The Beginner Research Assistant/Coordinator (CRC) Track – Basic Level

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

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

***Note: Job descriptions per MGH Human Resources. Depending on the study there may be overlap of responsibilities of a CRA and CRC I.*

MGH Clinical Research Program Education Unit (CREU): https://hub.partners.org/crp/

Please contact the CREU if you have an idea for a course that is not already offered - (sgrabert@partners.org).

Suggested courses for basic skill development:	Date Completed
☐ CITI (**mandatory**, online through PHRC website)	__ __/__ __/__ __
☐ IRB HIPAA Training (**mandatory**, online)	__ __/__ __/__ __
☐ Introduction to Clinical Research (online)	__ __/__ __/__ __
☐ Infection Control Principles and Practice in Clinical Research (**mandatory**, online)	__ __/__ __/__ __
☐ Overview of the Core Clinical Research Lab @ MGH (online) *Launch Winter 2013*	__ __/__ __/__ __
☐ IATA Shipping Training for Transportation of Biological Materials and Dry Ice (**mandatory**, online)	__ __/__ __/__ __
☐ Good Clinical Practice and Study Management Basics (online)	__ __/__ __/__ __
☐ Submitting your Medical Records/Health Information Research Protocol to the IRB (online)	__ __/__ __/__ __
☐ Recruitment and Retention Series (online) *Launch Fall 2012*	__ __/__ __/__ __
☐ eIRB Computer Based Training Modules (online, monthly in computer lab)	__ __/__ __/__ __
☐ Clinical Skills Training: Phlebotomy (monthly, more often in Spring and Summer)	__ __/__ __/__ __
☐ Clinical Skills Training: Vital signs (monthly)	__ __/__ __/__ __
☐ Clinical Skills Training: EKG (monthly)	__ __/__ __/__ __
☐ Luncheon Seminar Series – Hot topics in Clinical Research (monthly)	__ __/__ __/__ __
☐ An Overview of the Monitor Online Record Access System (MORA) (monthly, computer lab)	__ __/__ __/__ __
☐ IRB and QI Roundtable: IRB New Protocol Submissions (quarterly, not offered in Summer)	__ __/__ __/__ __
☐ IRB and QI Roundtable: QI New Protocol Submissions (quarterly, not offered in Summer)	__ __/__ __/__ __
☐ IRB and QI Roundtable: IRB Amendments and Reporting (quarterly, not offered in Summer)	__ __/__ __/__ __
☐ IRB and QI Roundtable: QI Protocol Adherence and Reporting (quarterly, not offered in Summer)	__ __/__ __/__ __
☐ IRB and QI Roundtable: IRB Continuing Review (quarterly, not offered in Summer)	__ __/__ __/__ __
☐ IRB and QI Roundtable: QI Source Documentation (quarterly, not offered in Summer)	__ __/__ __/__ __

Suggested courses for basic skill development:	Date Completed
☐ IRB and QI Roundtable: IRB Consent Form Writing (quarterly, not offered in Summer)	__ __/__ __/__ __
☐ IRB and QI Roundtable: QI Informed Consent Process (quarterly, not offered in Summer)	__ __/__ __/__ __
☐ IRB Hot Topics (quarterly, not offered in Summer)	__ __/__ __/__ __
☐ Issues for the Bench and Desk Scientist (Fall)	__ __/__ __/__ __
☐ Who Tells the IRB What to Do?: The Effects of Case Law on Regulations and Oversight (Fall)	__ __/__ __/__ __
☐ Meet the PHRC Protocol Administrators (Fall)	__ __/__ __/__ __
☐ Recruitment and Retention Series (Fall, live sessions and workshop)	__ __/__ __/__ __
☐ Maintaining Research Subject Privacy and Information Security (Spring)	__ __/__ __/__ __

If applicable:	Date Completed
☐ An Overview of REDCap: Data Management and Survey Tool (online)	__ __/__ __/__ __
☐ Introduction to the Research Patient Data Registry (RPDR) (online)	__ __/__ __/__ __
☐ Research Nurse Roundtable (monthly)	__ __/__ __/__ __
☐ REDCap Training Sessions: Basic Programming (TBD, computer lab) *TBD: To be determined*	__ __/__ __/__ __

The Experienced Clinical Research Coordinator (CRC) Track – Intermediate Level

Who:

- CRC II
- Sr. CRC

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.

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. Depending on the study there may be overlap of responsibilities of a CRC I and CRC II, as well as, a CRC II and Sr. CRC.*

MGH Clinical Research Program Education Unit (CREU): https://hub.partners.org/crp/

Please contact the CREU if you have an idea for a course that is not already offered - (sgrabert@partners.org).

