First name Last name
XXX-XXX-XXXX USA
email@email.com
Https://LinkedInacct

PROFESSIONAL SKILLS:

Management skills: active listening, problem solving, critical thinking, conflict resolution, time management, flexibility, training, leadership and prioritization across multiple tasks
Office administration: Microsoft Office (Excel, Word, PowerPoint, Outlook)
Sponsor relationship building and support
Strong written and oral communication
Good Clinical Practice (GCP) and FDA guidelines
Medical terminology fluency
Coordinating travel arrangements (scheduling flights, rental accommodations, and hotels) as well as reimbursement policies and procedures

WORK HISTORY

Site Manager and Lead CRC for the Decentralized team – **Research Organization March 2022 - Current**

- Perform a variety of clinical study procedures including but not limited to vital signs, biological sample collection and processing/shipping.
- Responsible for the training and compliance requirements of the study team and ensure access to various study platforms for specified site location as well as delegation
- Keep updated and knowledgeable for multiple studies across many sites
- Facilitate third party audits
- Coordinate with the study manager to ensure all resources, including lab supplies are available as necessary to complete research timelines
- Organize new sites quickly for study equipment and supplies in order to begin study on time
- Serve as the primary contact to ensure appropriate communications, trial management, and meeting of timelines
- Working under the supervision of the Principal Investigator(s), while exercising excellent clinical judgment in patient monitoring and care
- Maintaining weekly contact with the Principal Investigator(s) for recruitment activities, study start-up, and general communication to achieve oversight
- Responsibility for the execution of the protocol and ensuring that all staff working on any given protocol have been properly delegated by the Principal Investigator and adequately trained on specified delegations
- Maintaining and submitting IRB communications and regulatory documents
- Timely communications with internal teams, investigators, review boards, and study subjects
- Preparing other study materials as requested by the Principal Investigator, such as informed consent documents, case report forms, enrollment logs, and drug/device accountability logs
- Training of nursing staff in scientific and procedural aspects of studies including informed consent form processes, ALCOA+, good clinical practices, standard of care vs. clinical research and time management.

Clinical Research Associate II / Senior Clinical Research Coordinator - **Company nane- November 2020-May 2021**

- Coordinate clinical research studies and maintain a safe study environment according to health and safety policies under the direction and delegation of the Principal Investigator
- Safeguard the well-being of subjects, act as an advocate, and address subject's concerns while ensuring the highest quality of care practices
- Maintain up-to-date study protocols, case report forms (CRFs), Electronic Data Capture (EDC) systems, and other study documents
- Plan and coordinate logistical activity for study procedures according to the study protocol
- Perform clinical set-up and preparation for the study including labeling specimen collection tubes and containers, inventory of required supplies, and setting up or troubleshooting equipment and/or study issues
- Assist with data entry, data quality checking, and query resolution to ensure adherence to study protocol and quality control for content accuracy and completeness
- Correct custody of study drug according to site standard operating procedures
- Perform clinical study procedures including but not limited to vital signs, and sample processing/shipping
- Collect, record, and report clinical data and findings appropriately in CRFs while collaborating with study investigator about study-related adverse events and serious adverse events according to the study protocol
- Perform all clinical auditing and source document verification activities independently according to ALCOA+ standards

Sr. Ophthalmological Clinical Research Coordinator - **Clinic name and location** - **June 2021 - March 2022 and Clinic name and location February 2019 - February 2020**

- Act as primary point of communication between the sponsor, PI and the research team
- Manage investigational product accountability and temperature monitoring for assigned studies
- Perform clinical study procedures such as vitals, retinal imaging, biological sample collection processing and shipping within IATA standards
- Coordinate clinical research studies and maintain a safe study environment according to health and safety policies under the direction and delegation of the Principal Investigator
- Coordinate the study start-up activities of studies including submissions of essential documents to the Institutional Review Board such as Form 1572, and Financial Disclosure forms as well as feasibility questionnaires and coordinate site initiation visits with monitors
- Recruitment and screening of potential subjects using the protocol and inclusion/exclusion criteria cross referenced with data from the EHR/EMR and refer to Principle Investigator for final evaluation to ensure promised recruitment numbers are met on time or exceeded as allowed by the sponsor
- Collect and maintain records of study activities, including drug dispensing records and regulatory compliance
- Submissions and maintenance of essential documents in Investigator Site File
- Maintain contact with research associate/monitors to schedule and coordinate site visits

EDUCATION AND TRAINING

Illinois State University, Normal IL - Bachelor of Science in Education

Society of Clinical Research Associates (SOCRA) - Clinical Site Coordinator/Manager GCP Workshop Miami, FL - November 7-8, 2019

Glaukos Corp. - Excellence in Research Training: Stage I - Lynchburg, VA - January 29, 2022

CERTIFICATIONS AND CLINICAL TRIAL EXPERIENCE

- Phase 0-III clinical trials. Therapeutic areas of experience: ophthalmology (nAMD, CRVO, BRVO, DME, NPDR, Glaucoma, Refractive Error, Presbyopia, DES) Lyme Disease Vaccine, Alzheimer's Disease, COVID-19, and Cardiology.
- Experience with multiple study platforms: iMedidata, Veeva Vault, Trial Master, iMednet, InForm, DrugDev, PPD Preclarus, Box, Longboat, SIP, Firecrest, Clinical Ink, Study Hub, Study Team, ClinOne, Advarra, Silverlink, Greenphire, CRIO, Duke Transmission Site, Vienna Reading Center, Labcorp, Quintiles Inforsario, Signant Health, Cenduit, Almac, Suvoda, Endpoint, Prancer, Clinical Trial Systems, Flex Advantage, Zen QMS
- EMR/EHR systems: NexGen, Epic, IO Practiceware, Medinformatix, ModMed/EMA, SRS Health, Pluto, eClinical Works
- IATA and GCP certified through CITI program
- Basic Life Support through American Health Association
- COA through JCAHPO