Overview

• Review the state of the clinical research profession
• Provide an overview of the development and refinement of new job classifications
• Describe the planned process of employee mapping and migration into new positions
What is the national landscape?

CHANGES AND CHALLENGES:
• While job satisfaction and job security levels were generally the same among CRCs across the various investigative site types, **CRCs employed at academic medical centers/universities were significantly more likely to think their workload had increased in the past 3 to 5 years.**

• Increased workload was also mentioned as a top challenge by a significantly higher proportion of CRCs employed at academic medical centers/universities compared to other site types.

• The most significant change experienced by approximately 40% of the CRCs in their position is **the expectation of their employer to take on more responsibility in their current role.**

• Among those CRCs considering a job change in the next year (33%), the primary drivers were professional advancement and income.

2015 CenterWatch-ACRP Career and Salary Survey: The Clinical Research Coordinator Perspective
Best Path to Increase Salary & Upward Mobility

Which one of the following options do you consider the best way to increase your salary and move upward in your profession?

- Obtain a promotion within my current department from current employer
- Obtain a position outside my current department from current employer
- Obtain a new position from a new employer
- Become self-employed
- All Other

2015 CenterWatch-ACRP Career and Salary Survey: The Clinical Research Coordinator Perspective

ALL of these are happening at Duke

Sample Size = 612

26% Total

27% Academic Medical Center

25% Private Practice

28% Clinical Study Site
Outlook is bleak for AMCs... Time to take action!
Clinical Research Professional Working Group (CRPWG)

*SOM/R&R Advisors: Mark Stacy, Billy Newton, David Smithwick, Denise Snyder, Betsy Hames, Heather Gaudaur*

**Members:**
- Terry Ainsworth (DOCR)
- Rebecca Brouwer (DOCR)
- Leigh Burgess (DCI – Oncology CRU)
- Angie Cain (HR Medicine)
- Debbie Hannah (Dermatology CRU)
- Tara McKellar (Pediatrics CRU)
- Catee Mullen (DOCR)
- Mary Smith (HR DCRI)
Clinical Research Professional Working Group (CRPWG)
Faculty Advisory Committee (FAC)
Led by Vice Dean for Clinical Research, Mark Stacy, MD

- Jim Abbruzzese, MD (Oncology)
- Ebony Boulware, MD (Medicine – GIM)
- Michael Cotten, MD (Pediatrics)
- Schuyler Jones, MD (Heart Center)
- Allan Kirk, MD (Surgery)
- Andrew Muir, MD (Medicine – GI)
- David Rizzieri, MD (Oncology)
- Geeta Swamy, MD (OB/GYN)
- David Wallace, MD (Ophthalmology)
- Heather Whitson, MD (Medicine – Geriatrics)
Clinical Research Professional Working Group (CRPWG)

- SOM leadership (HR/finance)
- CRU RPMs
- HR/R&R
- DOCR

Research Community
Evolution of a profession

- Training, competency of staff performing clinical research
- Clinical Trials Billing (Maestro)
- Conflict of Interest
- Effort Reporting
- Human Subject Research Protection
- IT Security (HIPAA)
- ClinicalTrials.gov Disclosure
- Research Costing Compliance (Federal 90 day close out)
- Financial
- Reputational
The profession at Duke

What are we facing at home?

• Antiquated job descriptions
• Structural changes at Duke
• Workforce shortages
• Competing for limited personnel across Duke
• Lack of opportunities for growth
The workforce shortage

The profession at Duke

Open and filled CRC positions

FY13

FY14

FY15
CRCs On Call@ Duke

- 70% of the respondents provide some type of coverage/support for research activities outside of standard work hours
- 53% return to the work site during non-standard hours
- 77% manage this as a shared responsibility
- 10% of teams pay overtime to non-exempt staff
- Overwhelming acknowledgment of the challenging situation
What’s happening beyond Duke?

• CTSA initiatives
  – Harmonize training efforts
  – Professionalize those who hold support research jobs

• Workforce shortages
  – 10,000 CRA vacancies across the country
  – Hiring in the CRC role challenging (particularly for those with experience)
The vision moving forward

- Develop clear pathway for professional growth
- Develop leaders, create opportunity
- Enhance recruitment efforts to entice the best and brightest
- Think about creating a new workforce, not just about ourselves
- Be competitive with our peers institutions
- Consider new hiring models, improving recruitment to the profession
Development and refinement of job descriptions

- Model developed by CRPWG
- Stoplight evaluations of model with RPN, CRUs, others
- Job descriptions (JDs) developed, based on competencies
- JDs refined by individual CRPWG members
- JDs revised and shared with subject matter expert groups
  - Clinical Research Specialist (and CRS Sr)
  - Clinical Research Coordinator (and CRC Sr)
  - Clinical Research Coordinator RN (and CRC RN Sr)
  - Research Program Leader (and RPL Sr)
  - Regulatory Coordinator (and Reg Coor Sr)
Proposed model
Movement through tiers

• Likely no more than 3 tiers
• Associated with higher competency in domains
• Competency to be assessed by managers trained according to seven competency domains
• Annual review opportunity for tier movement in fall (Nov 1) – aligned with manager support
• Salary review occurs post review and is separate from PEP review cycle.
Estimated competencies within each domain:

