Regulatory Compliance Coordinator

New York, New York

Summary

A Regulatory Compliance Coordinator position is currently available within the Tisch Cancer Institute. The incumbent will work with investigators and the Cancer Clinical Trials Office (CCTO) infrastructure to manage cancer clinical trials for the division. Duties include, but are not limited to, management of clinical studies through the regulatory portion of the trial submission process, ensuring regulatory integrity of assigned clinical trials from approval to closure, develop new clinical trials and act as the main contact during the protocol development phase, correspond with the reviewing committees and personnel, assist in budget development by identifying research non-billables, and coordinate start-up meetings for new protocols. The position will report into the Manager of Regulatory

Responsibilities

- Duties include, but are not limited to, management of clinical studies through the regulatory portion of the trial submission process
- Ensuring regulatory integrity of assigned clinical trials from approval to closure
- Develop new clinical trials and act as the main contact during the protocol development phase
- Correspond with the reviewing committees and personnel
- Assist in budget development by identifying research non-billables
- Coordinate start-up meetings for new protocols.
- Protocol development: Assist multi-disciplinary group of hematology/oncology Principal Investigators and researchers with development of investigator-initiated clinical trial protocols. Must understand complex scientific terminology and local, state, and federal regulatory requirements. Create informed consent forms, case report forms, and additional study documents, as needed per protocol.
- Develop and/or revises regulatory standard operating policies and procedures.
- Coordinates communication with investigators and members of the research team to aid in study development and oversight throughout the life-cycle of clinical trial.
- Participate in Clinical Trial Feasibility, Site Selection Process, and the Site Initiation Visit, which includes conducting interviews with scientists, doctors and academics and others in a network of industry experts.

Qualifications

Education

- Bachelor's Degree required, Master's degree preferred, preferably in Science or Health Policy.

Experience

- A minimum of 3 years of research experience in Regulatory Affairs, Clinical Affairs or Quality Assurance with knowledge of Phase I-IV clinical studies and data management aspects of clinical research

More Information / How to Apply

https://careers.mountsinai.org/jobs/2658746?lang=en-us