Clinical Research Regulatory Manager
Job Description

JOB INFORMATION

Job Code:	135205
Job Title:	Clinical Research Regulatory Manager
FLSA Status:	Exempt
Supervisory:	
Job Family:	Clinical Research
Job Family Group:	USC Job Families
Management Level:	5 Manager

JOB SUMMARY

Responsible for the efficient management of regulatory departments/units. Provides in-depth knowledge, expertise, ongoing support, education, and training to regulatory and clinical research staff, as assigned, regarding the regulatory conduct of clinical research studies. Serves as regulatory lead for interdepartmental and external agencies, ensuring regulatory compliance for multiple clinical trials. Guides regulatory staff, setting and communicating priorities and performance standards. Stays up-to-date with new and revised standard operating procedures and regulations. Works with departmental leadership to align training and staff development, implementing new training programs to meet emerging/unmet needs.

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		3 years	in clinical research compliance, regulatory research and/or operations in the academic or private sector.	
	X	7 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 a management or leadership role.
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. Proven ability to interpret, analyze, and apply pertinent policies, procedures, regulations, and requirements.
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 diverse individuals and groups.
X		Ability to develop and manage diverse, high-performing teams, fostering an environment of trust, collaboration, transparency, and accountability.
X		Demonstrated experience developing communication plans, instructional materials and related content.
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) and/or Certified IRB Professional (CIP) certification
	X		Regulatory Affairs Professionals Society (RAPS) certification(s).

Other Job Factors

JOB ACCOUNTABILITIES

	% Time	Essential	Marginal	N/A
Responsible for the efficient management of regulatory departments/units. Provides expertise and leadership in the development, preparation and implementation of regulatory strategies to support clinical research missions. Coordinates all work to shepherd protocols through and open studies in a timely manner. Oversees regulatory framework, determines pathways and options, and interacts with sponsors, agencies and other academic institutions.				
Ensures and guarantees regulatory compliance for multiple clinical trials. Oversees and audits the creation, initiation, development, and revision of protocols, informed consents, and other study and clinical research documentation. Approves protocol and document submissions to internal and external regulatory bodies (e.g., Institutional Review Board), confirming trials are consistent with approved proposals to open new studies.				
Serves as regulatory lead for interdepartmental and external agencies, interfacing with sponsors and agencies to ensure compliance with all applicable local, state, and federal regulations, statutes, and laws. Creates and provides solutions to problems, negotiating compromises, and proposing alternatives and recommendations to facilitate and expedite research. Escalates issues as needed, and as requested and/or required by sponsors, participates in and facilitates monitoring visits.				

JOB ACCOUNTABILITIES

	% Time	Essential	Marginal	N/A
Participates in and completes study activations and regulatory activities. Oversees data management activities and process 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). Reviews documentation to support regulatory filings, and prepares annual progress reports for IRB renewal of ongoing studies.				
Prioritizes and manages workloads. Leads high-quality compliance reviews, including close-out and reporting. Organizes team meetings, and actively and proactively participates with committees, task forces and ad hoc groups. Leads clinical-specific training and development of staff, maintaining and improving quality assurance programs as needed. Encourages staff development by actively seeking out continuing education opportunities.				
Stays up-to-date with new and revised standard operating procedures 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.				
Attends and participates in regular leadership meetings. Supports departmental education efforts, helping ensure highest quality research and protection of human subjects. Works with Disease Teams managers and departmental leadership to provide training and staff development, implementing new programs to meet emerging/unmet needs. Provides regulatory lectures to graduate students, as needed/requested.				
Participates in centralized activities to support and promote research regulatory requirements. Completes and submits adverse event reports according to department- and sponsor-specific requirements. Approves amendments to protocols, trial forms, and documentation, as needed.				

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.