JOB DESCRIPTION
The UNIVERSITY of OKLAHOMA

Oncology Research Regulatory Specialist Senior

Job Code: 7438

Salary Grade: S08

FLSA Status: Non-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

POSITION INFORMATION: Under minimal supervision, performs tasks with judgement and determines the proper course of action while following established standards. Responsible for coordinating regulatory and Institution Review Board (IRB) activities of clinical research, revisions to the Informed Consent Form, and grant support. Adheres to University Compliance program, Code of Ethics, and Business Standards.

1. Format, collect, and timely preparation of documents for regulatory submissions in accordance with FDA and trial sponsor specifications. Track collection progress through regulatory workflows.
2. Maintain a working knowledge of regulations, submission requirements and processes for multiple regulatory systems.
3. Help create and update regulatory workflows in collaboration with Clinical Trials Manager ¿ Regulatory Affairs to adapt and adjust to changing regulations and processes.
4. Training regulatory specialists on current or new processes and workflows. Provide guidance and instructions to regulatory specialists, research personnel on regulatory affairs requirements and procedures.
5. Communicate important regulatory and study related information to the Research Team, Sponsors or regulatory authorities throughout the regulatory process.
6. Independently manage and maintain a palette of studies with minimal supervision. Ensuring studies continue to meet regulatory, GCP and institutional guidelines and processes.
7. Track milestones and ensure deadlines are met on multiple projects for a team of regulatory specialist.
8. Perform various duties as needed to successfully fulfill the functions of the position.

Minimum Requirements

Education:

- Bachelor's Degree.

Equivalency/Substitution: Experience or a combination of education & related experience can be considered in lieu of degree. A one-to-one ratio is used to determine the number of years of experience required in place of a degree.

Experience:

- None

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.
- Advanced level of proficiency with Microsoft Office Suite and other software systems.
- Must be detail oriented and have excellent organization skills.
- Ability to communicate verbally and in writing.
- Strong knowledge of compliance and regulatory principles, including applicable federal regulations and institutional research policies.
- Ability to manage competing priorities, track deadlines, and maintain accurate records.
- Ability to analyze complex regulatory information, interpret guidelines, and apply them appropriately
- Commitment to maintaining confidentiality and handling sensitive information in compliance with institutional and regulatory requirements.
- Ability to adapt to evolving regulatory landscapes and support continuous quality improvement in research compliance practices.

Working Conditions

Physical:

Sit for prolonged periods. Communicate effectively and listens. Engage in repetitive motion. Use of computer and telephone. Stand, stoop, bend, and reach.

Environmental:

Standard office environment.

Printed Date: 11/22/2026