

Human Research Participant Protection Quality Improvement Coordinator

Job Code: 7463

Salary Grade: S09

FLSA Status: Non-Exempt

The following statements are designed to outline the general functions and typical responsibility levels associated with positions in this classification. They are not intended to serve as an exhaustive list of specific duties or requirements for individual positions assigned to this classification.

Duties and Responsibilities

Responsible for supporting and advancing the Human Research Protection Program (HRPP) Quality Improvement (QI) Program by evaluating HRPP and IRB processes, interpreting and applying complex federal regulations, and identifying opportunities to improve compliance and efficiency. This role also recommends corrective and preventive actions as needed.

- Conducts quality improvement assessments of human subjects research, including in-depth reviews of study records, site activities, and HRPP/IRB processes to determine compliance with federal regulations, institutional policies, ethical standards, AAHRPP standards, and IRB determinations.
- Performs routine, targeted, and for-cause monitoring activities to evaluate research integrity, study conduct, and participant protections, documenting findings and recommending appropriate corrective or preventive actions.
- Collects, analyzes, and interprets quality-related data to identify trends, operational gaps, and opportunities for improvement within HRPP and IRB workflows.
- Prepares clear, comprehensive written reports summarizing findings, compliance concerns, and recommendations for corrective actions, quality improvements, or process enhancements.
- Provides guidance to investigators, research staff, and HRPP personnel on compliance expectations, quality standards, and best practices in human research protections.
- Collaborates with HRPP leadership and research stakeholders to support process improvements, develop educational content, and promote consistent application of regulatory and institutional requirements.
- Supports QI operations by maintaining tracking systems, documenting assessment outcomes, monitoring follow-up activities, and contributing to the refinement of QI processes and tools.
- Designs, plans, and participates in HRPP and IRB educational programs aimed at enhancing research quality, compliance, and accreditation readiness.
- Performs other duties as assigned to successfully fulfill the responsibilities of the position.

Minimum Qualifications

Education:

Required: Bachelor's Degree

Equivalency/Substitution: Experience or a combination of education & related experience can be considered in lieu of degree. A one-to-one ratio is used to determine the number of years of experience required in place of a degree.

Experience:

Required: 2 years of IRB administration, research administration, clinical research experience, or related field

Certifications or Licenses:

- Successful completion of the IRB Professional Certification required after two years.

Verification of education and licensure (if applicable) will be required if selected for hire.

Knowledge, Skills, and Abilities

- Knowledge of federal regulations and guidance governing human subjects research, including OHRP, FDA, HIPAA Privacy Rule, and ICH/GCP guidelines.
- Knowledge of or ability to learn HRPP and IRB policies, procedures, and institutional requirements related to human subjects protections.
- Ability to interpret and apply federal and state regulations, institutional policies, and regulatory guidance when conducting compliance reviews and assessing research records.
- Excellent verbal and written communication skills, with the ability to prepare clear, accurate, professional reports and correspond effectively with investigators and staff.
- Demonstrate independent judgement and strong organizational/time management abilities in prioritizing tasks, coordinating multiple projects, and meeting deadlines.
- Strong interpersonal skills and the ability to interact professionally with investigators, research coordinators, HRPP personnel, administrators, and other stakeholders.



JOB DESCRIPTION

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- High attention to detail and accuracy in documentation, record review, and data interpretation.
- Proficiency in Microsoft Office applications and Adobe Acrobat, with the ability to learn and master electronic systems such as iRIS.

Working Conditions

Standard office environment

Occasional travel may be required between campuses and research sites

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