

Clinical Trial Assistant Job Description

- Assist with participant recruitment activities such as prescreening, informed consent, and enrollment
- Schedule participant study visits and coordinate travel if needed
- Collect clinical trial data and specimens according to protocol
- Process, label, and ship specimens to central labs. Maintain shipment logs
- Administer study drug to participants following dispensing procedures
- Monitor and record adverse events and side effects reported by participants
- Maintain regulatory documents, including ethics submissions, site contracts, and essential documents binders
- Assist with preparing ethics amendment submissions and renewals
- Coordinate investigational product management including inventory, accountability logs, and destruction
- Perform randomization and unblinding procedures per protocol specifications
- Assist with data entry, cleaning, and queries in the EDC system
- Organize site initiation visits and coordinate staff training as needed
- Create study calendars and reminders for participant visits and follow-up
- Manage study supplies and track inventory and reorders
- Submit serious adverse event reports to sponsors and regulatory bodies
- Coordinate shipments of monitoring reports and other study documents
- Assist with preparation of site payments and study expense tracking
- Participate in internal and external audits to ensure GCP compliance
- Perform quality control on case report forms and study documents
- Communicate with study sponsors, CROs, and vendors regarding trial needs
- Maintain study databases, files, and archiving systems

- Participate in study team meetings and trainings
- Provide general administrative support for clinical research staff
- Coordinate translation services for non-English speaking participants
- Provide guidance and assistance to participants throughout trial completion.