



**IRBManager
Application for Project Review
User's Guide**

Summer 2020

Email IRB@franu.edu for questions or assistance.

Table of Contents

1.0	Before you begin.....	3
1.1	Who submits projects for IRB review?.....	3
1.2	What projects require IRB review?	3
1.3	Getting permission where your research is conducted	3
1.4	Feasibility Review Requirements	3
1.5	Get trained.....	4
1.6	Set up your IRBManager account	4
1.7	Prepare documents to upload to IRBManager	4
1.7a	HSR Project Documents	4
1.7b	NHSR Project Documents	5
1.8	IRBManager Navigation Tips.....	5
1.9	Required Information.....	6
2.0	Log-in to IRBManager.....	6
2.1	Dashboards	7
2.2	Begin an application	7
2.3	Example of Power Dashboard.....	7
2.4	Example of Bubble Dashboard.....	7
3.0	Welcome to FranU IRB and Instructions	8
4.0	Human Subjects Research Screening Questions	9
4.1	Determining if your project is Human Subjects Research	9
4.2	Example of Non-Clinical screening questions.....	9
4.3	Example of Clinical screening questions.....	10
5.0	Adding New Contact to IRBManager	11
5.0	Adding New Contact to IRBManager (continued)	12
6.0	Project Details.....	13
6.1	HSR vs. NHSR.....	13
6.2	Project Title.....	13
6.3	Principal Investigator/Project Lead (PI).....	14
6.4	Faculty Advisor Section	15
6.5	Study Staff Members.....	16
6.6	Funding Source	17
6.7	Other IRB	17

6.8	General Purpose.....	18
6.9	Example of HSR questions	18
6.10	Example of NHSR questions.....	19
7.0	Participant Population	20
7.1	Participant Types.....	20
7.2	Informed Consent Methodology.....	21
7.3	Signed informed consent.....	21
7.4	Waiver of documentation of informed consent	22
7.5	Waiver of informed consent.....	23
7.6	Implied consent.....	23
8.0	Research Setting	24
8.1	Setting for Study	24
8.2	Main Site.....	24
8.3	Additional Sites	24
8.4	Site Use Approval	25
8.5	Feasibility Review.....	25
8.6	Video or audio recordings	25
9.0	Risks/Benefits/Alternatives	26
10.0	Waiver of authorization of HIPAA criteria.....	27
11.0	Last Essentials	28
11.1	Other materials not previously attached	28
12.0	PI Signature for self-submission.....	28
12.1	How will the PI sign when submitted by others?.....	29
12.2	Print, wet signature, scan and attach.....	29
13.0	Form Complete and Submit	30
14.0	What's Next?	31

1.0 Before you begin

For details on using IRBManager see tutorial “*IRBManager User’s Guide*” located on the FranU IRB web page under Institutional Review Board (IRB) Documents.

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

1.1 Who submits projects for IRB review?

Complete an IRB application if:

- You are conducting 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.

1.2 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 this review process.

Based on your answers to questions in this application your project is categorized as Human Subjects Research (**HSR**) or Not Human Subjects Research (**NHSR**). Projects categorized as **NHSR** have fewer requirements and sections that only apply to HSR will automatically be removed.

Some projects involving human subjects may not need to go through the formal IRB review process. They include Scholarship of Teaching and Learning (SoTL), Quality Improvement (QI), and Evidence Based Practice (EBP). However, if submitted for IRB review, the IRB can affirm that the project is **NHSR** and does not require IRB oversight.

1.3 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.

1.4 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 request feasibility review before submitting your application to the IRB. This application is sent for feasibility review and a Letter of Endorsement is automatically attached upon approval.
- **OLOLRMC and FMOLHS Affiliates**
DO submit OLOLRMC Feasibility Review Submission through IRBManager to OLOLRMC Office of Research. You are prompted to attach their Letter of Endorsement to this application.
- **Sites off-campus** (not affiliated with FranU, OLOLRMC or FMOLHS)
Provide site-use approval and/or feasibility approval from facility. You are prompted to attach their site-use approval to this application.

1.5 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 - Students investigators should complete “Student” course*
- Save your CITI completion certificate to upload when prompted in IRBManager

1.6 Set up your IRBManager account

Don’t have an IRBManager account? For details see tutorial “*IRBManager User’s Guide*” located on the FranU IRB web page under Institutional Review Board (IRB) Documents.

