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.

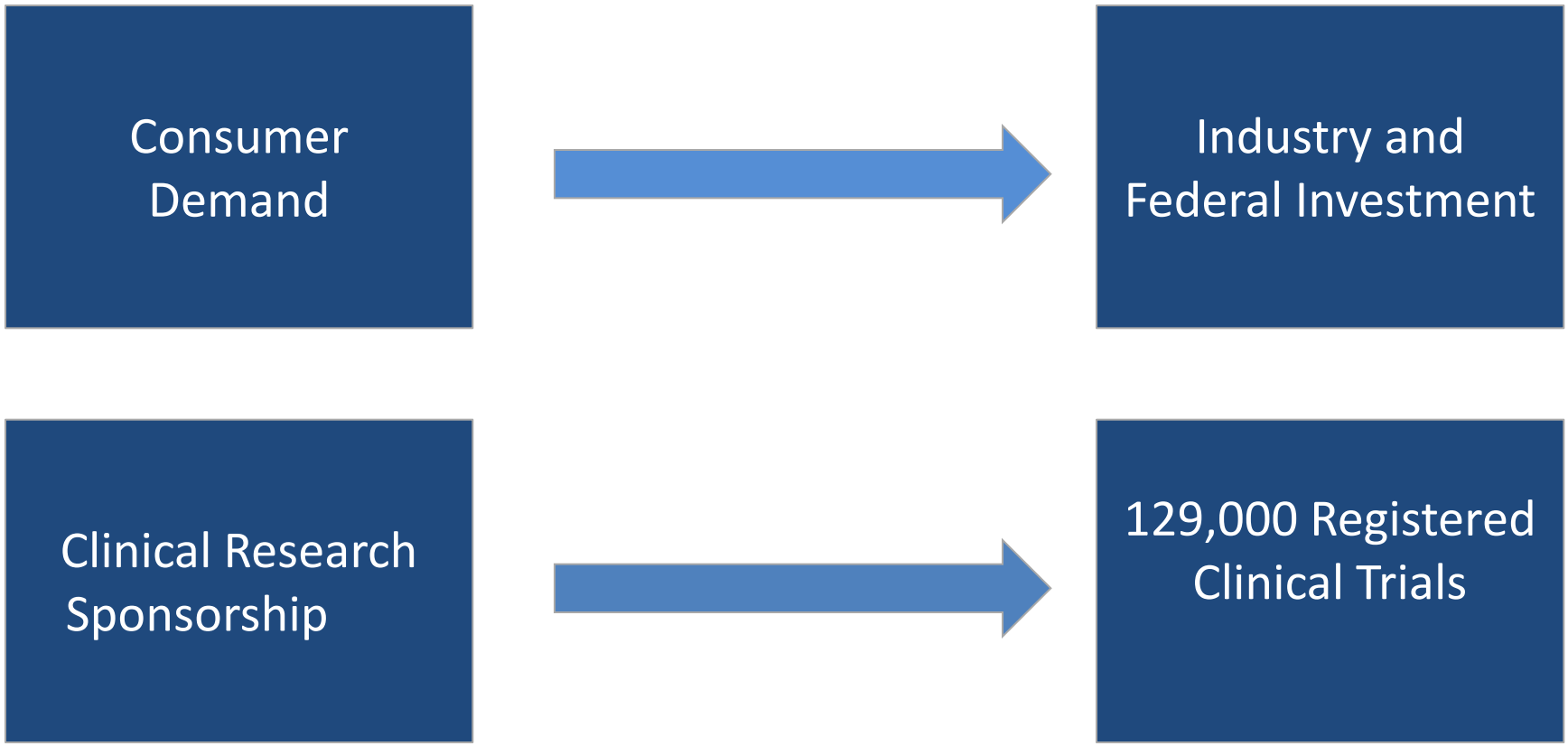
- Implement research protocol
- Support investigator
- Diverse training backgrounds
- Evolving, dynamic role

