Organization and Job Profile

Director, Clinical Trials Unit

Ochsner Health System
New Orleans, Louisiana

Position: **Director, Clinical Trials Unit**

Reports to: **System Vice President for Research**

Location: **New Orleans, Louisiana**

CORPORATE BACKGROUND

Ochsner Health System is a non-profit, academic, multi-specialty, healthcare delivery system dedicated to patient care, research and education. This award-winning system includes eight hospital campuses totaling 1,150 beds and over 35 physician clinics located throughout Southeast Louisiana. Its flagship hospital and clinic, Ochsner Medical Center, is located in New Orleans, Louisiana. Ochsner employs more than 770 physicians in 90 medical specialties and subspecialties, and performs more than 300 clinical research trials annually.

Ochsner continuously meets the ever-changing needs of patients and the community through electronically-linked hospitals and health centers. Electronic medical records are available from any Ochsner location allowing for the most consistent patient care, both for routine health needs and more complex medical conditions.

At Ochsner, close collaboration between clinicians and scientists brings medical discoveries from the laboratory to the bedside. Ochsner is a national leader in medical research with more than 300 ongoing research trials and 200 annual publications in medical literature. It is one of the largest non-university based physician training centers in the nation with over 375 medical residents, over 600 medical students, and 400 allied health students annually.

Ochsner is a leader in the industry and community. Ochsner has always played an important role in the health of the New Orleans' community, but that contribution has never been more important than it is today. No one is better positioned to lead the future of healthcare in the region, and their reputation as an exceptional place to receive care and build a career is growing. In 2007, Ochsner was:

- The only New Orleans-area hospital honored as one of "America's Best Hospitals" by *U.S. News and World Report*, singled out from more than 5,000 U.S. hospitals for exceptional medical care. Ochsner was listed as one of the nation's 50 best in the ear, nose and throat category.
- Recognized as one of the nation's "Most Wired" in *Hospitals & Health Networks* magazine, an honor Ochsner earned each of the past four years.
- Named as a "Consumer Choice Award" winner in the *National Research Corporation's Healthcare Market Guide*. New Orleans residents have chosen Ochsner for this honor for 12 consecutive years.

- Selected as one of AARP's "Best Employers for Workers Over 50" for the third straight year. Ochsner is now ranked by AARP as No. 37 in the nation.
- Named one of the "Best Places to Work" in New Orleans by *CityBusiness* newspaper for the third consecutive year.
- Honored with important industry recognition for two top executives. Ochsner Chief Executive Officer Dr. Patrick Quinlan was named the No. 1 most-powerful physician executive in the nation by *Modern Physician* magazine. Chief Operating Officer and President Warner Thomas was included for the second time by *Modern Healthcare* magazine's "Up and Comer" yearbook edition for his leadership during Hurricane Katrina.

MISSION

We Serve, Heal, Lead, Educate and Innovate.

VISION

“Ochsner will be a global medical and academic leader who will save and change lives. We will shape the future of healthcare through our integrated health system, fueled by the passion and strength of our diversified team of physicians and employees.”

POSITION DESCRIPTION

Direct all major functions and activities within the Clinical Trials Unit (CTU) and Biobank including implementing clinical trials, designing and developing protocols, acting as a liaison to both internal and external investigators and successfully supporting the CTU through grants and industry-funded research. Responsible for strategic planning, unit development and overall accountability for the Clinical Trials Unit and Biobank. Responsible for compliance with all applicable regulations and for ensuring proper subject protections are in place. Responsible for training and development of staff and investigators.

Demonstrates actions consistent with Ochsner Health System's "Expectations" as duties are performed on a daily basis.

SERVICE STANDARDS

Quality of Care, Patient Satisfaction, and Scientific Endeavors

- Responsible for developing the strategic direction of the Clinical Trials Unit and the Biobank, and for the management, oversight and monitoring of all research activity in these areas.
- Responsible for ensuring compliance with Human Subject Protections, Good Clinical Practices (GCPs), organizational policies and all other applicable regulatory requirements.
- Direct operational and logistical tasks of research and protocol implementation to ensure efficient execution of trials within established budgets and timelines.
- Develop protocols of scientific value and sound scientific design to be implemented in the CTU.