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

1.7 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. For a list of documents see sections **1.7a** and **1.7b**.

1.7a HSR Project Documents

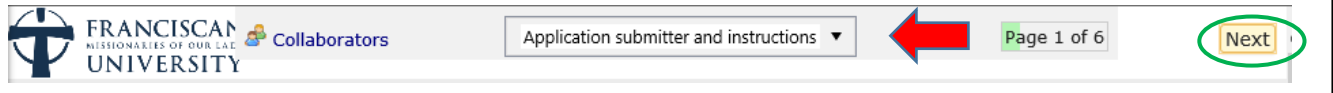
- Feasibility Letter of Endorsement from OLOLRMC (except FranU Students & Employees)
 - Or, Site-use approval if off-campus and not affiliated with OLOLRMC or FMOLHS
- Project member(s): CITI training certificate, CV, and clinical license (if applicable)
- Signed Financial Conflict of Interest (FCIO) form for **EACH** project member
 - Link to template: <https://s3.franu.edu/uploads/documents/IRB-Conflict-of-Interest-Form-FranU-2017.pdf?mtime=20190724105247&focal=none>
- 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-of-academic-research/institutional-review-board>

1.7b 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).

1.8 IRBManager Navigation Tips

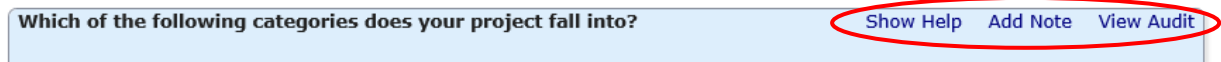
- **Across the top of each screen:**
 - “Navigation Drop-Down” allows you to jump to other screens (**red arrow**)
 - “Next” advance one screen (**green circle**)



- **Buttons across bottom of each screen (purple arrow):**
 - “Previous” return to prior screen
 - “Next” advance one screen
 - “Save for Later” save progress and return later from your **Dashboard**
 - “More” view questions, notes, changed responses and view application as PDF
 - “Submit” (last screen) application is complete, send for review



- **Links within sections (red circle)**
 - “Show help” additional guidance related to a specific section.
 - “Add Note” opens window to enter note applicable to the section
 - “View Audit” opens window to view audit and time stamp applicable to the section



1.9 Required Information

The designation (**Required**) at any section does not allow you to advance using “**Next**” until the requirement is satisfied. If this message appears, click on **red link(s)** to jump to the specific area and resolve the issue.

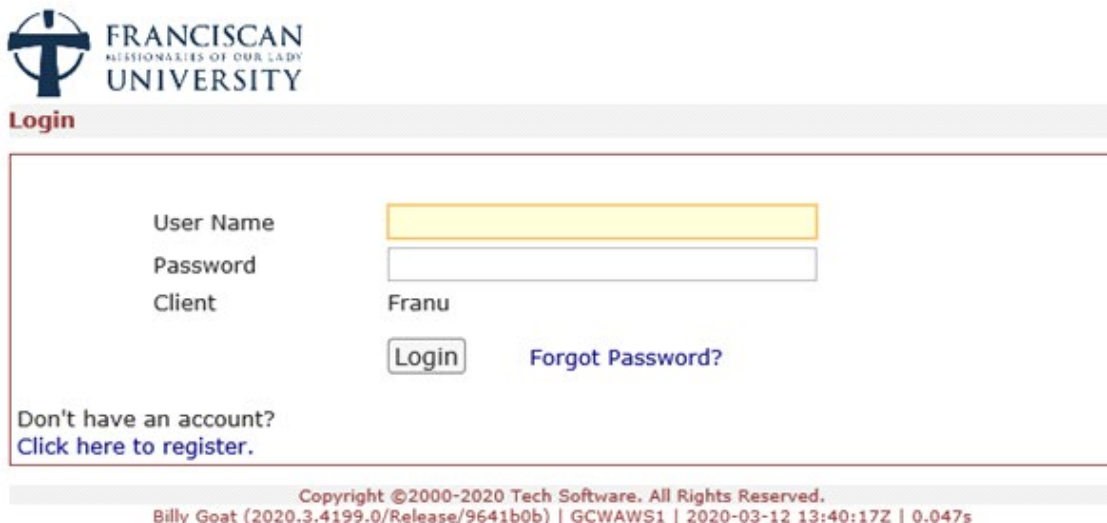
The following issues exist. Click on an issue to jump there.

