

# **RESEARCH REGULATORY SPECIALIST**

## ***JOB DESCRIPTION***

(Effective December 22, 2008)

Regulatory Specialists perform a wide variety of start-up activities integral to the successful application and acceptance of essential regulatory documents. Regulatory Specialists are responsible for insuring timely submission of complete, accurate and neat documents to pharmaceutical sponsors, IRB, and contract research organizations, where applicable. Regulatory Specialists work under the direction of the Clinical Research Director.

**Reports to:** Clinical Research Director and Study Investigators

**Classification:** Non-exempt position

### **QUALIFICATIONS/JOB REQUIREMENTS:**

- Ability to work consistently and effectively as part of a high performance work team.
- Ability to effectively devote keen and acute attention to detail.
- Demonstrated ability to operate basic office equipment including (but not limited to) copying machines, facsimile machines, multi-line telephones and personal computers.
- Strong written communication skills, including exceptional spelling abilities.
- Strong verbal skills.
- Strong interpersonal skills.
- Highly motivated “self-starter” with the ability to exercise initiative, together with ability to work as a team player as well as independently while managing a variety of study related projects simultaneously.
- Basic knowledge of computer operations and demonstrated computer skills in a variety of software environments (*i.e.*, Word, Excel, Internet).

### **RESPONSIBILITIES:**

Regulatory Specialists shall:

- On a weekly basis, prepare a summary of tasks reports.
- On a weekly basis, prepare regulatory status reports.

- Manage the update of study regulatory documents. These documents include but are not necessarily limited to Revised 1572, Protocol Amendments, safety reports, site delegation signature logs and other documents.

### **RESPONSIBILITIES (CONT):**

- Regularly, and as needed, meet with the Clinical Research Director to discuss new studies and the updating of current studies.
- As needed, meet with study monitors.
- As needed assist with site visits.
- On a monthly basis, update IRB summaries for current studies.
- On a timely basis, add all new studies to the cumulative reports and marketing reports.
- Complete, in a timely manner, all documents needed in preparation for submission to the pharmaceutical sponsor and/or CRO. Such documents include, but are not necessarily limited to, FDA Form 1572, Financial Disclosures, Protocol Signature Page and other documents.
- Complete, accurately and in a timely fashion, all documents needed in preparation for submission to the IRB. These documents include, but are not necessarily limited to, submission letters, questionnaires, generic advertisements, and other miscellaneous documents.
- Ensure IRB approval is granted before turning any documents over to Clinical Research Coordinators.
- Submits safety reports in a timely fashion
- Manage the update, on an annual basis or otherwise “as needed,” and maintain all curriculum vitae for physicians and physicians’ assistants.
- Regularly manage the update all nursing and medical licenses on file for physicians, physicians’ assistants, research coordinators, and other staff, and all outside physicians, physicians’ assistants, and nurse practitioners.
- Learn, apply and utilize computer software applications to enhance work flow and study activity efficiency.
- Travel to and perform duties of the position at other Heartland Research Associates, LLC locations when assigned or directed to do so.

### **WORKING CONDITIONS:**

- Medical office environment, specializing in family practice. Direct contact with patients, staff and physicians. Exposure to communicable diseases and body fluids, hazardous substances and other conditions common to clinic environment. Exposure to emergency situations.

**ACKNOWLEDGMENT**

I acknowledge receiving and reading this Job Description, and having the opportunity to ask questions about it and having those questions answered.

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“Employee”

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“Witness”