



FRANCISCAN MISSIONARIES OF OUR LADY UNIVERSITY
INSTITUTIONAL REVIEW BOARD BY-LAWS

I. Identifying Information

1. *Name*
 - a. Franciscan Missionaries of Our Lady University (FranU) Institutional Review Board (IRB).
2. Federalwide Assurance Number
 - a. FWA00011379
3. IORG Number
 - a. IORG0004976

II. Mission

Guided by Catholic ethical principles of respect for persons, beneficence and justice, the FranU IRB ensures the protection of the rights and welfare of human beings who serve as research participants. Members of the FranU IRB are committed to carrying out their duties in accordance with the University's mission and Franciscan core values.

III. Purpose

The purpose of the FranU IRB is to review all human subjects research proposed by FranU faculty, staff, and students, as well as minimal risk human subjects research proposed by employees of the Franciscan Missionaries of Our Lady Health System (FMOLHS).

IV. Objectives

1. *Review human subjects research proposals from FranU faculty, staff, and students*
 - a. Review human subjects research proposals that have already undergone a feasibility review authorized by the FranU Research and Scholarship Council (RSC).
 - b. Monitor ongoing research studies, as necessary, to ensure that they are being carried out consistent with approvals and that any adverse experiences or unexpected events are dealt with appropriately.
2. *Review minimal risk research proposals from Franciscan Missionaries of Our Lady Health System (FMOLHS) facilities*
 - a. Review and monitor *minimal risk* research proposals originating from FMOL facilities.
 - b. Review research proposals that have undergone a feasibility review and have been authorized by the Our Lady of the Lake Office of Research.
3. *Evaluate projects from FranU and other FMOLHS facilities not deemed to be human subjects research*
 - a. Evaluate projects involving human participants not deemed to be human subjects research (e.g., Quality Improvement (QI) projects, Evidence-Based Practice (EBP) projects).
 - i. *Note: QI projects from FMOLHS facilities may need to be preauthorized by the facility's Quality Director.*

V. Membership

1. The IRB shall be composed of at least six, and no more than 20, qualified members with diverse backgrounds with regard to race/ethnicity, gender, cultural background, and occupation.
2. Requirements for IRB membership shall include:
 - a. Member(s) whose primary concerns are scientific.
 - b. Member(s) whose primary concerns are nonscientific.
 - c. Registered Nurse(s) who has earned, at minimum, a Bachelor of Science degree in Nursing.
 - d. Representation from each of the following:
 - i. FranU School of Nursing.
 - ii. FranU School of Arts and Sciences.
 - iii. FranU School of Health Professions.
 - iv. FranU Graduate Programs
 - v. FranU Administration.
 - vi. Our Lady of the Lake Regional Medical Center.
 - vii. Community member who is unaffiliated with FranU or any other FMOLHS facility, and who is not an immediate family member of an employee of the same.
 - e. Human Subjects Research training certification as detailed in the IRB Standard Operating Procedures (SOP).
 - f. Signing the IRB Member Pledge.
3. Candidates for membership are selected to serve three-year terms, with optional renewal, based on recommendation and review as detailed in the IRB SOP.
4. The IRB Executive Committee reserves the right to remove a member for noncompliance with membership requirements and responsibilities as detailed in the IRB SOP.
5. Institutional Officer
 - a. The Institutional Officer is responsible for overseeing the activities performed by the FranU IRB and will also serve as the IRB Administrator.
 - b. The University Provost or other designated administrative leader.
 - c. The Institutional Officer is not a voting member of the FranU IRB.

VI. Officers

1. The officers of the IRB include the Chair and Vice-Chair.
 - a. Chair
 - i. The term of office for the IRB Chair shall be two years, with optional renewal.
 - ii. The IRB Chair shall:
 1. Call and oversee the meetings of the IRB.
 2. Assign proposals for member review.
 3. Designate research proposals for full board review.
 4. Manage amendment, continuing review, and closure processes.
 5. Communicate reports of adverse experiences or unanticipated events.
 6. Serve as the primary liaison for internal and external constituents.
 7. Serve as a standing member of the FranU Research and Scholarship Council.
 - b. Vice-Chair
 - i. The term of office for the Vice-Chair shall be two years, with optional renewal.
 - ii. The Vice-Chair shall:
 1. Assist the Chair with administrative functions, as needed.
 2. Perform the duties of the Chair should he/she resign, is absent, or has a conflict of interest.

2. Election of Officers
 - a. Biannual nominations for the Chair and Vice-Chair are confirmed by IRB member vote.

VII. Executive Committee

1. The committee shall be composed of the IRB Officers, one representative from each of the University's schools, and at least one member-at-large.
2. The committee shall:
 - a. Conduct biannual review of the bylaws and Standard Operating Procedures of the IRB.
 - b. Serve as representatives for the IRB Officers, as needed.
 - c. Recommend actions regarding reports of adverse experiences or unanticipated events, as needed.

VIII. Meetings

1. Regular meetings of the IRB will be held monthly as needed.
2. A quorum of five voting members must be present to constitute a formal meeting.
3. Full Board Reviews
 - a. A majority of the voting members of the IRB must be present and must include a member who is not affiliated with the institution.
 - b. Members must disclose any conflict of interest and excuse themselves before the review commences.
 - c. Individuals with competence in special areas may be invited to assist in the review of complex issues, which require expertise beyond or in addition to that available on the IRB.
 - d. Invited guests do not have voting privileges.

IX. Amendments

The bylaws may be amended, as recommended by the Executive Committee, at a regular meeting of the IRB. Any changes to the bylaws must be approved by a majority vote of a quorum.