CURRENT TITLE: Clinical Research Nurse

REPORTS TO: Principal Investigator/Clinical Research Manager

DEPT./UNIT: /IUPUI

SUMMARY: Initiate, conduct, complete, and report clinical studies/trials in (indicate study or assigned projects). Assign and coordinate activities of study sites to ensure protocol, regulatory and standard operating procedures (SOP) and Good Clinical Practice (GCP) compliance. Develop solutions to complex problems that impact the timely and accurate conduct of clinical research.

DUTIES and RESPONSIBILITIES: Solicit industry-sponsored trials through contacts and professional organizations. Access and extract information for protocol development for investigator-initiated trials. Summarize literature review for study hypothesis.

Participate in protocol development or review of risk assessment. Evaluate the protocol, study design and risk to subject population. Determine staff, facility, and equipment availability. Assess study population/availability.

Liaison with health-care professionals/providers to determine best recruitment practices for study.

Participate in preparation and negotiation of study budget. Reconcile study budget accounts with Business Manager.

Review, critically evaluate and comment on study contracts/agreement. Schedule and/or coordinate pre-study site visits of sponsor/s.

Prepare and submit Institutional Review Board (IRB) documents (i.e., Informed Consent, advertisement, protocol and protocol summary). Prepare regulatory documents for sponsor.

Schedule study-related meetings and training sessions. Provide instruction to study team for specific study assignments. Educate staff regarding scientific aspects of study. Train ancillary staff regarding clinical trial.

Develop advertising and other information materials for recruitment. Identify and schedule screening procedures and review results. Design recruitment strategies. Monitor enrollment goals and modify recruitment strategy as needed.

Identify potential subjects from review of existing protected health information based on Inclusion/Exclusion criteria.

Recruit subjects according to IRB/protocol approved methodologies; consent subjects including discussion of treatment and intervention alternatives and ensure that Informed Consent forms are properly signed before the start of the study.

Prepare and organize space for study related equipment and supplies.

Develop worksheet for “Standard of Care” versus study specific procedures.

Determine appointments per protocol. Schedule subjects for appointments. Perform subject interviews and assessments at study visits for data required by protocol. Assess and ensure subject safety throughout participation in trial.
Conduct study-related non-medical/behavioral assessments/interventions. Conduct study procedures/interventions. (appropriate licensure may apply)

Monitor study team compliance with required study procedures and GCP standards.

Contact outside health-care providers to obtain follow-up information. Communicate with subjects to obtain follow-up information.

Extract data from source documents. Complete Case Report Forms (CRF) or database entries. Audit for accuracy and correct CRFs. Resolve sponsor queries. Provide/create source documentation tools for subjects’ charts/records.

Order and receive drug/device supplies. Dispense drug/device supplies (calculate dosage as needed). Maintain files of drug/device dispensation, compliance and return.

Ensure proper collection, processing, shipment of specimens, and documentation. Communicate with laboratory, Principal Investigator, and sponsor regarding laboratory findings.

Record and document protocol deviations. Communicate with PI and sub-investigators about changes in the trial.

Review incoming subject adverse event (SAE) information and assist PI in making submission determination of SAEs. Maintain follow-up to determine resolution of adverse event. Capture and record adverse events data.Compose adverse event reports for oversight agencies.

Compose and submit continuing review/amendments/close out information. Schedule and prepare for monitor visits. Prepare and respond to Sponsor or FDA audits.

Audit documents and pertinent files and prepare for storage. Archive documents for study per sponsor/government/institutional requirements. Evaluate team effort at site. Document “drop outs” (e.g., causes, contact efforts).

Develop and implement teaching tools for subjects and families. Serve as an advocate for the subjects and their family.

Maintain current knowledge of regulatory affairs and/or issues. Maintain a high level of expertise through familiarity of clinical literature and/or attending continuing education classes, conferences, seminars, and project team meetings.

Perform other related duties incidental to the work described herein.

**QUALIFICATIONS:** BSN plus two years clinical research experience; or ASN plus two years nursing experience and two years clinical research experience; or LPN/diploma in nursing plus three years nursing experience and three years clinical research experience. Appropriate licensure and Clinical Research Certification (ARCP or SOCRA) are also required.