***This old UMB job description was created between 2000 and 2014 and is being provided as a template or guide in the preparation of a current job description. The essential functions are general in nature and may not accurately depict the duties of a specific unit. Managers are encourage to update and provide specific duties that are applicable to work being performed in the unit.***

Job Title: **Research Specialist Clinical Lead**

Job Family: Research Sub Family: Clinical

**Job Summary:**

The Lead Clinical Research Specialist functions as the lead in a clinical setting who is responsible for providing the highest technical expertise and guidance to research programs, projects, and activities. This position is responsible for ensuring design, development, documentation and implementation of research procedures and protocols using a variety of complex activities. This position is also responsible for networking with faculty and staff to achieve strategic goals and maximize efficiency.

**Essential Functions:**

* Leads the development of project timelines, work plan, recruitment strategy, and progress through the duration of the research study or clinical trial. Collaborates with Principal Investigators and regulatory staff in the preparation of new protocol submissions, protocol amendments, and renewals of ongoing clinical trials.
* Trains and provides mentoring to other research personnel in the submission of research protocols, IRB submissions, research procedures and policies, etc. Serves as subject matter expert and provides guidance on regulatory matters and compliance for staff, faculty, and leadership.
* Oversees day to day clinical research operations and leads study initiation, execution, and completion. Leads the design of research studies. Oversees interaction with subject participants including eligibility screening, recruitment, enrollment, ensuring informed consent is properly secured and documented, counseling, and obtaining patient medical history.
* Lead the management and analysis of clinical research data to include data analysis using statistical software, data collection, data entry, data verification, and ensure compliance and clinical relevance of data. Develops individualized monitoring plans and monitoring and site tracking tools to comply with data monitoring requirements per federal regulations and guidance. Independently cleans, validates, and analyzes research data in order to prepare research findings for publications of journal articles and grant proposals.
* Searches relevant literature, develops conclusions, writes reports, prepare and deliver presentations of relevant findings and conclusions, and recommends appropriate actions. Reviews analysis and reports of less experience members of the research team.
* Develop, recommend, modify and implements policies and procedures and/or methods of clinical research to meet changing needs and requirements and enforces standards. Perform Institutional Review Board (IRB) and Health Insurance Portability and Accountability Act (HIPPA) protocol development and ensure compliance of research operations with protocols.
* Perform day-to-day operational duties such as: monitoring the budget; budget negotiation and review, ensuring quality control and safety compliance; serving as liaison with IRB, submitting invoicing, develops policies, procedures, and/or methods for laboratory experimentation; and ordering supplies.
* Performs other duties as assigned.

**Minimum Qualifications**

Education: Bachelors in Epidemiology, Sociology, Psychology, Nursing or field of study related to the research of the clinic

Experience: Five (5) years clinical research including three (3) years in the relevant research specialization.

Supervisory:

Licensure/Certification:

Other: No subsitution of experience for minimum education requirement.

**Knowledge, Skills, and Abilities**

*Managers may provide prefered knowledge, skills, and abilities as necessary.*

Job Code: E3324F

SOC Code: 194060 IPEDS: Computer

EEO6 Code: Professional State Code: 9213601

USM eCode: E30333 AAP Code: 3C