Professionalizing Academic Health Center Research Coordinators

Nancy A. Needler BS, CCRC, Sylvia Baedorf Kassis, MPH, Eric P. Rubinstein JD, MPH, and Lisa A. Speicher, PhD
On Behalf of the CTSA Research Coordinator Workgroup

Research Coordinator Workgroup

Mission: Within the Regulatory Knowledge Key Function Committee, the Research Coordinator Workgroup's mission is to support the professional development of clinical research coordinators (CRCs) and to help guide institutions in how to organize and network their CRC workforce.

The Workgroup created 3 subgroups to focus on specific aspects:

Network Models	• **Goal** To identify models for organizing CRCs at the institutional level.
Job Descriptions	• **Goal** To create standardized job description templates that individual institutions might adapt for local use.
Education &Training	• **Goal** To identify the range of activities performed by research coordinators in contribution to study management.

Background

Historically, academic health centers (AHCs) have had a wide range of practices for the hiring, training and advancing of clinical research coordinators (CRCs). This poster outlines the activities of the Network Models subgroup, and presents the work products of the Job Descriptions and Education & Training subgroups.

Network Models

Process: Developed a survey to capture institutional approaches for bi-directional communication with and services provided to research coordinators, to facilitate collaboration, training and education. Secured IRB and CTSA Consortium Executive Committee approval to field the survey.

Next Steps:

- Distribute *CTSA Network Models Survey* for data collection
- Analyze data
- Develop dissemination plan for:
  - Relevant findings
  - Identified network models
  - Recommendations for institutional consideration

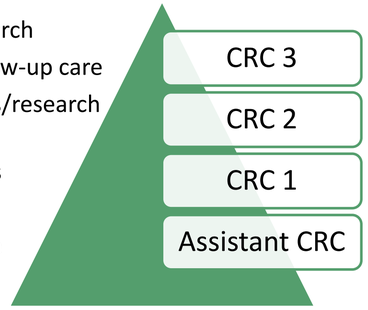
Job Descriptions

Process: Sample job descriptions from represented CTSA-funded AHCs were gathered, and the group assessed key components.

Products: A defined series of four job description templates, reflecting minimum qualifications and establishing a clear pathway for professional growth and advancement of research coordinators.

Core Responsibilities for all CRCs Regardless of Level

- Adhere to an IRB-approved protocol
- Participate in the informed consent process of study subjects
- Support the safety of clinical research patients/research participants
- Coordinate protocol-related research procedures, study visits, and follow-up care
- Screen, recruit and enroll patients/research participants
- Maintain study source documents
- Report adverse events
- Understand Good Clinical Practice and regulatory compliance
- Educate subjects/research participants and family on protocol, study intervention, study drug, etc.
- Comply with institutional policies, standard operating procedures and guidelines
- Comply with federal, state, and sponsor policies



Increasing levels correspond with expectations of increasingly complex additional responsibilities (detailed in available template).

Next Steps:

- Disseminate templates throughout the CTSA consortium to encourage institutions to adapt and use
- Share experiences with institutional adaptation for local use to learn from each other how best to facilitate adoption
- Produce manuscript to broadly share with Consortium and beyond

Documents and templates are available on the CTSAcentral.org, Regulatory Knowledge Key Function Committee webpage.

Education & Training

Process: Utilized the data collected through the *Clinical Research Coordinator Survey* disseminated by the Workgroup in 2008* and identified additional tasks performed by research staff. A comprehensive list was developed and mapped to the lifecycle of study management.

Products:

1. A comprehensive document, providing content areas typically relevant for research coordination.
2. A document listing useful references for training research staff.

Next Step:

Disseminate both lists throughout the Consortium to be used as the basis for institutional training programs for research coordinators and other research management staff, to ensure proper orientation to the related activities, before engaging human subjects in research.

*Speicher LA et al.: The Critical Need for Academic Health Centers to Assess the Training, Support, and Career Development Requirements of Clinical Research Coordinators: Recommendations from the Clinical and Translational Science Award Research Coordinator Taskforce. Clin Trans Sci 5(6):470-475, 2012

Recommendations

- Adapt standardized job descriptions
- Establish a career ladder
- Assess content of training programs and enhance as needed to ensure adequacy
- Consider enhancement of CRC networking infrastructure

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