USC University of Southern California

Manager, Clinical Monitors
Job Description

JOB INFORMATION

Job Code:	135062
Job Title:	Manager, Clinical Monitors
FLSA Status:	Exempt
Supervisory:	Supervises employees and/or student workers.
Job Family:	Project Management
Job Family Group:	Administrative Support
Management Level:	6 Supervisor

JOB SUMMARY

Oversees clinical monitors for sponsor- and investigator-initiated clinical research studies, and the team's study recruitment, progress, performance, and adherence to protocols. Ensures site qualifications, initiations, monitoring, and study closeout visits are conducted in accordance with relevant regulations, business processes, and standard operating procedures. Directs administration of the consent process, and ensures maintained records are accurate, complete, timely, and compliant. Serves as primary communications liaison for clinical monitoring and study teams, identifying, resolving, and escalating any issues, as appropriate. Recruits, screens, interviews, hires, and supervises clinical monitors, and develops and administers ongoing clinical trial education and training.

JOB QUALIFICATIONS:

Education

Req	*Pref*	*Degree*	*Field of Study*	
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		5 years		
	X	10 years	Six years' experience monitoring clinical research studies.	

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		Extensive clinical research experience, and experience monitoring clinical research studies.

Knowledge, Skills and Abilities

Req	*Pref*	*Functional Skills*
X		Experience with medical terminology, and with the drug development process. Demonstrated experience with Good Clinical Practices (GCP), ICH guidelines, and pertinent FDA regulations.
X		Proven ability to interpret and apply all relevant federal, state, and local laws, regulations, and policies regarding clinical trials and monitoring.
X		Ability to work effectively and independently at a senior level in a highly decentralized and diverse setting.
X		Demonstrated strong interpersonal skills to deal effectively and tactfully with staff at all levels.
X		Proven ability to communicate effectively, both verbally and in writing. Demonstrated planning, problem-solving, and management skills.
	X	Demonstrated experience with Microsoft Office suite, specifically Excel and PowerPoint, and/or any other relevant presentation software/tools.
X		May require work, and travel, on weekends, evenings, and/or holidays, based on business necessity.

Other Job Factors

JOB ACCOUNTABILITIES

	% Time	*Essential*	*Marginal*	*N/A*
Oversees clinical monitors for sponsor- and investigator-initiated clinical research studies. Oversees study recruitment, progress, performance, and adherence to protocols. Responsible for study site assignments, preparations, daily operations, monitor metrics reviews (e.g., source document verification rate), data query placements, and closures. Travels to study sites, collecting and analyzing delivery, productivity, and performance metrics. Ensures site qualifications, initiations, monitoring, and study closeout visits are conducted in accordance with relevant regulations, business processes, standard operating procedures (SOP), and Good Clinical Practices (GCP) and ICH guidelines.				
Monitors and manages ongoing documentation, regulatory, and policy changes and updates for clinical monitoring procedures. Directs administration of the consent process, and ensures maintained records (e.g., site-specific consent forms, verifications, electronic case report-form reviews) are accurate, complete, timely, and compliant with GCP, IRB, FDA, HIPAA, and sponsor and institutional regulations and policies. Manages updates to standard operating procedures (SOP), and coordinates with central administration, as needed or requested, to maintain compliance.				
Serves as primary communications liaison for clinical monitoring and study teams, ensuring protocols are followed and procedures are performed as directed and identifying, resolving and escalating any issues, as appropriate. Supports the medical monitor and the project and data managers with problem resolutions and follow-ups. Provides timely responses to sponsor and/or auditor inquiries. Directs preparations for internal/external auditor visits, confirming timely and accurate submission of site visit documentation, and that critical goals, timelines, and quality compliance standards are met.				
Recruits, screens, interviews, hires, and supervises clinical monitors. Trains and assigns work to new and current employees, and conducts performance evaluations, setting goals and providing counsel, mentorship, direction, and feedback. Reviews, coordinates, and approves work schedules, timesheets, and time-off requests. Administers merit and disciplinary actions, including terminations. Develops and administers ongoing clinical trial education, creating instructional and coaching plans for certified, appropriate staff qualifications and training. Generates reports and analysis of monitor metrics, and guides and directs monitors doing so, according to project schedules or on an ad hoc basis.				
Maintains currency with pertinent literature and developments in relevant fields, and any legal, regulatory and technology changes that may affect operations. Participates in relevant professional organizations, maintains memberships, and attends appropriate meetings and seminars.				
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 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.