Suggested courses for intermediate skill development:	Date Completed
☐ Clinical Research Resources at MGH: Orientation (April, June, August, October) *(If new to MGH)*	__ __/__ __/__ __
☐ Luncheon Seminar Series – Hot topics in Clinical Research (monthly)	__ __/__ __/__ __
☐ IRB Hot Topics (quarterly)	__ __/__ __/__ __
☐ What Does the IRB Want? How to Write a Human Subjects Protocol (Fall)	__ __/__ __/__ __
☐ FDA Inspections, 483's and Warning Letters: How to Avoid and Survive Them (Fall 2013)	__ __/__ __/__ __
☐ Genetics and Clinical Research: Points to Consider (Fall)	__ __/__ __/__ __
☐ Incidental Findings (Fall 2013)	__ __/__ __/__ __
☐ Basic Biostatistics (Winter)	__ __/__ __/__ __
☐ Problem Based Biostatistics (Winter)	__ __/__ __/__ __
☐ QI and FDA Audits (Winter)	__ __/__ __/__ __
☐ Budgeting, Invoicing and Tracking Expenses for Industry Sponsored Clinical Research (Winter/Summer)	__ __/__ __/__ __
☐ ClinicalTrials.gov: The Rules and How Partners is Implementing them (Winter)	__ __/__ __/__ __
☐ ClinicalTrials.gov: Does Your Study Need Results Reporting? (Winter)	__ __/__ __/__ __
☐ Applied Biostatistics (Spring)	__ __/__ __/__ __
☐ The Principles and Practice of Clinical Research Data Management (Spring)	__ __/__ __/__ __
☐ Results Reporting: Should Subjects be Told Clinical Research Results (Spring)	__ __/__ __/__ __
☐ Good Clinical Practices (Spring, 2-day course)	__ __/__ __/__ __
☐ Clinical Trial Billing: Subject Remuneration and eCheck (LSS, Summer)	__ __/__ __/__ __

If applicable:	Date Completed
☐ Research Nurse Roundtable (monthly)	__ __/__ __/__ __
☐ RedCap: Advanced Programming (various times)	__ __/__ __/__ __
☐ RPDR Advanced Training (various times)	__ __/__ __/__ __
☐ Welcome to the Genetic Code: An Overview of Basic Genetics (Winter)	__ __/__ __/__ __
☐ Genetic Literacy: Understanding Concepts of Modern Genetic Research (Spring)	__ __/__ __/__ __

Project Management Track – Advanced Level

Who:

- Project Manager
- Sr. Project Manager

This track focuses on the administrative processes behind the implementation and conduct of clinical trials.

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. Depending on the study there may be overlap of responsibilities of a Sr. CRC and PM as well as, a PM and Sr. PM.*

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Suggested courses for advanced skill development:	Date Completed
☐ Clinical Research Resources at MGH: Orientation (April, June, August, October) *(If new to MGH)*	__ __/__ __/__ __
☐ Scientific Writing (online)	__ __/__ __/__ __
☐ Critiquing an Article (online) *Launch Spring 2013*	__ __/__ __/__ __
☐ Clinical Trial Billing: Patient Care Charges and Directing Charges to Research Funds (Recorded)	__ __/__ __/__ __
☐ Clinical Trial Billing: Monitoring, Invoicing and Corrections (Recorded)	__ __/__ __/__ __
☐ Clinical Trial Billing: Investigational/Approved Devices with PMA or 510K Numbers (Recorded)	__ __/__ __/__ __
☐ Luncheon Seminar Series – Hot topics in Clinical Research (monthly)	__ __/__ __/__ __
☐ IRB Hot Topics (quarterly)	__ __/__ __/__ __
☐ How to Make a Poster (Fall)	__ __/__ __/__ __
☐ Operationalizing a Protocol (Winter)	__ __/__ __/__ __
☐ How to Give a Presentation (Winter)	__ __/__ __/__ __
☐ Understanding and Writing Clinical Research Literature (Winter)	__ __/__ __/__ __
☐ Sponsoring and Managing Multicenter Clinical Trials (Summer)	__ __/__ __/__ __

If applicable:	Date Completed
☐ Research Nurse Roundtable (monthly)	__ __/__ __/__ __
☐ Survey Design Series (Winter)	__ __/__ __/__ __
☐ Adding Pharmacogenomics to a Clinical Trials (Winter)	__ __/__ __/__ __
☐ A Primer on Complex Trait Genetics: Principles for the Clinical Investigator (Summer)	__ __/__ __/__ __