UNIVERSITY OF SOUTHERN CALIFORNIA
Research Coordinator II
Job Code: 135051

Grade: 00
OT Eligible: Yes
Comp Approval: 1/24/2013

JOB SUMMARY:
Serves as a lead coordinating aspects of sponsor-initiated and investigator-initiated research studies including subject recruitment, data collection, scheduling of study-related activities and follow-up of enrolled subjects. Assists with budget preparation and training of less experienced research coordinators. Provides guidance and direction related to research studies to investigators, research personnel, and subjects, from initial protocol design to completion of study and close-out report.

JOB ACCOUNTABILITIES:

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* Serves as a lead assisting with planning and staffing of project operations based on proposed research activities and timelines. Coordinates aspects of sponsor-initiated and investigator-initiated research studies including subject recruitment, data collection, scheduling of study-related activities and follow-up of enrolled subjects. Provides guidance and direction to investigators, research personnel, and subjects. Assists with training and demonstrating techniques or procedures to less experienced research coordinators.

* Plans, organizes and schedules assessments/tests/activities to meet research objectives and study protocol compliance. Communicates with study team personnel to ensure study procedures are followed and research is performed as described in protocol. Serves as contact for subjects, study personnel, Institutional Review Board (IRB) and study sponsor.

* Assists in recruiting subjects for studies and determines eligibility based on study criteria. Coordinates study participant activities including recruitment, screening, orientation and correspondence. Schedules subject appointments, tests, and procedures coordinating with external providers as needed. Produces reports, correspondence and other materials, as needed or required.

* Has responsibility for data collection for research studies following established data collection and management procedures. Collects, records, enters and prepares data for analysis. Performs basic study analysis under the direction of the Principal Investigator. Collects pertinent information from study participants through interviews, administration of tests or surveys or questionnaires, medical records review, or other collection procedures.

* Assists with development and management of project budgets. May authorize expenditures, monitor status and reconcile budget to ensure compliance with fiscal guidelines and regulations. Prepares and/or directs the preparation of financial reports as required. May direct ongoing purchasing activities including authorization of one-time purchases with approval from investigators.

* Organizes and prepares grant proposals. Collaborates with investigators to develop research proposals. Interfaces with funding and regulatory agencies to exchange information.
Maintains accurate, complete and timely records, including source documents, consent forms, case report forms, protocol documents, and regulatory documents, as required by sponsor and institutional guidelines.

Prepares and submits timely, accurate, and complete documentation of study continuing review and study amendments to Institutional Review Board (IRB). Assists investigators with reportable event submissions to IRB.

Assists with preparation of study documents such as informed consent, recruitment script, and other materials. Assists with preparation of proposal, protocol, case report forms and progress notes, as needed. Ensures consent process is performed and documented in compliance with FDA, GCP, IRB, HIPAA, SOPs, sponsor and institutional regulations and policies.

Provides ongoing education to study subjects about clinical trials and provides significant new information that may affect a subject’s willingness to participate in a study, when needed. Evaluates subject compliance and promotes compliance through education. Coordinates in-service classes for nurses, pharmacists and others regarding the study and/or investigational product.

Prepares site for monitor visit and external/internal audits. Provides timely response to queries from sponsor and/or auditors.

Collaborates with pharmacist or materials management personnel to maintain accurate accountability of investigational products and specimens.

Coordinates sample collection, processing and shipment for each study.

Maintains automated databases and other records for reporting and compliance purposes. Generates reports and analysis of data according to project schedules or on an ad hoc basis. Provides guidance and direction to less experienced research coordinators in these efforts.

Arranges and attends meetings, seminars, symposia and other events related to project efforts. Participates in educational opportunities to increase knowledge about clinical trials and regulations. Remains current with federal, state, and institutional regulations and best practices.

Orders supplies and equipment. Researches and develops recommendations for new equipment purchases.

Completes Research Order Form (ROF) for each subject visit and submits subject enrollment documentation as required.

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

Minimum Experience:

2 years

Minimum Field of Expertise:

Certified research coordinator. Administrative or research experience. Knowledge of medical environment and terminology. Knowledge and understanding of federal, state, and institutional research regulations as well as Good Clinical Practices (GCP) and HIPPA regulations. Proficient with MS Office applications. Demonstrated effective communication and writing skills. Ability to multi-task. Demonstrated ability to work as part of a team as well as independently.

Preferred Experience:

3 years

Preferred Field of Expertise:

Staff education and orientation experience. Knowledge of Electronic Data Capture (EDC) systems and Clinical Trial Management Systems (CTMS).

Skills: Administrative:

Balance figures
Clinical documentation
Communicate with others to gather information
Compose letters
Compute totals
Coordinate meetings
Customer service
Gather data
Input data
Maintain logs
Prioritize different projects
Research information
Schedule appointments
Understand and apply policies and procedures
Use database and/or word processing software

Skills: Other:

Analysis
Assessment/evaluation
Knowledge of applicable laws/policies/principles/etc.
Lead/guidance skills
Organization
Planning
Problem identification and resolution

Skills: Machine/Equipment:

Calculator
Computer network (department or school)
Computer network (university)
Computer peripheral equipment
Fax
Personal computer
Photocopier

**Supervises: Level:**

Leads employees performing similar work on a project basis.
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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