UNIVERSITY OF SOUTHERN CALIFORNIA
Clinical Research Data Specialist I
Job Code: 185480

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

JOB SUMMARY:
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).

JOB ACCOUNTABILITIES:

*E/M/NA % TIME

--- --- 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).

--- --- Maintains currency of research regulations including rules concerning reporting of
Serious Adverse Events (SAEs) and violations with department training and
feedback.

--- --- Interfaces with sponsors of externally sponsored trials. Provides timely data entry,
plans and organizes monitoring visits and responds to inquiries.

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

--- --- 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.

--- --- Assists in obtaining outside documents and study specimen procurement and
handling.

--- --- Attends new protocol start-up orientations. Completes required protocol specific
training.

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

--- --- 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
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:**
- Associate’s degree
- Combined experience/education as substitute for minimum education

**Minimum Experience:**
- 6 months

**Minimum Field of Expertise:**
- Requires good attention to detail with prior data entry experience. Some knowledge of medical terminology.

**Preferred Education:**
- Associate’s degree

**Preferred Experience:**
- 1 year

**Preferred Field of Expertise:**
- Data entry experience in a healthcare 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
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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