Associates and Coordinators Perspective: Roles and Responsibilities in Research

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Outline of Topics

I. Review evolution of CRC/CRA role
II. Examine CRC/CRA roles and responsibilities
III. Discuss training backgrounds and certifications
IV. Resources and References
V. Questions
Learning Objectives

I. Describe responsibilities, skills of CRC/RAs
II. Explain role of CRC/RAs in the following areas of protocol implementation:
   I. regulatory compliance
   II. data collection & management
   III. patient participation
   IV. logistical support
III. Illustrate information resources and training opportunities for CRCs
What is a Research Coordinator?

Clinical Research Coordinators (CRC) and Assistants/Analysts (CRA) are essential members of a research team.

- Implement research protocol
- Support investigator
- Diverse training backgrounds
- Evolving, dynamic role
The role of the CRC has changed significantly over the past few decades.

- Trends in Research
- Emergence of Occupational Group
- Clinical Research Enterprise
I. Trends in Clinical Research

- Consumer Demand
- Clinical Research Sponsorship
- Industry and Federal Investment
- 129,000 Registered Clinical Trials
Meeting the Increased Demand

- Complex Protocols
- Capacity Building
- Participant Recruitment and Retention
- Regulatory Compliance
Research Enterprise
Emergence of Occupational Group

Institutions and research benefit from CRCs “niche” set of expertise and experience in protocol implementation:

- Assume broad scope of duties, when appropriate
- Understand complex protocol
- Navigate regulatory requirements
- Overcome recruitment and retention challenges
- Facet of institutional capacity to conduct research
II. Clinical Research Coordinator

- PI
- Study Subjects
- Sponsor
- Ancillary Services
- Clinic Staff
- IRB
- Site Administration
- CRC
Principal Investigator

- Protocol Review and Logistics
- Project Planning
- Participant Management
- Adverse Event Manager
- Regular Communication
Research Subjects

• Screening and Enrollment
• Informed Consent
• Study Visit Coordination
• Adverse Event Management
• Source Document
• Data Management
• Advocate
Sponsor

- Study Start Up/Close-out visits
- Maintaining Regulatory Files
- Site Monitoring Visits
- Case Report Forms
  - Protocol Deviation Reporting
  - Adverse Event Reporting
Ancillary Services

• Laboratory
• Pharmacy
• Specialists
• Radiology
• Registration
• Clinical Research Center
• Other teams within the Institution
Research Staff

- Training CRA
- Supervision support
- Protocol adherence
- SOP adherence
Site Administration

- Budget
- Purchasing
- Admin/Clerical Support
- Space/Calendar Management
- Team Check-in
- Calendar
Institutional Review Board

- Protocol Approval
- Adverse Event Reporting
- Protocol Deviation Reporting
- Amendments
- Continuing Review
- Ethical Conduct of Research
Supporting Role of CRC

Key Points:

• PI is the official leader of the research team
• PI is ultimately responsible per ICH-GCP
• PI can delegate responsibilities to CRC
• PI involvement is required for study success
• PI must ensure and prioritize patient safety and ethical conduct of research
• Checks and Balances
Variation in Responsibilities

- Multi-site trial vs. Investigator-Initiated
- Observational vs. Intervention
- CRC educational background
  - Study Nurse
  - Non-licensed
- Professional experiences
- Relationship with Investigator
III. Training

- CNMC and Institutional Requirements
- On-the-job training
  - Investigator supervised certification process
  - Observing research team
  - Documenting, renewing certification
- Training Modules
  - CITI, ICH-GCP Guidelines
  - NIH Information Security
Training and Development

• Monthly CNMC Coordinator Meetings
• CTSI Training Modules
• Annual NIH Course in Clinical Research
• Professional Certifications
  – SOCRA
  – Association of Clinical Research Professionals
# Other Training Resources

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Don’t go off the rails on a crazy train

Suggestions for staying on track:

• Do seek answers to questions, don’t “assume”
• Do practice SBAR (Situation, Background, Assessment, Recommendation)
• Do involve research subject advocate, OPHS, etc.
• Do take advantage of professional development
• Do get 8 hours of sleep
# Citations & References

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<td>Responsible Research: A Guide for Coordinators</td>
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