- Title of Project - Required.
- Attach PI CV - Required.

*NOTE: Using “Navigation Drop-Down” (top of each screen) allows you to jump to other screens to continue filling out your form. Any missing (**Required**) items are identified when you click “Submit” on the final screen.*

2.0 Log-in to IRBManager

- Log-in to IRBManager with your User Name and Password
<https://franu.my.irbmanager.com>



The screenshot shows the login interface for IRBManager. At the top left is the Franciscan University logo, featuring a cross and the text "FRANCISCAN MISSIONARIES OF OUR LADY UNIVERSITY". Below the logo is the word "Login" in red. The main form area contains three input fields: "User Name" (highlighted in yellow), "Password", and "Client" (with "Franu" entered). Below the "Client" field are two buttons: "Login" and "Forgot Password?". At the bottom left of the form, it says "Don't have an account? Click here to register." At the very bottom of the page, there is a copyright notice: "Copyright ©2000-2020 Tech Software. All Rights Reserved. Billy Goat (2020.3.4199.0/Release/9641b0b) | GCWAWS1 | 2020-03-12 13:40:17Z | 0.047s".

Don't have an IRBManager account?

For details see tutorial “*IRBManager User's Guide*” located on the FranU IRB web page under Institutional Review Board (IRB) Documents.

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

2.1 Dashboards

- Your **Dashboard** is the first screen you see when you log-in to IRBManager.
- **Power Dashboard** or **Bubble Dashboard** (see examples below). The appearance is different, but the functionality is the same. The NEW **Bubble Dashboard** is considered more visually friendly using tabs to navigate. See tutorial - “*IRBManager User’s Guide*” on FranU IRB web page for details on selecting dashboards.
 - Link: <https://franu.edu/offices-services/office-of-academic-research/institutional-review-board>

2.2 Begin an application

- To start select – “**Click here to submit a new application to the IRB**” (green box).

2.3 Example of Power Dashboard

FRANCISCAN MISSIONARIES OF OUR LADY UNIVERSITY

Home | Find Study (Ctrl+Q) | Take a tour... | Help | Alfred's Settings | Sign off

My Studies

Actions

- Click here to submit a new application to the IRB
- Click here to submit a new SoTL, QI, or EBP application to the IRB
- OLOLRMC - Feasibility Review Submission
- OLOLRMC - Feasibility Review Submission
- Submit Researcher Information
- Start xForm
- Show Sponsor Ids
- Use Bubble Dashboard

Recent Items

2019-135-OLOLRMC

Messages

Welcome to IRBManager at FranU

Studies (4 Active)

- You are associated with **4 active** Studies and **6 total** Studies.
- You are the PI for **4 active** and **6 total** Studies.

xForms (13 Active)

- You have **11 unsubmitted** xForms.
- You have **2 xForms** being processed at a later stage.
- There are **2 xForms** awaiting your attention.

Events (5 Open)

Only show events where I am:

- You have **3 Initial Submission** events.
- You have **2 QI reports** events.
- You have **5 Total Open** events

Notices

Welcome to IRB Manager at Franciscan Missionaries of Our Lady University!

For more information about the IRB please click [FranU IRB](#).

Contact us at IRB@franu.edu.

Next Meeting:TBD

NOTE: During the COVID-19 Outbreak the FranU IRB is still able to review and approve proposals, amendments, and re-approval/closure requests.

2.4 Example of Bubble Dashboard

Home | Notices

My Studies

4 Studies | 4 IRB | 15 xForms | 5 Events

Export to Excel | **Click here to submit a new application to the IRB** | Click here to submit a new SoTL, QI, or EBP application to the IRB

OLOLRMC - Feasibility Review Submission | OLOLRMC - Feasibility Review Submission

Submit Researcher Information | Start Other xForm

4 Primary

2019-108-FranU
New From PI
Test created on 6/19/19

2019-119-FranU
New From PI
NHSR test (reviewers found to be HSR)

2019-138-FMOLHS
New From PI
TEST STUDY NHSR improve patient safety

test 6/5/19-FranU
New From PI
this is a fun title

Notices

Welcome to IRB Manager at Franciscan Missionaries of Our Lady University!

