research proposals, with special attention to operational aspects of proposed implementation.

4. **Ethical and participant safety considerations.** Comply with and provide leadership with regard to the ethical conduct of research, and safeguards needed when conducting research with vulnerable populations. Recognize the need to develop conflict of interest management plans with study teams. Assess and verify inclusion/exclusion criteria for study participants. Develop documents related to safety and security (e.g., Research Data Security Plans, Data Safety Monitoring Plans). Coordinate efforts of external monitoring boards. Be aware of and follow policies and regulations that govern the conduct of research.

5. **Communication and teamwork.** Prepare for and lead study team meetings. Provide strategies to improve productivity and efficiency of communications. Develop solutions to create a culture of teamwork and foster communication.

6. **Leadership and professionalism.** Complete & maintain appropriate Duke specific training competencies (such as HSR, CITI modules, etc.)
   - Provide, review and train others in various work assignments. Serve as a mentor to junior staff, including other Clinical Research Coordinators. Employ escalation and performance plans as needed.
   - Actively seek out continuing education opportunities for self and study team. Participate in or lead scientific presentations and publications.

7. **Data management and informatics.** Enter research data and score/tests measures according to study protocol. Conduct quality
Proposal for Duke Research Professionals

Version 3/13/2015

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<th>JOB LEVEL/INCREASING RESPONSIBILITY</th>
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Denotes tiered positions
Denotes possible entry level positions (no experience needed above minimum education requirements)

Minimum education/experience requirements
Associates degree (note A+2 = bachelors)
Bachelors degree
Bachelors in Nursing degree

Where “x” is minimum degree and “#” is years experience

Research Practice Manager
Assistant Research Practice Manager
Research Program Leader, Senior
Research Program Leader

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Movement through tiers

- Likely ~3 tiers
- Associated with higher competency in domains
- Competency to be assessed in standard fashion
- Salary increase when move through tiers
- Eliminates need to reclassify
Stoplight Evaluation

• For each item, mark either:
  – Green (no major concerns)
  – Red – major concerns, this is a deal breaker and would stop the process moving forward
  – If Red, must have comments written
• Make sure you have provided your title and CRU/center/institute/department
• Return your evaluation see we can incorporate feedback
Let’s go!

Regulatory Coordinator, Senior
BSN + 4

Clinical Research Nurse Coordinator, Senior
BSN

Clinical Research Coordinator
A + 2

Research Practice Manager
B + 8

Assistant Research Practice Manager
B + 6

Research Program Leader, Senior
B + 8

Research Program Leader
B + 4

Regulatory Coordinator
A + 6

Clinical Research Nurse Coordinator
BSN

Clinical Research Coordinator
A + 6

Clinical Research Coordinator
A + 2

Clinical Research Specialist
A

Denotes tiered positions
Denotes possible entry level positions (no experience needed above minimum education requirements)

Minimum education/experience requirements
Associates degree (note A+2 = bachelors)
Bachelor’s degree
Bachelor's in Nursing degree

Where “x” is minimum degree and “#” is years experience

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Next steps

- Review stoplight evaluations
- CRPWG continues to meet
- Market analysis planned once descriptions finalized
- Assessments for job competencies underway
- The big question... how will this affect me? Phase 2:
  - Map positions to new classifications
  - Move people into new positions
- Will revisit in ~3 years
Questions?

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