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)

Good Clinical Practice (GCP)

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected. From ICH E6 1.24, April 1996 http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf

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.

GCP Education Program

Our Federal wide Assurance (FWA) with OHRP (45 CFR 46.103) signed by Ochsner’s Institutional Official states “I recognize that providing research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education about human subject protections will help ensure that the requirements of this Assurance are satisfied.”

Ochsner Medical Center
1514 Jefferson Highway
New Orleans, LA 70121

IRB Administrator: Stephanie Gaudreau, CIP
Tel: 504-842-3563
Email: sgaudreau@ochsner.org

2016 Good Clinical Practice Education
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 or more of 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.
- Access the Mediasite Catalog https://ersa.ochsner.org/ochsner/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5BOID%5B65026%5D with links to the Mediasite GCP Center and CME/GCP questions.

You can receive both CME credit (for physicians) and GCP credit (for everyone) towards the continuing education requirement by watching the presentations and returning the completed questions of the IRB office.

Webpage Resources

- **Monthly IRB Newsletters**
  https://ersa.ochsner.org/ochsner/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5BOID%5B65026%5D
- **IRB Webpage Guidance Documents**
  http://ochpoint/academics/research/IRB/SitePages/sop.aspx
- **Human Subjects Research Protection Program**
  https://ersa.ochsner.org/ochsner/Doc/0/2C8QHM433AVKB7UP6ULDG5KR5E/66Overview%20of%20Ochsner%20HRPP.pdf

IRB members meet twice per year for GCP education sessions over dinner with two CME credits per session.

The IRB Member Education Sessions will be held on March 22, 2016 and October 11, 2016 in the Caldwell Room of the Brent House Conference Center.

**LSNA Provider Statement**

Ochsner Health System, Nursing Professional Development, is an approved provider of continuing nursing education by the Louisiana State Nurses Association, an accredited approver by the American Nurses Credentialing Center’s Commission on Accreditation. Nursing Contact Hours to be determined. To receive continuing nursing education, the participant must attend the entire presentation and complete the program evaluation.

**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 2016

**Second Tuesdays of the Month**

**Monroe Hall 12:00 pm -12:55 pm**

**Lunch, CME and Nursing Credit Provided**

- **January 12**
  Biospecimens in Research – Legal Issues and “Common Sense” Ben Meroney, JD, Micah Fincher, JD and Andrew Harris, JD, Jones Walker

- **April 12**
  REACHnet: Research Action for Health Network Thomas W. Carton, PhD, MS, Louisiana Public Health Institute

- **May 10**
  Electronic Consent: A Discussion of the eConsent Experience, Ethical and Regulatory Considerations, and IRB Review Stephanie Gaudreau, CIP, Manager, Ochsner Human Research Protection Program

- **July 12**
  Research Ancillary Committee Requirements & Process Stephanie Gaudreau, CIP, Manager, Ochsner Human Research Protection Program & Ancillary Committee Panel Representatives

- **Aug 9**
  Principal Investigator Responsibilities Barbara D Wright, Investigator District Bioresearch Monitoring Specialist, US Food & Drug Administration New Orleans District/Baton Rouge Resident Post

- **Oct. 11**
  Future Changes to IRB Regulations Speaker TBA

- **Nov. 8**
  HIPAA Compliance Research Reminders and Updates Paul Colomb, JD, Director & Assistant General Counsel, Investigations, HIPAA Privacy, Research & Academics and MaryAnn O’Brien, J.D., Compliance Specialist III