INSTITUTIONAL REVIEW BOARD BY-LAWS

Article I - Name

The name of the body shall be the Franciscan Missionaries of Our Lady University Institutional Review Board (FranU IRB).

Article II – Objectives

1. *Reviewing human subjects research protocols from FranU faculty, staff, and students*
    a. The FranU IRB serves as the official voice of FranU to review, require modifications in and then approve or disapprove all proposed research activities involving human subjects. The FranU IRB is obligated to review all human subjects research carried out by FranU faculty, staff, and students.
    b. Guided by the basic ethical principles of respect for persons, beneficence and justice, the primary purpose of the FranU IRB is to ensure the protection of the rights and welfare of the human subjects.
    c. The FranU IRB will only review human subjects research protocols that have already undergone a feasibility review authorized by the FranU Office of Academic Research.
    d. The FranU IRB will also monitor ongoing research to ensure that it is being carried out consistent with how it had been approved and that any adverse experiences or unexpected events are dealt with appropriately.
    e. Protocol approvals are valid for one year. The FranU IRB is authorized to approve renewal applications upon request. Protocols that have not been renewed will be administratively closed one year after the date of the initial approval.

2. *Reviewing minimal risk research protocols from Franciscan Missionaries of Our Lady (FMOL) Health System facilities*
    a. The secondary objective of the FranU IRB is to review and monitor *minimal risk* research protocols originating from FMOL facilities.
    b. The FranU IRB will only review protocols that have already undergone a feasibility review authorized by the FranU Office of Research.
    c. Protocol approvals are valid for one year. The FranU IRB is authorized to approve renewal applications upon request. Protocols that have not been renewed will be administratively closed one year after the date of the initial approval.

3. *Evaluating certain investigative activities not defined as human subjects research*
    a. The third objective of the FranU IRB is to assess certain proposed investigative activities, originating from either FranU or from other FMOL facilities, that would not necessarily be defined as human subjects research.
    b. These activities would include:
        i. Scholarship of Teaching and Learning (SoTL) research
            1. In most cases, FranU faculty members who want to conduct SoTL research would not need to seek IRB approval.
            2. Faculty members who wish to conduct SoTL research may choose to seek written IRB approval if they intend to share their findings with the scientific/scholarly community beyond the borders of our institution.
            3. The Office of Academic Research is authorized to act on behalf of the FranU IRB to approve minimal risk SoTL research projects that would be deemed exempt from IRB review.

ii. Quality improvement (QI) projects
    1. QI projects from FMOL facilities would need to be preauthorized by the facility's Quality Director
iii. Evidence-based practice (EBP)
    1. EBP projects would typically be exempt from IRB review, but the IRB has been authorized to assess these proposals to decide whether or not these activities would be defined as human subjects research.
    2. Clinical programs may require their students to complete EBP projects. In order to efficiently review a large number of student EBP projects, the IRB will form a subcommittee consisting of:
        a. The IRB Chair
        b. All IRB members with advanced training in that clinical field (e.g., Doctoral Nursing Faculty)
        c. Any other IRB members willing to serve on this subcommittee.

c. Investigators conducting SoTL, QI, or EBP projects would complete the FranU IRB Preliminary Proposal Application.
d. The FranU IRB would then form a review subcommittee to determine if:
    i. The proposal is human subjects research, and needs IRB approval, or
    ii. The proposal is not human subjects research or is exempt from IRB review, and does not need IRB approval.

Article III - Membership

1. Members to the IRB are selected for two year terms with optional renewal. Terms are staggered so that a minimum of 50% of the membership is retained. IRB members are selected by the IRB upon receipt of recommendations by the appropriate Dean or unit supervisor. If necessary, members can be removed by a majority vote of the IRB.

2. Full Member of the IRB
    a. The IRB committee is composed of at least five qualified members with diverse backgrounds with regard to race/ethnicity, gender, cultural background, and occupation. The IRB committee must also include members who have some familiarity with characteristics of the local community and are sensitive to its needs.
    b. The IRB committee must have adequate representation from the FranU School of Nursing, the School of Arts and Sciences, and the Academic Medical Center.
    c. The IRB must consist of at least one member whose primary concerns are scientific and one whose primary concerns are nonscientific.
    d. The IRB must also consist of at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
    e. No IRB member can participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
    f. All IRB members are required to complete training modules for Human Subjects Research developed by the Collaborative Institutional Training Initiative (CITI) before serving as voting members of the committee. IRB members must pass the following courses:
        i. IRB Members- Basic/Refresher, Basic Course
        ii. Social & Behavioral Research- Basic/Refresher, Basic Course
        iii. Biomedical Data or Specimens-Only Research – Basic/Refresher Course
    g. All IRB Members must sign the IRB Member Pledge

3. Standing Members
    a. The Chair of the Office of Academic Research will serve on the IRB as a standing member.
    b. The OLOL Regional Medical Center Bioethicist will also serve as a standing member.

