RENOVATING A WORKFORCE: 
BRINGING JOB CLASSIFICATIONS 
TO THE 21ST CENTURY

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DISCLOSURES

Neither speaker has relevant financial relationships in connection with this educational activity.
OVERVIEW

• Describe how revitalizing and professionalizing the research workforce will help produce high quality clinical research
• Distinguish roles for clinical research staff
• Recognize the value-added to workforce performance consistency and standardization of job expectations by adopting competency-based job classifications
Within Duke University

Duke University Health System
- Duke University Hospital
- Duke Raleigh Hospital
- Hospital Durham Regional Hospital

Separate not-for-profit corporation

School of Medicine

School of Nursing

PDC (SoM faculty clinicians)
Separate for-profit LLC
Ease the navigation challenges through:

- Investigator support
- Study team training and development
- Process improvement

“One stop shop”

PROBLEM STATEMENT

• Need to professionalize the research workforce in order to continue to produce high quality clinical research.
  • Roles need to be:
    • well-articulated
    • competency-based
    • matched to experience and educational level
  • Job descriptions updated frequently
  • Career ladder and career progression are defined
WHY WE DO WHAT WE DO

For AMCs, research is a collaboration, not a service.
CHANGES AND CHALLENGES

• Job satisfaction/security levels were generally the same among CRCs, those at AMCs were significantly more likely to think their workload had increased in the past 3-5 years.

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

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

2015 CenterWatch-ACRP Career and Salary Survey: The Clinical Research Coordinator Perspective
Outlook is bleak for AMCs... Time to take action!
CLINICAL RESEARCH PROFESSIONALS WORKING GROUP (CRPWG)
VISION

- Develop clearer pathway for professional growth
- Develop leaders, create opportunity
- Enhance recruitment efforts to entice and retain the best and brightest
- Focus on creating a new workforce
- Be competitive with our peer institutions
- Consider new hiring models
COMPETENCY-BASED FRAMEWORK

Joint Task Force for Clinical Trials
Competency, 2014
**Research Operations**

<table>
<thead>
<tr>
<th>COMPETENCY</th>
<th>CRS</th>
<th>CRS, SR.</th>
<th>CRC</th>
<th>CRC, SR.</th>
<th>ARPM/RPM</th>
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<tbody>
<tr>
<td><strong>Screening for potential eligibility</strong></td>
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<tr>
<td>Identify participants that meet eligibility requirements under the supervision of a CRC/CNRC. Document in record.</td>
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<td>Screen participants for minimal risk studies. May screen participants for studies with greater than minimal risk, under supervision.</td>
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<td>Screen participants independently and provide oversight and training to study team members who screen participants.</td>
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<td>Provide oversight and training to entire unit or department with regards to subject screening. Set up unit-wide systems, policies related to subject screening.</td>
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<td><strong>Collection and management of specimens</strong></td>
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<td>Collect, prepare, process, ship, and maintain inventory of research specimens.</td>
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<tr>
<td>Collect, prepare, process, ship, and maintain inventory of research specimens and train others in these tasks.</td>
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<tr>
<td>Improve systems related to specimen handling. May collect, prepare, process, ship, and maintain inventory of research specimens and train others in these tasks.</td>
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<tr>
<td>Create, optimize, and oversee systems to collect, prepare, process, ship, and maintain inventory of research specimens and train others in these tasks.</td>
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<td>Create unit-wide (and collaborate to create institution-wide) policies and guidelines related to research specimens.</td>
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<td><strong>Preparation and conduct of study visits</strong></td>
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<tr>
<td>Schedule participants for study visits as directed. Prepare necessary documents, equipment, supplies, etc. Conduct and document visits and protocol-specific testing/interviews according to study protocol, operational plans of clinical departments, and Standard Operating Procedures (SOPs) for minimal risk studies or for other studies under direction. Follow procedures and documentation of study payment.</td>
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<td>Schedule participants and conduct visits for all studies independently.</td>
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<tr>
<td>Schedule participants and conduct visits for minimal risk studies independently.</td>
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<tr>
<td>May conduct study visits independently. Serve as a unit/departamental resource and train others regarding preparation and conduct of study visits, creation of SOPs, and in implementing operational plans. Make recommendations to enhance efficiencies of research studies.</td>
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<tr>
<td>Create unit-wide (and collaborate to create institution-wide) policies and guidelines regarding conduct of study visits.</td>
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- Competencies refined (CTSA, Duke)
- Created levels for each competency
- Assigned level # that is associated with job description
- Revised job descriptions (from ~80 to 10): now competency-based.
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
JOB CLASSIFICATION MODEL

- Regulatory Coordinator, Sr
- Clinical Research Nurse Coordinator, Sr
- Regulatory Coordinator
- Clinical Research Nurse Coordinator
- Asst. Research Practice Manager
- Clinical Research Coordinator, Sr
- Research Practice Manager
- Clinical Research Coordinator
- Research Program Leader, Sr
- Clinical Research Specialist, Sr
- Clinical Research Specialist

Denotes tiered position, requiring competency assessment for advancement
• No more than 3 tiers
• Associated with higher competency in domains
• Competencies assessed by managers trained according to competency domains, standardized assessments
• Annual review opportunity for tier movement in fall (Nov 1) – aligned with manager support
• Compensation tied to tier advancement
NOW WE MAP

.... BUT WHAT IS MAPPING?
HOW DID IT WORK?

