

Title of Job: *Regulatory Coordinator*

Summary of Job Duties: Assist with the preparation, submission, and maintenance of clinical trials regulatory data. Assist with the initiation and maintenance of all Human Subjects and Regulatory documents necessary for submission to the Institutional Review Boards, study sponsors, and various agencies in order to obtain initial and continued approval of all clinical trials. These activities require compliance to several sources of complex regulations, policies, and procedures concerning the conduct of clinical trials, including those of the FDA, NIH, GCP, and ICH. The position requires strong written communication skills, attention to detail, ability to meet multiple and changing deadlines, the ability to interact with a variety of people and to consult numerous sources for information in order to prepare documents and assist with responses to IRB and sponsor questions that are compatible with numerous policies and procedures. Incumbent must be able to work in a very busy interactive environment with frequent interruptions and to perform tasks accurately and quickly.

Educational Qualifications: High School Diploma; some college preferred

Experience/Training:

- Familiarity with clinical research protocols including human subjects' applications and informed consent documents. Must be able to maintain confidentiality.
- Demonstrated organizational skills including ability to develop accurate filing systems.
- Familiarity with medical terminology.
- Experience with computer systems and software (including databases, spreadsheets, and word processing). Ability to use software to develop organized information sources and to provide a variety of reports. Experience with Microsoft Office products such as: Word, Adobe and Excel.

Licenses. etc: N/A

Status and Scope: Reports to the Director of Regulatory & QA.

FLSA Status: Non-Exempt

Essential Job Duties:

1. Reports, monitors, distributes and maintains files for all safety information including Investigational Drug Brochures, IND safety reports and Serious Adverse Events (SAE) reports.
2. Updates Clinical Trials Management System (CTMS) as needed with location profile information (CVs, medical licensures, laboratory accreditations), IRB status, consent form versions (protocol/consent form evolution), and safety information.

Regulatory Coordinator

3. Prepares regulatory documentation packets and creates all FDA 1572 Forms for IND filings. Ensures all necessary forms are submitted to Sponsor company to activate protocols.
4. Distributes and tracks financial disclosure forms, protocol signature pages and FDA 1572 Forms to obtain local investigator signatures.
5. Tracks expirations and retrieves current documentation for medical licensures, CVs and laboratory accreditations.
6. Posts regulatory documents including protocols, amendments, consent forms, SAE forms etc. on the CTMS.
7. Prepares, maintains, updates and audits study specific regulatory files, IRB files and location profile filing system per FDA guidelines and resolves queries as necessary. Maintains master location lists to be used for regulatory purposes.
8. Distributes IRB documentation and post IRB meeting information to study sponsors, research and clinical staff.
9. Ensures all regulatory files are prepared for off-site storage in accordance with FDA and other applicable regulatory guidelines.
10. Ability to verbally communicate effectively with company's coordinators, marketing staff and management; pharmaceutical companies; IRBs; and other team members.
11. Ability to communicate effectively when reading and writing e-mail, letters and other reports.
12. Strong focus on teamwork, attention to detail, excellent organizational and planning skills. Must have ability to prioritize, excellent communication skills, and ability to work in a multi-task environment.
13. Proficient with Microsoft Word, Excel. Training in GCP, and HIPAA regulations will be required.
14. Answers, transfers and handles incoming calls as needed.
15. May perform other duties not specifically listed in this job description as assigned by their immediate supervisor.