UNIVERSITY OF SOUTHERN CALIFORNIA

Research Coordinator Supervisor

Job Code: 135055

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Grade: 00
OT Eligible: No
Comp Approval: 1/24/2013

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JOB SUMMARY:

Supervises and coordinates all aspects of sponsor-initiated and investigator-initiated research studies including subject recruitment, data collection, scheduling of study-related assessments and follow-up of enrolled subjects, budget development and administration. Supervises staff and plans project operations based on proposed research activities and timelines. Provides leadership, 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:

*E/M/NA % TIME

______ Supervises and coordinates all aspects of sponsor-initiated and investigator-initiated research studies including subject recruitment, data collection, scheduling of study-related assessments and follow-up of enrolled subjects, and budget development and administration. Plans and staffs project operations based on proposed research activities and timelines.

______ Supervises staff engaged in sponsor-initiated and investigator-initiated research studies. Recruits screens, and hires staff. Performs performance evaluations and provides guidance and feedback to assigned staff. Counsels, disciplines and/or terminates employees as required.

______ Schedules assigns, and prioritizes workloads on a daily basis. Sets appropriate goals and deadlines. Ensures timely completion of unit’s work. Assigns and monitors progress on work assignments and special projects. Trains and demonstrates techniques or procedures to research coordinators.

______ Oversees the planning, organizing and scheduling of assessments/tests to meet research objectives and study protocol compliance. Communicates with study team personnel to ensure study procedures are followed and performed as described in protocol. Serves as primary contact for subjects, study personnel, Institutional Review Board (IRB) and study sponsor.

______ Develops and manages project budgets. Authorizes expenditures and monitors reconciliation and status to ensure compliance with fiscal guidelines and regulations. Prepares and/or directs the preparation of financial reports as required. Directs ongoing purchasing activities for supplies and equipment including authorization of one-time major purchases under supervision of investigators. Researches new equipment purchases and develops recommendations for supervisor’s consideration.

______ Assists in recruiting subjects for studies and determines eligibility based on study criteria. Coordinates and monitors study participant activities to include 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.
Has responsibility for overseeing data collection for research studies following established data collection and management procedures. Oversees collection, recording, entering and preparation of data for analysis. Performs basic and moderately complex study analysis under the direction of Principal Investigator. Oversees the collection of pertinent information from study participants through interviews, administration of tests or surveys or questionnaires, medical records review, or other collection procedures.

Organizes and prepares grant proposals. Works with investigators to develop research proposals. Interfaces with funding agencies to exchange information.

Oversees and ensures maintenance of accurate, complete and timely records, including consent forms, source documents, case report forms, protocol documents, and regulatory documents, as required by sponsor and institutional guidelines.

Supervises the preparation and coordination of the submission of timely, accurate, and complete documentation of study continuing review and study amendments to Institutional Review Board (IRB). Assists investigators with reportable events submission to IRB.

Oversees 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, sponsor and institutional regulations and policies. Monitors regulatory and policy changes over time and coordinates with central administration to ensure research coordinators comply with evolving requirements. Develops Standard Operating Procedures when needed or requested.

Provides ongoing education to study subjects about clinical trials and 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. Provides in-service classes for nurses, pharmacists and others regarding the study and/or investigational product.

Oversees preparation of study 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 product and specimens.

Oversees coordination of sample collection, processing and shipment for each study.

Oversees maintenance of 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 research coordinators in these efforts.

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

Ensures the Completes Research Order Form (ROF) for each subject visit is prepared and submission of subject enrollment documentation is submitted, 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:**

Master's degree

Combined experience/education as substitute for minimum education

**Minimum Experience:**

5 years

Combined education/experience as substitute for minimum experience

**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 including Good Clinical Practices (GCP) and HIPPA regulations. Budget control and development experience. Proficient with MS Office applications. Demonstrated effective communication and writing skills. Ability to multi-task and prioritize. Demonstrated ability to work as part of a team as well as independently. Knowledge of Electronic Data Capture (EDC) systems and Clinical Trial Management Systems (CTMS).

**Preferred Experience:**

7 years

**Preferred Field of Expertise:**

Demonstrated experience specific to specialty of the study.

**Skills: Other:**

Analysis
Assessment/evaluation
Budget control
Budget development
Coaching
Communication -- written and oral skills
Conflict resolution
Counseling
Human resource process and employment knowledge
Interpretation of policies/analyses/trends/etc.
Interviewing
Knowledge of applicable laws/policies/principles/etc.
Organization
Planning
Problem identification and resolution
Research
Scheduling
Supervisory skills
Teaching/training

**Skills:** **Machine/Equipment:**

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

**Supervises:** **Level:**

Supervises employees and/or student workers.

**Supervises:** **Nature of Work:**

- Administrative
- Professional/Paraprofessional

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**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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