USC University of Southern California

Research Coordinator II
Job Description

JOB INFORMATION

Job Code:	135051
Job Title:	Research Coordinator II
FLSA Status:	Non-Exempt
Supervisory:	Leads employees performing similar work on a project basis.; May oversee student, temporary and/or resource workers.
Job Family:	Project Management
Job Family Group:	Administrative Support
Management Level:	7 Individual Contributor

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 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.

	Combined experience/education as substitute for minimum education

Work Experience

Req	*Pref*	*Work Experience*	*Experience Level*	
X		2 years		
	X	3 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		Administrative or research experience.
X		Knowledge of medical environment and terminology.
X		Knowledge and understanding of federal, state, and institutional research regulations as well as Good Clinical Practices (GCP) and HIPPA regulations.

Knowledge, Skills and Abilities

Req	Pref	Functional Skills
X		Proficient with MS Office applications.
X		Demonstrated effective communication and writing skills.
X		Ability to multi-task.
X		Demonstrated ability to work as part of a team as well as independently.
	X	Staff education and orientation experience.
	X	Knowledge of Electronic Data Capture (EDC) systems and Clinical Trial Management Systems (CTMS).

Licenses

Req	Pref	License(s)
X		Certified research coordinator.

Other Job Factors

JOB ACCOUNTABILITIES

	% Time	Essential	Marginal	N/A
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.				

JOB ACCOUNTABILITIES

	% Time	Essential	Marginal	N/A
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.				

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.