CURRENT TITLE: Clinical Research Manager

REPORTS TO: Principal Investigator/s/Unit Director

DEPT./UNIT: /IUPUI

SUMMARY: Provide overall direction for the initiation, monitoring, completion and reporting of clinical studies in (indicate study or projects). Supervise the research staff and perform a variety of personnel functions. Responsible for budgetary and fiscal management, quality assurance, database maintenance, proper documentation and reporting, and compliance with various policies and regulations. Serve as liaison between the research staff and the sponsors, collaborators, and regulatory agencies.

DUTIES and RESPONSIBILITIES: Provide overall supervision and administrative direction to all clinical research activities in the (department/center/unit). Provide supervision of research personnel and support staff. Perform various personnel functions including recruitment, project assignments, training, performance appraisals, and discipline. Provide staff with adequate workspace and materials.

Develop and coordinate departmental policies and procedures to ensure the efficient operation of both clinical trials and patient care. Establish standard operating procedures for the clinical research unit and ensure compliance with all internal and external requirements of regulatory agencies. Train/educate the ancillary staff regarding the clinical trial. Ensure the continuing education for all staff as appropriate. Oversee the orientation and training of new staff.

Evaluate protocol, study design and risk to subject population. Determine staff and facility availability; assess study population/availability. Review and critically evaluate contract/letter of agreement.

Design patient recruitment strategies. Monitor enrollment goals and modify recruitment strategy as necessary. Schedule and coordinate pre-study visits with sponsor/s.

Prepare and negotiate initial budget. Prepare payment schedule with sponsor. Negotiate fees for associated services. Manage study account and ensure that expenditures do not exceed contracted amount. Monitor for appropriate charges. Reconcile study budget accounts with business manager. Ensure adherence to grant sponsors, IRB and university accounting and grant administration guidelines.

Oversee the proper screening of study subjects. Ensure that Informed Consent forms are explained to study participants and all required signatures are obtained prior to treatment. Ensure subject safety throughout the participation in the trial; monitor study team for compliance with study procedures and GCP standards.

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

Design and implement secure and separate databases to collect outcome data and track data collection or oversee design of such databases. Maintain master list of all studies and subject participation at sites.

Oversee and ensure the implementation of the Principal Investigator’s recommendation for adverse event interventions; ensure that serious adverse events are reported to sponsor and IRB and properly documented on source documents.

Oversee the proper documentation at close-out as required by sponsor including return or disposal of unused supplies, reconciliation of test article accountability, study summary, evaluation of team efforts, and study “drop outs” and other required reports. Prepare for and respond to sponsor or FDA audits.

Communicate with sponsors concerning progress of clinical trials, budget issues, patient study-related problems, recruitment strategies and specific policies and procedures. Ensure submission of renewal of grant/s in a timely manner.
Maintain communication with the IRB regarding annual updates, adverse events, safety reports, protocol amendments, Informed Consent modifications.

Act as liaison between the research staff and the sponsors, IRB, federal, state and university officials and other regulatory agencies to maintain accurate communication of costs, policy changes, fiscal requirements, and other regulatory issues. Serve as key resource to research participants and collaborators.

Prepare marketing materials, search for potential referral services within the community and contact and/or network with sponsors for new grants or contract funding.

Establish and implement a QA/QI system for department. Participate in peer-reviewed, intra-office quality assurance program that retrospectively evaluates accuracy and timeliness of study completion, and protocol violations.

Participate and serve as unit representative on appropriate University committees, work groups and task forces.

Coordinate related renovation and construction activities to include appropriate scheduling of services, patient management, and infection control practices during such projects as needed.

Expand knowledge base and keep abreast with new research developments by attending continuing education meetings, lectures, training sessions and conferences.

Perform other related duties incidental to the work described herein.

**QUALIFICATIONS:** Master’s degree with two years experience in clinical research or bachelor’s degree in Science or health-related field with four years experience in clinical research or Associate’s degree in Allied Health professions/any bachelor’s degree plus five years experience in clinical research.

Clinical research certification (ACRP or SOCRA) and supervisory experience are also required.