

Research Regulatory Specialist

Job Code: 7089

Salary Grade: S06

FLSA Status: Non-Exempt

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.

Duties and Responsibilities

Under direct supervision, performs tasks with discretion and asks questions to determine the proper course of action while following established standards. Assists with coordinating regulatory and Institution Review Board (IRB) activities of clinical research conducted at the University. Adheres to OUHSC Compliance program, Code of Ethics, and Business Standards.

- Assists with collection of required documentation from research sites in accordance with Food and Drug Administration (FDA) and trial sponsor specifications. Tracks collection progress through the regulatory process.
- Maintains a paper and/or electronic study trial file. Continually update the files and assist with the preparation for audits.
- Assist with notifying IRB of trial changes, enrollment status, and protocol deviations including the submission of continuing review data.
- Provides guidance and instructions to research personnel on regulatory affairs requirements and procedures with assistance from the supervisor. Assists with revisions to the Informed Consent Form (ICF) in compliance with sponsor and IRB requests.
- Assists with grant support including submission of legal documents and associated routing forms to the Office of Research Administration and OU Medical Center.
- Performs various duties as needed to successfully fulfill the functions of the position.

Minimum Qualifications

Education:

Required: High School Diploma or GED

Experience:

Required: No experience required.

Certifications or Licenses:

None.

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

Knowledge, Skills, and Abilities

- Working knowledge of office procedures.
- Proficient with Microsoft Office to include Word, Excel, and Outlook.
- Ability to read and understand instructions.
- Ability to communicate verbally and in writing.

Working Conditions

Physical:

Sitting for prolonged periods. Manual dexterity. Reaching, speaking, and listening.

Environment:

Standard Office Environment.

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