

The ABCs of IRB

March 2026

About the IRB Process

I. IRB Review

- a. An Institutional Review Board (IRB) protects the safety of people who participate in research (human subjects).
- b. All 'human subjects research' (HSR) needs review by IRB, including trials, surveys, and chart reviews.
- c. Some studies would be deemed exempt from IRB review:
 - i. No personally identifiable data collected (eg, anonymous survey or de-identified data)
 - ii. Data collected during normal educational practices
 - iii. Publicly available data
 - iv. Quality Improvement studies

Tip: Even if a study is 'exempt' from IRB review, it should be submitted to the IRB, especially if you're seeking publication as journals often require proof of IRB review.

- d. FranU IRB reviews only minimal risk studies; higher risk studies are reviewed by LSU Health
- e. Systematic reviews are not HSR because they do not directly involve human subjects; therefore, they don't need IRB
- f. ANY research being done by FranU faculty or students must be reviewed by the IRB, even if the research occurs off campus (Off-campus research through FranU IRB will require additional materials).
 - i. FranU is "IRB of Record" means the study originally is approved by FranU, although data may be collected off campus. This will require a letter of support (or endorsement) from the off-campus entity; for example, OLOL requires a specific feasibility review for any research performed there.
 - ii. If another university is the IRB of Record and data is collected on FranU's campus, the FranU IRB must review and approve if one or more members of the study team is an FMOLHS employee or student.
- g. External entities with IRB approval that are requesting FranU participation of faculty, students or staff:
 - i. For University-wide requests, these must go through RSC review and approval of the Provost
 - ii. For department-level requests, these do not require RSC review and can be decided on that level

II. IRB Application

- a. IRB applications are entered and maintained in the "IRB Manager" website (<https://franu.myirbmanager.com>) .
- b. [Details of the IRB are available here](#). The [User Manual can help you find answers](#) on the process.

Tip: If you have any problems or questions about your account or submission, email Mary.Lambert@Franu.edu

- a. Applications submitted to the FranU IRB first undergo a Research & Scholarship Council feasibility review and then review from 2 members of the IRB committee.
- b. Applications may be returned for clarifying or additional information at any point.
- c. After this IRB review is complete, you will be notified that your study has been:
 - approved as exempt

- approved as expedited, or
- referred for full board review

Tip: Make it easy for IRB reviewers to understand your study to make the process as smooth as possible and avoid delays. You can do this by understanding the process and terminology!

Beginning your Application

I. Register with the IRB

- a. Any individual involved with data collection needs to be registered with the IRB through the IRB Manager website prior to application
- b. Take a training course in protecting human subjects through the Collaborative Institutional Training Initiative (CITI) program [Follow guidelines here](#) (If you already have CITI Training in the past 3 years, secure your PDF certificate)
 - i. Visit <https://about.citiprogram.org> and Register
 1. Faculty/Clinicians: “Biomedical Data”
 2. For non-clinical research, the Social/Behavioral Research test would be acceptable.
 3. Students: Student Module only
 - ii. Keep PDF of your certificate
 - iii. **CITI requires renewal every 3 years.**
- c. Set up IRB Manager Account (including students)
 - i. Visit <https://franu.my.irbmanager.com/Login.aspx>
 - ii. You’ll need your CITI certificate, current CV and clinical license expiration & certificate (except for students)

II. Prepare your Proposal

- a. Consult with someone with experience in submitting to the IRB, even an IRB Committee member to help
- b. Several tools are available to help you build your proposal
 - i. [Reporting Guidelines](#): (Equator-Network.org) Standardized list of items to be included in a specific study design
 - ii. [Risk of Bias Tools](#): Graded checklists of study components that may bias outcomes
 - iii. [Rehabilitation Outcome Measures](#): Database of common clinical measures with validity, reliability, and psychometrics
- c. Before you start your application, prepare the materials you’ll need to submit and organize them in electronic files. [Here is a checklist you can follow.](#)

Tip: Save your filenames with consistent syntax. For example, a reference number to refer in your submission, followed the type of document, and your name or short study name (1_Proposal_MSKUSStudy_Page.doc)

- d. Templates can be helpful in getting your application together. Be sure you modify templates specific to your study. Note that different study designs may require different templates. Use ‘future tense’ for your study proposal.

- e. [This step-by-step guide will walk you through your IRB application](#). The most important components of a successful IRB application are:
- i. Necessary components correctly completed, paying attention to spelling and grammar
 - ii. Consistent language between various components of the application This table provides the list of files you may need for your application

Tip: Don't 'corner yourself in' with your application. Remember that you don't have to 'do everything' in your application, but you can't do things that aren't in your application. For example, include tests and measures you might use later if the study continues.