For more information about the IRB please click [FranU IRB](#).

Contact us at IRB@franu.edu.

Next Meeting:TBD

NOTE: During the COVID-19 Outbreak the FranU IRB is still able to review and approve proposals, amendments, and re-approval/closure requests.

3.0 Welcome to FranU IRB and Instructions

FRANCISCAN MISSIONARIES OF OUR LADY UNIVERSITY Collaborators Application submitter and instructions Page 1 of 9 **Next**

IRB Application Application submitter and instructions

Creating user Add Note View Audit

Newman, Alfred E

Email: _____ **Phone:** _____

Welcome to Franciscan Missionaries of Our Lady University Institutional Review Board

Complete this application if:

- You are conducting 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 any other Franciscan Missionaries of Our Lady Health System (FMOLHS) facility.

Human Subjects Research (HSR) vs. Non-Human Subject Research (NHSR)
Not all projects involving human subjects are classified as HSR. Examples of NHSR include Evidence-Based Practice (EBP) and Quality Improvement (QI) projects. The IRB is only authorized to review and approve HSR proposals. Based on your responses to questions in this application, the IRB will determine if your project is classified as HSR or NHSR. IRB approval or exemption is required if a project is classified as HSR before research commences.

Feasibility Review Requirements
Feasibility review for projects involving human subjects 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
Feasibility review is built in to this 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: Michael Ludwig, PhD, Chair of FranU Research & Scholarship Council (Michael.Ludwig@franu.edu).
- OLOLRMC and FMOLHS Affiliates
Submit Feasibility Review Submission form to OLOLRMC Office of Research through IRBManager. If approved, you are prompted to attach their Letter of Endorsement to this application prior to IRB submission. For questions please contact: Katie Vance, PhD, Director of Clinical Research (Katie.Vance@fmolhs.org).
- Sites off-campus (not affiliated with OLOLRMC or FMOLHS)
Provide site-use approval and/or feasibility review from that facility.

Navigation Tips – click drop-down/button/link

- Across the top of each page:
 - "Navigation Drop Down" allows you to jump to other screens
- Buttons across bottom of each page:
 - "Previous" return to prior screen
 - "Next" advance one screen
 - "Save for Later" save your progress and return to it later from your Home tab (Dashboard)
 - "More" view questions, notes, changed responses and view application as PDF
 - "Submit" (last screen) application complete, send for review
- Links within sections, if applicable:
 - "Show help" additional guidance related to a section
 - "Add Note" opens window to enter notes applicable to the section
 - "View Audit" opens window to view audit and time stamp applicable to the section

Previous **Next** Save for Later More ▶

Copyright ©2000-2020 Tech Software. All Rights Reserved.
Billy Goat (2020.4.4421.0/Release/ca7ed60) | GCWAWS1 | 2020-04-15 21:24:01Z | 0.220s

- Click "Next" at the top or bottom of the screen to proceed to the next screen.

4.0 Human Subjects Research Screening Questions

4.1 Determining if your project is Human Subjects Research

Not all projects involving human subjects are classified as Human Subjects Research. Based on your answers to questions in this section, and only for the purpose of completing your application your project is categorized as Human Subjects Research (**HSR**) or Not Human Subjects Research (**NHSR**). It is possible this determination could change as a result of the IRB review.

- For more information see “**Explanation**” (purple arrows) & click “**Show Help**” (red circle)
- Additional questions generate depending on your answers.

4.2 Example of Non-Clinical screening questions

FRANCISCAN UNIVERSITY
MISSIONARIES OF OUR CARE
Collaborators

Human subjects research screening q... Page 2 of 6

Next

IRB Application Human subjects research screening questions

Determining if your project is Human Subjects Research (HSR). Add Note

According to Office for Human Research Protections (OHRP), research can be defined as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge”. Your answers to the questions below will help us determine if your project is categorized as HSR only for the purpose of completing this application. Your answers will be evaluated by IRB members to ensure accuracy. It is possible the determination could change as a result of the IRB review when a decision is rendered.

