JOB DESCRIPTION

Title: Regulatory Compliance Specialist
Group: Ragon Administration
Supervisor Title: Administrative Director Regulatory Compliance
Date: January 2021

OVERALL RESPONSIBILITY

Supporting the day-to-day Regulatory Compliance functions for existing and new human subject protocols for all the Ragon Institute. This includes any required regulatory submissions, such as the initial and continuing reviews/expedited check-ins, amendments, adverse events, protocol deviations/violations and other reportable events as required by the MGB IRB. Works with Investigators, project managers and study staff on other Human Subject protocols using knowledge of the project and independent judgment to determine the most appropriate IRB application for the submission within the Insight system. Collaborates closely with the Clinical Research team in oversight of protocols enrolling human study participants. Maintains all protocols, based on the determinations of the MGB IRB. This may also include studies that are conducted at International locations in collaboration with the Ragon Institute. Works with investigators and individual grant administrators in preparing submissions of the Human Subject sections of an award or grant application and ensures the accuracy of funding information in reporting IRB documentation of funding.

PRINCIPAL DUTIES AND RESPONSIBILITIES

- Overall management of IRB submissions, including preparation and submission of protocol applications. This may also include protocol development, consent writing and preparation of recruitment and other study materials as required.
- Collaborates independently with the Clinical Research Team to prepare and submit any applications for review or maintenance of protocols that directly enroll study participants in the ongoing research of the Institute.
- Track and store electronically all related IRB documents associated with Initial and Continuing Review/Expedited Check-in submissions, as well amendments, notifications, approval letters and other similar materials.
- Working with International research studies to prepare MGB IRB applications and corresponding documentation for Ragon Investigators.
- Initiate, coordinate, and lead meetings with Principal Investigators, Project Managers and research scientists as needed.
- Preparation of human subject section for grant and award applications in consultation with Principal Investigators and assigned administrators.
- Strategizes ways to develop improved processes and efficiencies in response to changing regulatory requirements.
- Actively participates with other members of the Ragon Institute Administrative and operations team in meetings and projects.
- Other Responsibilities—perform other duties as assigned by Administrative Director

MINIMUM QUALIFICATIONS

- Five years prior work experience in professional administrative support or project management required, preferably in an academic or research environment. Bachelor's degree required.
- Previous experience in Institutional Review Board (IRB) communications, to include coordination of IRB submissions.
- Experience in managing compliance with Investigators and other research staff.
- Must be highly organized and pay strong attention to detail and accuracy; be self-motivated and assertive.
- Ability to work independently and as a team member, in fast-paced, demanding, clinical research environment in an effective and flexible manner.
- Must have excellent written and verbal communication skills.
- Proficiency with Microsoft Office