Clinical Research Regulatory Specialist
Job Description

JOB INFORMATION

Job Code:	135201
Job Title:	Clinical Research Regulatory Specialist
FLSA Status:	Exempt
Supervisory:	
Job Family:	Clinical Research
Job Family Group:	USC Job Families
Management Level:	8 Individual Contributor

Clinical Research Regulatory Specialist

JOB SUMMARY

Learns and masters the creation, initiation, development, and revision of protocols, informed consents, case report forms, and other study and clinical research documentation to support principal investigators and quality assurance systems. Provides regulatory affairs support, coordinating or performing a wide variety of administrative and data management activities for research-project goals. Helps prepare and conduct high-quality compliance reviews (e.g., close-out, reporting). Updates all databases, and regulatory binders with information pertinent to studying milestone progress. Maintains communication, attends meetings, and answers questions from all involved parties (e.g., regulatory bodies, pharmaceutical companies, principal investigators, colleagues).

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	in clinical research compliance, regulatory research and/or operations in the academic or private sector	

Additional Work Experience

Check here if education may substitute for some of the above work experience.

X	Combined experience/education as substitute for minimum work experience

Knowledge, Skills and Abilities

Req	*Pref*	*Functional Skills*
X		Experience in clinical research compliance, regulatory research and/or operations in the academic or private sector.
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 (ICHGCP), 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		Deft interpersonal and diplomatic skills for communicating tactfully with all levels of staff and varied individuals and groups.
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.

Other Job Factors

JOB ACCOUNTABILITIES

	% Time	*Essential*	*Marginal*	*N/A*
Learns and masters the creation, initiation, development, and revision of protocols, informed consents, case report forms, and other study and clinical research documentation to support principal investigators and quality assurance systems. 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.				
Provides regulatory affairs support, coordinating or performing a wide variety of administrative and data management activities for research-project goals. Manages and maintains electronic regulatory files (e.g., staff resumes, licenses, training certificates, equipment receipts, investigation logs). Reviews documentation as needed to support regulatory filings, and maintains research files and documentation required by regulations.				
Works with senior team members to support and facilitate clinical research. Helps prepare and conduct high-quality compliance reviews e.g., close-out, reporting). Interacting with research investigators and staff throughout the process, from helping activate study and research trials to escalating problems and issues, as needed. Provides support and clinical-specific training to staff, maintaining and improving quality assurance training and development programs as needed.				
Updates all databases, and regulatory binders with information pertinent to studying milestone progress (e.g., clinical trial management systems, IRB databases, internal and external spreadsheets, study electronic systems).				
Ensures compliance with all applicable local, state, and federal regulations, statutes, and laws, and with agencies (e.g., the IRB and Federal Drug Administration (FDA)). Maintains compliance with Good Clinical Practice (GCP) guidelines, patient confidentiality (HIPAA) and any other applicable laws.				
Maintains communication, attends meetings, and answers questions from all involved parties i(e.g., regulatory bodies (e.g., IRB), pharmaceutical companies (e.g., monitors), principal investigators and colleagues). Works with clinical trial coordinators, research staff and investigators to further communications, helping remove obstacles impeding trial progress.				
Participates in centralized activities to support and promote research regulatory requirements. Coordinates with and assists other staff and departments with educational efforts, helping ensure highest quality research and protection of human subjects. Identifies compliance training and educational needs, coordinates the reporting of serious adverse events and protocol deviations, and				

JOB ACCOUNTABILITIES

	% Time	Essential	Marginal	N/A
proposes, completes, and submits 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.