

CLINICAL TRIALS OFFICE

The principal charge of this focus group was to identify the key elements of a Clinical Trials Office at the LSUHSC-NO Campus. We propose that the mission of the Clinical Trials Office is to organize and enhance operational processes that support clinical research and facilitate the timely initiation, execution, management, and completion of clinician trials at the LSU Health Sciences Center. The Clinical Trials Office will function as a single point-of-contact for all aspects of clinical trials research. The primary goals of the Clinical Trials Office are to offer a full spectrum of services that include 1) planning and conducting high quality clinical research trials, 2) enhancing administrative efficiency, and 3) assisting in the development and implementation of policies and procedures that assure compliance with prevailing regulations that govern the conduct of research in humans. These services are focused in five major areas: administration and finance, contract review and sign-off, regulatory affairs, education, and quality assurance. The Clinical Trials Office will also aggressively market the research capabilities of the LSUHSC and thereby increase the number of clinical trials at our institution. These activities will help LSUHSC meet its mission goals of excellence in patient care, education, research, and community service. LSUHSC is committed to providing world class patient care with innovative therapies by facilitating access to cutting edge clinical research opportunities.

Services

Administrative

- Work with investigators to develop and negotiate an appropriate budget for successful trial completion
- Standardize agreements, provide legal and risk management assistance and review, and facilitate the routing of agreements
- Maintain a database of institutional expertise and interests in clinical research which will 1) assist the investigator in identifying potential collaborators and, 2) assist potential sponsors in identifying key investigators

Regulatory Compliance

- Assist in completion of IRB submission forms
- Ensure that clinical trials are conducted in compliance with federal, state, and local regulations and institutional policies and procedures

Specialized assistance with investigator initiated studies

- Assistance with developing and writing protocol and consent forms
- Development of case report forms, and flow sheets for data capture
- Assistance with FDA filing of IND and IDE
- Assist investigators with grant writing

Education /Training

- Provide training in clinical trials conduct
- Assist investigators to meet specific education requirement of industry in the training of their research staff
- Assist with education and training of investigators and clinical research personnel
- Assessment of candidate credentials

Quality Control/Quality Assurance

- Provide investigators with an evaluation of their clinical research program by conducting on-site audits