UNIVERSITY OF SOUTHERN CALIFORNIA

Clinical Research Data Specialist II

Job Code: 185484

Grade: 00
OT Eligible: Yes
Comp Approval: 7/25/2014

JOB SUMMARY:
Coordinates and manages the clinical data for various phases of clinical study. Ensures data is documented and recorded as appropriate. Acts as primary site contact with sponsor's Clinical Research Associate (CRA) for externally sponsored trials.

JOB ACCOUNTABILITIES:

*E/M/NA % TIME

---  ---
Coordinates and manages the clinical data for various phases of clinical study. Ensures data is documented and recorded as appropriate. Reads and understands clinical data from medical records and assists in obtaining outside documents. Extracts and enters required clinical data from medical records and patient research charts/reports into Clinical Research Forms (eCRFs/CRFs). Notifies PI or Study Coordinator of issues or violations.

---  ---
Acts as primary site contact with sponsor's Clinical Research Associate (CRA) for externally sponsored trials. Provides timely data entry, plans and organizes monitoring visits and responds to inquiries. Addresses all queries during and after audit for resolution.

---  ---
Maintains currency of federal regulations governing the protection of human subjects such as Food and Drug Administration (FDA), Good Clinical Practice/International Conference on Harmonisation (GCP/ICH) guidelines, Office of Human Research Protections (OHRP), Health Insurance Portability and Accountability Act (HIPAA), rules concerning reporting of Serious Adverse Events (SAEs) and violations with department training and feedback.

---  ---
Interacts closely with quality assurance teams to ensure data accuracy on Clinical Research Forms (eCRFs/CRFs) prior to submission for in-house, National Cancer Institute (NCI) sponsored and Cooperative Group studies. Discerns basic data discrepancies/protocol violations.

---  ---
Performs follow up for study patient survival by reviewing medical records. Contacts other institutions for data on patients hospitalized at other institutions.

---  ---
Assists with study specimen procurement and handling.

---  ---
Participates and attends internal and external new protocol start-up orientations and completes required protocol specific training.

---  ---
Prepares and participates in audits of assigned studies such as National Cancer Institute (NCI), Food and Drug Administration (FDA) and pharmaceutical audits.

---  ---
Participates in Quality Assurance Monitoring Committee (QAMC) in-house audits by reviewing assigned patient chart and reporting on findings as relates to protocol/patient compliance.

---  ---
Completes spreadsheets for industry studies in real time to ensure sponsor is invoiced appropriately and timely.
Ensures confidentiality, accuracy, security and appropriate access of all data and records.

Performs other related duties as assigned or requested. The university reserves the right to add or change duties at any time.

*Select E (ESSENTIAL), M (MARGINAL) or NA (NON-APPLICABLE) to denote importance of each job function to position.

**EMERGENCY RESPONSE/RECOVERY:**

Essential:  

☐ No  ☐ Yes  

In the event of an emergency, the employee holding this position is required to “report to duty” in accordance with the university’s Emergency Operations Plan and/or the employee’s department’s emergency response and/or recovery plans. Familiarity with those plans and regular training to implement those plans is required. During or immediately following an emergency, the employee will be notified to assist in the emergency response efforts, and mobilize other staff members if needed.

**JOB QUALIFICATIONS:**

Minimum Education:

- Bachelor’s degree
- Combined experience/education as substitute for minimum education

Minimum Experience:

- 1 year

Minimum Field of Expertise:

- Experience in clinical trials data management. Requires strong attention to detail with prior data entry experience. Basic medical knowledge such as understanding medical terms and familiarity with various assessment criteria. Strong verbal and written communication skills. Able to manage time efficiently.

Preferred Education:

- Bachelor’s degree

Preferred Experience:

- 2 years

Preferred Field of Expertise:

- Experience in clinical trials data management in a university setting.

**Skills:** Administrative:

- Answer telephones
- Communicate with others to gather information
- Compose correspondence
- Compose letters
- Coordinate meetings
- Customer service
- Gather data
- Input data
- Maintain filing systems
Maintain logs
Maintain records
Research information
Understand and apply policies and procedures
Understand and enforce regulatory guidelines
Use database and/or word processing software

Skills: Machine/Equipment:
- Computer network (department or school)
- Computer network (university)
- Computer peripheral equipment
- Fax
- Personal computer
- Photocopier

Supervises: Level:
- May oversee student, temporary and/or resource workers.

SIGNATURES:
Employee: ______________________________ Date: ______________________________
Supervisor: ______________________________ Date: ______________________________

The above statements are intended to describe the general nature and level of work being performed. They are not intended to be construed as an exhaustive list of all responsibilities, duties and skills required of personnel so classified.

The University of Southern California is an Equal Opportunity Employer