The project is a systematic investigation intended to generate NEW knowledge. (Required) Add Note View Audit

Agree
 Disagree

Explanation: A systematic investigation can be defined as a search for knowledge that is planned and carried out in a clearly describable way. Choose AGREE if your project will be investigating a new intervention, or if you will be gathering previously unknown information (behavioral and/or physiological) from your participants. Choose DISAGREE if you are applying an already well-established intervention based on current solid research evidence, and/or if the participant information you are gathering is already known or expected.

Which of the following categories does your project fall into? Show Help Add Note View Audit

Click “Show Help” for additional information.
(Required)

Clinical
 Non-clinical

Only de-identified data will be collected. (Required) Add Note View Audit

Agree
 Disagree

Explanation: Choose AGREE if you are gathering information about your participants that will be kept separate from any identifying information. Choose DISAGREE if participants’ names will be linked with their private information, or if there is a reasonable chance that a person’s private information could be revealed.

Is the project intended to be a direct benefit to the participants or local institution? (Required) Add Note View Audit

Agree
 Disagree

Explanation: Choose AGREE if the main intent is for the participants or the local institution to be directly benefited by the project. Choose DISAGREE if the direct benefit to each individual participant or for the local institution is NOT the main intent or is not certain.

Previous **Next** Save for Later More ▾

- Click “**Next**” at top or bottom of the screen to proceed to the next screen.

4.3 Example of Clinical screening questions


IRB Application - Human subjects research screening questions

Determining if your project is Human Subjects Research (HSR). [Add Note](#)

According to Office for Human Research Protections (OHRP), research can be defined as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge". Your answers to the questions below will help us determine if your project is categorized as HSR only for the purpose of completing this application. Your answers will be evaluated by IRB members to ensure accuracy. It is possible the determination could change as a result of the IRB review when a decision is rendered.

The project is a systematic investigation intended to generate NEW knowledge. (Required) [Add Note](#) [View Audit](#)

Agree Disagree



Explanation: A systematic investigation can be defined as a search for knowledge that is planned and carried out in a clearly describable way. Choose AGREE if your project will be investigating a new intervention, or if you will be gathering previously unknown information (behavioral and/or physiological) from your participants. Choose DISAGREE if you are applying an already well-established intervention based on current solid research evidence, and/or if the participant information you are gathering is already known or expected.

Which of the following categories does your project fall into? [Show Help](#) [Add Note](#) [View Audit](#)


Click "Show Help" for additional information.

(Required)

Clinical Non-clinical

The current accepted standard of care will be implemented. (Required) [Add Note](#) [View Audit](#)


Agree Disagree



Explanation: Choose AGREE if your intervention is consistent with best practices, based on current, solid research evidence. Choose DISAGREE if you are implementing a new type of treatment, or a treatment that has only been examined in a few small-sample research studies.

Results will be generalizable to specific internal patient population. (Required) [Add Note](#) [View Audit](#)

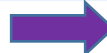
Agree Disagree



Explanation: Choose AGREE if the results are only intended to be relevant to the population of patients in the settings from where you would be drawing your sample. Extrapolation of results to other settings is possible, but not the main intent of the activity. Choose DISAGREE if you intend to generalize your findings to patients in other settings.

Information being collected is a routine part of care. (Required) [Add Note](#) [View Audit](#)

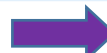
Agree Disagree



Explanation: Choose AGREE if you are gathering information about your patients that is routinely collected already. Choose DISAGREE if you are requesting additional patient information that goes beyond routine record collection.

Only de-identified data will be collected. (Required) [Add Note](#) [View Audit](#)

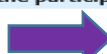
Agree Disagree



Explanation: Choose AGREE if you are gathering information about your participants that will be kept separate from any identifying information. Choose DISAGREE if participants' names will be linked with their private information, or if there is a reasonable chance that a person's private information could be revealed.

Is the project intended to be a direct benefit to the participants or local institution? (Required) [Add Note](#) [View Audit](#)

Agree Disagree



Explanation: Choose AGREE if the main intent is for the participants or the local institution to be directly benefited by the project. Choose DISAGREE if the direct benefit to each individual participant or for the local institution is NOT the main intent or is not certain.

