WAYNE STATE UNIVERSITY

ISSUED: 2/12

TITLE: Senior Research Compliance Administrator **SALARY SCHEDULE:** PE358 **CLASS CODE:** B

UNION: P&A – Local 1979, U.A.W **SALARY GRADE:** 12 **EEO CODE:** 30

FLSA: Exempt **E-CLASS:** PE

POSITION PURPOSE

Coordinate the administration of the Institutional Review Board (IRB), and other regulatory activities and operational procedures involved with reviewing and approving research protocols. Function as a liaison for multiple review boards, investigators, granting agencies and federal regulatory agencies. Provide structured, formal training and orientation to Research Compliance Administrators as well as ad hoc guidance as necessary.

ESSENTIAL JOB FUNCTIONS

- Review and process new and continuing research protocols for submission to appropriate research review boards. Resolve protocol submission errors/problems with investigators and key personnel. Direct unresolved issues to committee chair.

- Develop and deliver a formal training program for Research Compliance and Administrators (RCA). Develop curriculum, conduct sessions and discuss progress with management to determine next level of training. Serve as a resource and provide ad hoc guidance to RCAs as necessary.

- Coordinate and attend IRB/committee meetings. Serve as informational resource for regulatory and policy issues. Maintain record of committee decisions and activities. Create condition(s) of approval directives for investigators resulting from meetings to ensure policy and regulatory compliance.

- Assist faculty and research investigators with compliance and regulatory issues. Address questions resulting from meeting the conditions of approval directives. Provide procedural direction to ensure conditions of approval directives are addressed appropriately.

- Review investigator responses from IRB meeting conditions of approval directives and determine if issues are properly addressed. Generate approval letter or direct unresolved issue to committee chair as appropriate.

- Review adverse events and protocol violations and direct to committee chair, individual IRB, institutional officials, and regulatory agencies as appropriate. Provide procedural guidance to investigators when adverse events or violation is minor to ensure policy and regulatory compliance is maintained.

- Conduct, monitor and coordinate special projects as assigned. Prepare a wide array of statistical and administrative reports, summaries and questionnaires regarding department activities.

- Represent the department and serve as liaison to outside individuals, professional groups and administrators to interpret administrative procedures and policies and to disseminate information on department activities.

- Coordinate audits by federal regulatory agencies of research protocols and the regulatory committees (Food and Drug Administration, Office of Human Research Protection, Office for Laboratory Animal Welfare, U.S. Department of Agriculture, etc.)

- Assist and coordinate the development of institutional policies, procedures and manuals concerning the program for protecting human participants, animals and other regulatory activities.

- Perform related work as assigned.

ADDITIONAL COMMENTS

This classification level requires highly specialized non-theoretical skills coupled with an in-depth understanding of programmatic activities and requirements to assume responsibility for the administration of regulatory compliance committees of the University. Work activities demand the application of many procedures to differing situations and offer the incumbent latitude in determining the sequence in which these procedures should be applied while at the same time remaining in compliance with laws, regulations, guidelines, and institutional policies. Situations may also require the search for new applications of procedures and the establishment of new priorities. Work assignments are somewhat complex and require an understanding of the specific regulatory policies and guidance provided by a number of regulatory agencies and professional organizations.

Incumbents provide instruction and guidance to students, staff, faculty and the general public on the department's functioning and provide supervision to non-exempt department staff. Supervision, guidance and assistance are provided to department staff on administrative policies, procedures and functioning. Work assignments are performed independently and under the oversight of a professional and/or management position. This classification is typically located at the Division level of the University.

MINIMUM QUALIFICATIONS

- Graduation from an accredited college or university supplemented by coursework in research, business administration, or related field and/or an equivalent combination of education and/or experience.
- Considerable knowledge of pertinent federal regulators and state and local laws, e.g., Office of Human Research Protection, Food and Drug Administration, Office of Laboratory Animal Welfare, Office of Research Compliance and Assurance, Health Insurance Portability and Accountability Act, etc.
- Some knowledge and experience with University policies, procedures and practices surrounding the approval of research.
- Some knowledge of pharmaceutical and drug agency research requirements.
- Reasonable knowledge of and experience with PC and computer-based applications.
- Some supervisory experience required.
- Ability to communicate effectively with others.
- Strong analytical and problem-solving skills.
- Ability to establish and meet deadlines, work under extreme pressure, and function independently.
- Typically incumbents may have held a Research Compliance Administrator or regulatory compliance position.