

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."

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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>



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)
- Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products (Interim Rule) (21 CFR Part 50, subpart D)
- 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.



2021 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 date 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.

Webpage Resources

- Monthly IRB Newsletters <https://ochsnerhealth.sharepoint.com/system/academics/Pages/hrppirb.aspx?csf=1>
- IRB Webpage Guidance Documents <https://ochsnerhealth.sharepoint.com/system/academics/Pages/hrppirb.aspx?csf=1>
- Human Subjects Research Protection Program <https://eirb.ochsner.org/eIRB/sd/resource/doc/8D4CF7086EA5218/Overview%20of%20Ochsner%20Human%20Research%20Protection%20Program.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 3/30/2021 and 9/28/2021.

CNE

Ochsner Health System- System Nursing Professional Development is approved as a provider of nursing continuing professional development by Louisiana State Nurses Association Approver Unit, 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 in the activity.

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 in the activity.

Disclosure

All individuals in control of content have completed a disclosure form and have nothing to disclose.

Responsible Conduct in Research Lecture Series

Second Tuesdays of the Month
Via Zoom 12:00 pm -12:55 pm

January 12 Informed Consent Documentation: How to Do it Right!

Stephanie Henderson, CIP, HRPP Manager, IRB Administrator

February 9 "The FDA is Calling...?"

Perry Brown, MD, FAAP, *Director of Pediatric Education, Family Medicine Residency of Idaho, Co-Director, Cystic Fibrosis Center of Idaho, Clinical Associate Professor, University of Washington School of Medicine & Katelyn Penney, J.D., Manager Research Compliance St. Luke's Health System*

April 13 Protecting Vulnerable Populations in Research,

Misti Ault Anderson, MS, MA, *Senior Advisor for Public Health Education, Division of Education and Development, HHS Office for Human Research Protections*

May 11 HIPAA and Research

Paul Colomb Jr., JD, *AVP Compliance, Compliance & Privacy*

July 13 Health Equity & Research

Yvens Laborde, MD, *Medical Director, Global Health Education*

August 10 e Regulatory & Source Documentation

Tim Haynes & Connie Catha, *Quality Assurance Coordinators, HRPP*

October 12 Expanded Access, Emergency Use, Compassionate Use

Lydia Bazzano, MD, PhD, MPH, CIP, *Executive IRB Chair*

November 9 COVID Research – Lessons Learned

Leo Seoane, MD, *Senior Vice President, Chief Academic Officer & Julia Garcia-Diaz, MD, Senior Physician, Infectious Disease, Medical Director Dyad of Multispecialty Research*