Center for Infectious Disease Research

Opportunity Overview:

An exciting opportunity is available for a Regulatory Specialist at Center for Infectious Disease Research (CIDR). CIDR is a diverse and dynamic group with a broad research portfolio of globally-important infectious diseases and works on making transformative discoveries that will lead to drugs, vaccines, and diagnostics. The diseases include HIV/AIDS, TB, malaria, and other infectious diseases. This position will support all aspects of the Human Subjects Research programs across multiple Investigators within the Center, including CIDR's Human Challenge Center (HCC) and associated malaria programs, and other activates with the Center that are subject to Human Subject Regulations, 45 CFR Part 46. This position will report to CIDR's Director of the Office of Regulated Research (ORR).

General Functions

Key activities include are aimed at ensuring CIDR adherence to the Common Rule, FDA regulations and guidelines, as well as executing/coordinating clinical trial operations activities as needed.

Essential Position Functions

Regulatory Associate

- In collaboration with Director of ORR, provide comprehensive, timely, professional quality and fully documented reviews of all Center research, including review and determinations for Human Subjects Research
- Train and assist Center Investigators in obtaining complete and accurate information needed for the Director of ORR to provide Investigator with appropriate Human Subjects Determinations
- Collaborate with Center Investigators to complete and submit research to local Institutional Review Board (IRB) as necessary.
- Collect and maintain repository for clinical trial protocols, consent forms, and IRB approval documentation associated with secondary biospecimens utilized in Center research projects
- Maintain fully compliant, accurate and high quality document retention systems related to all aspects of human subjects regulation, including but not limited to: IRB submissions, IND filings, Master Files, Protocol Binders, Clinical Trial Master Files)
- Prepare and submit routine Investigational New Drug (IND) documentation (e.g., annual reports, letters of authorization, etc.)
- Act as regulatory liaison to the IRB
- Develop, manage and track training program and requirements for the following aspects of regulated research: Human Subjects, Good Clinical Practice (GCP), Financial Conflict of Interest (FCOI), and others as applicable.
- Execute Annual, Center-wide FCOI Disclosure process

- Review Clinical Trial Protocols, Informed Consent Forms, source documents, data management plans, laboratory manuals, etc. to ensure GCP compliance
- Maintain current knowledge of FDA regulations and guidelines
- Execute CIDR FCOI management plan
- Assist in execution of the controlled human malaria infection (CHMI) at the Center, including drug inventory, equipment maintenance and calibration,
- Other duties as assigned

Resume and Cover letter is required.

Organization Overview:

Over 40 years ago, the Center for Infectious Disease Research (formerly Seattle Biomedical Research Institute) was founded as an independent non-profit organization devoted to the research of global infectious disease. The Center holds true to those roots today, having grown to include over 250 staff members who work collaboratively with one common goal: to eliminate the world's most devastating infectious diseases. To learn more about the Center for Infectious Disease Research, please visit our website at www.cidresearch.org

Apply online through our website at https://cidresearchcareers.silkroad.com/. If you need assistance with our online application contact us at jobs@cidresearch.org.

The Center for Infectious Disease Research is an Equal Opportunity Employer and all qualified applicants will receive consideration for employment without regard to race, color, sex, sexual orientation, gender identity, religion, national origin, age, protected veteran status, disability status, or any other characteristic protected by law.