Clinical Operations Project Manager
Job Description

JOB INFORMATION

Job Code:	135163
Job Title:	Clinical Operations Project Manager
FLSA Status:	Exempt
Supervisory:	Trains employees on specific skills and tasks as required.
Job Family:	Project Management
Job Family Group:	Administrative Support
Management Level:	7 Individual Contributor

JOB SUMMARY

Collaborates with Project Director and other functional groups to develop clinical trial scopes of work and objectives. Assesses feasibility of clinical projects, identifies project priorities, enforces project timelines, and ensures that milestones are met. Operationalizes, implements and manages clinical trial protocols at multiple study sites. Develops written materials to guide study sites in clinical trial execution. Collaborates with other functional groups to create, revise, implement and monitor standard operating procedures (SOP) and internal procedural guidelines. Serves as point of contact and guidance expert for assigned projects and studies. Organizes and executes training for site principal investigators and study staff.

JOB QUALIFICATIONS:

Education

Req	*Pref*	*Degree*	*Field of Study*	
X		Bachelor's degree		In
X			Biological Science	Or
X			in related field(s)	
	X	Bachelor's degree		And
	X	Master's degree		In
	X		Neurosciences	Or
	X		Public Health	Or
	X		Pharmacology	Or
	X		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		2 years	in on-site clinical trial monitoring.	
	X	4 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 using medical devices and terminology.
X		Experience applying policies and procedures, with some familiarity with ICH-GCP guidelines and working knowledge of FDA guidance documents.
X		Skilled at technical documentation and writing, and at assembling, organizing and conceptualizing numerical data in spreadsheets, databases, reports and presentations.
X		Lead/guidance skills, with the ability to manage and prioritize different tasks and projects.
X		Deft interpersonal skills for communicating with all levels of staff and diverse individuals and groups coordinating and executing study activities.
	X	Experience in data management.
	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. Familiarity with academic medical centers.

Certifications

Req	*Pref*	*Select Certifications*	*Enter Additional Certifications*
	X		Certified Clinical Research Associate (CCRA) and/or Certified Clinical Research Coordinator (CCRC).

Other Job Factors

JOB ACCOUNTABILITIES

	% Time	*Essential*	*Marginal*	*N/A*
Drives the development of clinical project scopes and objectives, and ensures the integrity of data being collected. Develops templates and guidelines, informed by regulations, policies and standard operating procedures (SOP), for the advancement of research studies and trials. Conducts database management, building and updating project calendars and budgets with relevant stakeholders.				
Assesses feasibility of clinical projects, facilitating overall tracking, communication, accountability and documentation. Ensures that assigned projects are audit ready. Communicates findings to relevant teams and management. Prepares reports, abstracts and journal submissions.				
Ensures adherence to budgets, scopes of work, and all contracted timelines. Liaise with varied departments and trials to create, revise, implement and monitor SOP. Assists in identifying any operational barriers and risks to data, milestones and deliverables. Ensures departmental/trial activities meet SOP and coordinate resolution, if necessary.				
Compiles monthly project performance metrics, identifies problems through analysis, recommends corrective and preventative actions, and ensures their completion through internal and external audits. Participates in preparation and execution of FDA Bioresearch Monitoring (BIMO) audits.				
Participates in clinical trial/study team meetings, as required, as well as departmental initiatives aimed at improving process and efficiency. Attends project management meetings, providing overview of clinical trial quality and workload.				

JOB ACCOUNTABILITIES

	% Time	Essential	Marginal	N/A
Serves as point of contact and guidance expert for assigned projects/trials. Schedules, leads and documents regular team meetings, and facilitates planning for competing projects. Drives site selection process, educating investigators and study site staff on protocol implementation and study activities. Identifies systemic gaps and collaborates with stakeholders to improve processes.				
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.