Overview of Ochsner Human Research Protection Program (HRPP)

HRPP Mission

Ochsner’s Human Research Protection Program’s (HRPP) mission is protecting the rights, welfare and privacy of all human research subjects at Ochsner. The mission is accomplished by implementing the ethical guidelines of the Belmont Report, complying with applicable federal regulations, and educating its workforce in good clinical practices as defined by FDA and ICH. Our HRPP is a framework through which we hold ourselves accountable in carrying out high quality and effective clinical research while continuing to maintain the highest ethical standards in the protection of research subjects at Ochsner.

This document describes Ochsner’s commitment to comply with ethical and legal requirements for the conduct of human subjects research.

HRPP Organizational Chart

The HRPP organizational chart can be found at the end of this document and on the Ochsner eIRB website.

Federalwide Assurance

Ochsner has signed a Federalwide assurance with OHRP listing the ethical principles of the Belmont Report as the guide to how human subject research is conducted. The institution has not elected on the FWA to apply the Common Rule and Subparts B, C, D to all research regardless of funding. The IRB has adopted a flexibility policy in applying 45 CFR 46 to non-federally funded research. This policy is consistent with the HRPP’s primary triple mission of:

- Protecting human subjects
- Carefully following all federal, state and other required regulations for the ethical conduct of human research
- Making the IRB regulatory process as user friendly as possible by minimizing regulatory burdens when possible

External IRB’s

Ochsner may authorize the use of an external IRB for review of certain types of research studies, including industry sponsored multi-center trials, NIH trials and collaborative research trials (NCI, LaCats). The National Cancer Institutional (NCI) Central Institutional Review Board (CIRB) provides
IRB review for select NCI-sponsored clinical trials conducted at Ochsner. Eligible studies (determined by NCI) are listed on the NCI CIRB website.

When an external IRB reviews a study on behalf of Ochsner, only the IRB review is ceded to that IRB. The local requirements regarding research will remain the institutional responsibility. As such, the Principal Investigator will continue working with the Ochsner HRPP to ensure that investigators and research staff meet the Ochsner training/GCP requirements, COI disclosures are submitted and managed, and all ancillary reviews are obtained. All information is maintained in eIRB.

Research Policies

The Executive IRB Chair and Human Research Protection Program (HRPP) Manager, in conjunction with applicable contributing offices, are responsible for maintaining Institutional Research Policies. The HRPP office and research administration are involved in the continuous process of policy revisions as needed.

GCP Education Programs & Requirements

The HRPP Manager, in conjunction with the IRB Executive Chair, coordinates the GCP Education Program. These are detailed in the annual GCP Education brochure.

The IRB Office coordinates monitoring of whether the GCP training requirements are met for individuals involved in human subject research to gain access to the eIRB system. An institutional guideline outlines the requirements.

IRB Office & eIRB

The IRB SOPs and various guidance documents are listed on eIRB. The IRB members meet twice a year for GCP/HSP training. The Executive IRB Chair, HRPP Manager, and all IRB Office Staff meet several times a month to review regulatory issues and methodically review every SOP, guidance, and other documentation to assure they are updated as needed.

The IRB written procedures were initially signed off by the Chief Executive Officer, Institutional Official, and IRB Chair in 2002. Updates and revisions are coordinated by the HRPP Manager and Executive IRB Chair and are listed on each document. IRB members are kept aware of changes to the IRB written policies via announcement emails, newsletters or reports at IRB meetings.
The eIRB system is used for tracking of all human research subject submissions. This includes studies where the Ochsner IRB serves as the IRB of Record and those with an external IRB (NCI CIRB, WIRB, Schulman, etc). The eIRB system is based on Click Commerce/Huron software.

Research Administration

The Office of Sponsored Programs (OSP) is a research administration unit working under the Vice President of Research that provides contract, budget, and billing support to Ochsner investigators.

The Institute of Clinical Research is a research unit working under the Vice President of Research. It includes teams of doctors, scientists, clinical research professionals, pharmacists and many others who work together to improve patient care through clinical research. Clinical Research Coordinators are hired and managed centrally within this office to assure proper GCP training and standardization in operations.

The Scientific Director provides review and approval for all greater than minimal risk investigator initiated trials prior to IRB full review.

When applicable, the BioSafety Committee, the Radiation Control Committee, and the Laser Safety Officer are involved in approving research prior to IRB review. This is coordinated through the eIRB system.

The IO appoints an ad hoc research misconduct investigation committee when it is needed for formal charges of research misconduct in compliance with the HHS Office of Research Integrity policies.

Research Quality Assurance

Under the direction of the HRPP Manager, the Quality Assurance (QA) Team conducts activities to measure and improve the effectiveness, quality, safety and compliance of research involving human subjects. These QA efforts seek to comply with Institutional policies and procedures and applicable federal, state and local laws.

Research Compliance & Privacy

The Research Compliance & Privacy office is led by a Vice-President that reports directly to both the CEO and the Audit Committee of the Board of Directors. While research issues are only a small part of their responsibilities, they have staff members well trained in research issues. Their work with research includes:
• doing independent study audits when requested by the HRPP, VP of Research, or the IO
• assisting the Executive IRB Chair and HRPP Manager with the revision of research policies
• coordinating the system wide conflict of interest (COI) policy and physician/executive disclosure of assets and outside income that may be a financial conflict. The research compliance officer coordinates with the Executive IRB Chair and HRPP Manager to develop and enforce COI policy in the IRB written procedures and to manage COI disclosures in eIRB.

HRPP Accreditation

The institution is committed to maintaining the highest standards for the Ochsner HRPP. The HRPP received full accreditation from AAHRPP in March 2012 and full re-accreditation in March 2015.

Participant Outreach Activities

D. Participant Outreach

Most research subjects come from the wider community and Ochsner works to educate the community about research issues by:

• The Ochsner Patient Research Advisory Board (OPRAB) provides participants and the community with information designed to enhance understanding of and involvement in research and to provide an opportunity for feedback regarding research.
• Ochsner maintains a website with frequently asked questions for participants. The website includes links to government websites (e.g., OHRP, FDA, NIH) and provides an opportunity to submit concerns and give feedback.
• Ochsner holds an annual “Research Day” to which members of the community are invited.

The HRPP office periodically evaluates its outreach activities and makes changes when appropriate. These evaluations take place in an informal, ongoing manner. On an annual basis, the IRB Manager will review:

• The specific community outreach activities being used
• Whether or not these community outreach activities have an evaluative component, and if so what, if any, changes in the outreach activities have resulted from these
• Feedback provided via the “Contact the IRB” section on the Ochsner participant website
• Feedback provided from other sources (IRB members, HRPP staff, investigator, research staff, students, etc.)
The results of the review will be used to establish both the adequacy of current outreach activities and any additional resources that may be needed to meet the needs of the research community regarding participant outreach.