

CLINICAL RESEARCH NURSE COORDINATOR JOB DESCRIPTION

DUTIES AND RESPONSIBILITIES:

A Clinical Research Nurse Coordinator's responsibilities include, but are not limited to, the following:

- Coordinates the clinical trial from phone screening to randomization to study completion.
- Within the nursing scope of practice, assists the Investigator with the care and evaluation of research participants.
- Writes new procedures when required by protocol.
- Reviews study protocol and investigator's brochure. Independently communicates to appropriate resources to resolve research questions or issues.
- In collaboration with the Investigator, Project Manager, Community Outreach Coordinator, and Associate Director of Study Conduct Patients plans recruitment procedures for potential participants.
- Reviews and participates in the determination of eligibility and recruitment of candidates for study participation.
- Attends investigator's meetings, pre-study site visits, study initiation visits, and all other study-related visits by monitors or Sponsor representatives.
- Works closely with the Project Manager to ensure flow of study.
- Based on demonstrated clinical trial knowledge and skills, provides protocol specific education and training to appropriate personnel.
- Establishes study regulatory document binder to maintain complete and accurate records of all Sponsor, site, CRO, IRB/IEC correspondence and regulatory documents pertaining to the study.
- Performs quality checks on source documents specific to the study.
- Reviews approved regulatory documents from the IRB.
- Coordinates procedures performed by external vendors that are necessary to the conduct of the study.
- Attends in-house protocol meetings to review study-related procedures, staffing and visit flow.
- Utilizes nursing skills to coordinate research-related activities (e.g., scheduling study visits and medical coverage for physicals and dosing, assisting with nursing assessment of participants, adverse events, and data collection including laboratory and diagnostic studies).
- Uses experience to schedule study procedures so they are efficient and timely for all involved while maintaining study integrity.
- Participates in the ongoing Informed Consent process with the Investigator to ensure that research participants and their families (if applicable) have their questions answered and understand the consent form, as well as participant's responsibilities in the study.
- Responsible for ensuring subjects qualify for study prior to each dose and remains present for subject monitoring post-dose.
- Maintains communication with Sponsor or Sponsor Representative(s) throughout the clinical trial.

- Within the nursing scope of practice, assists the Investigator with the care and evaluation of research participants.
- Utilizes knowledge of disease processes to observe and report adverse events and protocol violations / deviations in a timely and accurate manner to the Investigator and Project Manager to ensure the health, safety and welfare of the participant.
- Responsible for giving subject instructions at check-in and serves as the primary contact for subjects by being available to handle study-specific questions, concerns or events.
- Ensures randomization procedures are completed per protocol.
- With minimal supervision, and when necessary, accurately records and abstracts data from source documentation onto case report forms (paper or electronic) in a timely manner. Maintains accurate and timely source documentation.
- Assures quality and completeness of source documents and case report forms collected during the course of the study. Enters data into case report forms using 100% source documentation verification.
- Files interval (interim), annual reports, and/or final reports to the IRB/IEC, IND safety reports and other pertinent information throughout conduct of study.
- Assists with monitoring visits on site and is available during visits for corrections, questions, etc.
- Maintains tracking systems for the effective communication and submission of required documentation to the IRB.
- After closeout visits has been conducted, prepares study documents for archiving according to timelines.
- Reviews and signs final study reports (if applicable).
- Responsible for completing all necessary training for their position, including DOPs and SOPs.
- Adheres to policies and procedures to ensure confidentiality, privacy and security of clinical research interactions and participant information, and responsible use of subject's research databases in compliance with CEDRA Clinical Research policies.
- Helps train new Coordinators / Assistant Coordinators / Research Associates / and other CEDRA personnel by serving as a mentor.

EDUCATION AND EXPERIENCE:

Minimum of a diploma from an accredited nursing school required. 1-2 recent clinical nursing experience in a hospital, clinic or similar health care setting required. A bachelor's degree may be substituted for 1-year work experience. A master's degree may be substituted for 2 years work experience; RN with 5 years of clinical nursing experience with 1-2 years of clinical trials research experience preferred.