Template File	
Financial Conflict of Interest	
0_FCOI	- Financial Conflict of Interest form - Required of everyone on IRB application - Fill in PDF; Be sure study title is the same - Unless PI, students are “Research Assistant”
1_Proposal-General 1_Proposal-Observational 1_Proposal-Survey 1_Proposal-Retrospective	- Choose template. “Proposal-General” or choose a template specific to a design reporting guideline - Includes background and methods <= 12 pages (excluding references)
Consent	
2.1_Informed Consent	See checklist for informed consent here - Follows FranU IRB template 8th grade reading level (Use AI to help) - Separate document not required for electronic survey - May be electronically signed and saved
2.2_Assent	Only required if study involves minors; parents give consent, while children give ‘assent’. Follow guidance here. See example here
2.3_Financial Liability	Sign after consent
Data Collection Forms	
3.0_Deidentifier	- After signing consent, this spreadsheet links subject ID to name - Keep this document separate from other identifiable information
3.1_Data Collection (Word) 3.1_Data Collection (Excel)	- Typically in Excel, but can vary - Generally should not include personal identifier
3.2_Intake Form	- Optional if used for eligibility or other data - May be completed by subject
3.3_Medical Clearance or Referral	Optional if clearance is necessary (See guidelines for exercise studies here)
3.4_Survey Questions	Optional if survey is used ; may include surveys in proposal or submit existing survey
3.5_Participation Log	Optional if used by subjects to track their participation
Recruiting	
4.1_Recruiting Methods	See subject recruiting guidelines here See policy on using students as subjects here - Include copy for emails, newsletters, social media or other methods
4.2_Recruiting Copy	If fliers are used, include here
Endorsements	
5.1_Offsite Endorsement	- If data is collected off campus, use this feasibility form as endorsement from offsite official - Offsite officials may use their own form
5.2_DPT Feasibility	Faculty advisors must sign off on feasibility for student projects

Tip: Use a file name strategy and filing system for your forms. “STUDYNAME-IRB-CONSENT_FORM-date”

- f. Here is some common 'boiler plate' language you can use in your application, particularly for exercise interventions. Be sure the information is correct for your study and is consistently worded throughout the application
- **Costs**
 - Expenses are expected to be minimal. The DPT department will provide supplies and equipment needed.
 - This study was supported by a grant from >>
 - **Exclusion Criteria:**
 - Unable to speak or read English
 - Unable to follow instructions
 - Contraindications to ___ testing or intervention___
 - Use of medications affecting ___outcome measures___
 - Signs and symptoms at rest or during activity including pain, discomfort in the chest, neck, jaw or arms, shortness of breath at rest or with mild exertion, dizziness or faintness, difficulty breathing, ankle edema, heart palpitations, or leg pain/cramps during walking
 - Recent trauma or fracture of extremity
 - Recent (less than 6 months) surgery of extremity
 - Pacemaker, chronic venous disease
 - **Setting:**
 - Franciscan Missionaries of Our Lady University Physical Therapy Gyms
 - Specific settings (have agreement)
 - **Recruitment:** Participants will be recruited from Franciscan Missionaries of Our Lady University or local community through word-of-mouth, flyers, emails, newsletters, or personal inquiries.
 - **Risks:**
 - There will be no risks beyond what is experienced in normal, everyday activity.
 - Minimal risk is expected at a similar level to moderate exercise.
 - Muscle soreness or minor injury: Participants may experience muscle soreness or injury while exercising, although the risk is no more than would normally be expected.
 - Discomfort from Equipment: Wearing monitoring equipment might cause short-term discomfort or irritation.
 - Loss of Confidentiality: There is a risk of loss of confidentiality in the event of a breach of data protection protocols.
 - **Benefits:**
 - Potential Cognitive and Physical Benefits: Participants might experience improvements in physical fitness
 - Contribution to Health Research: This research can contribute to broader health initiatives by exploring ways to optimize health and physical fitness. Students may benefit from an educational opportunity by participating in research.
 - **Data Management:**
 - All data will be de-identified and stored securely to maintain participant confidentiality.
 - Any information and documents containing participants' identifying information and protected health information including participant names, date of birth, etc., as well as information and documents linking participants with their participant ID will be stored on a password protected computer, cloud account, flash drive, or external hard drive that only the investigators will have access to. Paper documents will be stored in a locked file cabinet and destroyed after 5 years.
 - To de-identify the participants, a non-identifiable number/alphanumeric will be used to link the participants' name to their data. All data collection will be recorded under the participants non-identifiable number/alphanumeric. Any personal data will be stored separately in an Excel

spreadsheet located in its own individual passcode-required folder on the researcher's password-protected personal computer, cloud account, flash drive, or external hard drive.

