Franciscan Missionaries of Our Lady University
Institutional Review Board (FranU IRB):
Basic Information for Researchers

What is an Institutional Review Board (IRB)?

- An IRB committee is a group of dedicated individuals ensuring the protection of the rights and welfare of human beings who serve as research participants.

Who is the FranU IRB?

- 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.
- 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).

Who submits projects for IRB review?

Complete an IRB application if:

- You want to conduct a project directly involving human subjects, or on retrospective data collected from human subjects, **and**,
- You, or one or more members of your project team, are affiliated with Franciscan Missionaries of Our Lady University (FranU), Our Lady of the Lake Regional Medical Center (OLOLRMC), or other Franciscan Missionaries of Our Lady Health System (FMOLHS) facility.

PLEASE NOTE: All IRB applications must be submitted through IRBManager, our online protocol management system, accessed through this link: https://franu.my.irbmanager.com/.

What projects require IRB review?

All projects involving human subjects should be submitted to the IRB for review. Not all projects involving human subjects are classified as Human Subjects Research, but the IRB makes that determination through the review process.

Based on your answers to questions in the IRB application your project is categorized as Human Subjects Research (**HSR**) or Not Human Subjects Research (**NHSR**).

Getting permission where your research is conducted

The IRB only ensures that your project adequately minimizes risks to human subjects. It DOES NOT grant permission to conduct your research at a facility. That must come first through feasibility review.

Feasibility review requirements

Feasibility review for **HSR** projects is necessary to ensure project feasibility and that it does not violate the core values of FMOLHS.

- Franciscan Missionaries of Our Lady University (FranU) Employees & Students
  Do NOT submit FranU Feasibility review request before submitting your IRB applications. FranU Feasibility review is built in to the IRB application. If approved, your Letter of Endorsement will be attached to this application and your submission will automatically be forwarded to the IRB for review. For questions please contact: Chair of FranU Research & Scholarship Council (RSC@franu.edu).
- OLOLRMC and FMOLHS Affiliates (facilities, staff, patients or resources)
  Feasibility review request must be submitted BEFORE your IRB application to either OLOLRMC Office of Research (research@fmolhs.org) or through a REDCap xForm (https://redcap.fmolhs.org/redcap/surveys/?s=F9KWFW9AT3N3WHLM). A feasibility request should include protocol/proposal, consent document (if applicable), CV, CITI training certificates, and medical/nursing/pharmacy license (if applicable). For more information, please contact Christine LeBoeuf, Sr. Director Research and Grant Administration at (Christine.LeBoeuf@fmolhs.org). If approved, you will be provided a Letter of Endorsement and asked to attach it to your IRB application.
- Sites off-campus (not affiliated with OLOLRMC or FMOLHS)
  Provide site-use approval and/or feasibility review from that facility.

Get trained

If your project is **HSR**, you need to take the training modules developed by the Collaborative Institutional Training Initiative (CITI). To access CITI modules used by FMOLHS:

- Click the link: https://www.citiprogram.org/Default.asp
- Click “Register” and select “Franciscan Missionaries of Our Lady Health System” as your organization affiliation, and complete the registration process
- Take one or both of the following courses, depending on the type of research:

- Social & Behavioral Research - Basic/Refresher, Basic Course
- Biomedical Data or Specimens-Only Research - Basic/Refresher Course
- *NOTE - Student investigators should complete "Student" course*

- Save your CITI completion certificate to upload when prompted in IRBManager

Set up your IRBManager account

Don't have an IRBManager account? For details see *"IRBManager User's Guide"* located on the FranU IRB web page under **User's Guides**.

Link: https://franu.edu/offices-services/office-of-academic-research/institutional-review-board

Prepare documents to upload to IRBManager

Before you submit your IRB application, you need to prepare documents in advance. **HSR** projects require more documents than **NHSR** projects.

HSR project documents

- Feasibility Letter of Endorsement from OLOLRMC Office of Research for research conducted at OLOLRMC or FMOLHS affiliates)
  - Or Site-use approval if off-campus and not affiliated with OLOLRMC or FMOLHS
- Project member(s): CITI training certificate, CV, and clinical license (if applicable)
- Signed Financial Conflict of Interest (FCIO) form for **EACH** project member. See link to "*Financial Conflict of Interest (fillable PDF)*" on the FranU IRB web page under **Forms**.
- Project protocol document - *12 page limit including title page and references*
  - If you do not have a project protocol document, prepare a more detailed description of the project, including sufficient details about the methods.
- Document(s) that detail your data collection (survey questions, interview guide, etc.)
- Materials indicating how your sample is collected (such as recruitment materials)
- Informed consent documents unless you are requesting to waive the requirement for documentation of informed consent (if there is minimal risk).
  - For details see FranU IRB web page: https://franu.edu/offices-services/office-ofacademic-research/institutional-review-board

NHSR project documents

- Project member(s): CV and clinical license (if applicable)
- Project document or furnish detailed description of your project.
- Document(s) that detail your data collection (survey questions, interview guide, etc.)
- Materials indicating how your sample is collected, such as recruitment materials (if applicable).

Review process after submission

Once you submit your application in IRBManager, the IRB Chair will assign a team of two IRB members to review your proposal. Within a week, you will receive an email that your proposal is under review, giving you the names and contact information of the reviewers. Within 30 days, the reviewers will render their decision or will request additional information. If additional information is needed, please furnish your response to their comments, and/or make revisions and resubmit your application.

Decision process after IRB review

After requested revisions are addressed, you receive an email from the IRB Chair with one of the following responses:

- Proposal is approved as exempt
- Proposal is approved as expedited, either with or without a requirement for continuing review.
- Proposal requires full IRB committee for review. A meeting of the full committee is scheduled, and you are asked to attend respond to the committee members' questions regarding your proposal. The committee votes on your proposal and makes one of the following decisions:
    - Proposal is approved, and will require continuing review at least once a year.
    - Proposal is tabled if there are serious issues that must be addressed. The researcher is asked to revise and resubmit the proposal.
    - Proposal is disapproved if there are unacceptable risks to the safety and welfare of the participant. It cannot be resubmitted.
- **Please note:** If you submit a NHSR project, you receive one of the following:
    - IRB oversight is not required, and you may proceed with your project
    - Proposal **IS** deemed human subjects research, and you **MUST** update and resubmit your IRB application.

Begin your project!

You may begin your project *only if* you receive notification from the FranU IRB that your research proposal is approved, or your NHSR project does not require IRB oversight.

Need to make some changes?

If after your proposal is approved by the IRB and you wish to make any substantial changes to your research, you will need to submit a Request for Amendment form. If you wish to change personnel, you must submit a Study Personnel Change form. Both forms may be accessed through IRBManager at this link: https://franu.my.irbmanager.com/. You may commence with the changes only after the IRB approves them.