Clinical Research Data Specialist Lead
Job Description

JOB INFORMATION

Job Code:	185488
Job Title:	Clinical Research Data Specialist Lead
FLSA Status:	Non-Exempt
Supervisory:	
Job Family:	Business Data Analysis
Job Family Group:	Data Analysis
Management Level:	7 Individual Contributor

JOB SUMMARY

Coordinates, facilitates and manages the clinical data for various phases of complex clinical trials. Assists Study Coordinators and Clinical Research Data Specialist II with complex clinical trials. Provides leadership, guidance and direction to Clinical Research Data Specialists.

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	3 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		Experience in clinical trials data management.
X		Requires strong attention to detail with prior data entry experience.
X		Understands medical terms and familiar with various assessment criteria.
X		Strong verbal and written communication skills.
X		Able to manage time efficiently.

Knowledge, Skills and Abilities

Req	Pref	Functional Skills
	X	Experience in clinical trials data management in an academic research setting or other clinical trials office.

Other Job Factors

JOB ACCOUNTABILITIES

	% Time	Essential	Marginal	N/A
Coordinates, facilitates and manages the clinical data for assigned protocols. Ensures data is documented and recorded as appropriate. Reads and understands clinical data from medical records. Extracts and enters required clinical data from medical medical records and patient research charts/reports to Clinical Research Forms (eCRFs/CRFs). Notifies PI or Study Coordinator of issues or violations.				
Attends and participates in new protocol startup orientations with sponsors and completes protocol specific training.				
Acts as primary site contact with sponsor's Clinical Research Associate (CRA) for externally sponsored trials. Provides timely data entry. Plans and organizes monitoring visits.. Addresses all data queries for resolution.				
Maintains currency of federal regulations governing the protection of human subjects such as Food and Drug Administration (FDA), Good Clinical Practice/International Conference on Harmonisation (GCP/ICH) guidelines, Office of Human Research Protections (OHRP), Health Insurance Portability and Accountability Act (HIPAA) violations. Reports Serious Adverse Events (SAEs) to Study Coordinator and to various agencies, as required. Assists Clinical Research Data Specialists in reporting SAEs and assessing protocol violations.				
Ensures data collection is available per contract obligations at time of monitoring visit.				
Interacts closely with quality assurance supervisor to ensure data accuracy on eCRFs/CRFs prior to submission for in-house, National Cancer Institute (NCI) sponsored and Cooperative Group studies. Discerns data discrepancies/protocol violations.				
Assists supervisors with orientation, training and mentoring newly hired Clinical Research Data Specialists.				
Provides leadership, guidance and direction to Clinical Research Data Specialists as pertains to data entry into databases, as assigned.				
Prepares and participates in audits of assigned studies such as National Cancer Institute (NCI), Food and Drug Administration (FDA) and pharmaceutical audits. Reviews assigned patient charts and reports results.				
Assists Study Coordinator with eligibility work-ups for new potential research subjects.				
Provides assistance and input to PIs for publishing study results, as requested.				
Participates in Quality Assurance Monitoring Committee (QAMC) in-house audits by reviewing assigned patient chart and reporting on findings as relates to protocol/patient compliance.				
Completes spreadsheets for industry studies in real time to ensure sponsor is invoiced appropriately and timely.				
Ensures confidentiality, accuracy, security and appropriate access of all data and records.				
Performs other related duties as assigned or requested. The university reserves the right to add or change duties at any time.				

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/	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.