- **Informed Consent:**
 - All participants will provide informed consent acknowledging their voluntary participation, the risks involved, and the nature of the study.
- **Alternatives, Participation & Withdrawal**
 - Participation is voluntary. Subjects may withdraw from the study at any time. Students may be offered alternative opportunities for bonus points if they do not choose to participate.
 - Participants can choose not to participate in the study without repercussions. Participation in this study is completely voluntary, and participants may choose to discontinue participation at any time.
- **Confidentiality:**
 - All data will be de-identified and stored securely to maintain participant confidentiality.
- **Adverse Events**
 - Subjects will be informed of and monitored for:___
 - Any adverse events or discomfort experienced by participants will be immediately addressed by the researcher, with the option to withdraw at any time without penalty. These will be reported to the IRB by protocol.
- **Student Involvement**
 - Students may be offered bonus points for participation in this study by their instructors; if so, alternative bonus point opportunities for those choosing not to participate will be offered.
- **Data Analysis**
 - **Descriptive Statistics:** Means, SD, frequencies for all conditions
 - **Validity / Reliability**
 - **Inferential Statistics:**
 - Paired t-tests for dual-task vs. single-task differences
 - ANOVA or Repeated measures ANOVA for condition comparisons
 - Correlation between ___ and ___
 - Regression analysis to evaluate ___
 - **Effect Size:** Cohen's d
 - **Minimum Clinically Important Difference (MCID):** Referenced from prior literature where available

III. Gather your materials

- a. Set up a folder in One Drive for your study labeled "Studyname IRB"
- b. Make a rough outline of the documents you'll need to submit. Use the templates linked above to create the files. Rename the files with the "study title-name of form-date"
 - i. Methods/Proposal including title, purpose, investigators
 - ii. FCOI
 - iii. Informed Consent
 - iv. Data Collection forms
 - v. Recruiting copy
- c. Have all investigators (including students) complete the FCOI; be sure they have already registered with the IRB Manager. You will upload the FCOIs with the application.
- d. Start with the Methods/Proposal. **Be sure all documents (and the online application) have exactly the same language!**

Tip: You can also use AI to craft language for your proposal by describing your study and asking specific questions. For example, you can upload your Informed Consent form and ask AI to be sure it's at an 8th grade level. Of course, you MUST check the AI's work to be sure it's consistent with your study!

Submit

I. Submission

- a. After you have completed your registration and gathered all your application information, you're ready to submit
- b. Student-led projects (as PIs) must have a faculty advisor listed (who must also have an IRB account)

Tip: Double check your proposal before submitting that your online application, FCOI, recruiting materials, and consent state the same thing!

II. Review

- a. After submission, your application will be reviewed for completeness and feasibility by the Research & Scholarship Council. You may be asked to submit clarifying information before it's approved for review.
- b. Your application will undergo review by 2 IRB committee members who must reach agreement on the status.

III. IRB Outcomes

There are generally 3 outcomes of a review:

- i. Exempt: IRB oversight not necessary. These include
 1. No personally identifiable data collected (eg, anonymous survey or de-identified data)
 2. Data collected during normal educational practices
 3. Publicly available data
- ii. Expedited: minimal risk of harm or confidentiality
 1. May be Expedited with or without annual review (See below)
- iii. Committee Review
 1. The proposal will be reviewed by the full IRB committee
 2. Proposals may then be
 - a. Approved
 - b. Tabled
 - c. Disapproved (Cannot resubmit)

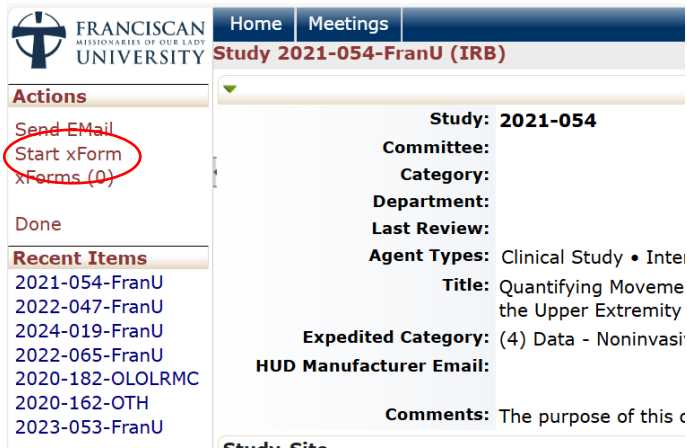
After Approval

I. Data Collection

- a. You cannot collect data until IRB approval is received.
- b. IRB approval is noted by a number (eg "2024-22"). This number should be reported in disseminations as "This study was approved by the FranU IRB Committee, #2024-22"
- c. The study will be listed in your dashboard

II. Ongoing Communication

- a. You must keep in contact with IRB and report any injuries or breach of confidentiality
 - i. X-forms are used in IRB manager to 'communicate' with the IRB about your study. Some X-forms should be accompanied by separate documents (such as amendments)
 - ii. X-forms are accessible by a link in the upper left of the study dashboard "Start X-form" (You need to pull up the individual study in your IRB manager dashboard).



