Position Title: Principal Investigator (PART TIME)

Position Summary: Responsible for serving as the Principal Investigator and Medical Safety Officer for all Phase I-IV clinical research studies performed at the Frontage Clinical Research Center and for assuring that studies are conducted in compliance with applicable regulations and GCP guidelines.

Responsibilities:

- Required to review all charts and patient records and countersign all medical orders, within seven days of their entry by a Physician Assistant.
- For any medical order prescribing or administering medication, the supervising physician shall review and countersign the order within 48 hours of its entry by a Physician Assistant.
- Fulfill Principal Investigator responsibilities in compliance with FDA regulations.
- Provide medical supervision as the Principal Investigator for all Phase I studies in healthy volunteers and outpatient Phase II-IV clinical studies in selected patient populations.
- Perform physical examinations and efficacy and safety assessments on healthy volunteers and patients.
- Review and provide clinical interpretation of serious and non-serious adverse events, laboratory test results, efficacy and safety assessments, physical examinations, medical and surgical histories, and ECG interpretations.
- Work with Drug Safety personnel in the assessment of and narrative preparation for adverse events.
- Review and approve case report forms.
- Manage and/or supervise management of adverse events and medical emergencies.
- Establish strategic relationships with physician specialists (*e.g.,* cardiologists, endocrinologists, urologists, ophthalmologists, fertility/reproductive medicine clinic, radiologists) and scientists in the surrounding medical and scientific community and adjacent medical centers.
- Provide input into study protocol feasibility assessments and study protocol design.

Requirements:

- Doctor of Medicine (MD) or Doctor of Osteopathic Medicine (DO) degree and a current medical license in the State of New Jersey.

- Practicing physician with at least 3 years of clinical research experience at a research site. Detailed knowledge of medical safety assessments.

- Familiarity with FDA regulations particularly as they pertain to Principal Investigator responsibilities and safety reporting requirements (*i.e*., treatment-emergent adverse events, serious adverse events), Good Clinical Practices, and ICH guidelines