

UMMS Career Ladder Matrix

Regulatory and Compliance Specialist

Job Title	Regulatory and Compliance Specialist I	Regulatory and Compliance Specialist II	Sr Regulatory and Compliance Specialist
Job Code	MB0567	MB0568	MB0569
Pay Grade	43	44	46
Position Summary	Under the direction of the Director or designee, the Regulatory and Compliance Specialist I is responsible for ensuring research regulatory affairs and compliance with federal and state regulations and institutional policies and procedures.	Under the direction of the Director or designee, the Regulatory and Compliance Specialist II is responsible for ensuring research regulatory affairs and compliance with federal and state regulations and institutional policies and procedures.	Under the direction of the Director or designee, the Regulatory and Compliance Specialist III is responsible for ensuring research regulatory affairs and compliance with federal and state regulations and institutional policies and procedures.
Essential Functions /Scope	<ul style="list-style-type: none"> * Gather data, review, and triage the submissions of various initial and continuing review requests ensuring accuracy and the appropriate level of review according to the state and federal regulations * Assess submissions for consistency with regulation & compliance requirements * Track the metrics of the performance of processes (initial, continuing review, new information reporting, etc) as well as responses from investigators and research staff for resolution * Ensure that delegated pre-review process communications for investigators are handled efficiently * Prepare, review, and submit regulatory and compliance documents * Coordinate training to the research community * Coordinate central committee communication for meetings, agendas, approvals, etc. * Provide support for all web changes and enhancements of information * Compile data and assist in designing reports for internal and external audiences * Prepare, maintain and revise research application forms, procedures or instruction manuals, and integrate changes 	<ul style="list-style-type: none"> * Participate in or lead special projects from concept to completion. Activities may include conducting research/collecting information, establishing project schedule, organizing team meetings, and monitoring/reporting project status * Ensure that delegated pre-review process communication to investigators is handled efficiently * Ensure that post- award documents are consistent with the original submission and ongoing amendments. Request additional material or information in order to address concerns * Coordinate activities with researchers, sponsors, and regulatory/compliance agencies * Follow up on late and/or incomplete submissions * Facilitate the expedited review process * Perform internal audits of research activities * Assess the educational needs of the research community, recommend training opportunities, and conduct individual and/or group training sessions * Attend central committee meetings, coordinate activities, and respond to committee requests for special information and monitoring requirements * Assist in preparing for inspections and program review, following up with deficiencies and preparing reports * Interpret regulatory/compliance developments and make recommendations for changes when current business processes are impacted * Compile and analyze data and prepare reports for internal and external audiences 	<ul style="list-style-type: none"> * Lead protocol design, document control, and protocol compliance with NIH and Federal regulations * Ensure compliance in the submission of various initial and continuing review requests * Recommend and implement changes when current business processes are impacted by regulatory/compliance developments * Lead the implementation of changes to regulatory/compliance processes and documents * Identify organizational education requirements and develop a strategy to ensure that all educational requirements are met with appropriate courses/trainings. Evaluate results, recommend improvements, and implement new course design * Lead Regulatory and Compliance Specialists, ensuring the flow of work and act in the role of content expert on regulations, protocol, and federal and state regulations and institutional policies and procedures * Develop priorities, policies, and define associated requirements for oversight of protocols * Process expedited reviews * Schedule and conduct semiannual inspections and program review * Assess submissions for consistency with regulation & compliance requirements * Perform internal audits of research activities, make recommendations to resolve complaints, and verify that deficiencies are corrected
Required Qualifications	Bachelor's degree in science, a related field, or equivalent experience 1-3 years of experience in research or regulatory/compliance administration or other relevant experience <ul style="list-style-type: none"> * Experience in handling confidential and sensitive material * Effective oral and written communication skills * Ability to prioritize, problem-solve and work under pressure in a deadline-driven environment 	Bachelor's degree in science, a related field, or equivalent experience 3-5 years of experience in research or regulatory/compliance administration or other relevant experience <ul style="list-style-type: none"> * Experience in handling confidential and sensitive material * Effective oral and written communication skills * Ability to prioritize, problem-solve and work under pressure in a deadline-driven environment 	Bachelor's degree in science, a related field, or equivalent experience 5-7 years of experience in research or regulatory/compliance administration or other relevant experience <ul style="list-style-type: none"> * Experience in handling confidential and sensitive material * Effective oral and written communication skills * Ability to prioritize, problem-solve and work under pressure in a deadline-driven environment
FLSA Status	Exempt	Exempt	Exempt
Promotional Process	Requisition	Requisition or In-family Promotion from Research and Compliance Specialist I	Requisition or In-family Promotion from Research and Compliance Specialist II