Title: Senior Regulatory Analyst

Pay Scale Group: 20

Essential Function
Under general supervision from a designated administrator, develop and implement comprehensive, education-based programs designed to ensure compliance with regulatory requirements.

Characteristic Duties

• Develop and implement comprehensive, education-based programs designed to ensure compliance with regulatory requirements.

• Develop and deliver education and training to research investigators and regulatory analyst in correctly interpreting and apply federal, state, and local research regulations.

• Monitor the completion and timely filing of all reports required by regulatory agencies.

• Audit the research study documentation filed with regulatory agencies (e.g., the university, FDA, AAHRPP, etc.).

• Keep abreast of current regulatory issues and their impact on university research operations.

• Develop and maintain standard operating procedures and implement policies related to compliance.

• Ensure site/laboratory visits are conducted and results reported according to policy.

• Provide guidance on completion of annual reports, protocol modifications, and adverse event reporting.

• Report suspected or known instances of noncompliance. Assist with resolution of compliance issues.

• Assist with quality assurance/quality improvement programs.

• Provide direct supervision to exempt and non-exempt staff (i.e., hiring/firing, performance evaluations, disciplinary action, approve time off, etc.).

• Perform related duties based on departmental need.

Minimum Qualifications

• Bachelor’s degree with seven (7) years experience; -OR- Associate’s degree with nine (9) years experience; -OR- eleven (11) years experience. Degree must be in Science or a related field. Experience must be in regulatory compliance and must include at least three (3) years supervision.

Last updated: June 2007