USC University of Southern California

Clinical Monitor
Job Description

JOB INFORMATION

Job Code:	135060
Job Title:	Clinical Monitor
FLSA Status:	Non-Exempt
Supervisory:	May oversee staff, students and/or resource employees
Job Family:	Project Management
Job Family Group:	Administrative Support
Management Level:	7 Individual Contributor

JOB SUMMARY

Participates in the development, preparation and execution of clinical trials. Oversees the progress of clinical investigations by conducting pre-study, initiation, interim and close out visits to sites. Monitors clinical trials in accordance with Good Clinical Practices and sponsors. Works closely with the Clinical Trial Manager 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		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		Monitoring of clinical trials and medical terminology.
X		Knowledge of the drug development process.
X		Thorough knowledge of ICH guidelines and Good Clinical Practices (GCP).
X		Understanding of FDA regulations pertaining to Good Clinical Practices.

Knowledge, Skills and Abilities

Req	Pref	Functional Skills
X		Thorough knowledge of local and/or country's regulation pertaining to clinical trials and monitoring.
	X	Thorough knowledge of clinical trials.
	X	Experience monitoring clinical trials and with medical terminology.
	X	Knowledge of the drug development process.
	X	Thorough knowledge of ICH guidelines and Good Clinical Practices (GCP).
	X	Understanding of FDA regulations pertaining to Good Clinical Practices.
	X	Thorough 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 independent visits to assigned study sites, as needed. Assists in the planning of data collection. Performs 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.				
Administers all applicable trial batteries (e.g., Neuropsychiatric Inventories) and trains personnel on battery administration. 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. Performs investigatory 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.				
Instructs study personnel on proper protocol and quality assurance procedures. Responds to questions regarding data collection, coding, and management and analysis methods. Works closely with the Project Coordinator 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.				
Conducts and attends regular meetings with the principal investigator to participate in study implementation. Sets goals and timelines for the monitoring group and provides innovative contributions for ongoing research projects.				
Oversees and provides guidance to the Project Coordinator concerning quality control activities within the Coordinating Center. Considers ongoing and competing Coordinating Center projects to establish a timeline for project completion.				
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. Tests online applications for functionality. Proposes potential solutions or procedural changes based on interaction with different groups.				
Stays current with pertinent literature and developments in field of specialization.				

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.