- Study operations: 15
- Study & Site management: 14
- Data: 6
- Scientific concepts: 6
- Leadership & Professionalism: 4
- Ethics & Participant safety: 4
- Communication & Teamwork: 2
# Competency levels

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<thead>
<tr>
<th>Competency</th>
<th>Task Description</th>
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<tbody>
<tr>
<td><strong>D1:</strong> Describe the typical flow of data throughout a clinical trial, ensuring data provenance</td>
<td>Identify examples of the elements of data flow in a sample protocol: data capture, storage, management, quality, and preparation for analysis. Define source documentation and ECRF.</td>
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<td><strong>D2:</strong> Employ appropriate data collection and capture methods</td>
<td>Use EDCs, technologies and software necessary for study operations with little assistance. Enter data accurately. Score tests and measures according to protocol. Complete ECRFs accurately and according to protocol.</td>
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<td><strong>D3:</strong> Ensure security and provenance of research data</td>
<td>Describe appropriate security of physical and electronic data. Use required processes, policies, and systems to ensure data security and provenance.</td>
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<td><strong>D4:</strong> Appropriately use ICH GCP requirements for data correction and queries</td>
<td>Recognize the need for data correction and queries. Assist in investigating incomplete, inaccurate or missing data/documents to ensure accuracy and completeness of data.</td>
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<td><strong>D5:</strong> Use data quality assurance systems, guided by standard operating procedures</td>
<td>Define data quality assurance and a standard operating procedure. Follow SOPs for data QA.</td>
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<td><strong>D6:</strong> Manage contractual necessities relating to data</td>
<td>Recognize owners of data. Recognize when data agreements are necessary. Assemble the necessary parties to ensure that all agreements are in place (DUA, DTA, etc.)</td>
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**Data Management and Analytics**

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<td><strong>1:</strong> Identify examples of the elements of data flow in a sample protocol: data capture, storage, management, quality, and preparation for analysis. Define source documentation and ECRF.</td>
<td>Provide examples of the elements of data flow plan: data capture, storage, management, quality, and preparation for analysis.</td>
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<td><strong>2:</strong> Train others on study team in use of technologies and software, and in completion of ECRFs.</td>
<td>Detect issues related to data capture, collection or management; suggest solutions. Provide input into design of ECRFs and EDCs to collect data according to protocol.</td>
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<td><strong>3:</strong> Come up with solution to vulnerabilities related to security of data and data provenance.</td>
<td>Select methods of data capture and discuss advantages and disadvantages of each. Design ECRFs or EDCs.</td>
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<td><strong>4:</strong> Provide leadership to study team with regard to data security practices and data provenance</td>
<td>Provide leadership to study teams with regard to data security practices related to innovative technologies. Serve as a resource to others regarding data provenance.</td>
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<tr>
<td><strong>5:</strong> Design plan for flow of data over the course of a trial/study that include elements related to data capture, storage, management, quality, and preparation for analysis.</td>
<td>Serve as institutional resource on ECRFs, EDCs, technologies, and software to ensure highest quality data collection and capture.</td>
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</table>
Competency levels

D2: Employ appropriate data collection and capture methods

- Use EDCSs, technologies and software necessary for study operations with little assistance. Enter data accurately. Score tests and measures according to protocol. Complete ECRFs accurately and according to protocol.
- Train others on study team in use of technologies and software, and in completion of ECRFs.
- Detect issues related to data capture, collection or management; suggest solutions. Provide input into design of ECRFs and EDCs to collect data according to protocol.
- Select methods of data capture and discuss advantages and disadvantages of each. Design ECRFs or EDCSs.
- Serve as institutional resource on ECRFs, EDCSs, technologies, and software to ensure highest quality data collection and capture
## Competency Levels

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<td><strong>Clinical Research Specialist</strong></td>
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<td><strong>Clinical Research Specialist, Senior</strong></td>
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<td><strong>Regulatory Coordinator</strong></td>
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<td><strong>Regulatory Coordinator, Senior</strong></td>
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<td><strong>IRNC, Sr</strong></td>
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<td><strong>Research Program Leader</strong></td>
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<td><strong>Research Program Leader, Senior</strong></td>
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<td><strong>Assistant Research Practice Manager</strong></td>
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<tr>
<td><strong>Research Practice Manager</strong></td>
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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
Next steps

• Final JDs submitted for market analysis
• Draft “mapping” conducted with FAC teams
  – Teams submitted packet
  – Mock mapping by CRPWG members
  – CRU feedback of mock mapping
Timeline

• Spring 2016
  – Employees are mapped into new classification
  – New hires move into new classifications

• Summer 2016
  – Perform salary review for employees in new CRU classifications

• Fall 2016
  – Salary modifications effective
  – Tiers and associated assessments formalized
FAQs – visit the wiki

https://ori.duke.edu/wiki/display/DOCR/Clinical+Research+Professional+Working+Group
Clinical Research Appreciation for Faculty and Staff
Sponsored by the Duke Office of Clinical Research

Tuesday, October 6, 2015

11am - 2pm (drop in any time)
Trent Semans Center, Great Hall

information tables • raffle drawings • food and beverage

Open to all faculty and staff involved in clinical research at Duke

Don’t forget! Clinical Research Appreciation event on Tuesday, October 6th. Drop in anytime from 11-2!