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.

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
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New Orleans, LA 70121

IRB Administrator: Stephanie Gaudreau, CIP
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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

2017 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 of the following:

- Retake the 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%5B5A19B125BCB4B641B10C861DDF5BF84D%5D%5D

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%5B5A19B125BCB4B641B10C861DDF5BF84D%5D%5D
- Human Subjects Research Protection Program https://ersa.ochsner.org/ochsner/Doc/0/2C8QHM433AVKB7UP6ULDG5KB5E/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 3/28/2017 and 9/26/2017 in the Caldwell Room of the Brent House Conference Center.

CME

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 2017

Second Tuesdays of the Month
Monroe Hall 12:00 pm - 12:55 pm
Lunch, CME and Nursing Credit Provided

Tuesday, February 14, 2017 Investigator Initiated Trials: Getting Started & Maintaining Compliance
Stephanie Gaudreau, CIP, Manager, Ochsner Human Research Protection Program (HRPP) & Marcia Henry, PhD, Ochsner Research Education Specialist

Tuesday, April 11, 2017 Death During Research Trials: Lessons Learned
Joseph Breault, MD, Executive IRB Chair, Stephen Ramee, MD, FACC, FSCAI, Cardiology & Marc Matrana, MD, Hematology/Oncology

Tuesday, May 9, 2017 Disaster Planning for Research
Representatives from Research Administration including IRB, OSP and Research Pharmacy

Tuesday, July 11, 2017 Use of Legally Authorized Representatives in Research
MaryAnn O’Brien, JD, Senior Compliance Specialist

Tuesday, August 8, 2017 Clinical Trials Research Pharmacy: Regulations, Operations, and Schematics: Ochsner Research Pharmacy
Christy Schexnayder, RPh, Paritosh Pandya, RPh and Geralyn Magee Isaac, RPh, Pharm D

Tuesday, October 10, 2017 Be Careful What You Ask: Update on Survey Research
Karen Rice, DNS, APRN, ACNS-BC, ANP and Shelley Thibeau, PhD, RNC, Center for Nursing Research

Tuesday, November 14, 2017 The What, Why, When, and How of Informed Consent
Stephanie Gaudreau, CIP, Manager, Ochsner Human Research Protection Program (HRPP)