UNIVERSITY OF SOUTHERN CALIFORNIA
Protocol Coordinator (Research Nurse)
Job Code: 185615

Grade: HG
OT Eligible: Yes
Comp Approval: 7/20/2007

JOB SUMMARY:
Assists principal investigator in coordinating all phases of research studies including recruitment, assessment, treatment, data collection and follow-up for enrolled patients. Provides input to principal investigators, staff nurses and patients that effects clinical research studies from the initial protocol design to completion of study.

JOB ACCOUNTABILITIES:

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Assists principal investigator in coordinating all phases of research studies including recruitment, assessment, treatment, data collection and follow-up for enrolled patients. Plans, organizes and schedules activities to meet research study objectives. Critiques in-house research studies prior to implementation. Provides input to principal investigators regarding the protocol design and analysis. Implements multiple research studies, as needed. Participates in recruitment of patients, data collection and follow-up for patients enrolled in a research study.

Attends start-up meetings for new industry trials off site. May at times represent the principal investigator and the university. Provides input at meetings regarding such matters as data management. Attends on site study initiation meetings with sponsor and entire research team after IRB approval to discuss protocol and identify potential problems and resolutions.

Determines patient eligibility for a research study and assesses patients for eligibility for a protocol. Assesses psychosocial needs to ensure patient compliance. Conducts thorough pre-study assessment to determine baseline toxicities. Explains study to patients and potential patients. Answers patient’s questions regarding study, drug toxicities and effectiveness. Educates patient regarding possible toxicities and instructs patients to call if questions or problems. Ensures that written informed consent is obtained, readable and that risks are described accurately based on experience. Completes protocol specific data management forms to aid in protocol compliance.

Reviews research schedules for studies and informs principal investigator if there is concern that a test or the timing is inappropriate. Schedules required tests and procedures and follows through on completion and return of results. Corresponds with any outside physicians to ensure protocols are followed and that tests and procedures are performed. Obtains appropriate treatment records from hospital or physician and obtains outside laboratory results.

Ensures safe administration of investigational drugs. Works with pharmacists and hospital nurses to ensure that protocol agents are administered accurately and safely and the maintenance of accurate drug records.
Monitors patient’s status throughout the study. Reviews and evaluates health status, lab findings and reactions. Assesses patients for adverse effects of treatment based on knowledge of the patient’s disease and clinical status, which includes recognizing unusual or unexpected side effects that may represent delayed or cumulative toxicity. Monitors any deviation that may occur and are instrumental in seeing that amendments are made to the study, so that the integrity of the study is not compromised.

Serves as a consultant to the principal investigator. Discusses patient eligibility questions and any patient concerns. Notifies physician of serious adverse events. Discusses toxicities, protocol deviations or violations that may require a protocol revision. Reviews patient response to therapy. Informs other health team members regarding patient’s response to treatment and/or medications, adherence to protocol’s schedule, need to reevaluate treatment and specific medical concerns and personal assessment. Generates data for ongoing evaluation of study, as requested.

Ensures study toxicities are recorded correctly and accurately. Follows FDA guidelines for prompt reporting. Communicates serious adverse events to the IRB, government, sponsors, outside agencies and coworkers. Communicates any patient related problems or concerns to staff nurses, social workers, and home health coordinators.

Develops systems and procedures to complete requirements of the protocols. Resolves inconsistencies in the protocols. Conveys, implements and interprets policies and procedures. Makes recommendations regarding procedural matters or departmental improvements.

Performs basic nursing procedures such as phlebotomy, vital signs, and other tests specific to the study. Many administer treatments specific to the study.

Coordinates the collection, processing and transporting of research specimens including packing and shipping to sponsor. Arranges for admission to research center so that blood samples can be obtained. Coordinates the drawing of specimens with a clinical lab, if necessary.

Coordinates data collection and ensures accuracy. Evaluates, recommends and implements procedures for data acquisition, management and quality control. Obtains, verifies, organizes, codes and enters data. Completes forms and maintains files. Meets with industry study auditor as needed to clarify data collected. Participates in federally mandated audits.

Interacts with patients and families to ensure study compliance, obtain information and provide emotional support. Functions as liaison with patient’s personal physician, other research studies, affiliated hospitals and other medical personnel.

Gathers facts and figures to develop a budget. Prepares financial status reports, as needed.

Conducts in-service classes for nurses, pharmacists and other personnel for new investigational drugs and protocols.

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:**
- Bachelor's Degree

**Minimum Experience:**
- 1 Year

**Minimum Field of Expertise:**
- Registered Nurse, California Registered Nurse license, current CPR certification, clinical research experience. Ability to communicate effectively and professionally with patients and their families, other medical staff and administrative personnel.

**Preferred Experience:**
- 2 Years

**Preferred Field of Expertise:**
- Two years directly applicable experience.

**Skills: Administrative:**
- Clinical documentation
- Communicate with others to gather information
- Compute totals
- Coordinate work of others
- Develop office procedures
- Establish filing systems
- Gather data
- Input data
- Maintain filing systems
- 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
- Counseling
- Interpretation of policies/analyses/trends/etc.
- Interviewing
- Knowledge of applicable laws/policies/principles/etc.
- Organization
- Planning
- Problem identification and resolution
Scheduling
Teaching/Training

Skills: Machine:

- Calculator
- Computer Network (Department or School)
- Computer Network (University)
- Computer Peripheral Equipment
- Fax
- Personal Computer
- Photocopier

Supervises: Level:

May oversee student, temporary and/or casual 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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