Job Description for Project Manager **Version 2.0; December 2019**

Job Summary: The Project Manager (PM) is responsible for the management and coordination of conduct of assigned clinical research trials sponsored by the pharmaceutical industry. These activities include effective planning, execution, reporting and evaluation of clinical trials. The Project Manager provides direction, but not supervision, to the clinical trial project team, including Clinical Trial Assistants (CTAs), Clinical Trial Specialists (CTSs) and Clinical Research Associates (CRAs). The Project Manager serves as the primary contact with the sponsor for project-related activities and as liaison with CRAs, CTAs, CTSs, clinical research sites, vendors, and other internal departments. The Project Manager ensures assigned projects proceed according to the project scope of work, protocol and other planning documents, which outline designated timelines and within the approved budget.

Reports To: Chief Operating Officer (CEO) & President

Primary Responsibilities

- Overall coordination and management of clinical trials from contracting to closeout
- Execution of technical, protocol-specific and operational aspects of assigned trials
- Collaborate with all stakeholders ensuring effective resolution of study issues as they arise to effectively meet timelines, deliverables, and budget constraints
- Ensure trials meet sponsor requirements, as well as adhered to Catawba Research's Standard Operating Procedures (SOP) and Work Instructions

Clinical Trials Management

- Will oversee multiple clinical trials simultaneously
- Ensures assigned trials and Trial Master File are always "audit ready"
- Assist in the review and approval of clinical protocols, Informed Consent Forms (ICF) and Case Report Forms (CRF)
- Create study-specific planning documents to manage trial safety, data, monitoring and timelines
- Coordinates effective execution of work to conduct trials with CRAs, CTSs and CTAs, as well as sponsors and vendors
- Ensures study team, both internal and site-based, is compliant with SOPs, protocol and other documents as required
- Provides consistent updates to staff, sponsor, vendors and other stakeholders regarding status and progress of trial
- Responsible for writing/approving clinical project deliverables, such as scope definition documents, source documents, monitoring tools and training materials
- Establish and oversee IRB submission and approval process
- Review and approve monitoring visit reports
- Collaborate with sponsor and vendors to manage Investigational Product (IP) and clinical trial supplies, including shipment and retention
- Responsible for providing study-specific training and documentation of training
- Responsible for developing presentations and other materials for Investigator Meetings and/or remote Site Initiation Visits (SIVs)
- Provide timely processing and completion of safety concerns and/or Serious Adverse Events (SAE) and Pregnancies occurring within trials
- Perform site monitoring, as needed
- Ensures timely resolution of data queries
- Review and approve Clinical Study Reports (CSRs)

Reporting

- Timely submission of expense and other administrative reports (i.e., time tracking)

Qualifications

- At a minimum, a Bachelor's Degree in the field of biomedical science (i.e., biology, chemistry, microbiology, health/life sciences, biomedical engineering, pharmacology, etc.), or equivalent experience within a clinical research organization.
- At least two years' experience overseeing clinical trials from study start-up to closeout
- Knowledge and proficient use of CTMS, EDC, project management software, and other technology-based programs (including Microsoft Office programs)
- Excellent oral and written communication skills
- Excellent time management and organizational skills
- Mindset of superior customer service for sponsors and sites

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Employee Signature Date

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Supervisor Signature Date