POSITION DESCRIPTION

CURRENT TITLE: Clinical Research Specialist
REPORTS TO: Principal Investigator/Clinical Research Manager/Administrator
DEPT./UNIT: /IUPUI

SUMMARY: Assist in the conduct and implementation of clinical research in (indicate nature of study, program or assigned projects, e.g., diabetes, pulmonary disorders, etc.). Participate in the initiation; monitoring, completion, and reporting of routine to moderately complex clinical studies in accordance with Standard Operating Procedures (SOP) and Good Clinical Practices (GCP).

DUTIES AND RESPONSIBILITIES: Assist in soliciting industry-sponsored trials through contacts and professional organizations. Summarize literature review for study hypothesis. Participate in the evaluation of the protocol, study design and risk to subject population. Access and extract information for protocol development for medical library and online databases. Participate in protocol development or review of risk assessment for investigator-initiated trial. Assist in determination of staff availability and assessment of study population/availability. Participate in the preparation and negotiation of study budget. Determine facility/equipment availability. Participate in critical evaluation and make comment on contracts/agreement. Compose and supervise preparation of regulatory documents including updates to Informed Consent forms. Assist in developing advertisement and other information materials for recruitment. Identify and schedule screening procedures and review results. 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. Determine appointments per protocol. Schedule and/or call subjects for appointments. Coordinate subject visits with support services. Contact outside health-care providers to obtain follow-up information. Communicate with subjects to obtain follow-up information. Assist in developing and implementing teaching tools for subjects and families. Train support personnel on study-specific tasks. Serve as an advocate for the subjects and their family. Extract data from source documents. Compete Case Report Forms (CRF) or database entries. Assist in resolving sponsor queries. Oversee the proper handling of laboratory specimens including processes, shipping, storage, and documentation. Review incoming subject adverse event (SAE) information and assist PI in making submission and/determination of SAEs. Capture and record adverse events data. Compose adverse event reports for oversight agencies. Compose and submit continuing review/amendments/close out information. Assist in the preparation for monitoring visits.
Monitor and ensure study team compliance with protocol and SOPs. Record, document, and report protocol deviations. Communicate with PI and sub-investigators about changes in the trial. 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 meeting.

Perform other related duties incidental to the work described herein.

**QUALIFICATIONS:** Bachelor’s Degree in Science or health-related field with at least 1 year health-related or research experience; or Bachelor’s Degree in any other field/Associate’s Degree in Allied Health professions with 3 years health-related or research experience or 2 years experience in clinical research. See guideline for other applicable combination of qualifications.