UNIVERSITY OF SOUTHERN CALIFORNIA
Clinical Monitor
Job Code: 135060

OT Eligible: Yes
Comp Approval: 4/20/2016

JOB SUMMARY:
Participates in the development, preparation and execution of clinical trials. Oversees the progress of clinical investigations by conducting pre-study, initiation, interim and close out visits to sites. Monitors clinical trials in accordance with Good Clinical Practices and sponsors. Works closely with the Clinical Trial Manager to ensure all monitoring activities are conducted according to study requirements.

JOB ACCOUNTABILITIES:

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<tr>
<th>E/M/NA</th>
<th>% TIME</th>
<th>Description</th>
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<tr>
<td>_____</td>
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<td>Conducts independent visits to assigned study sites, as needed. Assists in the planning of data collection. Performs audits of multiple centers and ensures all necessary data has been collected and documented accurately. Works with sites to resolve data queries. Identifies areas which need improvement. Reduces/controls unforeseen problems of all projects. Contributes to the documentation and update of study procedures.</td>
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<td>Administers all applicable trial batteries (e.g., Neuropsychiatric Inventories) and trains personnel on battery administration. Reviews and evaluates clinical test results and interviews (e.g., Clinical Dementia Rating) and ensures that interviews and tests are rated, scored and standardized. Reviews and reports on the quality and integrity of clinical data.</td>
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<td>Documents accountability, stability and storage conditions of clinical trial materials as required by sponsor. Performs investigational product inventory. Ensures return of unused materials to designated location or verifies destruction as required. Ensures that management of all clinical trial materials is compliant with local and federal regulations.</td>
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<td>Instructs study personnel on proper protocol and quality assurance procedures. Responds to questions regarding data collection, coding, and management and analysis methods. Works closely with the Project Coordinator to review current protocol status and identify protocol compliance issues. Communicates changes in conduct of the protocol, if applicable. Verifies that all protocol deviations have been accurately documented and reported.</td>
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<td>Conducts and attends regular meetings with the principal investigator to participate in study implementation. Sets goals and timelines for the monitoring group and provides innovative contributions for ongoing research projects.</td>
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<td>Oversees and provides guidance to the Project Coordinator concerning quality control activities within the Coordinating Center. Considers ongoing and competing Coordinating Center projects to establish a timeline for project completion.</td>
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<td>Analyzes databases for accuracy, completeness and reliability. Designs and implements corrective procedures when necessary. Works with monitors from other groups to implement new distributed data entry systems and procedures. Tests online applications for functionality. Proposes potential solutions or procedural changes based on interaction with different groups.</td>
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</table>
Stays current with pertinent literature and developments in field of specialization.
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:**
- 2 years

**Minimum Field of Expertise:**
- Monitoring of clinical trials and medical terminology. Knowledge of the drug development process. Thorough knowledge of ICH guidelines and Good Clinical Practices (GCP). Understanding of FDA regulations pertaining to Good Clinical Practices. Thorough knowledge of local and/or country’s regulation pertaining to clinical trials and monitoring.

**Preferred Education:**
- Bachelor's degree

**Preferred Experience:**
- 4 years

**Preferred Field of Expertise:**

**Skills:**

- **Administrative:**
  - Clinical documentation
  - Communicate with others to gather information
  - Compose correspondence
  - Conduct meetings
  - Coordinate events
  - Coordinate meetings
  - Counseling
  - Customer service
  - Draft routine correspondence
  - Edit routine documents
  - Establish filing systems
Establish records
Gather data
Input data
Interpersonal skills
Maintain filing systems
Maintain logs
Maintain records
Prepares official documents
Prioritize different projects
Prioritize different tasks
Read handwritten text
Research information
Schedule appointments
Understand and apply policies and procedures
Understand and enforce regulatory guidelines
Use computerized spreadsheets
Use database and/or word processing software

Skills: Other:
Analysis
Assessment/evaluation
Documentation and technical writing skills
Interpretation of policies/analyses/trends/etc.
Interviewing
Organization
Planning
Problem identification and resolution
Teaching/training

Skills: Machine/Equipment:
Audio/Visual equipment
Calculator
Computer network (department or school)
Computer network (university)
Computer peripheral equipment
Fax
Navigation system
Personal computer
Personal mobile communication devices
Personal workstation
Photocopier
Scanners
Teleconferencing equipment

Supervises: Level:
May oversee staff, students and/or resource employees

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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