DIRECTOR-OFFICE OF CLINICAL TRIALS

DISTINGUISHING FEATURES OF THE CLASS: Under general supervision, an incumbent of this position will be responsible for the administration, systems development and oversight of processes relating to clinical trials/research activities and medical research on human subjects. This includes the development of systems and management of processes that enable the Medical Center to identify and receive payment for resources used in clinical trials, review of protocols to ensure compliance with Federal, State and other regulations governing human subject research and to evaluate impact on resources, and monitoring of research results at the Westchester Medical Center. Identification of opportunities for expansion of clinical trial activities, and positioning WMC as an attractive site for industry sponsored research are also responsibilities of this position. Does related work as required.

EXAMPLES OF WORK: (Illustrative Only)

Administers the systems development for clinical trials and research activities of the Medical Center;

Monitors the processes and systems developed for medical research on human subjects and clinical trials activities of the Medical Center;

Negotiates federally funded or pharmaceutical company funded contracts for research;

Oversees the development and maintenance of patient databases;

Manages the processes and systems designed for clinical trials and research activities;

Develops and implements procedural reviews to ensure patient safety, compliance to procedures, and expeditious review of proposed protocols;

Reviews and assesses IRB protocol procedures, ensuring compliance to all Federal, State, and Health department regulations regarding medical research activities;

Develops external database for clinical trial costs including a system to identify direct and indirect costs;

Develops and implements systems to assess financial and service resource utilization and resulting impact to patient care and ancillary support departments;

Develops systems and policies and procedures to evaluate and categorize specific clinical trial contributions as educational, charitable, and/or scientific;

Develops systems and procedures to ensure compliance with various regulations and contractual obligations regarding billing and reimbursement in the area of clinical trials;

Facilitates the Regulatory and Risk Management review;

Develops procedures, controls, and systems for program development, cost effectiveness, and appropriate resource allocation in assigned divisions to meet operational goals and objectives;

EXAMPLES OF WORK: (Cont'd)

Develops systems to facilitate/integrate the timing of the IRB review;

Supervises the collection, recording, and reporting of clinical trial data, to evaluate the effectiveness of services and ensure conformance to operational objectives;

Provides instructions as necessary regarding policies and procedures for clinical trial compliance;

Advises the Senior Vice President on problems or issues, and makes recommendations for problem resolution;

Attends and leads the Clinical Trials Administrative Committee meetings and arranges for documentation accordingly;

Accessed protected health information (PHI) in accordance with departmental assignments and guidelines defining levels of access (i.e. incidental vs. extensive);

Uses computer applications or other automated systems such as spreadsheets, word processing, calendar, e-mail and database software in performing work assignments;

May perform other incidental tasks, as needed.

REQUIRED KNOWLEDGE, SKILLS, ABILITIES AND ATTRIBUTES: Thorough knowledge of all modern procedures, techniques and protocols involved in the treatment of patients through the conduct of clinical trials and research; thorough knowledge of governmental regulations, laws, healthcare regulations, issues and trends related to human subject research; thorough knowledge of the principles and techniques of hospital management; knowledge of medical terminology and human anatomy; ability to handle multiple projects and analyze complex problems; ability to assess and monitor health care delivery programs and evaluate their effectiveness and efficiency of operation; ability to organize and direct the work of others; ability to communicate effectively both orally and in writing; ability to maintain working relationships with all levels of health professionals in order to achieve desired objectives; ability to effectively use computer applications such as spreadsheets, word processing, calendar, e-mail and database software; tact; thoroughness; accuracy; sound professional judgment; physical condition commensurate with the demands of the position.

MINIMUM ACCEPTABLE TRAINING AND EXPERIENCE: A Bachelor's Degree* and six years of experience in a health care or research setting which must have involved work in human subject research and the conduct of clinical trials, two of which must have been in an administrative or supervisory capacity.

SUBSTITUTION: Possession of a Master's Degree* in Heath Care Administration or closely related field may be substituted for two years of the required experience, exclusive of the two years of specialized experience.

NOTE: Unless otherwise noted, only experience gained after attaining the minimum education level indicated in the minimum qualifications will be considered in evaluating experience.

*SPECIAL NOTE: Education beyond the secondary level must be from an institution recognized or accredited by the Board of Regents of the New York State Education Department as a post-secondary, degree-granting institution.