• Each manager reviewed employee list for their unit
• Employees prepare CV; manager highlight relevant experience
• Manager sent all CVs & unit’s organizational chart
• Employee received email with REDCap™ link to complete the job responsibility tool
• Manager reviews responses from each employee and updates tool as needed.
• Submit to CRPWG upon completion; summary report generated
Employee completes REDCap™ tool; routed to manager for review/updates
## SAMPLE SUMMARY REPORT

**Name:**

**Unit:**

**Current title:**

**Manager:**

### Overall competency levels (Manager report trumps employee report):

| Operations | 3.2 |
| Ethics     | 2.3 |
| Data       | 2.2 |
| Sci Concepts | 0   |
| Leadership | 2.125 |
| Site/Study Mgmt | 2.875 |
| Commun     | 1   |

Discrepancy magnitude (positive number means employee believes higher competency): -1

### Top 5 responsibilities:

<table>
<thead>
<tr>
<th>Screening</th>
<th>Study visits</th>
<th>Informed consent</th>
<th>Data collection</th>
<th>IRB</th>
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### Competency detail

<table>
<thead>
<tr>
<th>Competency</th>
<th>screen</th>
<th>subdoc</th>
<th>visits</th>
<th>spec</th>
<th>IP</th>
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**Summary report** provides view of “raw” data as updated by manager; competency detail maps to job description listing the associated with the competency level (e.g., CRC = 3);

- Used combination of top 5 responsibilities and competencies deemed “key” for the role
NEXT STEPS FOR COMMITTEE

• Reviewed summary reports and CV
• Compared competency levels with new job classifications (take into account top 5 job responsibilities)
• Mapped to best fit, comment as appropriate on forms when questions emerge
• Communicate back to manager with results and/or questions
• Discrepancies—meetings held for adjudication
RESULTS OF MAPPING

- Research Program Leader
- Regulatory Coordinator
- Clinical Research Nurse Coordinator
- Clinical Research Coordinator
- Clinical Research Specialist

PROCESS FOR MAPPING (CONT.)

RESULTS OF MAPPING

<table>
<thead>
<tr>
<th>Role</th>
<th>Tiered/Base</th>
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</thead>
<tbody>
<tr>
<td>Research Program Leader</td>
<td>50</td>
</tr>
<tr>
<td>Regulatory Coordinator</td>
<td>40</td>
</tr>
<tr>
<td>Clinical Research Nurse Coordinator</td>
<td>100</td>
</tr>
<tr>
<td>Clinical Research Coordinator</td>
<td>275</td>
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<tr>
<td>Clinical Research Specialist</td>
<td>15</td>
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</tbody>
</table>

Legend: Senior | Tiered/Base
Turn our current workforce pyramid upside down = better qualified workforce!
KEYS TO SUCCESS

• Central office coordination
• Leadership committee & governance
• Stakeholder engagement
• Communication plan
  • Multi-modal: memos, presentations, town hall Q&As, wiki, newsletters
  • Include staff, faculty, business managers, HR
KEYS TO SUCCESS (CONTINUED)

• Transparency of process
• Pilot mapping conducted with 10 faculty
• Incorporated feedback (SLE, pilot, sessions)
• Trained Managers
• Tracking
VALUE ADD TO WORKFORCE

• Consistent (and transparent!) standards:
  • for performance
  • for job expectations
• Aligned with clinical research workforce initiatives elsewhere
LESSONS LEARNED & CHALLENGES

- Engage and communicate 1) multiple stakeholders 2) governance, 3) faculty
- Workgroup 1) dedicated effort to commit and 2) paid staff to coordinate
- All units did not operate the same – exhibit flexibility
- Financial impact can be substantial
- Process can be improved – wording of competencies, specificity in levels
- Time consuming, but worthwhile… and just the start
• New salary ranges need to be approved before you can post the new job classifications
• Financial impact can be substantial
• Large-scale mapping is time consuming – dedicated FTE
• Expect pushback, listen and incorporate where possible
• Consistent message tailored to stakeholders
• Over communication is not possible
RESEARCH PROFESSIONALS NETWORK

• Provide opportunities for career advancement
• Leverage expertise of clinical research professionals across Duke
• Create strong research community
• Foster resource sharing and best practices
THANK YOU!

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