Ochsner Health System

Human Research Protection Program

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1. 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.

2. HRPP Chart

The HRPP and organizational chart can be found at the end of this document and at:

https://ersa.ochsner.org/ochsner/Doc/0/P7NFK3P1GCDKRD3CQ7IKSVE257/Human%20Subject%20Protect%20Org%20Chart%202013.pdf

3. Federalwide Assurance

FWA#00002050
Institutional Official (IO): Dr. William W. Pinsky, Chief Academic Officer and Executive Vice President Clinical Affairs International Business & Head, UQ Clinical School
Human Protections Administrator (HPA): Dr. Joe Breault, Executive Chair, Ochsner Institutional Review Boards

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 regardless of funding. The institution has not elected on the FWA to apply the Common Rule and Subparts B, C, D to all research regardless of funding. However, Ochsner intends to apply the same rules (the Common rule and Subparts B, C, D) to all research regardless of funding internally, but elects not to apply external reporting to OHRP for studies unless they are federally funded.

The Executive IRB Chair or designee can accept an outside IRB being the IRB of record for minimal risk studies, or where Ochsner participation is limited to minimal risk portions of the study. Otherwise, the IO of VP of Research is responsible for accepting an outside IRB as the IRB of record. Generally this will not occur for FDA regulated studies unless the major liability of the study is not at an Ochsner site. When it is approved to have an outside IRB as the IRB of record for a study at Ochsner, the IRB will work with

the study PI/CRC to assure that the study meets the documentation requirements at Ochsner (consent format and Ochsner required special wording in consents are meet with the IRB of record approving the consent for the Ochsner site; entered and tracked in ERSA; protocol, consent form and IRB approval letters uploaded to ERSA; appropriate updates to these documents in ERSA, etc.). In these situations the IRB role is administrative, and no local IRB approval letters are needed.

4. Research Policies

The Executive IRB Chair and Human Protection Program Manager, working with Corporate Integrity, are responsible for maintaining Institutional Research Policies. The IRB and many other groups are involved in the continuous process of policy revisions for various policies.

5. GCP Education Programs & Requirements

The IRB Administrator in conjunction with the IRB Executive Chair coordinates the GCP Education Program. These are detailed in the annual GCP Education brochures.

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 ERSA system (Electronic Study Application System). An institutional guideline outlines the requirements. All Ochsner employees involved in human research take the basic biomedical modules of the Collaborative IRB Training Initiative (CITI) course at http://www.citiprogram.org. There are annual renewal modules also available that can fulfill the continuing education requirements for GCP (or take at least 4 hours a year of other CME educational events).

All GCP credits are tracked and everyone in clinical research is in one of three cohorts for tracking. Each Dec 31, one of the cohorts are reviewed and anyone not having met their required minimum of GCP education credits is locked out of ERSA and studies will be transferred to another PI. A series of notices and appropriate email reminders are sent to each person in the cohort over the three year period

6. IRB & ERSA

The IRB written procedures and various guidance documents are listed on the IRB intranet webpage and ERSA,. The IRB members meet twice a year for GCP/HSP training. The Executive IRB Chair, HRPP Manager, and all IRB Office Staff meet three times a week 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 CEO, IO, and IRB Chair in 2002. Updates are coordinated by the Executive IRB Chair and are listed on each document. IRB members are kept aware of changes to the IRB written policies via an

annual update email and occasional other announcement emails or reports at IRB meetings.

The ERSA system is used for more than the local IRB approval and monitoring support process. It is also the mechanism used for tracking studies with approvals from outside IRBs (including the NCI CIRB) and assuring all regulatory requirements The ERSA system is based on Click Commerce/Huron software.

7. Research Administration

The Office of Grants Management is a research administration unit working under the VP of Research that provides contract, budget, and feasibility support to Ochsner investigators. The Office of Research Services is a research administration unit working under the VP of Research that provides CRC operational support to Ochsner investigators. CRCs are hired and managed centrally to assure proper GCP training and standardization in operations.

The Scientific Director has a major role in investigator initiated studies where the sponsor-investigator is the same person. All such in-house trial protocols must be approved by the Scientific Director who often convenes an ad hoc scientific review group that has the expertise to review and evaluate all aspects of that particular in-house study before he approves it to go to the IRB.

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

The IO appoints the 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.

8. Corporate Integrity

Corporate Integrity is headed 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 auditors and compliance officers well trained in research issues..

