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

Individuals affiliated with FranU, Our Lady of the Lake Regional Medical Center (OLOLRMC), or any other Franciscan Missionaries of Our Lady (FMOL) facility who wish to conduct research on human subjects, or on retrospective data collected from human subjects, **must** obtain IRB approval or exemption prior to beginning the study. The FranU IRB serves as the IRB of record for all members of the FranU community and for some studies within the FMOL health system.

PLEASE NOTE: All IRB applications are now submitted online from this link: https://franu.my.irbmanager.com/.

If you are thinking about doing a project involving human subjects, please follow these steps:

1. Spread the word!

If you are with the college, please inform your school dean about your scholarly activity. If you are with OLOLRMC or another FMOL facility, notify your supervisor. It is important that we share our scholarship, instead of remaining isolated.

2. Is your project *human subjects research*?

Some projects involving human subjects may not need to go through the formal IRB review process. These include:

- **Scholarship of Teaching and Learning (SoTL)**
  - **Example:** A university faculty member wants to conduct research to test out a new teaching method to improve student learning.
- **Quality Improvement (QI)**
  - **Example:** A medical professional at OLOLRMC wants to implement an improved process of patient evaluation in an Emergency Room.
- **Evidence-Based Practice (EBP)**
  - **Example:** A nurse wants to implement a preoperative procedure that has been shown in past research to be effective in reducing postoperative pain.

If you wish to submit one of these types of projects for IRB review, the IRB can affirm that the project is NOT human subjects research and does not need IRB oversight. For more information about these types of projects, please visit the FranU IRB web site (https://www.franu.edu/offices-services/office-of-academic-research/institutional-review-board). .

3. Get Trained!

If you are proposing human subjects research, then you need to take the training modules developed by the Collaborative Institutional Training Initiative (CITI). This is the human subjects protection training course that is used by FMOLHS. If your project is SoTL, QI, or EVP, CITI training is only required for **student** investigators.

- Click on the following link to the modules: https://www.citiprogram.org/Default.asp
- Click the "Register" button
- Where it says "Select Your Organization Affiliation," type in "Franciscan Missionaries of Our Lady Health System" and then click "Continue to Step 2" to complete the registration process
- Take one or both of the following courses, depending on the type of research you are doing:
  - Social & Behavioral Research - Basic/Refresher, Basic Course
  - Biomedical Data or Specimens-Only Research – Basic/Refresher Course
- **Please note:** These modules take time to complete; you can complete part of it and go back to it later.
- Save your completion certificate and prepare to submit it.

4. Write your proposal!

Prepare to submit a *brief* proposal (12 pages max) that will explain the purpose of your project and a *complete* description your planned methodology. Also, prepare to submit *all* measures (questionnaires, physiological assessments, etc.) that you plan to use: every assessment that participants will be given.

5. Get Endorsed!

If you are doing any kind of project that involves human subjects, you will need to obtain permission from the site where the project will take place. This is the feasibility review.

- If the research is at the college, submit your proposal, measures, and CITI certification to the Chair of the FranU Research and Scholarship Council, currently Dr. Kirk Nelson (Timothy.Nelson@franu.edu). The council will meet monthly to assess the feasibility of all scholarly projects.
- If the research is at OLOLRMC or another FMOL facility, fill out a Feasibility Review Submission form on IRB Manager (https://franu.my.irbmanager.com/). There you will submit all study-related documents and your proposal will be reviewed for feasibility by the OLOL Office of Research. For more information, please contact Christine LeBoeuf, Director of Clinical Research (Christine.LeBoeuf@fmolhs.org).
    - If you are planning a QI project at OLOLRMC, please contact Christi Pierce, Vice President of Quality and Safety: Christi.Pierce@fmolhs.org.
- After the feasibility review is complete, you will be emailed a letter of endorsement. However, this letter does not yet authorize you to conduct your research. You will still need IRB approval. When you submit your proposal online to the FranU IRB, you will be prompted to upload your letter of endorsement with your submission.

6. Your proposal will be considered only if you complete an IRB application!

Click on the following link to begin the process of submitting your IRB Application using IRB Manager: https://franu.my.irbmanager.com/. This platform will allow you to upload all necessary study documents.

Here are some tools to help you use IRB Manager:

- IRB Manager, Navigating the Portal: https://franu.edu/assets/uploads/documents/IRB_Manager__Navigating_the_Portal.pdf.
- Submitting a Research Project: https://franu.edu/assets/uploads/documents/Submitting_a_Research_Project.pdf
- Submitting a QI/SoTL/EBP Project: https://franu.edu/assets/uploads/documents/Submitting_an_EBP_Project.pdf

7. Documents you will need to submit to the IRB:

Using IRB Manager, you will fill out your application online and upload the following materials:

- A signed feasibility letter of endorsement
- Your CITI training completion certificate(s)
- Financial Conflict of Interest form (https://franu.edu/assets/uploads/documents/Conflict_of_Interest_Policy1.pdf).
- A project proposal (maximum 12 pages)
- All questionnaires/assessments that will be given to participants
- Informed consent documents, unless you are requesting to waive the requirement for documentation of informed consent (if there is minimal risk).

8. Review process after you submit:

Once you have completed your application, and submitted all documents, onto IRB Manager, the IRB Chair will be notified and will assign a team of two IRB members to review your proposal. Within a week, you will receive notification via email that your proposal is under review, giving you the names and contact information of the reviewers assigned to your proposal. Within 30 days, reviewers will post their comments onto your online application and you will be able to respond to these comments and make revisions, if necessary.

9. Decision process after IRB review:

After any requested revisions have been addressed, you will receive an email from the IRB Chair with one of the following responses:

- Your proposal has been deemed exempt or given expedited approval.
- Your proposal will go to the full IRB committee for review. The full committee will meet and you will be asked to attend the meeting to respond to the committee members' questions regarding your proposal. The committee will then vote on your proposal and make one of the following decisions:
    - Your proposal will be approved.
    - Your proposal will be tabled if there are serious problems that must be addressed in the proposal. The researcher must revise and resubmit the proposal.
    - Your proposal will be disapproved if there are unacceptable risks to the safety and welfare of the participants in your proposed research study. It cannot be resubmitted.
- **Please note:** If you submitted an EBP, QI, or SoTL project, then you will receive one of the following two responses from the IRB:
    - IRB oversight is not required, and you may proceed with your project
    - Your proposal **IS** human subjects research, and you **MUST** submit a formal IRB Application

10. Begin your project!

You may begin your project *only if* you have received emailed notification from the FranU IRB that your research proposal has been approved, or that your EVP, QI, or SoTL project does not require IRB oversight.

11. Need to make some changes?

If after your proposal has already been approved by the IRB you wish to make any substantial changes to your research, you must notify the IRB first (irb@franu.edu). You may commence with the changes only after the IRB chair approves them.

If you are adding or removing any personnel from your project, please also notify the IRB.

12. Ready to close?

IRB approval is granted for a period of one year. When your study is completed during that time, you will need to notify the IRB that your study is closed (irb@franu.edu). A reminder letter, as well as a copy of the closure/continuation form, will be sent to you 90 days before your IRB approval is set to expire.

13. Going past one year?

If you wish to continue your research project for more than one year, you will need to request a continuing review. You would need to fill out the closure/continuation form NO LATER than two weeks before your IRB approval is set to expire.