USC University of Southern California

Associate Clinical Monitor
Job Description

JOB INFORMATION

Job Code:	135059
Job Title:	Associate Clinical Monitor
FLSA Status:	Non-Exempt
Supervisory:	May oversee student, temporary and/or resource workers.
Job Family:	Project Management
Job Family Group:	Administrative Support
Management Level:	7 Individual Contributor

JOB SUMMARY

Participates in the development, preparation and execution of sponsor- and investigator-initiated clinical research studies. Oversees the progress of clinical investigations by conducting pre-study, initiation, interim and close-out visits to study sites. Monitors clinical trials in accordance with good clinical practices and sponsors. Works closely with management to ensure all monitoring activities are conducted according to study requirements.

JOB QUALIFICATIONS:

Education

Req	*Pref*	*Degree*	*Field of Study*	
X		Bachelor's degree		
	X	Bachelor'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		<1 year		
	X	2 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		Familiarity with monitoring of clinical trials and medical terminology. Familiarity with the drug development process. Knowledge of ICH guidelines and Good Clinical Practices (GCP).
X		Understanding of FDA regulations pertaining to Good Clinical Practices.
X		Knowledge of local and/or national regulations pertaining to clinical trials and monitoring.

Knowledge, Skills and Abilities

Req	Pref	Functional Skills
	X	Experience with clinical trials. Experience with monitoring clinical trials and medical terminology.
	X	Knowledge of the drug development process. Knowledge of ICH guidelines and Good Clinical Practices (GCP).
	X	Understanding of FDA regulations pertaining to Good Clinical Practices. Knowledge of local and/or country's regulation pertaining to clinical trials and monitoring.

Other Job Factors

JOB ACCOUNTABILITIES

	% Time	Essential	Marginal	N/A
Conducts remote monitoring visits as necessary. Verifies site training, cross-referencing with assessments performed. Assists with audits of multiple centers and ensures all necessary data has been collected and documented accurately. Works with sites to resolve data queries. Identifies areas which need improvement. Reduces/controls unforeseen problems of all projects. Contributes to the documentation and update of study procedures. Operates appropriate customer support software and tools. May conduct visits to assigned study sites, as needed.				
Reviews applicable trial batteries (e.g., Neuropsychiatric Inventories) and study data as described in study documentation. Reviews and evaluates clinical test results and interviews (e.g., Clinical Dementia Rating) and ensures that interviews and tests are rated, scored and standardized. Reviews and reports on the quality and integrity of clinical data.				
Documents accountability, stability and storage conditions of clinical trial materials as required by sponsor. Keeps and updates study-specific regulatory trackers for monitoring team to use on site. Assists with investigational product inventory. Ensures return of unused materials to designated location or verifies destruction as required. Ensures that management of all clinical trial materials is compliant with local and federal regulations. Performs remote source document verification and responds to related queries. Analyzes databases for accuracy, completeness and reliability. Designs and implements corrective procedures when necessary. Works with monitors from other groups to implement new distributed data entry systems and procedures. Files appropriate monitor artifacts in electronic trial master file (eTMF) format. Tests online applications for functionality. Proposes potential solutions or procedural changes based on interaction with different groups.				
May instruct study staff on proper protocol and quality assurance procedures. Responds to questions regarding data collection, coding, and management and analysis methods. Escalates more complex questions to management or lead. Works closely with project staff to review current protocol status and identify protocol compliance issues. Communicates changes in conduct of the protocol, if applicable. Verifies that all protocol deviations have been accurately documented and reported. May attend meetings with principal investigators to participate in study implementation. Sets goals and timelines for the monitoring group and provides innovative contributions for ongoing research projects. Takes meeting minutes and maintains in-house regulatory documentation. Oversees and provides guidance to the project coordinators concerning quality control activities within the coordinating center. Considers ongoing and competing projects to establish a timeline for project completion. Stays current with pertinent literature and developments in field of specialization.				
Promotes an environment that fosters inclusive relationships and creates unbiased opportunities for contributions through ideas, words, and actions that uphold principles of the USC Code of Ethics.				

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		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

Other Requirements

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

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.