USC University of Southern California

Protocol Coordinator (Research Nurse)
Job Description

JOB INFORMATION

Job Code:	185615
Job Title:	Protocol Coordinator (Research Nurse)
FLSA Status:	Non-Exempt
Supervisory:	May oversee student, temporary and/or casual workers.
Job Family:	Nursing - Research
Job Family Group:	Nursing Services
Management Level:	7 Individual Contributor

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 QUALIFICATIONS:

Education

Req	*Pref*	*Degree*	*Field of Study*	
X		Bachelor's degree		

Additional Education

Check here if experience may substitute for some of the above education.

X	Combined experience/education as substitute for minimum education

Work Experience

Req	*Pref*	*Work Experience*	*Experience Level*	
X		1 year		
	X	2 years		

Additional Work Experience

Check here if education may substitute for some of the above work experience.

	Combined experience/education as substitute for minimum work experience

Knowledge, Skills and Abilities

Req	*Pref*	*Functional Skills*
X		Registered Nurse, California Registered Nurse license, current CPR certification, and clinical experience or clinical research experience.
X		Ability to communicate effectively and professionally with patients and their families, other medical staff and administrative staff.
	X	Two years directly applicable experience.

Certifications

Req	Pref	Select Certifications	Enter Additional Certifications
X		Registered Nurse - RN (CA Board of Registered Nursing)	
X		BLS/CPR	

Other Job Factors

JOB ACCOUNTABILITIES

	% Time	Essential	Marginal	N/A
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 psycho-social 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				

JOB ACCOUNTABILITIES

	% Time	Essential	Marginal	N/A
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.				

Other Requirements

Essential:	*Emergency Response/Recovery*	*Essential:*	*Mandated Reporter*
	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.		A mandated reporter who in his or her professional capacity has knowledge of, or reasonably suspects a person who is under the age of 18 years, elderly, or a dependent adult has been the victim of abuse or neglect must report the suspected incident. The reporter must contact a designated agency immediately or as soon as practically possible by telephone or in writing within 36 hours. By virtue of the associated job duties, this position qualifies as a mandated reporter as required by state law and USC's policy at: https://policy.usc.edu/mandated-reporters/

Campus Security Authority (CSA)	*Essential:*
By virtue of the associated job duties, this position qualifies as a Campus Security Authority as required by law and USC's policy at: https://dps.usc.edu/alerts/clery/	No

ACKNOWLEDGMENTS

The above statements reflect the essential and non-essential functions as necessary to describe the principle contents of the job. They are not intended to be a complete statement of all work requirements or duties that may be required of the position. I understand that I may be asked to perform other duties as assigned. USC reserves the right to add or change duties at any time.

The University of Southern California is an Equal Opportunity Employer. USC prohibits discrimination on any basis protected under federal, state, or local law, regulation, or ordinance or university policies. All employment decisions are based on individual qualifications and business need.

I acknowledge receipt of this job description and its associated physical requirements. I have read and understand the job description and job requirements and agree to abide by their contents. I realize that duties may be requested of me that are not specifically stated herein. I understand that I will be expected to adjust to potential fluctuations in work volume. I understand that, if I have any questions about the essential functions or expectations of my position, my supervisor and/or HR partner are available to discuss them with me.

_____ _____ _____

Print Employee Name	Signature	Date
_____	_____	_____
Print Manager Name	Signature	Date

This job description describes the general nature and level of work required by the position. It is not intended to be an all-inclusive list of qualifications, skills,
duties, responsibilities or working conditions of the job. The job description is subject to change with or without notice, and Management reserves the right to add, modify or remove any qualification or duty. Nothing in this job description changes the existing at-will employment relationship between the university and the employee occupying the position.