

## **JOB DESCRIPTION**

**Title:** Clinical Rsch. Coord.

**Group:** Ragon Administration

**Supervisor Title:** Regulatory Compliance Program Director

**Date:** April 2021

### **OVERALL RESPONSIBILITY**

Assists in supporting the day-to-day Regulatory Compliance functions for existing and new human subject protocols for the Ragon Institute. This includes preparing the required regulatory submissions, such as initial and continuing reviews/expedited check-ins, amendments, adverse events, protocol deviations/violations and other reportable events as required by the MGB IRB utilizing the Insight system. Maintains protocol documentation and tracking of human subject research submissions and deadlines.

### **PRINCIPAL DUTIES AND RESPONSIBILITIES**

- Supports the management of IRB submissions, includes preparation and submission of protocol applications. This may also include assisting with protocol development, consent writing and preparation of recruitment and other study materials as required.
- 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.
- Initiate, coordinate, and lead meetings with Principal Investigators, Project Managers and research scientists as needed.
- Assists investigators with Human Subject section of grant applications
- Actively participates with other members of the Ragon Institute Administrative and operations team in meetings and projects.
- Assists with Quality Assurance and Quality Control internal audits to monitor regulatory compliance of investigators and research staff
- Strategizes ways to develop improved processes and efficiencies in response to changing regulatory requirements.
- Other Responsibilities—perform other duties as assigned by Regulatory Compliance Program Director

### **MINIMUM QUALIFICATIONS**

- One to two 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 with 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