- Click ["Next"](#) at top or bottom of the screen to proceed to the next screen.

5.0 Adding New Contact to IRBManager

- Anyone affiliated with your proposed project will need to have his or her contact information added to IRBManager.

Please read these instructions before using the following sections:

6.3 Principal Investigator/Project Lead (PI)

6.4 Faculty Advisor Section

6.5 Study Staff Members

To populate names for selection in the drop-down list in **PI, Faculty Advisor and Study Staff Member** section(s) the name must first be entered in the IRBManager contact list.

If the person you are adding is not found in the drop-down list, you are instructed to click the “Click here to add a new contact” link (red circle).

If the person you are adding is not found in the drop down list above, please click the link below to add them to the system. Once submitted you will receive an automated confirmation email and you can then use the newly added contact in your form.

[Click here to add a new contact](#)

- After clicking “Click here to add a new contact” a new window opens.
- Enter the email address for the user you are adding to IRBManager. Use professional email addresses (i.e., @franu.edu, @fmoths.org, @lsuhsc.edu).
- **Warning** message appears if the email is already assigned to another contact.

Enter the email address for the user to add. Use professional email address (i.e., @franu.edu, @fmoths.org, @lsuhsc, etc.). (Required) [Add Note](#) [View Audit](#)

E-Mail already assigned to another contact.

- Complete required fields.

New Contact Information [Add Note](#) [View Audit](#)

Prefix (Required)

First Name (Required)

Last Name (Required)

Degree(s)

Telephone Number (Required)

Institutional Affiliation (Required)

5.0 Adding New Contact to IRBManager (continued)

- If “other” is selected above, enter the name of other institutional affiliation (**red arrow**).

Institutional Affiliation (Required)
*Other

Please enter your other institutional affiliation. (Required) 

- Enter expiration dates and attach backup documents.

Enter CITI training expiration date. [Add Note](#) [View Audit](#)

Attach CITI training document here. [Add Note](#) [View Audit](#)

Attach CV here. [Add Note](#) [View Audit](#)

Enter licensure expiration date. [Add Note](#) [View Audit](#)

Attach licensure here. [Add Note](#) [View Audit](#)


- Click “Next” if you are ready to submit this form (**red arrow**).
- Or click "Save for Later" to save progress and return later from your **Dashboard**

After clicking next and submit, the contact is submitted to IRB Manager. IRB Manager processes the new contact information and a notification email is sent to the new contact and submitter confirming the information is registered with IRB Manager. [Add Note](#)



- Click “Submit” (**purple arrow**) and close window.

Form Completed
You've completed the form. You can now either save the form for later revision, or submit it.



NOTE: After you click “Submit” IRBManager processes the new contact information and a notification email is sent to you (the submitter) and the new contact just entered confirming the information is registered with IRBManager.

You **MUST FIRST** receive the confirmation email **BEFORE** the new contact name appears in the drop-down list to use as the **PI, Faculty Advisor or Study Staff Member(s)**.

6.0 Project Details

6.1 HSR vs. NHSR

Based on your answers on the previous screen and only for the purpose of completing this application your project is categorized as either **HSR** or **NHSR** (red arrows) and generates questions and sections to complete. It is possible this determination could change as a result of the IRB review when a decision is rendered.

The screenshot shows the top navigation bar of the IRB Application system. It includes the Franciscan University logo, the text "FRANCISCAN UNIVERSITY MISSIONARIES OF OUR L.A.E.", a "Collaborators" icon, a "Project Details" dropdown menu, "Page 3 of 7", and a "Next" button. Below the navigation bar, there are two tabs: "IRB Application" and "Project Details". The "IRB Application" tab is active, and a red arrow points to the "HSR" label. The main content area contains a text box with the following text: "Based on your answers on the previous page and only for the purpose of completing this application your project is categorized as Human Subjects Research (HSR). It is possible this determination could change as a result of the IRB review when a decision is rendered." There is an "Add Note" link in the top right corner of the text box.

The screenshot shows the same IRB Application interface as above, but with the "NHSR" label highlighted by a red arrow. The main content area contains a text box with the following text: "Based on your answers on the previous page and only for the purpose of completing this application your project is categorized as Not Human Subjects Research (NHSR). It is possible this determination could change as a result of the IRB review when a decision is rendered." There is an "Add Note" link in the top right corner of the text box.

