

Job ID 235628

Full/Part Time Full-Time

Location School of Medicine & Dentistry

Regular/Tem... Regular

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Opening

Full Time 40 hours Grade 055 Clin & Trans Science Institute

Schedule

8 AM-5 PM

Responsibilities

GENERAL PURPOSE:

With minimal direction and considerable use of independent judgement, the Office of Clinical Research (OCR) Senior Feasibility and Analytics Coordinator will utilize clinical research expertise, communication skills, and experience and knowledge of process development to provide clinical research feasibility and pipeline data project leadership to the OCR. This position will focus on the understanding of metrics related to clinical research, and will be responsible for collecting, organizing, and analyzing data about processes for the clinical research enterprise for the University of Rochester.

This position will require excellent communication and organizational skills, and solid foundational and operational knowledge in clinical research. Previous research coordinator experience is required.

Supervision and Direction:

Reports to and is given direction by OCR Director and is accountable to senior team leaders according to specific project activities.

SPECIFIC RESPONSIBILITIES

Feasibility Project Management – 50%

The primary project for this position will be the development and implementation of a feasibility analysis tool, and database, to review financial, resource and technical aspects of clinical research trials that will provide a high-quality feasibility analysis prior to study selection. This will be a consultative role, which will include the collection, organization, analysis and reporting of data about the clinical research processes throughout the enterprise. This will include, but will not be limited, to:

- Development, implementation and ongoing refinement of a feasibility analysis tool and database to review financial, resource and technical aspects of a new study that will provide a high-quality feasibility analysis prior to a new study selection.
- Determines institutional research capabilities and creates a robust, centralized index of clinical trial feasibility information.

- Influences the direction and daily operations of clinical trial feasibility activities as it relates to incoming research trial opportunities.
- Identifies and defines meaningful metrics that describe clinical research within the institution. Collects those metrics and organizes it in a meaningful and dependable dashboard or other solution.
- Collaborates with appropriate institutional departments to assist with metrics collection and organization. Analyzes metric data and presents metric data and information to a variety of stakeholders.
- Collects comparable external metric data and analyzes its relationship to institutional metric data.
- Collaborates with Clinical Trial Management System (CTMS) team members in harmonizing the collection, organization, analysis, and reporting of metric data about the clinical research enterprise.
- Uses analysis and expertise to recommend process revisions, tools (e.g., software applications), and other considerations to allow for increased efficiency, quality and timeliness.
- Assesses the feasibility of a protocol prior to study commitment.
- Evaluates and systematically prepares data relating to conducting a clinical trial at the University with focus on whether a protocol is a good fit, including details related to study design, if the department has sufficient experience in the therapeutic area, availability of patient population, availability of research staff, if the budget is financially sufficient to cover the cost of the trial, if similar trials are being conducted at UR that compete for the same patient population, as well as investigator interest.
- Executes cohort discovery, aimed to determine if the patient population is available at the University of Rochester for preparatory research purposes.
- Reviews cohort queries with study teams and exchanges information between the principal investigator and study sponsor.
- Develops a manual which documents specific internal technical capabilities at the University by department as it relates to clinical research.
- Cultivates a task analysis including operational specifics on contract negotiation, regulatory documents and budget, study coordination services, patient recruitment and enrollment, and clinical services and support.
- Maintains records of correspondence with a variety of agencies and officials that provide source of information.

Operational Support for Clinical Trials Start Up – 20%

- Guides study teams that have gone through the OCR Feasibility Analysis through the complex research landscape to place studies on the right path to the right resources at the right time by directing, advising and, when necessary, facilitating “next steps” in clinical research start up.
- Collaborates with other offices and departments, and finds information and resources needed to navigate research studies through the University.
- Works with departmental and institutional Finance offices to establish guidelines for distribution of expenses, provide budget information, and prepare financial reports based on the cost factors of the project.

Communication – 20%

- Interacts with research enterprise stakeholders to evaluate needs, identifies specific issues, and develops processes that will result in the dependable collection of appropriate process metrics.
- Prepares and delivers presentations.
- Develops functional and collaborative relationships with department leaders across the institution.

Other – 10%

- Facilitates and participates in meetings, makes recommendations, meets with colleagues, attends educational activities, and keeps current on state of the research industry.

Other projects and job duties as assigned.

REQUIREMENTS:

- Bachelor's degree/Master's degree strongly preferred. At least 5 years of documented experience as a clinical research coordinator; ACRP- or SOCRA-certified strongly preferred; or an equivalent combination of education and experience.
- Strong understanding of data collection and analysis.
- Excellent interpersonal and communication skills, including presentation and writing skills.
- Demonstrated experience planning and overseeing projects.
- Ability to function both independently and within a team. A process-driven thinker.

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How To Apply

All applicants must apply online.