05/03/2019

Johns Hopkins University Position Vacancy – IRB & Regulatory Specialist.

Below is the job listing. Candidates may apply online at : https://jobs.jhu.edu/job/Baltimore-IRB-&-Regulatory-Specialist-MD-21205/551878700/

IRB & REGULATORY SPECIALIST
The IRB & Regulatory Specialist will work with the faculty within the Center for Clinical Global Health Education whose research focuses on international public health, infectious diseases, HIV/AIDS, and tuberculosis in India. The IRB & Regulatory Specialist will report directly to the Indo-US Research Program Manager, and be responsible for maintaining accurate and up-to-date regulatory files for a large portfolio of clinical and non-clinical studies and sub-studies. Working closely with US and India faculty, clinic coordinators, and regulatory specialists situated in India, this position will be responsible for ensuring regulatory compliance and preparing IRB submissions using the Johns Hopkins IRB electronic application system.

Duties and Responsibilities:
Collaborate with investigators, students, fellows, and staff in India and the US, providing guidance and training in human subjects research and regulatory requirements for new and ongoing research studies. Assist investigators during protocol development, prior to submission to India and JHU IRBs, to ensure that regulatory and human subjects requirements are met. Obtain all required US and international documents for new submissions to the Johns Hopkins IRB. Works closely with the study sites to ensure all protocol amendments are accurately incorporated into protocol documents and consent forms. Prepares applications to the JHU School of Medicine IRB for new studies, amendments to studies, annual reports adverse events, and protocol violations for clinical trials and studies taking place in India. Assists students and fellows with IRB submissions. Communicates with the IRB, addressing questions they have about study applications. Track the status of a large number of studies, including India and US approvals, study staff, study stage, progress and grant support. Participates in weekly meetings and conference calls with both US and India team members. Frequent and direct contact with all research site investigators and staff; responsible for responding to questions and concerns as they arise. Stays up-to-date of NIH, GCP, OHRP and federal regulations for human subject participation in clinical research. Develops standard operating procedures as needed, and updates group guidelines based on changing regulatory guidelines and regulations. Compiles bioethics and other IRB-related documentation for grant submissions and reports to funders. Assists with compiling and formatting personnel documentation for grant submissions, as needed. Completes administrative and scheduling tasks related to IRB and regulatory activities. Perform other duties as needed.
This description is a general statement of required duties and responsibilities performed on a regular and continuous basis. It does not exclude other duties as assigned.

Qualifications:
Bachelor's Degree in related discipline required. Minimum of 3 years' experience in academic or industry-based clinical research required. Additional experience may substitute for some education, to the extent permitted by the JHU Equivalency Formula.
General computer skills, with experience with Microsoft Office required. Experience with Microsoft Access preferred. Excellent verbal communication and interpersonal skills. Must be a team player. Outstanding organizational skills required. Excellent attention to detail skills required. Ability to manage multiple projects at once, and effectively prioritize each.