https://arizona.csod.com/ux/ats/careersite/4/home/requisition/10255?c=arizona

SPECIALIST, REGULATORY	
Posting Number	req10255
Department	Senior VP Health Sciences
Department Website Link	
Location	University of Arizona Health Sciences
Address	1670 East Drachman Street, Tucson, AZ 85721 USA
Position Highlights	A successful candidate is responsible for assisting with the preparation and submission of IRB applications and regulatory documents, information management, data integrity, file maintenance, and coordination of tasks across multiple departments. They will work closely with faculty, research nurses, study teams, and our medical partner, Banner Health, to provide timely and expert support in the administrative start-up and maintenance of clinical research projects. Our Regulatory Specialists will have the opportunity to attend professional conferences as well as other professional development opportunities. Individuals successful in this role will be encouraged to explore opportunities for growth within our team's established career ladder. *Outstanding UA benefits include health, dental, and vision insurance plans; life insurance and disability programs; paid vacation, sick leave, and holidays; UA/ASU/NAU tuition reduction for the employee and qualified family members; state and optional retirement plans; access to UA recreation and cultural activities; and more!* The University of Arizona has been recognized for our innovative work-life programs. For more information about working at the University of Arizona and relocations services, please **click here**.
Duties & Responsibilities	• Assists in the support of faculty, trainees, staff, and others across multiple departments and medical disciplines in preparing, finalizing, and submitting timely and complete IRB applications and authorizations including: new projects, amendments, modifications, deferrals, partial HIPAA waivers, continuing review reports, safety/adverse event or deviation reports, and IND/IDE applications. • Assists in the coordination of regulatory activities from study start-up to close-out. Including completion and management of internal and external forms related to clinical trials: UAccess eIRB, Research Intake Application, FDA Form 1572, financial disclosures, Banner routing, regulatory binder maintenance, etc. • Drafts proposal language and protocol guidance regarding human subject protections. • Obtains and organizes other essential documents necessary for study approval.

	• Maintains electronic and hard copy regulatory files for assigned studies, including human subjects training certificates and financial conflict of interest reporting. • Communicate timelines and/or impact of approvals to research team operations. • Assists the institutional administrator for Clinicaltrials.gov. • Applies for and maintains NIH Certificates of Confidentiality for studies as needed. • Stays up-to-date on IRB policies and processes to ensure accurate and timely submissions. • Update OnCore Clinical Trial Management System (CTMS) and eRegulatory Management System (eReg) relating to study statuses and actions. • Provide OnCore and eReg training and support to UAHS community. • Quality Assurance/Quality Control (QA/QC) oversight for OnCore CTMS and eReg. Work with Data Administrator and department coordinators to ensure accuracy of system data. • Demonstrated ability to work in a fast paced, dynamic team environment with changing priorities in a manner that is effective and efficient. • Self-motivated, takes initiative, and a strong ability to multi-task multiple projects. • Excellent written and verbal communication skills and significant attention to detail. • Demonstrated ability to interact professionally and effectively with investigators, sponsors, and cross-functional teams to resolve issues with a positive outcome. • Other duties as assigned.
Minimum Qualifications	• Bachelor's degree and one year of experience in a professional environment, or equivalent combination of experience and education. • 1 year of relevant work experience required.
Preferred Qualifications	* Demonstrated experience working with IRBs (University & central). * Demonstrated knowledge of university and sponsor agency policies and procedures. * Demonstrated knowledge of the principles and practices of a OnCore CTMS and eReg. * Experience with UA systems, specifically UAccess Research and UA eIRB. * Excellent computer skills in Microsoft Office Suite. * Willingness to adjust schedule to work weekend and evening hours when necessary.
FLSA	Exempt
Full Time/Part Time	Full Time
Number of Hours Worked per Week	40
Job FTE	1.0

Work Calendar	Fiscal
Job Category	Research
Benefits Eligible	Yes - Full Benefits
Rate of Pay	$33,977 - $44,510
Compensation Type	salary at 1.0 full-time equivalency (FTE)
Grade	4
Career Stream and Level	PC1
Job Family	Research Compl
Job Function	Research
Type of criminal background check required:	Name-based criminal background check (non-security sensitive)
Number of Vacancies	1
Target Hire Date	
Expected End Date	
Contact Information for Candidates	Christine Gaul | cagaul@email.arizona.edu | 520-626-1542
Open Date	5/26/2022
Open Until Filled	Yes
Documents Needed to Apply	Resume and Cover Letter
Special Instructions to Applicant	
Diversity Statement	At the University of Arizona, we value our inclusive climate because we know that diversity in experiences and perspectives is vital to advancing innovation, critical thinking, solving complex problems, and creating an inclusive academic community. As an Hispanic-serving institution, we translate these values into action by seeking individuals who have experience and expertise working with diverse students, colleagues, and constituencies. Because we seek a workforce with a wide range of perspectives and experiences, we provide equal employment opportunities to applicants and employees without regard to race, color, religion, sex, national origin, age, disability, veteran status, sexual orientation, gender identity, or genetic information. As an Employer of National Service, we also welcome alumni of AmeriCorps, Peace Corps, and other national service programs and others who will help us advance our Inclusive Excellence initiative aimed at creating a university that values student, staff and faculty engagement in addressing issues of diversity and inclusiveness.