

# **STUDY COORDINATOR – LEVEL I**

## ***JOB DESCRIPTION***

(Effective December 22, 2008)

Level I Study Coordinators perform multiple and varied tasks critical to the management of clinical research studies. Level I Study Coordinators learn all basic clinical research study activities and learn and apply all federal and other regulatory matters having impact on those studies. Without Level I Study Coordinators' efforts, knowledge and expertise; success acquisition, maintenance and completion of clinical research would not be possible.

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

**Classification:** Exempt position

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

- Successful completion of formal/clinical training program(s), such as those required of registered nurses, licensed practical nurses, CNAs, emergency medical technician, R.T., and certified medical assistants or equivalent job experience.
- No less than one year of clinical experience involving patient care in a healthcare environment.
- Ability to interpret, and perform if needed, clinical, laboratory and diagnostic tests.
- Ability to function independently without close supervision, and to consistently exercise discretion and the highest level of good clinical and other professional judgment.
- Ability to quickly adapt to working in a wide variety of dynamic therapeutic areas of medicine.
- Ability to effectively devote keen and acute attention to detail.
- Ability to multi-task and perform multiple critical tasks simultaneously (under dynamic and ever-changing circumstances).
- Strong written and verbal communication skills.
- Strong interpersonal skills.
- Strong self-motivation skills and the ability to be a “self-starter,” coupled with the capability to work as a team player, as well as independently, while simultaneously managing a variety of clinical research study related projects.
- Ability to meet and satisfy flexible, dynamic work schedules and be “on-call” if necessary.

- Successful completion of FAA training concerning the handling and shipping of hazardous goods and materials, followed by recertification every two years following initial certification.

### **QUALIFICATIONS/JOB REQUIREMENTS (CONT):**

- Ability to be ambulatory most of work day
- Ability to lift / transfer / carry a minimum of 25 pounds without difficulty

### **RESPONSIBILITIES:**

Level I Study Coordinators shall:

- Provide administrative support to the Clinical Research Director and to Study Investigators engaged in the performance of clinical research studies. Tasks required to fulfill this responsibility include interpretation of clinical, laboratory and diagnostic tests; applying such interpretations to advise the Clinical Research Director and to Study Investigators concerning management of clinical research studies.
- Design and maintain organizational tools to ensure that each clinical research study is conducted accurately and in compliance with good clinical practice guidelines.
- Communicate with clinical research sponsors, CROs, monitors, laboratories and clinical personnel within the research industry to assist in placement of specific trials and the implementation of clinical research studies.
- Research and apply all federal Food and Drug Administration (FDA) regulations and guidelines applicable to clinical research studies to ensure compliance with federal law.
- Interpret clinical, laboratory and diagnostic tests for each clinical research study to which a Study Coordinator is assigned. Such interpretations must be accurate and in compliance with research study protocol to maintain the integrity of the study.
- Coordinate and assume responsibility for initiating and maintaining clinical research studies.
- Know and comply with Family Medicine East employee handbook, standard operating procedures, and other policies, procedures and regulations where applicable.
- Coordinate and supervise direct patient/study participant care associated with various clinical research studies. Tasks required to fulfill this responsibility include, but are not limited to, reacting to and providing recommendations based on new/unanticipated adverse events; performing electrocardiograms, taking and interpreting vital signs; properly identifying and obtaining relevant

laboratory specimens, receiving the results of laboratory tests associated therewith, and recording those tests; coordinating and assisting with physical examinations; and recommending changes in required medications.

**RESPONSIBILITIES (CONT):**

- Supervise and coordinate personnel and events associated with clinical research studies to promote compliance with study protocols and ensure the safety and welfare of all patients/study participants.
- Interpretation and collection of medical data and information.
- Advise Study Investigators and physicians in protocols and procedures required for the successful implementation and completion of each clinical research study, and monitor compliance with procedures and protocols.
- Recruit and screen potential patient/study participant's compliance with each clinical research study protocol's inclusion and exclusion criteria. To successfully satisfy this responsibility, Level I Study Coordinators must be wholly familiar with the protocols, procedures and criteria associated with each clinical research study and accurately interpret and apply those protocols, procedures and criteria. This responsibility also requires Level I Study Coordinators to obtain proper written informed consent from each potential study participant, prior to participation in the study.
- Identify all adverse experiences, and hypothesize the cause or reason for such experiences, that occur in clinical research studies. Report such experiences and basis for the occurrence to principal investigators and/or subinvestigators. Successful completion of this responsibility requires Level I Study Coordinators to apply and interpret medical knowledge, data, events and occurrences that may constitute and cause adverse experiences.
- Maintain accurate and complete case histories for each study participant that record and reflect all observations and data collected from those participants during clinical trials. Successful completion of this responsibility requires the exercise of independent judgment as to what information is relevant for inclusion in case histories.
- Advise and inform Study Investigators and Clinical Research Director concerning preparation of documentation for each clinical study, reviewing and ensuring that all required documentation has been accurately and successfully completed. Successful completion of this responsibility requires the exercise of independent judgment whether case report forms are properly completed and that discrepancies are noted and fully explained for use of clinical experimental drugs and supplies.
- Effectively communicate with pharmaceutical company sponsors concerning all aspects of study activities. Successful completion of this responsibility requires the Study Coordinator to meet and discuss with monitors and other representatives the progress and results of clinical research studies.

- Utilize computer software applications to enhance workflow and study activity efficiency. Successful completion of this responsibility requires knowledge of the requirements of each clinical research study and exercising independent judgment to identify appropriate software applications.

**RESPONSIBILITIES (CONT):**

- Travel and attend meetings and activities associated with clinical research studies, including, but not limited to, professional meetings to acquire additional specialized knowledge in the area pertaining to a clinical research study.
- 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.

**ESSENTIAL FUNCTIONS:**

- Ability to lift, push, manipulate equipment and patients which requires strength, gross motor and fine motor coordination. Ability to administer prescribed treatments. Ability to perform CPR and venipuncture. Ability to stand for long periods of time.

**ACKNOWLEDGMENT**

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

---

“Employee”

---

“Witness”