

Job Title: Clinical Research Program Manager

The Department of Rheumatology seeks an employee to assume a position in the Division of Rheumatology as a **Clinical Research Program Manager**, driving major programmatic initiatives in precision medicine, cancer and autoimmunity, and scleroderma. The position requires strong data analysis, project management, and organizational skills, with an ability to work independently and with diverse collaborators and stakeholders. This position will be supervised by the Associate Director of the Division of Rheumatology.

Specific Duties & Responsibilities:

The person in this position will assist the Associate Director in the precision medicine program and multiple research projects. The role includes overseeing data pipelines and quality control, performing data analysis, assisting with preparation of manuscripts and grants, and recruiting participants for research studies and conducting study visits. It is anticipated that 80% effort will be allocated to specific research projects, largely focused in scleroderma and the link between cancer and autoimmunity. The remaining 20% will be allocated towards divisional research operations. This allocation may be subject to change over time.

Leadership/Strategy:

- Assist in development of grant proposals, project reports, and manuscripts for publication.
- Assist in new study development by assessing new protocols for clarity, thoroughness, feasibility, maintaining subject safety and other considerations.

Data Analysis, Data Management, and Study Execution:

- Aid in conducting sophisticated statistical modeling, using tools such as Python, R, Stata, or SAS.
- Provide statistical expertise and data analytic support, including exploratory analysis, descriptive statistics, and regression analysis. Generate tables and figures during manuscript preparation.
- Provide assistance in study design, sample size and study power estimation, and data analysis planning, during the development of grant proposals, project reports, and manuscripts for publication.
- Contribute to the development, management, and safe archiving of research databases, including but not limited to REDCap, OpenSpecimen, and Microsoft Access.
- Lead the harmonization of data from multiple sources, including legacy databases, Epic EMR, Open Specimen, and novel data sources (e.g. device, imaging data) into the Johns Hopkins Precision Medicine Analytics Platform (PMAP; SQL computing environment).
- Identify prospective study participants and conduct study visits as necessary.

Project Management:

- Participate in the design and implementation of complex data pipelines, and work with Associate Director and IT to develop project management roadmaps and timelines.
- Prioritize rheumatology center of excellence (COE) requirements based on estimated impact to users, cost to implement, and availability of existing solutions.
- Perform project management duties to ensure that COE development progress aligns with the project roadmap and remains on schedule and within budget, from initial deployment plans through implementation.
- Coordinate with medical, data science and IT professionals from multiple groups, drawing resources from within and outside the Division in coordination with the Associate Director.
- Communicate proactively with team members to provide encouragement, identify problems, create solutions, and implement efficiency improvements to resolve project barriers.

- Provide oversight for adherence to institutional standards and guidelines for security, continuous service improvement, and customer service.

Administrative:

- Collaborate with the Principal Investigator(s) and divisional administrators to oversee study budgets, contracts, generation of invoices, and payment of invoices.
- Manage site agreements, IRB approvals, and budget development for new and ongoing studies, in collaboration with study investigators.
- Participate in meetings with external sponsors, collaborators, or others as required to ensure progress of study aims. Some travel may be required.
- Interface with the Office of Research Administration, the Department of Medicine, the Technology Transfer Office and other offices to manage contracts, data use agreements, material transfer agreements, and other aspects of relationships with external research collaborators.
- Collaborate with appropriate stakeholders, including the Associate Director and Principal Investigator(s), to create accurate and timely reports of study progress and to document study procedures, results, and conclusions.
- Develop documentation to help rheumatology division with human resources issues, such as recruitment and onboarding of divisional research staff, and standard operating procedures.
- Complete and maintain up to date documentation of human subjects' research training for divisional faculty and staff as required by the JHM IRB and protocol Sponsors including and not limited to: JHM Research Compliance, HIPAA, Bloodborne Pathogens, and CPR.
- Attend and participate in staff and division meetings, protocol and research related meetings and trainings, performance improvement and quality assurance activities, and other meetings as required or assigned.

Minimum Qualifications (Mandatory):

- Bachelor's degree in related discipline.
- Five years related experience.
- Knowledge of and experience with clinical research practices and principles, including basic biostatistics, is required.
- Proficiency in Microsoft Office applications and a statistical program such as Stata, R or SAS is required.

Preferred Qualifications:

- Related Master's degree preferred.
- Knowledge of SQL preferred.

Special Knowledge, Skills & Abilities:

- Strong organizational skills, high attention to detail, ability to work independently, excellent verbal and written communication skills, and strong interpersonal skills are a must.
- Must be experienced in handling multiple tasks at once, and working well as a member of a team.