I. Evolution of CRC/CRA 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



Meeting the Increased Demand

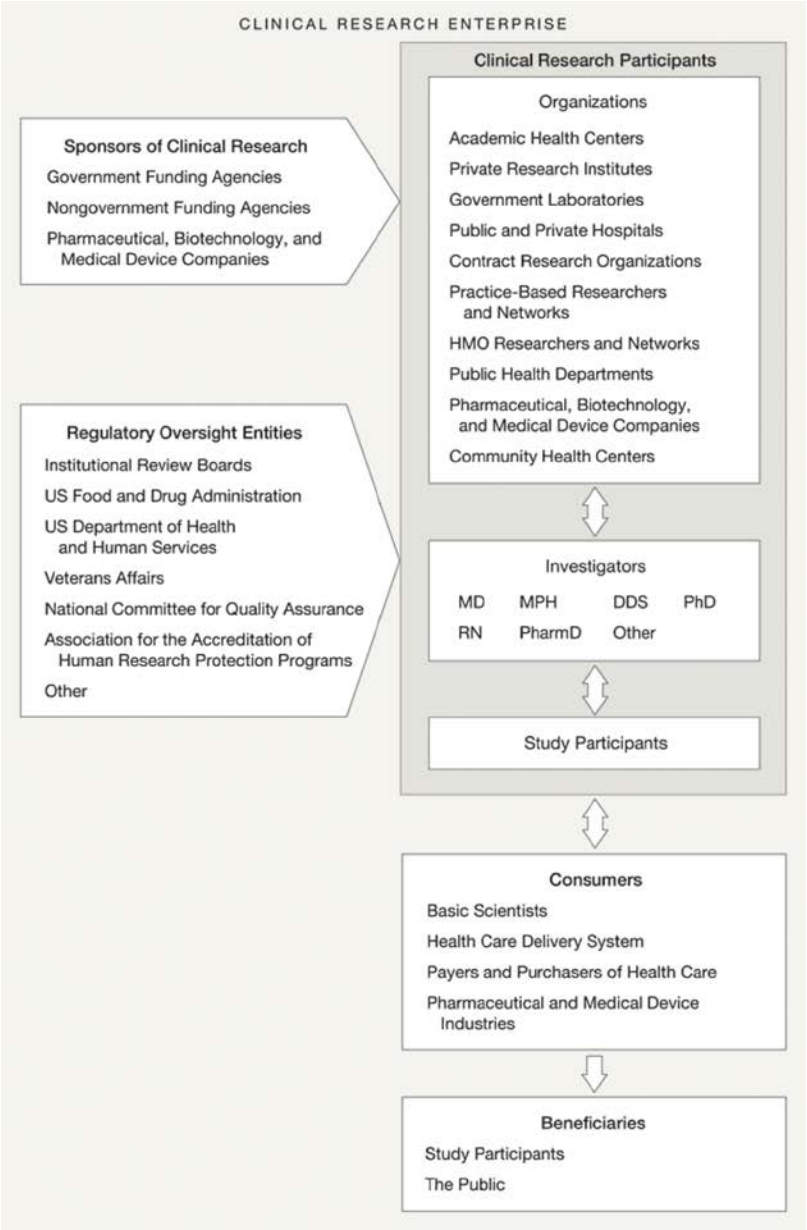
Complex Protocols

Capacity Building

Participant Recruitment and Retention

Regulatory Compliance

Research Enterprise

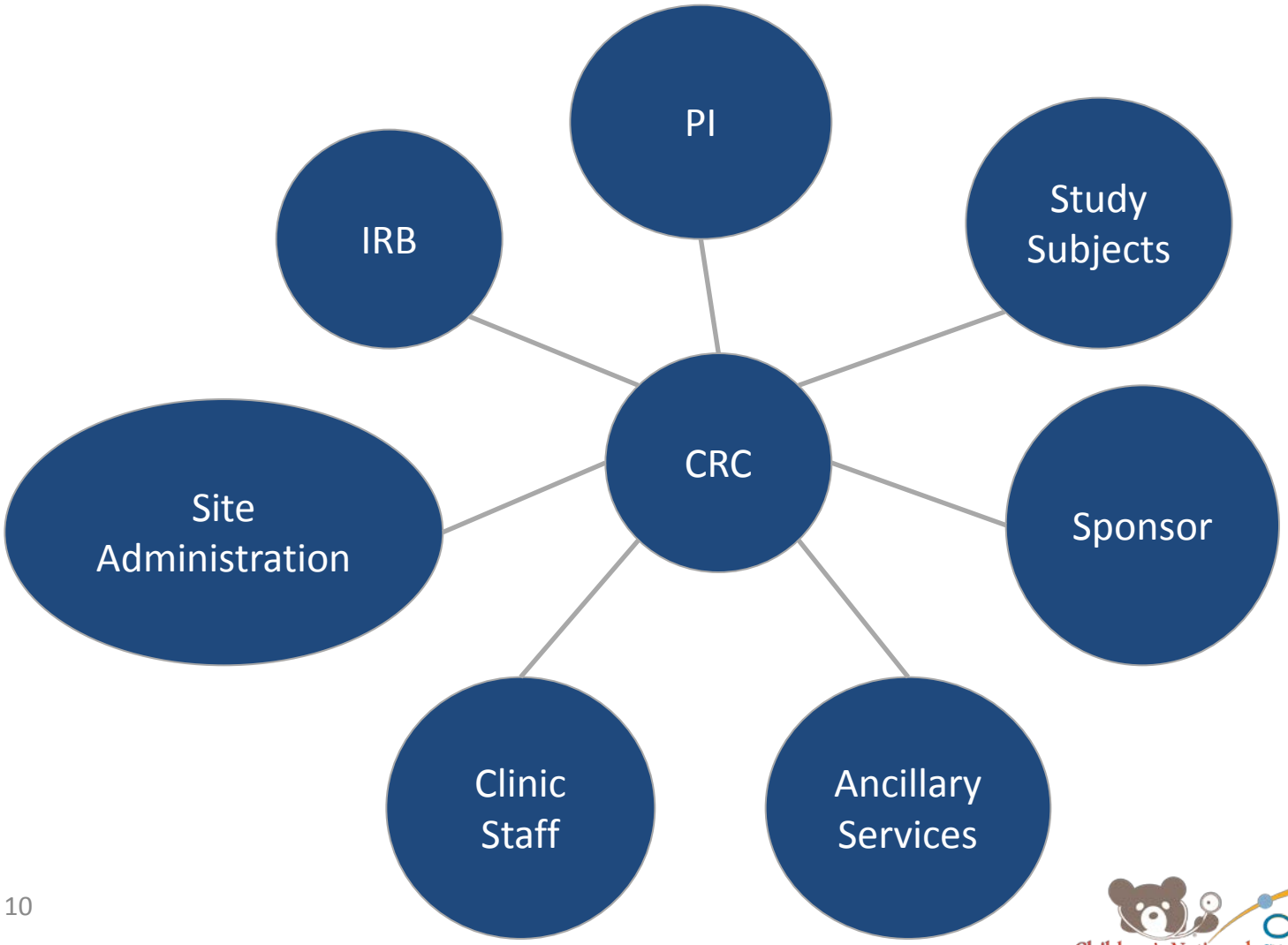


Emergence of Occupational Group

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



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

Web Site	Address
FDA	www.fda.gov
ICH Guidelines	www.ich.org
NIH Online	www.NIH.gov
OHRP	http://ohrp.osophs.dhhs.gov
Code of Federal Regulations	www.access.gpo/gov

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

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CTSI CN Clinical and Translational Science Institute at Children’s National
THE GEORGE WASHINGTON UNIVERSITY MEDICAL CENTER WASHINGTON DC

Citations & References

Reference
Responsible Research: A Guide for Coordinators
https://www.dcri.org/trial-participation/KeysBuildingSuccessfulResearchSite.pdf