Their work with research includes:

- doing independent study audits when requested by the IRB, 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/executives disclosure of assets and outside income that may be a financial conflict. The VP of Corporate Integrity coordinates with the Executive IRB Chair so that the IRB COI policy in the IRB written procedures and the COI disclosures in the ERSA application at least meet the institutional standards.

9. HRPP Accreditation

The institution is committed to maintaining the highest standard for the Ochsner HRPP. The HRPP received full accreditation from AAHRPP in March 2012.

10. Community Outreach

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

- TV spots on the institutional TVs in patient areas for the hundreds of thousands who pass though our system annually
- Research brochures in many patient locations
- Press releases about the Responsible Conduct of Research lecture Series which is open to the public
- Website upgrades to the public research pages to educate the inform the wider community
- OHRPNational Research Community Forum: Protecting Human Research Subjects: Best Practices in the Big Easy, January 2012, was held at the Canal Place Westin in New Orleans and was open to the public.
- A public service outreach program to help change the public perception of medical research volunteers to “medical heroes” rather than “guinea pigs.”

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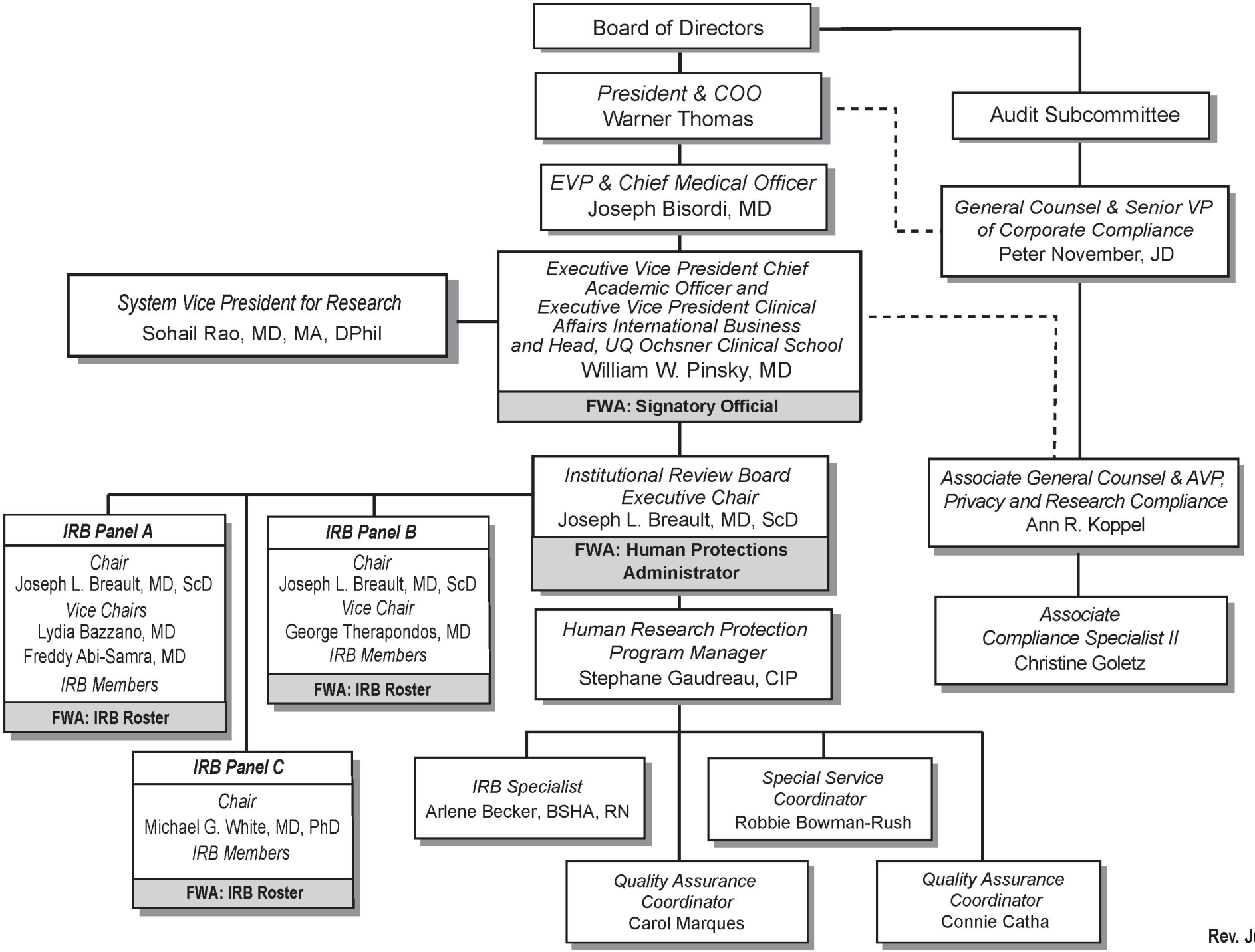
Human Subject Protection Organizational Chart



