Clinical Operations Project Coordinator
Job Description

JOB INFORMATION

Job Code:	135161
Job Title:	Clinical Operations Project Coordinator
FLSA Status:	Non-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

Provides specialized support to clinical investigators and project management in the development of research protocols for projects and/or studies. Oversees the site selection process, and initiates, drives and tracks site staff training and start-up activities. Develops reports on metrics related to site start-up and presents data and status reports at meetings. Drafts source documents for data collection. Organizes teleconferences, meetings and training sessions, and prepares meeting minutes. Communicates and interfaces directly with leadership, project staff, consultants and vendors, supporting adherence to ICH-GCP guidelines.

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		2 years		
	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		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 two or more years' experience in on-site clinical trial monitoring. Demonstrated experience using medical devices and terminology. Experience applying policies and procedures, with some familiarity with ICH-GCP guidelines and working knowledge of HIPAA and FDA guidance documents. Skilled at technical documentation and writing, and at assembling, organizing and conceptualizing numerical data in spreadsheets, databases, reports and presentations. Lead/guidance skills, with the ability to manage and prioritize different tasks and projects. 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. Excellent organizational skills, and ability to interact with all levels of staff to coordinate and execute study activities. Ability to handle several priorities within multiple, complex clinical trials. An 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
Provides specialized support to clinical investigators and project management in the development of research protocols for projects and/or studies Executes, tracks and reports on the site-selection process and addition of new sites to the network. Initiates, drives and tracks the training of site staff and start-up activities, develops reports on start-up metrics, and presents data and status reports at meetings.				
Develops and maintains spreadsheets and other data management systems for effective oversight of clinical trial sites and study activities, tracking and disseminating necessary information. Assists project management in the development of working procedures and operations manuals, helping trials meet priorities and timelines for completion, and in the organization of trial master files.				
Drafts data collection forms. Assists project management in the procurement and packaging of study drug(s) for protocol(s), and the distribution of necessary supplies and materials for each.				
Develops project calendars, goals and metrics for evaluation, as assigned. Organizes teleconferences, meetings and training sessions, and assists project management in the organization and execution of larger meetings involving 100-150 investigators and study staff from participating sites. Prepares and distributes meeting minutes.				
Participates in trial and study set-ups, executions and close-outs. Assists in monitoring environments and equipment for safety, as necessary. Gathers and compiles data for reports, and assists with periodic audits of procedures for compliance and files for completeness and accuracy.				
Communicates and interfaces directly with on-site project staff, consultants and vendors, supporting adherence to procedures and ICH-GCP guidelines. Oversees new vendor set-up, pricing and payments, and tracks deliverables.				

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		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

Other Requirements

Essential:	*Emergency Response/Recovery*	*Essential:*	*Mandated Reporter*
	following an emergency, the employee will be notified to assist in the emergency response efforts, and mobilize other staff members if needed.		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.