4. Invited Guests
    a. 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.
    b. These guests may not vote with the IRB.

Article IV - Officers

1. The IRB shall elect officers for the positions of:

    a. Chair
    b. Vice-Chair

2. Chair

    a. The term of office for the IRB Chair shall be two years, with optional renewal.
    b. Duties of the IRB Chair shall be:
        i. Conducts the meetings of the IRB.
        ii. Serves as the primary liaison between the IRB, the investigators, and all Administrative and Academic bodies of the Institution.
        iii. As a standing member of the FranU Research and Scholarship Council, the IRB Chair will represent the interests of the IRB and will assist the council in facilitating and promoting research activities at FranU

3. Vice-Chair

    a. The term of office for the Vice-Chair shall be one year, with optional renewal.
    b. Duties of the Vice-Chair shall be:
        i. Assists the IRB Chair in various administrative functions, as needed.
        ii. Performs the duties of the Chair if he/she should resign or is absent.

4. Selection of Officers

    a. Nominations for the Chair and Vice-Chair will be made in the Fall semester of the selection year.
    b. Selection takes place at an IRB meeting convened by the Chair.

Article V – IRB Administrative Assistant

1. The IRB Administrative Assistant is not a voting member of the IRB committee, but will serve an essential role, and will have the following duties:

    a. Assists the IRB Chair in preparing agendas and other materials for meetings.
    b. Attends all IRB meetings and takes minutes.
    c. Prepares and/or maintains records of all correspondences between the IRB, the investigator, and administration.
    d. Assists the IRB Chair in assigning review committees
    e. Sends regular reminder notices to investigators and reviewers.
    f. Maintains records of IRB member training certifications.
    g. Notifies IRB members and Officers when their terms are due to expire or be renewed

Article VI – Executive Board

1. The elected officers of the IRB (Chair & Vice-Chair), as well as the Standing Members, shall constitute the executive board.

2. The executive board shall have general supervision of the affairs of the IRB between its business meetings, fix the hour and date of meetings and perform such other duties as are specified in these bylaws. It is subject to the orders of the IRB and none of its acts shall conflict with action taken by the IRB.

3. The IRB Administrative Assistant will assist the Executive Board in the performance of its duties.

Article VII – Meetings

1. Regular meetings of the IRB will be held on a monthly basis, or as needed.

2. A majority of voting members must be present to constitute a formal meeting.

3. Members are expected to attend all of the regular meetings of the IRB. After two unexcused absences the member will receive a reminder letter from the Chair. After three unexcused absences, the member may be asked to resign from the Committee.

Article VIII – Committee(s)

1. In most cases, review subcommittees of two IRB members are formed upon the initial receipt of an investigator's completed application to the IRB. The proposal review procedure will be as follows:
    a. The IRB Chair will receive the initial proposal to the IRB
        1. If it is a proposal for human subjects research, then investigators will submit the FranU IRB Application for Initial Review.
        2. If the proposal is SoTL, QI, or EBP, then investigators will submit the FranU IRB Preliminary Proposal Application.
    b. The IRB Chair, with the assistance of the IRB Administrative Assistant, will assign two committee members, one who will serve as the "primary reviewer" and one who will serve as the "secondary reviewer."
    c. It is the responsibility of the primary reviewer to communicate directly with the investigator during this review process.
    d. If the investigators submit the Preliminary Proposal Application, then the two reviewers will assess whether or not the project is human subjects research and inform the IRB Chair of their decision.
    e. If the investigators submit the Application for Initial Review, then the two reviewers will review the research to determine if the project is exempt, expedited, or requires a full review.
    f. If the reviewers deem the project to be exempt or expedited, then they will inform the IRB Chair, and the Chair will send out an approval letter to the investigator.
    g. If the reviewers believe the project requires full IRB review, then they will inform the IRB Chair, and the Chair will schedule a full review of the proposal at the next scheduled IRB Committee meeting.
2. Special subcommittees may also be formed, as needed, to address other issues and would then report to the full IRB committee.

Article IX – Parliamentary Authority

All meetings of the IRB and its committees shall be conducted according to the most recent edition of *Robert's Rules of Order.*

Article X - Amendment

The bylaws may be amended at a regular business meeting by a two-thirds vote of the IRB membership. The IRB members must receive notice of proposed amendments at least two weeks prior to the voting.