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| Job Title: | Lead Principal Investigator – Clinical Trials | **Department:** | **Envision Research** |
| Reports To: | Executive Director | Classification Type: | Exempt |
| Level/Salary Range: |  | **Master Job Description:** | Yes No |
| Supervises: | N/A |
| Job Description |
| POSITION SUMMARYEnvision Research LLC seeks a full-time or part-time Lead Principal Investigator (LPI) dedicated to the conduct and supervision of clinical trials with pharmaceutical and medical device companies in accordance with pertinent research protocols, Good Clinical Practice (GCP), and federal/state regulations. The clinical trials will be managed by Envision Research and offer the opportunity for the PI to spend ample patient-centric time with each study participant. The LPI will also be responsible for initiating and cultivating collaborative relationships with regional physicians to further develop Envision Research’s network and clinical trial activities.**About Envision Research LLC**Envision Research (<https://www.envisionresearch.org/>), a division of BRF in North Louisiana (<https://brfla.org/about/brf-board/>), develops and implements strategic initiatives in clinical & translational research and pursues clinical trials with healthcare providers, start-up companies, academic medical centers and research institutions. Envision Research identifies and facilitates the initiation and conduct of Phase II to IV clinical trials by experienced research coordinators, manages all regulatory requirements, develops standard operating procedures (SOPs) and negotiates contracts and budgets with industry sponsors.ESSENTIAL FUNCTIONS* Serve as Principal Investigator on clinical trials managed by Envision Research
* Guide and oversee research staff in the conduct of clinical trials, according to the study protocol and GCP
* Provide training for collaborating physicians and clinic nurses on study protocol and investigational product
* Delegate study responsibilities as appropriate and ensure necessary training and qualifications of clinical trial team members
* Perform clinical procedures and assessments as required by the study protocol
* Assist with expansion of Envision Research’s physician investigator network
* Assist with patient recruitment to meet or exceed enrollment goals, and ensure patient recruitment, screening and enrollment activities are conducted according to the study protocol and GCP
* Consult patient and family regarding disease under investigation and ensure understanding of experimental treatment
* Ensure clinical trials are conducted according to the approved protocol, GCP, FDA/ ICH guidelines, federal and state regulations and Envision Research standard operating procedures
* Adhere to HIPAA Guidelines and maintain strict confidentiality in the conduct of clinical trials
* Protect patient’s rights, safety and welfare
* Assess for all adverse events and serious adverse events and interpret laboratory results, EKGs and other safety assessments as required per protocol
* Ensure patient’s informed consent and IRB approval of the study
* Evaluate participants’ compliance with study’s medication as specified in the study protocol. Submit safety, protocol noncompliance and other reports, as required
* Responsible for administration and accountability of investigational product
* Provide accurate and detailed documentation per study protocol to ensure data integrity
* Attend Investigator and other clinical research training meetings, meet with Sponsors, CROs, IRB and regulatory authorities in the conduct of clinical trials as needed, and participate in community outreach activities
* Other duties as assigned.

MINIMUM QUALIFICATIONS AND EDUCATION REQUIREMENTSActive M.D or DO License in Louisiana with authority for prescriptions, DEA license or ability to obtain, unrestricted ability to participate in federal programs. Prior experience in clinical trials as Principal Investigator, or minimum of five years of experience as Sub Investigator, is required. REQUIRED KNOWLEDGE SKILLS AND ABILITIES* Leadership, excellent interpersonal, communicational and organizational skills
* Adequate clinical experience as a licensed physician to ensure high quality patient care
* Proficient in Microsoft Office and/or other equivalent software platform
* Excellent verbal and written communication skills. Communicate effectively with sponsor representatives, community physicians, patients and family, media and Envision Research staff
* Able to multitask effectively and efficiently
* High degree of professionalism, self-motivation and integrity
* Able to adapt to changes in responsibilities and workloads

The job description is not designed to cover or contain a comprehensive listing of activities, duties or responsibilities required for the position. Assigned responsibilities and activities may be changed as needed. |
| Reviewed By: |  | Date: |  |
| Approved By: |  | Date: |  |
| Last Updated By: |  | Date/Time: |  |