JOB DESCRIPTION
The UNIVERSITY of OKLAHOMA

Research Regulatory Specialist Lead

Job Code: 6289

Salary Grade: S08

FLSA Status: Exempt

Job Family: Research

The following statements are designed to outline the general functions and typical responsibility levels associated with positions in this classification. They are not intended to serve as an exhaustive list of specific duties or requirements for individual positions assigned to this classification.

Job Responsibilities

Performs in a lead capacity ensuring that a proper course of action is followed according to established regulatory standards. Responsible for ensuring regulatory and Institution Review Board (IRB) activities of clinical research are conducted according to the University Compliance Program, Code of Ethics, and Business Standards.

- Responsible for leading and scheduling work assignments to employees. Responsible for training and performance evaluations. Discusses disciplinary and possible termination with supervisor. May recommend salary increases and promotions to supervisor.
- Collects required documentation from research sites in accordance with FDA and trial sponsor specifications. Responsible for tracking collection progress through the regulatory process.
- Responsible for maintaining paper and/or electronic study trial files. Conducts internal audits to ensure files are continually updated and in proper order for audits.
- Responsible for notifying IRB of study trial changes, enrollment status, and protocol deviations including submission of continuing review data. Discusses any problems with IRB office and if necessary, makes changes to documentation or data.
- Provides guidance and instructions to research personnel on regulatory affairs requirements and procedures. Revises Informed Consent Form (ICF) in compliance with sponsor and Institutional Review Board (IRB) requests. Maintains current regulations and guidance documents.
- Liaison between Office of Research Administration and OU Medical Center providing grant support to include but not limited to submission of legal documents and associated routing forms.
- Performs various duties as needed to successfully fulfill the functions of the position.

Minimum Requirements

Education:

Required: Bachelor's Degree

Equivalency/Substitution: Will accept 48 months of equivalent regulatory experience in lieu of the Bachelor's Degree for a total of 84 months experience.

Experience:

Required: 36 months of regulatory experience in a clinical research environment.

Required Certifications or Licenses:

None

Verification of education and licensure (if applicable) will be required if selected for hire.

Knowledge, Skills, and Abilities

- Advanced knowledge of compliance and regulatory concepts, guidelines, and principles.
- Identify problems, review information, develop and implement solutions.
- Excellent communication and interpersonal skills.
- Ability to research and obtain information from relevant sources.
- Must be detail oriented and thorough in completing tasks.
- Ability to work independently and as a team player.
- Ability to lead, assign tasks, and ensure completion in a timely manner.

Working Conditions

Physical:

Environmental:

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