<table>
<thead>
<tr>
<th>Job Title</th>
<th>Regulatory and Compliance Specialist I</th>
<th>Regulatory and Compliance Specialist II</th>
<th>Sr Regulatory and Compliance Specialist</th>
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</thead>
<tbody>
<tr>
<td>Job Code</td>
<td>MB0567</td>
<td>MB0568</td>
<td>MB0569</td>
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<tr>
<td>Pay Grade</td>
<td>43</td>
<td>46</td>
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<td>Position Summary</td>
<td>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.</td>
<td>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.</td>
<td>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.</td>
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<td>Essential Functions</td>
<td>* 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 &amp; 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 and analyze 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.</td>
<td>* Participate in or lead special projects from concept to completion. Activities may include conducting research/gathering information, establishing project schedule, organizing team meetings, and monitoring/reporting project status. * Ensure that delegated pre-review process communication to investigators is 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 and analyze 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.</td>
<td>* 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. * 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 &amp; compliance requirements. * Perform internal audits of research activities, make recommendations to resolve complaints, and verify that deficiencies are corrected.</td>
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<td>Required Qualifications</td>
<td>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. * 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.</td>
<td>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. * 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.</td>
<td>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. * 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.</td>
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<tr>
<td>FLSA Status</td>
<td>Exempt</td>
<td>Exempt</td>
<td>Exempt</td>
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<td>Promotional Process</td>
<td>Requisition</td>
<td>Requisition or In-family Promotion from Research and Compliance Specialist I</td>
<td>Requisition or In-family Promotion from Research and Compliance Specialist II</td>
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**University of Massachusetts Medical School (UMMS) Career Ladder Matrix**

**Date:** 11-2019

**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

**ESSENTIAL FUNCTIONS:**
- 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.
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- Prepare, review, and submit regulatory and compliance documents.
- Coordinate training to the research community.
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- Provide support for all web changes and enhancements of information.
- Compile and analyze 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.

**REQUIRED QUALIFICATIONS:**
- Bachelor’s degree in science, a related field, or equivalent experience.
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- 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.

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