The Experienced Clinical Research Coordinator (CRC) or Project Manager (PM)

Who: CRC II, Sr. CRC, Project Manager, Sr. Project Manager

This track targets the experienced CRC with more than 2 years of experience. These individuals will have a fair understanding of MGH policies and procedures, are very familiar with the conduct of clinical trials, possess adequate understanding of GCP's and are able to apply to current practice. This track focuses on the administrative processes behind the implementation and conduct of clinical trials.

CRC II Responsibilities
(in addition to CRC I Responsibilities)

- Maintains research data, patient files, regulatory binders and study databases
- Performs analysis and QA/QC data checks
- Organizes and interprets data
- Develops/implements recruitment strategies
- Acts as study resource for patient and family
- Monitors and evaluates data
- Administers/scores/evaluates study questionnaires
- May contribute to protocol recommendations
- Assists with preparation for annual review
- May assist PI to prepare study reports

Sr. CRC Responsibilities
(in addition to CRC II Responsibilities)

- Recommends protocol changes and may assist with writing protocols and manuscripts
- Plans, performs and designs statistical analyses
- Responsible for quality control
- Designs research protocols in conjunction with PI
- Files adverse events with IRB
- May develop systems for QA/QC
- Independently judges suitability of research subjects
- Coordinates lab activities
- Develops study budgets
- May assume grant management responsibilities
- Acts as liaison between Research Affairs and Unit
- Reviews work of trainees

***Note: Job descriptions per MGH Human Resources. Job responsibilities may vary*

Project Manager Responsibilities
(in addition to Sr. CRC Responsibilities)

- Writes operations manuals
- Prepares Case Report Forms
- Edits manuscripts
- Supervises operations of all study staff
- Resource for patients and staff
- Monitors drug accountability logs
- Oversees all study meeting plans
- Coordinates multi-center trials with NIH, FDA and private foundations
- Attends conferences
- Reports study progress at investigators' meetings
- Takes minutes at central meetings/conference calls and disburses information to investigators/sponsor

Sr. Project Manager Responsibilities
(in addition to PM Responsibilities)

- Develops detailed protocol documents that meet federal/institutional standards
- Ensures study design's compatibility with clinical practices
- Provides critical input as to feasibility of study design and available resources
- Ensures document consistency
- Conducts on and off-site training sessions to appropriate audiences
- Attends meetings and scientific conferences
- May be responsible for developing/managing the clinical trial's operating and capital budgets
- Coordinates and implements research design process at multiple sites

***Note: Job descriptions per MGH Human Resources. Job responsibilities may vary*

Suggested courses for skill development (you may have completed some of these courses)

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- ☐ Good Clinical Practice in Research at an Academic Research Institution *(If not taken already)*
- ☐ Basic Biostatistics
- ☐ Applied Biostatistics
- ☐ Introduction to R Statistical Software
- ☐ R Users Working Group
- ☐ Budgeting for Industry Sponsored Clinical Research
- ☐ Clinical Trial Billing Series and Epic Charge Review and Insight Patient Care Corrections Workshop
- ☐ IRB Issues for the Bench and Desk Scientist
- ☐ What Does the IRB Really Want? How to Write a Human Studies Protocol
- ☐ CT.gov: Introduction, Registration and Results Reporting
- ☐ Maintaining Research Subject Privacy and Information Security
- ☐ IRB: New Protocol Submissions
- ☐ IRB: Consent Form Writing
- ☐ IRB: Amendments and Reporting
- ☐ IRB: Continuing Review
- ☐ QI Bootcamp: What is the QI Program? How can they help me?
- ☐ QI Bootcamp: Informed Consent Process
- ☐ QI Bootcamp: Study Documentation
- ☐ QI Bootcamp: Unanticipated Problems, Adverse Events and Deviation/Violations
- ☐ QI Bootcamp: Investigational Product Accountability and Storage (drug and device)
- ☐ QI Bootcamp: Starting and Maintaining a Regulatory Binder
- ☐ QI Bootcamp: Potpourri of Regulatory Issues (ct.gov, audit readiness etc.)
- ☐ Clinical Research Skills Intermediate Module: Study Monitoring: Preparing for a visit

Suggested courses for skill development (you may have completed some of these courses)

- ☐ Clinical Research Skills Intermediate Module: Transitioning a study: What to do when you inherit a study
- ☐ Clinical Research Skills Intermediate Module: Managing up! How to work effectively with your PI
- ☐ Clinical Research Skills Intermediate Module: Developing a strategy for IRB submission
- ☐ Clinical Research Skills Intermediate Module: Monitoring the budget, invoicing and tracking payments
- ☐ Clinical Research Skills Intermediate Module: Creating CRFs for study visits
- ☐ Clinical Research Skills Advanced Module: How to Manage Multiple Studies
- ☐ Clinical Research Skills Advanced Module: Checklists to Manage Projects during the Start-up Stage
- ☐ Clinical Research Skills Advanced Module: Managing PI-initiated Studies
- ☐ Clinical Research Skills Advanced Module: How to Write Study-related SOPs
- ☐ Clinical Research Skills Advanced Module: Training a New Hire: What happens in the first 2 weeks
- ☐ Clinical Research Skills Advanced Module: Personalizing Recruitment Programs
- ☐ Monthly Spotlight Series (8-10 sessions)*, i.e. Research Match, E6 Revisions
- ☐ Communicating Science Program: The Art of a Scientific Presentation (online)
- ☐ Communicating Science Program: What makes a Good Article? Critical Appraisal of Scientific Literature
- ☐ Communicating Science Program: Basics of Manuscript Writing for Clinical Researchers (online)
- ☐ Communicating Science Program: Writing a Scientific Abstract (online)
- ☐ Communicating Science Program: Drafting a Poster (online)

If applicable:

- ☐ SOCRA Certification Exam (annually) (at least 2 years of clinical research experience)
- ☐ Electronic Data Capture: RedCap and StudyTrax
- ☐ RedCap: Basic and Advanced Programming
- ☐ Introduction to the Research Patient Data Registry (RPDR) (online through Healthstream)
- ☐ RPDR Advanced Training

- ☐ Welcome to the Genetic Code: An Overview of Basic Genetics
- ☐ Genetic Literacy: Understanding Concepts of Modern Genetic Research
- ☐ Responsible Conduct of 'Omics' Research
- ☐ Introduction to Bioinformatics: Next Generation Sequencing
- ☐ A Primer on Complex Trait Genetics: Principles for the Beginning Investigator
- ☐ Community Access, Recruitment, and Engagement (CARE) Seminar
- ☐ Introduction to Qualitative Research Design and Methodology- Research Assistant Section
- ☐ Applied Methods in Survey Research & Design
- ☐ Introduction to Bioinformatics of Next-Generation Sequencing
- ☐ Recent FDA Inspections at MGH: Observations, Citations, and Lessons Learned
- ☐ Developing a Peer Review Program (online through Healthstream)
- ☐ Best Practices for Conducting Study-related Home Visits (online through Healthstream)