Quality Assurance/Quality Improvement Coordinator

Job no: 515711

Work type: Staff
Senior management: Vice President for Research
Department: Scholarly Integrity & Research Compliance
Location: Blacksburg Area
Categories: Grants / Contracts, Other, Research / Scientific

Job Description:

The Division of Scholarly Integrity and Research Compliance (SIRC) at Virginia Tech supports the business management of the Human Research Protection Program (HRPP). SIRC is deeply committed to both the highest ethical standards in scholarship, and to the proactive facilitation of basic, translational and transformative scientific research for the improvement of the human condition across the world. The office assists researchers with the fulfillment of their responsibility for compliance with policies and regulations pertaining to research.

SIRC is a critical unit within the Office of the Vice President for Research and Innovation (OVPRI) which supports university-wide strategic initiatives and operational functions of Virginia Tech's $542+ million research enterprise and associated technology commercialization activities, which span nine academic colleges, eight university research institutes, and three affiliated corporations. The university is embarking on its next phase of strategic growth in research across its Blacksburg, Roanoke, and Northern Virginia locations, including the recent integration of the Virginia Tech Carilion medical school as Virginia Tech's 9th college in 2018. Managing over 4500 IRB protocols a year, Virginia Tech's HRPP team is committed to ensuring protection of the rights, dignity, and safety of all human subjects involved in teaching and research activities. The HRPP Quality Assurance/Quality Improvement (QA/QI) Coordinator holds a key position in support of Virginia Tech's ambitious plans to become a leading 21st century land grant university that delivers innovative solutions to the most pressing global challenges of our time.

The QA/QI Coordinator will be part of a dedicated team of HRPP professionals. The QA/QI Coordinator will provide oversight and management of QA/QI activities for the HRPP/IRB. These activities include Post Approval Monitoring (PAM), FDA IND/IDE support, management of the clinicaltrials.gov institutional account, and internal quality assurance and improvement activities. The primary goal of the QA/QI activities is to ensure compliance and provide the most current information to researchers through education, training, and monitoring. These activities are an essential part of being able to identify areas where education and training are needed in order to minimize risks to human subjects.

This role will serve as a liaison between the faculty and HRPP and will advise on

regulatory and ethical compliance for HRPP and IRB submissions and contributes to the division's overall mission to protect the rights and welfare of human subjects involved in research.

The QA/QI Coordinator is responsible for, but not limited to:
- Creating an organizational culture within the team and across the research community that provides a safe, supportive, and enriching environment
- Serving as a liaison between the division, the IRB, and principal investigators to monitor regulatory compliance post approval
- Providing excellent customer service to all staff, faculty, and IRB members for project-related inquiries and needs
- Conducting FDA, and non-FDA, on-site reviews of selected human subject research projects to assess compliance with federal regulations, IRB requirements, and other relevant policies
- Educating and assisting researchers with maintaining compliance, including preparing related reports and making recommendations regarding observations and suggested actions
- Conducting for-cause reviews and assisting researchers with improvements that will ensure continued regulatory compliance and ethical treatment of human subjects
- Managing Virginia Tech's clinicaltrials.gov entries to ensure compliance with the NIH/FDA clinical trial requirements
- Advising and supporting researchers in the area of regulatory requirements for the use of investigational devices and drugs in human subjects research
- Staying abreast of and responds appropriately to relevant regulations, laws, guidelines, ethical considerations, and common practices to be a reliable resources resource to the broader university community
- Assisting the HRPP Director with policy, procedural, and guidance development; developing review checklists, writing review guidance, and creating educational materials for website, reviewers, researchers, and board members focusing on the areas that will help reduce noncompliance
- Identifying areas where additional trainings are needed and work with HRPP Director and Staff to develop and deliver training modules for researchers

Required Qualifications:

• Bachelor's degree in health/science or related field(s) or equivalent training or experience
• Demonstrated progressive experience related to IRB issues and human subjects research protections
• Demonstrated experience serving as a member of a research team conducting research or other experience working in an academic or medical center/school environment supporting IRB research activities
• Demonstrated customer service experience
• Strong analytical, time management and multi-tasking skills, communication skills,

effective interpersonal skills
• Ability to work independently, prioritize work, organize and manage a complex workload effectively under tight deadlines
• Demonstrated ability to read and interpret complex documents such as research protocols, consent forms, federal regulations and guidelines, policies, and standard operating procedures (SOPs)
• Demonstrated learning orientation to changing technology
• Experience in handling complex and confidential material

Preferred Qualifications:

• Knowledge of and experience with quality assurance/quality improvement activities, regulatory compliance policies/processes, and/or internal investigations
• Certification as an IRB Professional (CIP) preferred at time of employment, required within two years of employment
• Broad knowledge of research methods and terminology
• Prior IRB experience with biomedical and/or behavioral research
• Experience with or knowledge in the area of regulatory submissions for IND and IDE applications

Pay Band: 4

Appointment type: Regular

Salary information: Commensurate with experience

Review date: May 10, 2021

Additional information: The successful candidate will be required to have a criminal background check

About Virginia Tech: Dedicated to its motto, *Ut Prosim* (That I May Serve), Virginia Tech pushes the boundaries of knowledge by taking a hands-on, transdisciplinary approach to preparing scholars to be leaders and problem-solvers. A comprehensive land-grant institution that enhances the quality of life in Virginia and throughout the world, Virginia Tech is an inclusive community dedicated to knowledge, discovery, and creativity. The university offers more than 280 majors to a diverse enrollment of more than 36,000 undergraduate, graduate, and professional students in eight undergraduate colleges, a school of medicine, a veterinary medicine college, Graduate School, and Honors College. The university has a significant presence across Virginia, including the Innovation Campus in Northern Virginia; the Health Sciences and Technology Campus in Roanoke; sites in Newport News and Richmond; and numerous Extension offices and research centers. A leading global research institution, Virginia Tech conducts more than $500 million in research annually.

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If you are an individual with a disability and desire an accommodation, please contact **Lynn Byrd** at **byrd@vt.edu** during regular business hours at least 10 business days prior to the event.

To Apply: https://careers.pageuppeople.com/968/cw/en-us/job/515711/quality-assurancequality-improvement-coordinator