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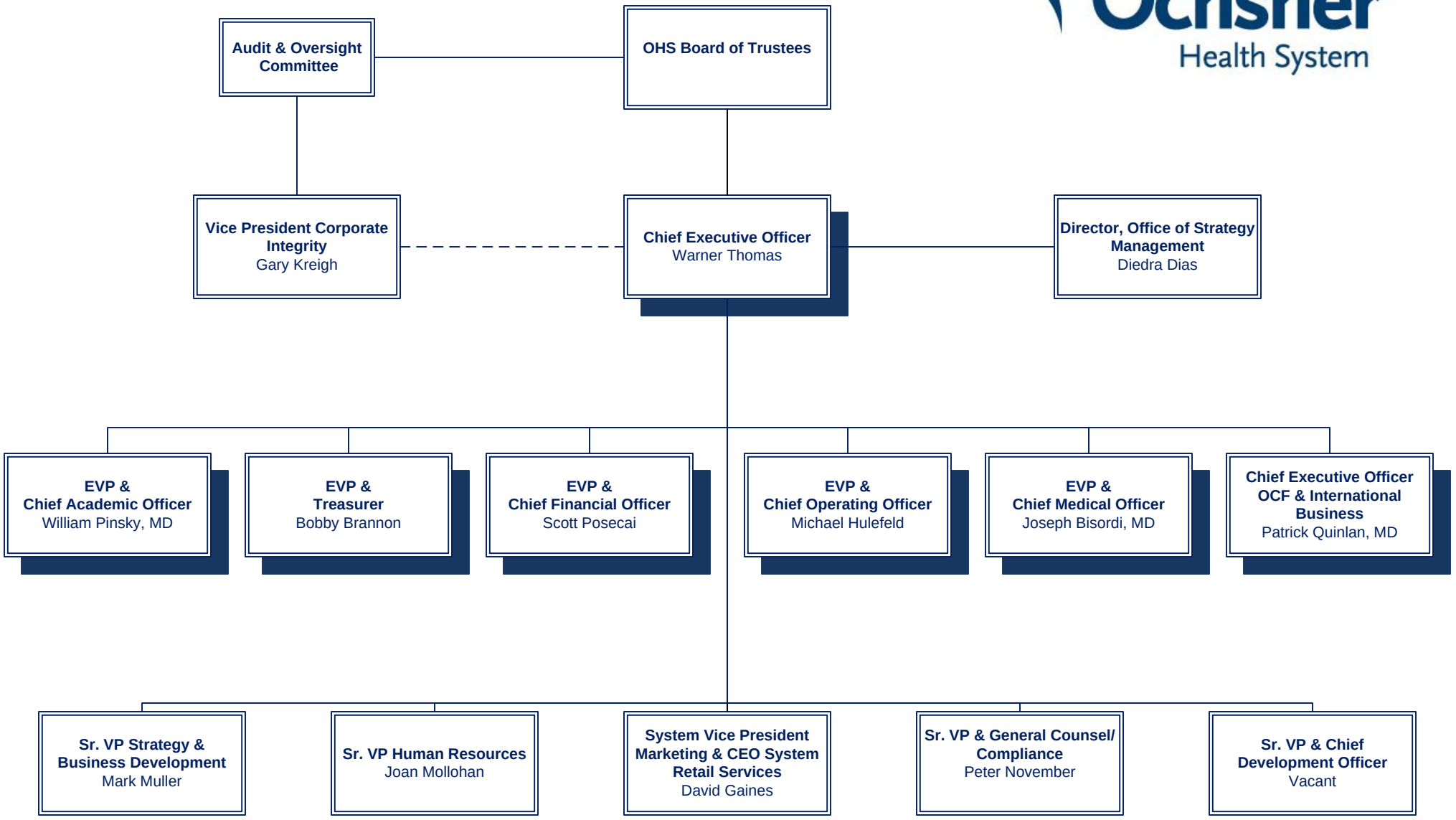
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