COOK COUNTY HEALTH

Standard Job Description

Job Code: 9778
Grade: 20
HCWR: N

Job Title	**Department**
Quality Assurance Specialist, Clinical Research	Research & Clinical Trials

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

Job Summary

The Quality Assurance Specialist, Clinical Research is responsible for identifying and analyzing clinical research key performance metrics, facilitating performance improvement activities, and ensuring compliance with all Federal, Local, Institution Review and Good Clinical Practice (GCP) standards. The Clinical Research Quality Assurance Specialist will have direct involvement in improving the quality and compliance of clinical research activities through system risk assessments, auditing programs, and benchmarking reports of identified key performance indicators. Serves as a resource on quality assurance and clinical research, clinical trial monitoring and auditing procedures, and regulatory standards across Cook County Health (CCH).

Typical Duties

- Manages quality assurance activities across CCH clinical research operations
- Analyzes and measures collected data, such as, quality assurance data and customer feedback data, as part of monitoring for continuous improvement. Designs, plans, and delegates new clinical research initiatives
- Implements and ensures efficient processes for research activities by monitoring effectiveness and fiscal integrity
- Provides strategic leadership and ensures alignment of policies and procedures to technology systems i.e., bioinformatics, data integration, EHR data extraction
- Reviews and updates departments policies and procedures, including protecting the privacy of research participants
- Understands and maintains current knowledge of federal and local standards and regulations. Communicates regulatory changes, updates procedures according to best practices
- Provides current and accurate research compliance information and resources to the research community. Evaluates research compliance by planning and performing monitoring activities (i.e., routine and for-cause audits) to assess risk and ensure adherence to institutional policies and procedures, local and federal regulations (i.e., Office for Human Research Protections (OHRP), Food and Drug Administration (FDA), etc.) and Conference on Harmonization and Good Clinical Practices (ICH-GCP)
- Investigates research compliance breaches, gathers relevant information, assesses impact, determines steps to mitigate risk, and reports findings
- Documents detailed compliance findings and recommendations (with regulatory citations) in a timely manner that allows for proper review and assessment of the risks identified (including root cause analysis) and the conclusions drawn. Exercises appropriate judgment in evaluating audit findings, develops Corrective and Preventive Action (CAPA) plans, provides targeted education and resources for resolution in a collegial and educational

Typical Duties

manner. Assists research teams in resolving issues and ensures responses and corrective and preventative action plans

- are implemented in a timely manner
- Collects data on audit findings, prepares comprehensive reports (QA metrics) and analyzes trends to identify process failures and direct quality improvement and training initiatives. Presents data, trends, and risk assessments to the Institutional Review Board (IRB) and the Office of Research Integrity & Compliance
- Performs comprehensive clinical research records reviews to identify quality of research documentation and compliance, risks, and compile inspection reports
- Develops and maintains quality assessment standards, tools, policies, and procedures needed to perform internal assessments of the conduct of clinical research at the institution
- Drafts the clinical research monitoring and auditing plans. Reports on results and trends based on findings for clinical research compliance
- Reviews and present audit findings
- Acts as a liaison to research leadership to support managing research portfolios
- Assists in the management of external audits by regulatory agencies or business partners. Provides information and services to help research with FDA inspection readiness
- Facilitates development of quality metrics, guides development of clinical research dashboards and assists in tracking and trending data
- Analyzes trends of performance metrics, identifies opportunities for improvement, and develops action plans
- Collaborates with and trains staff to implement monitoring and measurement tools, and data analysis techniques
- Facilitates quality efforts and coaches others in the development of performance improvement activities with an emphasis on process redesign and measurement
- Conducts root cause analysis (RCA) to proficiently facilitate clinical research efforts and group discussion
- Aids in the development of Corrective and Preventive Action (CAPA) planning and tracking to follow all non-conformities to resolution
- Performs other duties as assigned

Minimum Qualifications

- Bachelor's degree from an accredited college or university or higher
- Three (3) years of relevant clinical research experience
- Two (2) years of quality, monitoring, and/or auditing research experience
- One (1) year supervising and/or managing staff
- Proficiency with Microsoft Office (Word, PowerPoint, Excel)

Preferred Qualifications

- Professional Research certification (i.e., SOCRA, ACRP)
- Society of Quality certification
- Project Management experience and/or certification
- Working knowledge of GCP, GMP, GLP, 21 CFR 50, 21 CFR 312 and 21 CFR 812 compliance

Preferred Qualifications

- Knowledge of Lean / Six Sigma and / or ISO 9001 concepts

Knowledge, Skills, Abilities and Other Characteristics

- Excellent verbal, written communication, and interpersonal skills necessary to communicate with all levels of staff and a patient population composed of diverse cultures and age groups. Persuasive communications skills to support role as an internal change agent and to strengthen working relationships with external stakeholders
- Mentoring skills for developing core grant administration competencies across CCH operating units
- Ability to plan, direct and integrate a complex operation using available resources to accomplish short- and long-term goals of the institution
- Excellent presentation and team building skills
- Strong qualitative, quantitative, analytic, and critical thinking and organizational problem-solving skills
- Detail oriented and have high standards of accuracy
- Ability to prioritize, plan, and organize projects and tasks to meet deadlines in a fast-paced and stressful environment

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.