Clinical Operations Senior Project Manager
Job Description

JOB INFORMATION

Job Code:	135166
Job Title:	Clinical Operations Senior Project Manager
FLSA Status:	Exempt
Supervisory:	Trains new employees and allocates and monitors work of others.
Job Family:	Project Management
Job Family Group:	Administrative Support
Management Level:	7 Individual Contributor

JOB SUMMARY

Develops and implements standard operating procedures (SOP) and process improvements. Collaborates with project director and other functional groups to develop clinical trial protocols. Independently operationalizes, implements and manages large, multi-site clinical trial protocols. Establishes and drives project timelines, monitors progress toward project goals and ensures all aspects of clinical trials and studies are conducted efficiently and successfully. Reviews and ensures accuracy of trial master file. Integrates, oversees and reports on information between on- site monitors, staff and functional groups. Compiles monthly project performance metrics, identifies problems through analysis, recommends corrective and preventive actions, and ensures their completion through internal and external audits. Develops and drives agenda, reports on study status, and identifies action items in multifunctional study team meetings.

JOB QUALIFICATIONS:

Education

Req	*Pref*	*Degree*	*Field of Study*	
X		Bachelor's degree		
	X	Bachelor's degree		
	X	Master'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		3 years		
	X	5 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		Bachelor's degree in life sciences or similar field, or a combination of experience and an Associate's degree as substitute for minimum education. Industry experience in a pharmaceutical, biotechnology, clinical research organization and/or nursing setting, with at least three or more years' experience in on-site clinical trial monitoring. Demonstrated experience managing and supervising others, using medical devices and terminology, and managing study records, finances and vendors. Theoretical understanding of health sciences research and ICH-GCP guidelines, with experience applying policies and procedures. Skilled at technical documentation and writing, and at assembling, organizing and conceptualizing numerical data in spreadsheets, databases, reports and presentations. 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	Bachelor's and/or Master's degree in neuroscience, public health, pharmacology, healthcare administration or related field. Certified Clinical Research Associate (CCRA) and/or Certified Clinical Research Coordinator (CCRC). Experience in data management. Excellent written and verbal communication skills to express complex ideas to study staff at research and clinical institutions. Ability to handle several priorities within multiple, complex clinical trials. Strong understanding of current GCP guidelines applicable to the clinical research conduct. Proficient in OmniPlan or other timeline applications. Familiarity with academic medical centers.

Other Job Factors

JOB ACCOUNTABILITIES

	% Time	Essential	Marginal	N/A
Develops and implements standard operating procedures (SOP) and process improvements. Independently operationalizes, implements and manages large, multi-site clinical trial protocols. Assists in providing quality reviews of trial conduct, protocols and data. Establishes and drives project timelines, monitors progress toward project goals, and ensures study operations and documents are developed and implemented in compliance with FDA regulations and ICH-GCP guidelines.				
Conducts quality control reviews of trial protocols, study reports and associated documentation, including, but not limited to: patient information letters, informed consent documents, patient questionnaires and case report forms. Reviews and ensures accuracy and completeness of trial master file and trial close-out procedures.				
Integrates, oversees and reports on information between on-site monitors, staff and functional groups. Develops partnerships with internal and external groups with goal of increasing site performance and optimal patient experiences. Proactively anticipates and identifies trial operational, monitoring, and regulatory risks, ensuring early intervention when needed.				
Compiles monthly project performance metrics, identifies problems through analysis, recommends corrective and preventive actions, and ensures their completion through internal and external audits. Participates in preparation and execution of FDA Bioresearch Monitoring (BIMO) audits.				
Develops and drives agenda, reports on study status, and identifies action items in multifunctional study team meetings. Participates in departmental initiatives aimed at improving process and efficiency. Attends project management meetings, providing overview of clinical trial quality and workload.				
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 SOP and any trial documentation, and ensures alignment. 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		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

Other Requirements

Essential:	*Emergency Response/Recovery*	*Essential:*	*Mandated Reporter*
	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.		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.