The Beginner Research Assistant/Coordinator

Who: Clinical Research Assistant (CRA), CRC I

This track was designed for the CRA/CRC I with less than 2 years of clinical research experience. Individuals may be new to clinical research or to MGH with limited knowledge of clinical trial conduct, good clinical practices, regulations and common terminology associated with clinical research.

CRA Responsibilities

- Good communication skills
- Knowledge of clinical research protocols
- Collects and organizes patient data
- Maintains records and databases
- Assists with recruiting patients for trials
- Uses software programs to generate graphs and reports
- Conducts library searches
- Obtains patient study data from medical records, physicians
- Performs administrative support duties as required

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

CRC I Responsibilities
(in addition to CRA Responsibilities)

- Ability to demonstrate respect and professionalism for subjects' rights and individual needs
- Verifies accuracy of study forms
- Updates study forms per protocol
- Prepares data for analysis and data entry
- Assists with formal audits of data
- Verifies subject inclusion/exclusion criteria
- Documents patient visits and procedures
- Performs study procedures such as phlebotomy, vitals, EKG
- Assists with interviewing study subjects
- Administers and scores questionnaires
- Provides basic explanation of study and in some cases obtains informed consent from subjects
- Assists with regulatory binders and QA/QI
- Assists with study regulatory submissions
- Writes consent forms

Suggested courses for skill development:

- ☐ MGH DCR Clinical Research Study Staff Orientation Manual (online through Healthstream)
- ☐ Clinical Research Conduct: Training for Research Staff at MGH (online through Healthstream)
- ☐ CITI (online through Partners Navigator website)
- ☐ IATA Shipping Training for Transportation of Biological Materials and Dry Ice (online through DCR)
- ☐ MGH DCR Insight eIRB Training (online through Healthstream)
- ☐ eIRB Computer Based Training Modules (monthly in computer lab)
- ☐ Good Clinical Practice in Research at an Academic Research Institution
- ☐ Ethics and Clinical Research

- ☐ 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.)
- ☐ Maintaining Research Subject Privacy and Information Security
- ☐ Recruitment and Retention
- ☐ Subject Remuneration: Partners Policy
- ☐ Community Access, Recruitment and Engagement for study staff
- ☐ Conducting Out of Hospital Research Visits (online)
- ☐ Monthly Spotlight Series (8-10 sessions)*, i.e. Research Match, E6 Revisions
- ☐ Clinical Skills Training: Phlebotomy
- ☐ Clinical Skills Training: Vital signs
- ☐ Clinical Skills Training: EKG
- ☐ Clinical Research Skills Beginner Module: I'm new – what should I know?
- ☐ Clinical Research Skills Beginner Module: How to read a clinical research protocol

- ☐ Clinical Research Skills Beginner Module: Essential Documents: What are they? What do they mean?
- ☐ Clinical Research Skills Beginner Module: Informed consent: The speed dating of clinical research
- ☐ Clinical Research Skills Beginner Module: Effective communication with your PI and study staff
- ☐ Clinical Research Skills Beginner Module: Making connections: Essential patient outreach skills
- ☐ Clinical Research Skills Intermediate Module: Study Monitoring: Preparing for a visit
- ☐ 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 Case Report Forms to help study visits run smoothly and per protocol