ASSOCIATE IRB ADMINISTRATOR

This position is within the Office of Research Administration at The Research Foundation (RF) for The State University of New York (SUNY) at Downstate and supports the SUNY Downstate Health Sciences University Institutional Review Board & Privacy Board (IRB) and the SUNY Downstate Central Methodology Research Committee (CMRC). The Downstate IRB and CMRC deliver high quality, focused, efficient, and friendly service to Downstate investigators and fosters an environment which facilitates collaboration with external investigators. The Downstate IRB and CMRC support investigators from University Hospital SUNY Downstate, the Colleges and Schools of SUNY Downstate Health Sciences University, NYC Health+Hospitals/Kings County, University Physicians of Brooklyn, and other sites, including private companies who are tenants of the Downstate Incubator. Downstate is experiencing significant opportunities for research: from the basic sciences; to translational investigation; to clinical trials; to population research and health equity and disparities research; to health information technology; to evidence-based research in nursing. SUNY Downstate is in the process of significantly increasing their clinical trial portfolio, enhancing the quality and efficiencies of IRB operations, and building the capacity of the Downstate research enterprise. This position will serve to enhance the overall service and operations of the research enterprise.

DESCRIPTION OF DUTIES:

- Responsible for preliminary review and processing of new IRB applications and other submissions, facilitation of ancillary reviews and creation of IRB agendas, IRB minutes, IRB letters, and other IRB records.
- Notifies IRB Members of IRB review requests and sends reminders for delayed reviews.
- Serve as an IRB member to review, deliberate, vote on the approval of research protocols, and recommend necessary modifications to protocols.
- Fulfill delegated responsibilities of the IRB Chair, including making Exempt, Not-Research, Not-Human Research, Not-Engaged determinations.
- Serve as subject matter expertise in human research protections to provide support and client service to IRB members, investigators, and the research community to ensure regulatory compliance and research integrity.
- Carry out process improvement activities, training of IRB members, Investigators, and staff.
- Performs Quality Assessment Program (QAP) reviews and other compliance activities.
- Facilitate review and execution of IRB related agreements: DUA, BAA, MTA, Confidentiality and Non-Disclosure Agreements, IRB Reliance Agreements, and Individual Investigator Agreements and confirmation of local research context for research approved by a reviewing IRB.
- Reviews and contributes to IRB policies and procedures, guidance materials, and templates.
• Provides regulatory guidance to the IRB Chairs and IRB Members and anticipates regulatory issues for which IRB members may need assistance (e.g., IND/IDE questions).
• Assist with AAHRPP accreditation and/or GAP analysis and implementation of new IRB software.
• Takes administrative lead on special projects as assigned by supervisor.
• In times of high work volumes or as needed, assist with duties of lower-level staff as needed.
• Other related duties to be assigned as needed, including other duties within the SUNY Research Foundation, including support for ClinicalTrials.gov and the Clinical Trials Office.

REQUIRED:

• Bachelor’s degree.
• 6 years of experience with an IRB, clinical research, human research compliance, or similar area.
• Expert knowledge of Federal and State regulations and guidelines, including but not limited to FDA, Common Rule, and HIPAA.
• Excellent time management skills.
• Demonstrated skills in providing excellent customer service.
• Demonstrated strong interpersonal, verbal, and written communication skills.
• Demonstrated knowledge and understanding of the IRB process.
• Ability to respect strict confidentiality.
• Solid computing skills: word processing, spreadsheets
• Knowledge of AAHRPP accreditation standards.

PREFERRED:

• MD, Master’s, or PhD degree in health sciences or a related field.
• CIP Certification or be eligible for certification within 1 year of hire.
• Experience with virtual meeting technology.
• Experience serving on an IRB, Privacy Board, of Conflict-of-Interest Committee.
• Experience reviewing Full Board, Exempt, and Expedited research.
• Experience making non-human research and not engaged determinations.
• Experience with IRB software system(s).
• Experience training IRB staff or Investigators.
• Familiarity with International human research regulations and privacy laws.
• Working knowledge of scientific and medical concepts and terminology.
• Understanding of research design and methodology.

FLEXIBILITY:

• Scheduled Days/ Hours: 9 AM to 5 PM, flexible.
• May need to work occasional weekends, evening hours, or holidays.
• Flexibility available for remote work schedule.

SALARY RANGE: $90,000 - $99,507
TO APPLY:

Interested candidates must send their resume/CV and cover letter with salary requirements to: kevin.nellis@downstate.edu

Closing Date for Receipt of Applications: 8/21/24

As an Equal Opportunity / Affirmative Action Employer, The Research Foundation for SUNY will not discriminate in its employment practices due to an applicant's race, color, creed, religion, sex (including pregnancy, childbirth or related medical conditions), sexual orientation, gender identity or expression, transgender status, age, national origin, marital status, citizenship, physical and mental disability, criminal record, genetic information, predisposition or carrier status, status with respect to receiving public assistance, domestic violence victim status, a disabled, special, recently separated, active duty wartime, campaign badge, Armed Forces service medal veteran, or any other characteristics protected under applicable law.