Select xForm to start		
Action	Form (Click to start)	Description
	Adverse Event Reporting Form	Adverse Event Reporting Form
	Annual Check-in Form	Annual Check-in Form
	IRB Application	NEW all-in-one application for project review.
	IRB Manager-New Contact	IRB Manager-New Contact
	Re-Approval Application or Closure Notification Form	This form can be used to renew an expiring study, as for continuing review, or to report on its closure.
	Remote Submit CITI, License and C.V. or Resume	To submit on behalf of a researcher (not yourself) to load researcher's CITI, License, and CV/Resume.
	Request for amendment	This form can be used for requesting approval of any changes in study procedures.
	Study personnel change form	This form can be used to add or remove personnel on a study.
	Submit CITI, License and C.V. or Resume	For faculty and researchers to load their CITI, License and C.V. or Resume

- b. X-Forms are used for several functions

Adverse Event Reporting Form	You must report any injuries or breach of confidentiality
Annual Check-in Form	may be required annually; you should get an email reminder
IRB Manager-New Contact	Use this to register new personnel before they are added
Re-approval Application or Closure Notification Form:	Close your study after completed, OR ask for it to be re-opened after expiration
Remote Submit CITI, License and CV	Use this to update CITI, license for study personnel if they are not updated
Request for Amendment	Describe your request with the form and Attach template downloaded here with changes and rationale

Study personnel change form	Use this to change PI, add or remove staff
Submit CITI, License and CV	All investigators should be up to date. CITI expires after 3 years; update Update your licensure when you renew your license

III. Updating your information

- a. Use the X-form "Submit CITI, License & CV" to update your CITI and licensure. CITI expires after 3 years.
- b. Upload PDFs of your CITI certificate, license & CV as updated

IV. Adding/Removing Personnel

- a. All added personnel must have a completed Financial Conflict of Interest form signed (with the same study title). Do this first.
- b. In the study dashboard, click on X-forms and choose "Study personnel change form."
- c. Anyone collecting data should be on the IRB, while those not involved in the study should be removed
- d. If not already registered with IRBManager, they will also need current CITI certificate, resume, and clinical license (unless a student) to register their account
 - i. Individuals can register themselves OR researchers can add them through the study in IRB Manager (using "New Contact")
 - ii. Identify their role as Co Investigator

Amending an IRB

I. When to Amend

- a. Any major changes to an existing IRB-approved study within its expiration period must submit a request for Amendment through the X-form in the study's dashboard in IRB Manager
 - i. If you are adding a population, changing inclusion/exclusion, or methods that may affect the risk of the study, you should request an amendment
 - ii. "Minor" changes to the protocol or title do not require amendments. While 'major changes' are not clearly defined, it's suggested to err on the side of caution
- b. Any changes to study personnel (e.g., students who graduate) should be requested using the X-form.
- c. Amendments to an existing IRB can save time and resources when approved studies are continued or modified

II. How to Amend

- a. These must be done through the study dashboard in IRB Manager, which is accessible by study personnel (if you don't have access in your dashboard)
 - i. Login franu.myirbmanager.com and click on your study
 - ii. If a previously approved study has expired, you may request it be re-opened for amendment using an X-form "Re-approval Application or Closure Notification Form"
 - iii. If you are not currently on the study, you should have the PI submit the Personnel Change first to give you access (see process below)
- b. Use this [template](#) with the X-form to explain your amendment

Change	Description	Rationale
<i>Personnel (submitted xform)</i>		
<i>Title</i>		
<i>Subjects (inclusion/ exclusion, recruitment)</i>		
<i>Methods</i>		
<i>Data collection procedures</i>		
<i>Informed Consent</i>		

- c. Adding/Removing Personnel
 - i. All added personnel must have a completed Financial Conflict of Interest form signed (with the same study title). Do this first.
 - ii. In the study dashboard, click on X-forms and choose "Study personnel change form."
 - iii. Anyone collecting data should be on the IRB, while those not involved in the study should be removed
 - iv. If not already registered with IRBManager, they will also need current CITI certificate, resume, and clinical license (unless a student) to register their account
 1. Individuals can register themselves OR researchers can add them through the study in IRB Manager (using "New Contact")
 2. Identify their role as Co Investigator