



Job Code: 9971
Grade: 17
HCWR: N

Job Title

Clinical Research Data Coordinator

Department

Research & Clinical Trials

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

Job Summary

The Clinical Research Data Coordinator (DC) is responsible for supporting and maintaining the integrity and quality of clinical research data. The DC coordinates data collection, management, and quality control as assigned for the active clinical research projects. The DC collaborates with study teams to ensure data collected is reported accurately.

Typical Duties

- Extracts and input complex data into appropriate databases from multiple sources
- Collaborates with cross-functional teams (e.g., clinical research nurses, clinical research coordinators) to document and report study participant data, including enrollment, treatment, and follow-up, and adverse events or treatment outcomes
- Reviews and synthesizes data from medical records (e.g., clinic notes, patient questionnaires, laboratory reports) to extract and document data as required by study protocol
- Prepares documents required for internal and/or external compliance audits and ensures that all documentation is completed and accurate. Participates in the audit and address findings in a timely manner
- Consolidates clinical data and reports for investigators as needed
- Participates in protocol related training meetings and complete all required study training
- Attends study team meetings and provides updates related to protocol data management activities, including data entry timelines, database locks, and query management
- Creates and maintains study databases. Resolves database queries in a timely manner
- Identifies and participates in training, continuing education, and development activities to broaden knowledge and enhance professional development
- Ensures staff remain current with training and compliance in accordance with complex state and federal regulatory statues and rules

Minimum Qualifications

- Associate degree from an accredited college or university
- Two (2) year of experience in a clinical research setting
- Experience in electronic data capture (EDC) and/or data analysis software such as Statistical Analysis Software (SAS), Research Electronic Data Capture (RedCAP), NVivo, Qualtrix or SPSS
- Experience and knowledge of phases of clinical trials
- Proficiency using Microsoft Office



Preferred Qualifications

- Bachelor's degree from an accredited college or university in data informatics, public health, or a health-related field
- Clinical Research Coordinator (CCRC) and/or Certified Clinical Research Professional (CCRP)

Knowledge, Skills, Abilities and Other Characteristics

- Knowledge of Case Report Form (CRF) completion including timely and accurate transcription of study data.
- Knowledge of Good Clinical Practice (GCP) and Good Clinical Data Management (GCDM) concept.
- Knowledge of quantitative and qualitative research designs.
- Knowledge and understanding of policies, procedures, regulations, and ethics governing human subject research.
- Knowledge and understanding of the Federal regulations and guidelines governing the protection of human subjects (e.g., Food and Drug Administration (FDA), Office of Human Research Projection (OHRP), Good Clinical Practice (GCP), International Conference on Harmonization (ICH) guidelines, and Health Insurance Portability and Accountability Act (HIPAA) regulations).
- Knowledge of medical terminology and experience with Electronic Medical Records (EMR).
- Knowledge of regulations regarding the use of human subjects in clinical trials, outcomes research, and other research areas.
- 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.
- Ability to identify, produce, organize, evaluate, and interpret data.
- Ability to work extended hours, as needed, to meet grant and proposal deadlines.
- Strong program management skills and the ability to multi-task, prioritize and meet deadlines.
- Demonstrate attention to detail and accuracy, time management skills, and proven ability to successfully follow-through on assigned projects.
- Strong critical thinking and reasoning skills.

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.