FDA Regulations Relating to Good Clinical Practice and Clinical Trials

- Electronic Records; Electronic Signatures (21 CFR Part 11)
- Human Subject Protection (Informed Consent) (21 CFR Part 50)
- Financial Disclosure by Clinical Investigators (21 CFR Part 54)
- Institutional Review Boards (21 CFR Part 56)
- Investigational New Drug Application (21 CFR Part 312)
- Forms 1571 (Investigational New Drug Application) and 1572 (Statement of Investigator)
- Applications for FDA Approval to Market a New Drug (21 CFR Part 314)
- Applications for FDA Approval of a Biologic License (21 CFR Part 601)
- Investigational Device Exemptions (21 CFR Part 812)
- Premarket Approval of Medical Devices (21 CFR Part 814)

Human Subject Protection is one aspect of GCP. The Office of Human Research Protections (OHRP) has a leadership role in human subject protection for the Department of Health & Human Services.
Good Clinical Practice Training Requirements

In the interest of maintaining a quality research program and compliance with federal regulations, Ochsner has requirements for training in Human Subject Protection and Good Clinical Practices (GCP) for all investigators and staff involved in human research at Ochsner. All investigators who wish to conduct research at Ochsner must initially complete the CITI required human subject protection courses at http://www.citiprogram.org.

Ongoing educational requirements have been established as a mechanism to support the best and safest care to Ochsner’s research subjects, to fulfill our obligations under Ochsner’s Federal Wide Assurance and other federal regulatory guidance, and to assist members of the Ochsner research community in honing their GCP skills. The initial CITI training requirement will expire 3 years after the initial year the course was completed.

During the 3 year period, investigators can remain certified by doing one the following:
• Retake the full initial CITI course
• Take the CITI refresher course
• Take 12 hours of GCP credits approved by the IRB. There are at least 8 hours offered each year, and they are detailed in this brochure. CNE and CME credit are provided

Our goal is to provide education and training that will support ongoing quality research and growth in individual competence in our research staff. This allows us to do what is most important, protect our patient volunteers.

Webpage Resources

• Monthly IRB Newsletters
• HRPP Guidance Documents
• Human Subjects Research Protection Program
• HRPP Organizational Chart
• Ochsner Guidance – GCP Education Requirements

IRB members meet twice per year for GCP education sessions over dinner. The IRB member education sessions will be help on March 26th and September 24th.

The IRB Member Education Sessions will be held on 3/26/2019 and 9/24/2019.

CNE
Ochsner Health System, Nursing Professional Development is an approved provider of continuing nursing education by South Central Accreditation Program, an accredited approver by the American Nurses Credentialing Center’s Commission on Accreditation.

Accreditation Statement
The Ochsner Clinic Foundation is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Designation Statement
The Ochsner Clinic Foundation designates this live activity for a maximum of 1 AMA PRA Category 1 Credit™. Physicians should claim only the credit commensurate with the extent of their participation.

Responsible Conduct in Research Lecture Series 2019

Second Tuesdays of the Month
Monroe Hall 12:00 pm - 1:00 pm
Lunch, CME and Nursing Credit Provided

Tuesday, January 8, 2019 Research with Data & Biospecimens Under the Revised Common Rule Lydia Bazzano, MD, Ochsner IRB Vice-Chair

Tuesday, February 12, 2019 Electronic Informed Consent: Ethical, Regulatory & Practical Implications Stephanie Gaudreau, CIP, Human Research Protection Program Manager

Tuesday, April 9, 2019 The Federal “Right-to-Try” Law and its Impact on the FDA’s Expanded Access Program Meredith M. Miceli, JD, CPHRM, Associate General Counsel, Legal Affairs and Risk Management

Tuesday, May 14, 2019 Lessons Learned from Clinical Investigation Warning Letters Barbara D. Wright, Supervisory Investigator, Office of Regulatory Affairs, U.S. Food and Drug Administration

Tuesday, July 9, 2019 Conflicts of Interest in Research Kelsey Williams, Compliance Specialist, Ochsner Compliance & Privacy & Janae Thompson, MHCM, Project Manager & Conflict of Interest Administrator

Tuesday, August 13, 2019 HIPAA 101 for Clinical Research Kelsey Williams, Compliance Specialist, Ochsner Compliance & Privacy

Tuesday, October 8, 2019 Conducting Research with Children: The Ochsner Experience Amanda England, MD, MPH, Director of Neonatal Research, Ochsner Baptist

Tuesday, November 12, 2019 Correcting & Avoiding Non-Compliance: Examining Real Life Cases Stephanie Gaudreau, CIP, Human Research Protection Program Manager & the Research Quality Assurance Team