Class Code:.....0487
Position #:(PSA)...108959
Developed by:.....DL
Reviewed by:.....SG
Approved by:.....LK
Date:.....10/10; 2/11

UNIVERSITY OF RHODE ISLAND
Position Description

TITLE: Specialist, IRB/RCR Compliance

DIVISION: Research & Economic Development

REPORTS TO: Director, Compliance (Research Compliance Office)

GRADE: 9

SUPERVISES: Support Staff; student workers

BASIC FUNCTION:

Under the supervision of the Director of Compliance, provide administrative oversight, guidance and support relating to all activities of the Institutional Review Board (IRB), the Responsible Conduct of Research Program, as well as other Research Compliance committees or areas of responsibility as required. Provide expertise and advice on current regulatory, policy, and procedural requirements to committee members, researchers and staff. Attend committee meetings, and work with and provide support to committee chairs.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

Under the general supervision of the Director of Compliance, the IRB Compliance Specialist is responsible for the day-to-day management of all administrative responsibilities relating to the University's IRB program. The IRB Compliance Specialist will also provide support to other committees and programs as needed.

Provide expert assistance to investigators, graduate students, research staff and administrators relating to online IRBNet-assisted IRB protocol applications, review and approval.

Responsible for acting as submissions coordinator for all IRB projects using the web-based IRBNet program. Provide expert assistance to faculty, staff and students in the proper use of IRBNet, including developing and revising training materials and facilitating workshops on a regular basis in the use of IRBNet.

Uphold the terms of the Federal-Wide Assurance, the Common Rule, and all other relevant federal, state and University regulations, policies and procedures.

As the online IRBNet project submissions specialist, provide advance review of research protocol submissions for accurate and thorough content; work with researchers as needed to revise submissions; determine, as part of the advance review process, whether multiple approvals are required, and coordinate efforts between committees to ensure appropriate approvals are obtained in correct succession.

Review externally-funded research protocols in conjunction with the Office of Sponsored Projects Review as needed to ensure that appropriate compliance approvals are in place prior to grant funds being released.

Coordinate planning, training and implementation efforts for IRBNet, the Web-based committee support program, and act as submissions coordinator as well as liaison with IRBNet.

Establish new database and tracking system to allow the University to enter into IRB Authorization Agreements (IAA) with external research institutions, and maintain cooperative IRB relationships and agreements with those institutions through formal contracts and informal networking.

In response to federal regulations enacted in 2010, the IRB/RCR specialist will oversee the development and implementation of a training program in the Responsible Conduct of Research, delivering training modules in research misconduct, data acquisition and management, responsible authorship, peer review, mentoring and collaborative research. The specialist will work with representatives from the Graduate School and Colleges to tailor the program to specific needs of various constituents. The specialist will deliver a minimum of eight hours of in-person training workshops supplemented by online modules and supported by an auditable database to ensure compliance.

Design and conduct training workshops, and coordinate online CITI training and certification programs.

Supervise and work with support staff on the evaluation of protocol information to ensure accurate entry of data into the appropriate database; maintain auditable database and paper records.

OTHER DUTIES AND RESPONSIBILITIES:

Develop documents for review by the appropriate committees, and make decisions about appropriate items for meeting agendas; take highly technical and complex meeting minutes to conform with federal regulatory requirements; inform researchers about committee decisions in a timely manner.

Serve as an information resource to researchers and students in meeting requirements and standards consistent with federal and state regulations and institutional policies and procedures.

Work closely, cooperatively, and professionally with other Research Compliance staff members, and coordinate efforts with the Division as a whole, including providing coverage as needed.

Engage in professional development opportunities as available; maintain memberships in professional listservs, and regularly review postings to gain updated information about relevant regulations and best practices, and apply them to Research Compliance materials and procedures.

Perform additional duties as required.

LICENSES, TOOLS AND EQUIPMENT:

Personal computers, printers; word processing, database management and other computer software as needed; all equipment necessary to conduct effective programs.

ENVIRONMENTAL CONDITIONS:

This position is not substantially exposed to adverse environmental conditions.

QUALIFICATIONS:

Required: Bachelor's degree and at least two years' experience in a research compliance or research protections office or equivalent research experience as may have been gained by working as a research assistant or associate in a similar capacity, or a Master's degree and at least one year of experience in a research compliance or research protections office or equivalent research experience as may have been gained by working as a research assistant or associate in a similar capacity; familiarity with federal regulations relating to human subjects protections; experience as a submissions coordinator using IRBNet or a comparable web-based compliance submission program; computer proficiency; demonstrated knowledge of research ethics; experience designing and conducting training workshops in the Responsible Conduct of Research (RCR); demonstrated knowledge of Conflict of Interest (COI) regulations; ability to organize, coordinate and supervise support staff; demonstrated excellent verbal and written communication skills; strong interpersonal skills, and ability to work well both independently and as part of a team; ability to prioritize and multi-task effectively; excellent organizational skills, including the ability to problem-solve and develop solutions to improve accuracy and efficiency.

Preferred: Master's degree and one year of experience in a research compliance or research protections office or equivalent research experience such as may have been gained by working as a research assistant or associate in a similar capacity; familiarity with FDA regulations and requirements; experience with IRB Authorization Agreements and contract negotiations.

ALL REQUIREMENTS ARE SUBJECT TO POSSIBLE MODIFICATION TO REASONABLY ACCOMMODATE INDIVIDUALS WITH DISABILITIES.