OREGON MEDICAL RESEARCH CENTER

Clinical Research Nurse - Job Description

The Clinical Research Nurse, under the guidance and supervision of the Principal Investigator (PI), ensures the integrity and quality of clinical trials are maintained and conducted in accordance w/ federal, state, and local regulations, Institutional Review Board (IRB) approvals, and OMRC policies and procedures. This position is primarily responsible for the accurate completion of visit procedures and collection of information from study patients according to protocols, and for protecting the health, safety, and welfare of research participants. In addition, the clinical trial nurse also acts as study coordinator for limited studies.

Essential Functions:

Providing nursing care to research study patients:

- Ensures compliance with each study's protocol by providing thorough review and documentation at each subject study visit
- Participates in recruitment and selection of study participants by interviewing and documenting medical history to determine compliance with eligibility requirements
- Performs medical tests, including, but not limited to, vital signs, imaging studies, and electrocardiograms
- Administers investigational medications and performs patient assessments during clinic visits to determine presence of side effects; notifies Principle Investigator of findings/issues
- Provides patient education and medical information to study patients to ensure understanding of proper medication dosage, administration, and disease treatment
- Documents medical data in patient chart to capture protocol requirements

As Study Coordinator, ensures assigned studies are conducted in accordance with the Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), and Good Clinical Practices (GCP) guidelines:

- Ensures site compliance with research protocols by reviewing all regulatory requirements to confirm implementation of appropriate methods, practices, and procedures for all research activities
- Develops accurate source materials and ensures compliance from site staff
- Provides accurate and timely data collection, documentation, entry, and reporting in both sponsor and OMRC databases
- Ensures appropriate credentialing and training of the entire OMRC team
- Supports the regulatory staff in the maintenance of regulatory documents in accordance with OMRC SOP and applicable regulations
- Interfaces with research participants, to support efforts to determine eligibility and consenting of study participants according to protocol
- Communicates and collaborates specific study requirements to the research team, including internal and external parties, sponsor, monitors, PI, and study participants
- Ensures compliance with research protocols, by providing ongoing quality control audits, including maintaining ongoing investigational drug accountability
- Disburses investigational drug and provides patient teaching regarding administration, as necessary
- Communicates and collaborates w/ study team including internal and external parties, sponsors, PI, and study participants

Other:

- Participates with the PI and study team to identify and prioritize the development of systems and infrastructure to maintain research quality and compliance
- Occasional travel to attend sponsor study training meetings as required

- No supervisory responsibilities
- Other duties as assigned
- CPR certification required

Qualifications:

- Valid RN license from the State of Oregon
- Minimum of a diploma from an accredited nursing school required; Bachelor of Nursing or other Science degree preferred
- Two (2) years of recent clinical nursing experience in a hospital, clinic or similar health care setting (Bachelor's degree may be substituted for one (1) year work experience)
- Nursing competency skills per scope of practice (i.e., performing vital signs, nursing assessments, performing ECG/EKG, administering injections, etc.)
- At least one (1) year clinical trials research experience preferred
- Knowledge of medical terminology, drug calculation skills, clinical medicine, clinical trials and GCP concepts
- **Detail oriented and meticulous in all aspects of work**
- **Strong follow through skills and ability to proactively identify and solve problems; demonstrated initiative is imperative**
- Must have professional demeanor, strong communication skills with the public as well as physicians and co-workers
- Ability to work well independently as well as in team environment
- Strong interpersonal, customer service and multi-tasking skills are critical
- Must be proficient in Microsoft Office Word and Excel, electronic health systems and databases used in research environment, or have a willingness to learn and demonstrate proficiency within six months of hire
- Possess the ability to work well under pressure, multi-task, and manage deadlines
- Knowledge of GCP, federal, state, and local regulations, including HIPAA policies and procedures

Physical Requirements

- Physical Requirement - Feeling (sensing textures and temperatures) **(Frequently)**
- Physical Requirement - Fine Motor Skills (pinching, gripping, etc) **(Frequently)**
- Physical Requirement - Hearing **(Frequently)**
- Physical Requirement - Pushing/pulling **(Occasionally)**
- Physical Requirement - Reaching **(Occasionally)**
- Physical Requirement - Sitting **(Frequently)**
- Physical Requirement - Standing **(Frequently)**
- Physical Requirement - Stooping/crouching/kneeling/crawling **(Occasionally)**
- Physical Requirement - Talking **(Frequently)**
- Physical Requirement - Tasting/smelling **(Occasionally)**
- Physical Requirement - Walking **(Frequently)**
- Physical Requirement - Near Vision **(Constantly)**
- Physical Requirement - Color Discrimination **(Occasionally)**
- Physical Requirement - Use of keyboard, mouse and/or computer equipment **(Constantly)**
- Physical Requirement - Lift up to 35 pounds without assistance **(Occasionally)**
- Occupational Exposure/Risk Potential - Inside office environment **(Applicable)**
- Occupational Exposure/Risk Potential - Airborne communicable diseases **(Applicable)**
- Occupational Exposure/Risk Potential - Bloodborne pathogens or bodily fluid **(Applicable)**
- Occupational Exposure/Risk Potential - Fumes or airborne particles **(Applicable)**

Full-time position – 40 hours. Work days: Monday through Thursday, Hours: 7:00 am – 5:00 pm