

# **DOCUMENTATION SPECIALIST**

## ***JOB DESCRIPTION***

(Effective December 22, 2008)

Documentation Specialists perform a wide variety of clinical study related activities integral to the successful conduct and completion of clinical research studies. Documentation Specialists gain knowledge of, and complete, case report forms legibly, and accurately, under the general supervision of Clinical Research Coordinators. In addition, Documentation may also render clerical assistance to a variety of staff.

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

**Classification:** Non-exempt position

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

- Possess, at time of hire, a good concept and knowledge of medical terminology and the ability to correctly use such terminology on a daily basis; in the alternative, Documentation Specialists must have a strong desire to learn such terminology and a demonstrated ability to learn quickly.
- Demonstrate ability to operate basic office equipment including (but not limited to) copying machines, facsimile machines, multi-line and telephones.
- Ability to effectively devote keen and acute attention to detail.
- Ability to work consistently and effectively as part of a high performance work team.
- Ability to multi-task and perform multiple critical tasks simultaneously (under dynamic and ever-changing circumstances).
- Strong written communication skills, including exceptional spelling abilities.
- Strong mathematical skill.
- Strong verbal communication 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:**

Documentation & Computer Specialists shall:

- Become familiar with all federal *Food and Drug Administration* (FDA) regulations and guidelines applicable to clinical research studies. Such familiarity will help ensure that studies are conducted in accordance with federal law. This responsibility requires close and careful study of relevant legal provisions and keeping abreast of changes in applicable laws. Additionally, this responsibility requires Documentation Specialists to apply this knowledge on a daily basis to help minimize the risk of regulatory noncompliance.
- Assist in all assigned phases of conducting clinical research studies in compliance with FDA regulations and guidelines.
- Study, learn and comply with Family Medicine East employee handbook, standard operating procedures, and other policies, procedures and regulations where applicable.
- Accurately, completely and in a timely manner complete case report forms for each assigned study.
- Transmit case report forms via facsimile when applicable.
- Make copies of complete case report forms where applicable.
- Assist Clinical Research Coordinators in responding to inquiries from pharmaceutical sponsors. Satisfaction of this responsibility requires Documentation Specialists to learn and maintain familiarity with aspects of individual clinical research studies and to respond in timely fashion to all internal and external inquiries, both scheduled and unscheduled.
- Meet with monitors to complete case report form training at the time of new study start ups.
- Meet with monitors periodically throughout the conduct of clinical trials when applicable.
- Willingly accept special assignments.
- Assist with the receipt and distribution of daily shipments from Airborne, FedEx and UPS as needed.
- Travel to and perform duties of the position at other Heartland Research Associates, LLC locations when assigned or directed to do so.
- Complete and execute source documents as needed.

**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”