

Standard Job Description

Job Code:	9779
Grade:	21
HCWR:	Ν

Job Title Training & Education Specialist, Clinical Research Department Research & Clinical Trials

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

Job Summary

The Training and Education Specialist is responsible for identifying and assessing the effectiveness of clinical research curriculums for faculty and staff across the Cook County Health (CCH). This position provides professional and technical leadership to the clinical research team through training, community outreach, and communications. This individual develops and executes a comprehensive training program that enables clinical research team members to perform clinical research that complies with all governing laws and regulations and furthers the overall strategic initiatives of CCH. The Training and Education Specialist designs and implements a comprehensive communication program to share training and development program information using the web, printed publications, and meetings tailored to the needs of clinical research constituents.

Typical Duties

- Plans, develops, implements, and evaluates education programs based upon assessment of learning needs such as, orientation, in-service education, and continuing education
- Trains trial staff on data quality related procedures and provide oversight and support in cases of doubt or risk for non-compliance
- Supports cross-functional team efforts, provide teaching to internal staff, investigators, and other stakeholders about pending or current guidance or regulations, such as the documentation about training planned for updated ICH
- Facilitates development of clinical research curriculum
- Requires remaining abreast of emerging trends in clinical research (innovative technologies, concepts, and techniques), and updating the current institutional training curriculum as appropriate
- Supports cross-functional team efforts, provide teaching to internal staff, investigators, and other stakeholders about pending or current guidance or regulations, such as the documentation about training planned for updated ICH
- Ensures that the personnel conducting studies are appropriately trained
- Recommends and conducts safety training for study teams
- Develops both generalized and study-specific quality management plan training programs and delivers these programs to others
- Trains trial staff on data quality related procedures and provide oversight and support in cases of doubt or risk for non-compliance
- Collaborates with the Quality Assurance specialist team to identify educational needs based on audit and monitoring trends
- Provides consultation and serves as a clinical research resource to Research & Clinical Trials staff and leadership
- Provides oversight and trains others in relation to the relevant authority and associated



Typical Duties

regulatory frameworks, including how these harmonize with ICH GCP, the approved study protocol, and sponsor study related standard operating procedures (SOP) to ensure the safety and rights of study participants

- Co-sponsors educational clinical research programs with other departments within the institution
- Collaborates to establish strategy and direction for institution-wide continuing education related to clinical research, ensuring operational excellence and regulatory compliance
- Engages community members in the development of external initiatives related to clinical research training and communication
- Oversees the investigation of new training and development program methodologies and makes recommendations for implementation of those that support enhanced organizational effectiveness in this area
- Develops and executes a tracking system to maintain a Clinical Research Training Record for each employee involved in clinical research at CCH
- Acts as an internal consultant to further improve systems and processes related to clinical research training and communication as defined by the organization's strategic initiatives
- Assists staff in identifying and meeting ongoing learning needs and pursuing opportunities for professional development
- Develops, implements, and leads internal and communication strategies and programs that support and promote clinical research initiatives and develops/maintains web-based learning materials
- Conducts weekly meetings with new hires to assess progress and provide feedback to supervisor
- Creates and implements the training and orientation program for new hires working to support CCH
- Mentors and conducts performance monitoring reviews of staff at the request of supervisors
- Works with Quality Assurance specialist team to identify and develop training tools and training material to increase efficiency and reduce errors
- Collaborates with Quality Assurance Specialist team to develop, implement, and maintain SOPs to ensure staff adherence

Minimum Qualifications

- Bachelor's degree from an accredited college or university or higher
- Three (3) years of relevant clinical research experience
- Proficiency with Microsoft Office Suite (Work, PowerPoint, Excel)

Preferred Qualifications

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

Knowledge, Skills, Abilities and Other Characteristics

• A "customer service" orientation to providing CCH program managers with support in



Knowledge, Skills, Abilities and Other Characteristics

- managing their programs
- Good interpersonal and communications skills to interact with the broad range of professionals at CCH. Equally comfortable in discussions with clinical and research faculty members, senior managers, administrators, and clerical staff
- 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

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.