Supervising Clinical Operations Project Manager
Job Description

JOB INFORMATION

Job Code:	135169
Job Title:	Supervising Clinical Operations Project Manager
FLSA Status:	Exempt
Supervisory:	Manages through subordinate supervisors.
Job Family:	Project Management
Job Family Group:	Administrative Support
Management Level:	7 Individual Contributor

JOB SUMMARY

Responsible for all aspects of clinical trial management and execution, overseeing trial conduct and monitoring internal and external work. Develops a risk management plan and compiles trial master files for pre- and post-audit activities. Collaborates with functional groups to write study protocols, ensuring all elements required are included before implementation. Operationalizes, implements and manages large, multi-site clinical trials. Provides direction to central labs related to study activities for assigned trials, and reports on protocol progress to Principal Investigator and other leads via teleconferences. Contributes to hiring decisions, screening and interviewing candidates; trains and assigns work, mentors and provides direction, sets performance goals, and conducts evaluations. Supervises the content, design and development of data collection forms, and develops lab safety specifications.

JOB QUALIFICATIONS:

Education

Req	*Pref*	*Degree*	*Field of Study*	
X		Associate's degree		Or
X		Bachelor's degree		
X		Bachelor's degree	Biological Science	Or
X		Bachelor's degree	Biomedical Sciences	Or
X		Bachelor's degree	in related field(s)	
	X	Master's degree	Neurosciences	Or
	X	Master's degree	Public Health	Or
	X	Master's degree	Pharmacology	
	X	Master's degree	in related field(s)	

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		5 years	in on-site clinical trial monitoring.	
	X	8 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		Industry experience in a pharmaceutical, biotechnology, clinical research organization and/or nursing setting.
X		Demonstrated experience supervising others, using medical devices and terminology, and managing study records, finances and vendors.
X		Theoretical understanding of health sciences research and ICH-GCP guidelines, with experience applying policies and procedures.
X		Skilled at technical documentation and writing, and at assembling, organizing and conceptualizing numerical data in spreadsheets, databases, reports and presentations.
X		Ability to manage and prioritize different tasks and projects, with deft interpersonal skills for communicating with all levels of staff and diverse individuals and groups coordinating and executing study activities.
	X	Excellent written and verbal communication skills to express complex ideas to study staff at research and clinical institutions.
	X	Ability to handle several priorities within multiple, complex clinical trials.
	X	Strong understanding of current GCP guidelines applicable to the clinical research conduct.
	X	Proficient in OmniPlan or other timeline applications.
	X	Familiarity with academic medical centers.

Certifications

Req	*Pref*	*Select Certifications*	*Enter Additional Certifications*
	X		Certified Clinical Research Associate - CCRA
	X	Certified Clinical Research Professional - CCRP	
	X		Certified Clinical Research Coordinator - CCRC

Other Job Factors

JOB ACCOUNTABILITIES

	% Time	*Essential*	*Marginal*	*N/A*
Responsible for all aspects of clinical trial management and execution. Independently develops standard operating procedures (SOP) and utilizes performance metrics and quality indicators to ensure protocol procedures are completed accurately, safely and in a timely manner. Oversees trial conduct, monitors internal and external work, and develops a risk management plan. Compiles trial master file for pre- and post-audit activities, ensuring all documents filed and archived appropriately. Reconciles any data discrepancies in final analyses, reports, publications and internal/external presentations.				
Works directly with project director(s) and collaborates with functional groups to write study protocol based on concept sheets, ensuring all elements required are included before implementation. Serves as liaison with clinical labs for assigned trials. Develops guiding statements of work, interacting with lead managers, statistical staff and vendors.				
Reports on protocol progress to lead management via live video-streaming teleconferences, with agendas developed and data integrated from all functional groups. Coordinates with data management staff, ensuring data is reported in manner consistent with database and issues are timely escalated. Proactively identifies and resolves issues, addressing and analyzing problems related to study integrity and project operations.				
Aids in strategic planning by designing and generating analytical, comparative tracking reports. Creates timelines for protocols, interfaces with leadership to set priorities for project initiation and completion, and accurately describes each step of a process in an independently developed operations manual.				

JOB ACCOUNTABILITIES

	% Time	Essential	Marginal	N/A
Coordinates procurement of study drug(s) for protocol, ensuring the packaging and distribution schedule appropriately reflects the clinical trial's design and maintains the integrity of the biospecimens. Responsible for determining inventory, supply needs (including biospecimen supplies), vendors, and appropriate shipping procedures.				
Oversees the content, design and development of data collection forms, and develops the lab safety specifications. Ensures that drafted study operations and documents are implemented in compliance with FDA regulations and ICH-GCP guidelines, and that data is collected in accordance with the protocol with standardized format and content.				
Prioritizes, assigns and tracks project coordinator and project manager tasks that support study activities. Ensures clear delegation of duties are documented. Works with project coordinator, setting agenda for training meetings with 100-plus investigators and site staff, providing instructions for appropriate procedures and administration of tasks.				
Contributes to hiring decisions, screening and interviewing candidates. Trains and assigns work to new and current employees, mentoring and providing direction, and monitors tasks to ensure critical goals and timelines are met. Coordinates and approves employee work schedules and time-off requests, reviewing and approving time sheets.				
Sets performance goals for employees and conducts evaluations, making recommendations for merit increases or other incentives. Determines discipline to be imposed for subordinates, with authority to apply such, and/or submits recommendations to senior management.				
Stays abreast of current, relevant literature and clinical practice norms for project/program area(s), as well as any changes within legal, regulatory and technology environments which may affect operations. Maintains membership and participates in relevant professional organizations, attending appropriate meetings and seminars.				

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.