UNIVERSITY OF SOUTHERN CALIFORNIA

Clinical Research Data Specialist Lead

Job Code: 185488

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

JOB SUMMARY:
Coordinates, facilitates and manages the clinical data for various phases of complex clinical trials. Assists Study Coordinators and Clinical Research Data Specialist II with complex clinical trials. Provides leadership, guidance and direction to Clinical Research Data Specialists.

JOB ACCOUNTABILITIES:

<table>
<thead>
<tr>
<th><strong>E/M/NA</strong></th>
<th><strong>% TIME</strong></th>
<th><strong>ACCOUNTABILITY</strong></th>
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<tr>
<td>________</td>
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<td>Coordinates, facilitates and manages the clinical data for assigned protocols. Ensures data is documented and recorded as appropriate. Reads and understands clinical data from medical records. Extracts and enters required clinical data from medical records and patient research charts/reports to Clinical Research Forms (eCRFs/CRFs). Notifies PI or Study Coordinator of issues or violations.</td>
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<td>Attends and participates in new protocol startup orientations with sponsors and completes protocol specific training.</td>
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<td>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. Addresses all data queries for resolution.</td>
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<td>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) violations. Reports Serious Adverse Events (SAEs) to Study Coordinator and to various agencies, as required. Assists Clinical Research Data Specialists in reporting SAEs and assessing protocol violations.</td>
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<td>Ensures data collection is available per contract obligations at time of monitoring visit.</td>
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<td>Interacts closely with quality assurance supervisor to ensure data accuracy on eCRFs/CRFs prior to submission for in-house, National Cancer Institute (NCI) sponsored and Cooperative Group studies. Discerns data discrepancies/protocol violations.</td>
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<td>Assists supervisors with orientation, training and mentoring newly hired Clinical Research Data Specialists.</td>
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<td>Provides leadership, guidance and direction to Clinical Research Data Specialists as pertains to data entry into databases, as assigned.</td>
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<td>Prepares and participates in audits of assigned studies such as National Cancer Institute (NCI), Food and Drug Administration (FDA) and pharmaceutical audits. Reviews assigned patient charts and reports results.</td>
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<td>Assists Study Coordinator with eligibility work-ups for new potential research subjects.</td>
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Provides assistance and input to PIs for publishing study results, as requested.

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.

Perform 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:**

2 years

**Minimum Field of Expertise:**

Experience in clinical trials data management. Requires strong attention to detail with prior data entry experience. Understands medical terms and familiar with various assessment criteria. Strong verbal and written communication skills. Able to manage time efficiently.

**Preferred Education:**

Bachelor’s degree

**Preferred Experience:**

3 years

**Preferred Field of Expertise:**

Experience in clinical trials data management in an academic research setting or other clinical trials office.

**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: Other:
Lead/guidance skills

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.

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