

BRIGHAM AND WOMEN'S HOSPITAL

Job Title: Clinical Research Coordinator I for BWH Mastocytosis Center

Date: 11/16/2025

Job Code: 00950R

Grade: 450Z

FLSA Status: Exempt

Department/ Unit/ Section: Medicine/ Allergy and Clinical Immunology

Reviewed By:

Reports To: Mariana Castells, MD, PhD; Director of the Mastocytosis Center
Matthew Giannetti, MD; Associate Director of the Mastocytosis Center

Date revised:

GENERAL SUMMARY/ OVERVIEW STATEMENT: Summarize the nature and level of work performed.

The RAI will be directly supervised by Drs. Castells and Giannetti. The coordinator develops, executes, and oversees work on several clinical trials involving patients with systemic mastocytosis, chronic spontaneous urticaria, and other mast cell activation disorders. The RAI will be responsible for screening, enrolling, and following subjects through the trials, managing the administrative aspects of this trial, and monitoring the studies/ progress to assure data quality and adherence to protocols as well as timelines. The position requires a detail-oriented individual with an ability to understand complex protocols and become certified for procedures such as phlebotomy, electrocardiogram (ECG), and related challenges.

PRINCIPAL DUTIES AND RESPONSIBILITIES: Indicate key areas of responsibility, major job duties, special projects and key objectives for this position. These items should be evaluated throughout the year and included in the written annual evaluation.

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<i>For all positions that include direct patient care, indicate with an "X" the age(s) of all patient populations served</i>			
No Direct Patient Care			
All age groups		Adolescence (13 to 17 years)	X
Neonates (birth to 1 month)		Young Adult (18 to 25 years)	X
Infant (1 month to 1 year)		Adult (26 to 54 years)	X
Early Childhood (12 months to 5 years)		Senior Adult (55 to 64 years)	X
Late Childhood (6 to 12 years)		Geriatric (65 years and up)	X

1. Contributes to protocol authorship and plans for the implementation of the specified procedures for research studies evaluating mastocytosis treatments, medications and drug desensitization. May draft clinical research forms (CRFs) and build or maintain databases.
2. Performing study visits, including the administration of consent, phlebotomy, sample processing in the lab, following procedures for study visits, and appropriate follow-up with subjects.
3. Collects and reviews study data, ensuring compliance with protocol and data integrity. Drafts corrective action plans for any issues identified through quality control. Ensures queries are responded to in a timely manner.
4. Assists investigators in overseeing regulatory aspects of trials, including monitoring, safety, and protocol deviation documentation as appropriate. Develops and prepares content for study IRB/IND amendments and reports. Ensures audit-ready files are kept.
5. Serves as the primary contact for assigned project for both internal and external communications. Directly responds to inquiries regarding study protocol and policy.
6. Prepares and presents regular and ad-hoc study progress reports for weekly meetings, departmental managers, and study sponsors.
7. Participates in the Bio Bank and tissue repository obtaining patients consent and materials, including blood and tissue samples.
8. All other duties as assigned.

QUALIFICATIONS: (MUST be realistic, neither overstated nor understated, and related to the essential functions of the job.)

- B.S. or B.A.
- At least one year of work experience in clinical research or internship preferred

SKILLS/ ABILITIES/ COMPETENCIES REQUIRED: (MUST be realistic, neither overstated nor understated, and related to the essential functions of the job.)

- Strong organizational and communication skills.
- Excellent interpersonal skills are required for working with the study participants.

- Experience in a clinical environment.
- Strong analytical and computer skills required, proficiency with Microsoft Access, Excel, Word, and Outlook. Proficiency in Research Electronic Data Capture (REDCap) preferred.

WORKING CONDITIONS: Describe the conditions in which the work is performed.

Coordinators will primarily work from the Alumnae Hall at 41 Avenue Louis Pasteur, Boston, MA 02115. Coordinators are expected to participate in patient care at the Brigham and Women's Hospital Main Campus (60 Fenwood Road), Allergy and Clinical Immunology outpatient office (850 Boylston St), and associated Mastocytosis Center facilities.

SUPERVISORY RESPONSIBILITY: List the number of FTEs supervised.

None

FISCAL RESPONSIBILITY: Indicate financial "scope" information, i.e.: size of budget, volume, revenue, etc.

Coordinators will learn OnCore for clinical trial billing. All coordinators will have a working knowledge of clinical trial billing.

APPROVAL:

(NAME)

Department Mgr. _____ Title: _____ Date: _____

(NAME)

Other, As Appropriate _____ Title: _____ Date: _____

Other Duties and Responsibilities:

The above is intended to describe the general contents and requirements of work being performed by people assigned to this classification. It is not intended to be construed as an exhaustive statement of all duties, responsibilities or skills of personnel so classified.

Works within legal, regulatory, accreditation and ethical practice standards relevant to the position and as established by BWH/Partners; follows safe practices required for the position; complies with appropriate BWH and Partners policies and procedures; fulfills any training required by BWH and/or Partners, as appropriate; brings potential matters of non-compliance to the attention of the supervisor or other appropriate hospital staff.

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