Clinical Research Regulatory Administrator
Job Description

JOB INFORMATION

Job Code:	135203
Job Title:	Clinical Research Regulatory Administrator
FLSA Status:	Exempt
Supervisory:	
Job Family:	Clinical Research
Job Family Group:	USC Job Families
Management Level:	8 Individual Contributor

Clinical Research Regulatory Administrator

JOB SUMMARY

Works closely with the Clinical Research Regulatory Manager, and supports principal investigators. Leads high-quality compliance reviews and coordinates all work to shepherd protocols and open studies in a timely manner. Removes obstacles from study activation, influencing timely IRB submission. Liaises with sponsors and agencies to ensure compliance with all applicable local, state, and federal regulations, statutes, and laws, resolving issues and problems, negotiating compromises, and proposing alternatives and recommendations to facilitate and expedite research. Maintains awareness of new and updated rules and regulations, alerting appropriate staff to changes, and ensuring appropriate interpretation and application to new and existing studies and trials.

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	in clinical research compliance, regulatory research and/or operations in the academic or private sector.	
	X	5 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 with submissions to the Institutional Review Board and/or the Federal Drug Administration for Investigational Drugs and Devices (IND/IDE).
X		Knowledgeable of Informational Conference on Harmonization Good Clinical Practice (ICH-GCP), Department of Health and Human Services (DHHS), Office of Human Research Protections (OHRP) and FDA regulations and procedures.
X		Ability to evaluate the risks and benefits of different solutions, and proven problem-solving and decision-making skills to uncover causes of problems.
X		Exemplary organization skills and attention to detail.
X		Proven ability to interpret, analyze, and apply pertinent policies, procedures, regulations, and requirements.
X		Participates in process management activities.
X		Ability to provide both detailed information as well as summaries to management-level individuals and groups, with experience presenting ideas and solutions in non-technical, business-friendly terms.
X		Deft interpersonal and diplomatic skills for communicating tactfully with all levels of staff and heterogeneous individuals and groups.
X		Experience with office management communication software/tools (e.g. Google suite, Slack, Skype).
	X	Extensive experience in compliance oversight, coordination, monitoring, and/or auditing of clinical research studies and trials.
	X	Advanced knowledge of regulations governing human research.
	X	Familiarity with intellectual property rights, inventions, patents and technologies.
	X	Exemplary communication and interpersonal skills, with the ability to present the business side of technical topics to non-technical audiences, and persuasively and effectively interact with relationships with various stakeholders and diverse individuals and groups.

Certifications

Req	Pref	Select Certifications	Enter Additional Certifications
	X		Collaborative Institutional Training Initiative (CITI) certification.

Other Job Factors

JOB ACCOUNTABILITIES

	% Time	Essential	Marginal	N/A
Works closely with the Clinical Research Regulatory Manager, and supports principal investigators. Ensures regulatory compliance for multiple clinical trials, Initiating, revising, and overseeing all regulatory aspects of study opening process. Submits protocols and supporting documents to internal and external regulatory bodies (e.g., Institutional Review Board), ensuring trials are consistent with approved proposals to open new studies, conduct SIV, close out visits.				
Prioritizes and manages own workload, and reports progress regularly to assistant director and team manager(s) as needed or requested. Creates and provides solutions to problems, reviewing processes and suggesting improvements. Escalates problems and issues, as needed.				
Oversees data management activities and maintenance of electronic regulatory files and binders with information pertinent to studying milestone progress (e.g., clinical trial management systems [CTMS], IRB databases, internal/external spreadsheets). RReviews documentation to support regulatory filings. Prepares annual progress reports for IRB renewal of ongoing studies.				
Liaises with sponsors and agencies to ensure compliance with all applicable local, state, and federal regulations, statutes, and laws. As requested and/or required by sponsors, participates in monitoring visits.				
Researches new and updated rules and regulations associated with clinical research studies and trials involving human subjects. Alerts appropriate staff to changes, and ensures appropriate interpretation and application to new and existing studies and trials. Maintains compliance with good clinical practice (GCP) guidelines, patient confidentiality (HIPAA), and any other applicable laws.				

JOB ACCOUNTABILITIES

	% Time	Essential	Marginal	N/A
Participates in centralized activities to support and promote research regulatory requirements. Participates in departmental education efforts, helping ensure highest quality research and protection of human subjects. Completes and submits external, reportable, adverse event reports according to department- and sponsor-specific requirements. Approves amendments to protocols and trial forms and documentation, as needed.				
Encourages a workplace culture where all employees are valued, value others and have the opportunity to contribute through their ideas, words and actions, in accordance with 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.