- Assist investigators with protocol development and logistics, as needed.
- Proactively identify and resolve any issues or hurdles that may hinder the conduct of a protocol.
- Review and approve all potential CTU projects for scientific merit, logistics, financial implications, and available resources.
- Provide input and expertise for pharmacokinetic, pharmacogenetic, clinical and pre-clinical studies.
- Recruit, screen and select competent investigators and industry partners.

People Development and Workforce

- Retain and recruit high performance employees focused on accomplishment of the mission.
- Responsible for determining the appropriate staffing levels and the interviewing, hiring and performance reviews of employees.
- Staff work areas with appropriate numbers of qualified employees to assure appropriate coverage.
- Allocate and delegate work effectively to make efficient use of resources and employee capabilities.
- Forecast and anticipate staffing needs to accommodate changing needs.
- Establish clear work objectives that prioritize and focus employee efforts.
- Act to contain overtime on an ongoing basis.
- Provide ongoing performance feedback to employees and take corrective action when necessary.
- Perform corrective action counseling when necessary in a fair and consistent manner.
- Complete and conduct performance evaluations by established review date.
- Provide opportunity for skill development for employees.
- Ensure staff competency through appropriate use of educational resources.
- Distribute information to staff and follow up with training and updates as needed.
- Responsible for scientific and career growth of employees.
- Monitor and evaluate completion of tasks and projects.

Growth and Operational Profitability

- Direct all funding activities within the CTU.
- Responsible for developing the operating plan of the Clinical Trials Unit and the Biobank.
- Actively pursue research grants and funding opportunities.
- Instrumental in attracting and securing new business contracts.
- Develop tactics to ensure effective achievement of scientific/business objectives.
- Establish and maintain relationships with industry partners, external investigators, and opinion leaders to maximize opportunities.
- Make decisions on recruitment/selection of new investigators, contract research organizations and outside vendors.

Biobank

- Oversee all aspects of the Ochsner Biobank.
- Act as Principal Investigator for institutional Biobank project.
- Ensure compliance with all applicable regulations regarding human subject protection, specimen collection and optimal storage; ensure compliance with HIPAA.
- Oversee Biobank lab staff to ensure proper laboratory techniques are used to maximize specimen quality.
- Advise and mentor physician-investigators on protocol design for collection of human specimens.
- Develop Standard Operating Procedures (SOPs) for biospecimen research including, but not limited to, sample quality, clinical data consistency and usability.
- Advise the Biobank governing committees with regard to specimen collection, processing, scientific validity and merit of proposed protocols and requests for specimens.
- Develop strategy for increasing patient, physician, investigator, scientist and community awareness.
- Ensure accurate data collection and entry; develop Quality Assurance monitoring program for specimens and clinical data.
- Responsible for maintaining patient confidentiality.
- Responsible for oversight of Biobank database.
- Act as Secretary for the Biobank Steering Committee.

Education and Training

- Adhere to a personal plan of professional development and growth through professional affiliations, activities and continuing education.
- Support division goals to provide cutting edge services to meet the organization's mission and goals.
- Design appropriate research practices to guide department services.
- Coordinate the use of quality data to support decision making.
- Attend professional meetings and trainings, as needed.

Physical and Technology Infrastructure

- Develop and revise organizational structures to meet functional needs; ensure communication, reporting and incentives align people and processes.
- Ensure that the physical environment and job structures are designed to promote employee safety.
- Ensure the proper tools are available to accomplish the mission of high quality patient care.
- Organize administrative systems and structures to support program development.

QUALIFICATIONS

Education, Experience & Training:
M.D., PharmD, or PhD. Minimum of five years of healthcare management experience with proven success in operating a clinical trials unit. Experience designing and conducting clinical and pre-clinical research with desire to continue doing such. Expertise in the medical and legal requirements for human subject research. Demonstrated ability as a Principal Investigator to secure grants and external funding to support research activities for the unit. Experience conducting Phase I trials required. Strong industry ties and/or industry experience in clinical trials desired.

Other Qualifications:
Professional attitude and ability to communicate well with executive management, professionals, and business and community leaders. Exhibits excellent leadership and self-direction, good judgment in handling difficult situations and good organizational, time management, interpersonal and conflict resolution skills. Requires only strategic guidance. Demonstrates management and tactical planning skills. Proven presentation skills and ability to write manuscripts and complex protocols. Able to successfully manage multiple projects simultaneously.

COMPENSATION

Compensation arrangements are competitive and will be commensurate with the selected candidate's experience and achievements, and responsibilities of this position.

CONSULTANTS

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