COOK COUNTY HEALTH

Standard Job Description

Job Code: 9972
Grade: 19
HCWR: N

Job Title	**Department**
Clinical Research Regulatory Coordinator	Research & Clinical Trials

This position is exempt from Career Service under the CCH Personnel Rules.

Job Summary

The Clinical Research Regulatory Coordinator is responsible for supporting clinical research regulatory compliance operations at the institution. Manages and executes the regulatory compliance activities of a clinical research study being conducted in accordance with Good Clinical Practice Guidelines, federal and sponsor regulations, guidelines and institutional policies and procedures. Actively collaborates with internal and external teams.

Typical Duties

- Analyzes regulatory requirements, identifies any potential conflicts, and ensures smooth implementation of trials
- Maintains compliance and integrity of clinical research regulatory files in paper and electronic formats
- Prepares, manages, completes, and submits protocol Institutional Review Boards (IRB) submissions throughout the clinical research lifecycle from study startup through study closeout, including amendments, safety reports, renewals, unanticipated problems, deviations, etc.
- Facilitates IRB approval for subject recruitment materials as required by the IRB of record, state, and federal research regulations
- Ensures that research patient informed consent materials adhere to institutional, sponsor, and IRB policies and guidelines. Revises, negotiates, and finalizes informed consent language with Sponsors to ensure adherence to protocol, IRB requirements, and institutional policies
- Collaborates with the Principal Investigator (PI) and external Sponsor teams to complete required regulatory documents including, but not limited to conflict-of-interest forms, delegation of authority logs, legal agreements, investigational pharmacy forms, serious adverse event (SAE) forms, etc.
- Provides timely and accurate updates to the research team throughout the lifecycle of the trial, including notification of clinical trial activation, enrollment closures, protocol amendments, and final study closures
- Ensures files are continuously updated, prepared and audit ready. Participates in internal and external audits. Addresses questions and compliance-related findings in a timely manner
- Ensures accurate completion of internal department tracking tools with protocol specific information
- Evaluates processes for recurrent problems and develops and implements quality control systems or processes to reduce errors
- Assists in the development and implementation of clinical research and regulatory Standard

Typical Duties

Operating Procedures (SOPs)

- Remains current regarding regulations, regulatory guidance, and/or local institutional policies
- Creates and foster a collaborative, positive relationship with staff and external agencies/organizations
- Assists with any education, training, and/or mentorship needs pertaining to the program as needed
- Performs other duties as assigned

Minimum Qualifications

- Bachelor 's degree from an accredited college or university
- Three (3) years of clinical research experience
- Experience in clinical research regulatory setting
- Experience in Institutional Review Board (IRB) and Federal Regulations governing human subject research
- Experience with Good Clinical Practice and International Conference on Harmonization (GCP/ICH) guidelines, Food and Drug Administration (FDA) guidance, regulations
- Proficiency using Microsoft Office

Preferred Qualifications

- Regulatory Affairs Certification (RAC), Clinical Research Coordinator (CCRC) and/or Certified Clinical Research Professional (CCRP)

Knowledge, Skills, Abilities and Other Characteristics

- Knowledge of medical terminology
- Knowledge of Good Clinical Practice (GCP) and human research protections
- Knowledge of clinical trial regulatory tasks and ensures operations are managed in compliance with Knowledge and experience with clinical trials
- Knowledge of regulations governing the use of human subjects in clinical trials, outcomes research, and other clinical research areas
- Knowledge and of the IRB submission and approval process
- Excellent verbal and written communication skills necessary to communicate with all levels of staff and a patient population composed of diverse cultures and age groups
- Knowledge of FDA regulations and institutional policies and procedures
- Ability to prioritize, plan, and organize projects and tasks
- Ability to multi-task and meet deadlines in a fast paced and stressful environment
- Strong critical thinking and reasoning skills
- Strong customer service skills
- Demonstrate attention to detail, accuracy, and precision

Physical and Environmental Demands

This position is functioning within a healthcare environment. The incumbent is responsible for adherence to all hospital and department specific safety requirements. This includes but is not limited to the following policies and procedures: complying with Personal Protective Equipment requirements, hand washing and sanitizing practices, complying with department specific engineering and work practice controls and any other work area safety precautions as specified by hospital wide policy and departmental procedures.

The above statements are intended to describe the general nature and level of work being performed by people assigned to this classification. They are not intended to be construed as an exhaustive list of all responsibilities, duties and skills required of the personnel so classified.

For purposes of the American with Disabilities Act, "Typical Duties" are essential job functions.