COOK COUNTY HEALTH

Standard Job Description

Job Code: 9782
Grade: 16
HCWR: N

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

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

Job Summary

The Clinical Research Coordinator assists with the study recruitment process, including screening and obtaining consents from eligible candidates. Supports study conduct throughout the lifecycle of the study. Supports and maintains the integrity and quality of clinical research, by ensuring that research is conducted in accordance with Good Clinical Practice (GCP) Guidelines, federal and sponsor regulations and guidelines, institutional policies and procedures, and study protocol.

Typical Duties

- Maintains accurate and timely documentation and actively communications with investigators, colleagues, study participants, sponsors, IRB, and other research related entities as needed.
- Ensures study-related procedures are executed per protocol and performed in accordance with protocol timelines.
- Participates in study recruitment, including identifying and screening research participants for study eligibility
- Implements processes to ensure study-related procedures are executed per protocol and performed in accordance with protocol timelines
- Obtains consent from research participants and ensures participants understand the protocol and what is expected of them while participating
- Identifies adverse events based on gained knowledge and reports them in a timely and accurate manner to the principal investigator and appropriate regulatory authorities (IRB, sponsor, etc.)
- Maintains source documents in accordance with institutional procedures
- Packages and ships study-related specimen and/or samples in accordance with Cook County Health System, International Air Transport Association (IATA) and sponsor guidelines
- Obtains and organizes supplies needed to complete study tasks
- Proactively identifies and participates in training, continuing education, and development activities to broaden knowledge and enhance professional development
- Keeps up to date on relevant State and Federal research guidelines and regulations
- Manages risk to the organization(s) and principal investigators by ensuring up-to-date training and compliance in accordance with complex state and federal regulatory statues and rules
- Manages variety of work requiring critical attention to detail and prioritization

Minimum Qualifications

- Associate degree from an accredited college or university or higher
- Two (2) years in a clinical research or relevant experience
- Proficiency using Microsoft Office (Excel and Word)

Preferred Qualifications

- Bachelor's degree from an accredited college or university

Knowledge, Skills, Abilities and Other Characteristics

- Knowledge of medical terminology
- Knowledge of GCP concepts
- Knowledge in setting up, coordinating, and managing clinical research studies
- Knowledge and understanding of policies, procedures, and regulations governing human subject research
- Knowledge and understanding of the Federal regulations and guidelines governing the protection of human subjects (e.g., FDA, OHRP, GCP/ICH guidelines, and HIPAA regulations) prior to interacting with research subjects
- Knowledge of components of clinical research operations, including study implementation, oversight, and coordination
- Knowledge of CRF completion, and documentation standards, including timely and accurate transcription of study data
- Ability to analyze, organize, and prioritize work under pressure while meeting deadlines
- Ability to maintain confidentiality
- Skill in completing assignments accurately and with attention to detail
- Excellent interpersonal, written, and verbal communication skills
- Ability to work independently and/or in a collaborative environment
- Proficient in understanding phases of clinical trials
- Demonstrate an understanding of clinical research compliance

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.