If your project is categorized as NHSR it has fewer application requirements. All sections that only apply to HSR will automatically be removed from your application.

*NOTE: This tutorial is designed to show all details necessary for **HSR** submissions.*

- *Keep in mind that some questions and sections are shown in this tutorial for the benefit of **HSR** submissions but are not needed for **NHSR** projects.*
- *Please ignore/skip sections shown in this tutorial that do not apply to **NHSR** projects, they are automatically removed from the application.*

6.2 Project Title

- Enter the title of your project.

The screenshot shows a form field for entering the project title. The label reads "Enter the title of your project. (Required)". To the right of the label are "Add Note" and "View Audit" links. Below the label is a large empty text input box with a small "ABC" icon and a checkmark in the bottom right corner.

6.3 Principal Investigator/Project Lead (PI)

- Start typing the last name of the Principal Investigator/Project Lead (PI) in the space provided to select from the IRBManager contact drop-down list (**purple arrow**).
- If the name is not found in the drop-down list, click the link below (**red circle**) to add new contact. For details see – **5.0 Adding New Contact to IRBManager**. After receiving the confirmation email, you can use the newly added contact by repeating the previous step.
- Is the Principal Investigator/Project Lead a **FranU Student** (**green arrow**)?
 - Faculty Advisor section only appears if the PI is a **FranU Student**.
 - **FranU Students** DO NOT NEED to request feasibility review before submitting your application to the IRB. Once your application is submitted, it is sent for feasibility review and a Letter of Endorsement is automatically attached upon approval.
- Is the Principal Investigator/Project Lead a **FranU Employee** (**gold arrow**)?
 - **FranU Employees** DO NOT NEED to request feasibility review before submitting your application to the IRB. Once your application is submitted, it is sent for feasibility review and a Letter of Endorsement is automatically attached upon approval.
- Details regarding CITI training, licensure and CV are conditioned on the project category of **HSR** or **NHSR** and auto populate in your form from the IRBManager contact record. If information is missing or expired, you are prompted to attach document(s) here (**red box**).
- Attach PI's Financial Conflict of Interest (FCOI) form (**blue arrow**).
 - FCOI template: <https://s3.franu.edu/uploads/documents/IRB-Conflict-of-Interest-Form-FranU-2017.pdf?mtime=20190724105247&focal=none>

Enter the name of the Principal Investigator/Project Lead (PI). (Required) Add Note View Audit

Newman, Alfred E

Newman, Alfred E

If the person you are adding is not found in the drop down list above, please click the link below to add them to the system. Once submitted you will receive an automated confirmation email and you can then use the newly added contact in your form.

[Click here to add a new contact](#)

Is the Principal Investigator/Project Lead a FranU student? (Required)

Yes

No

NOTE: When a FranU student or employee is the PI this application will automatically route to FranU's Research and Scholarship Council Chair for feasibility review. If approved, your Letter of Endorsement will be attached to this application and your submission will be forwarded to the IRB for review.

Is the Principal Investigator/Project Lead a FranU employee? (Required)

Yes

No

PI CITI expiration
12/01/2020 CITI training is up to date if an unexpired date is shown here.

Does the PI have a clinical license
Yes

PI clinical licensure expiration
Missing Clinical License is up to date if an unexpired date is shown here.

Attach PI's clinical licensure here (Required)
 A copy of clinical licensure (if applicable) is required for human subjects research.

Is the PI's CV attached to the contact record
No

Attach PI's CV here (Required)

Attach PI's Financial Conflict of Interest (FCOI) form here (Required)


Financial Conflict of Interest

6.4 Faculty Advisor Section

If the PI is a **FranU Student** the Faculty Advisor section appears, otherwise it does not appear.

- Start typing the last name of the Faculty Advisor in the space provided to select from the IRBManager contact drop-down list (**purple arrow**).
- If the name is not found in the drop-down list, click the link below (**red circle**) to add new contact. For details see – **5.0 Adding New Contact to IRBManager**. After receiving the confirmation email, you can use the newly added contact by repeating the previous step.
- Details regarding CITI training, licensure and CV are conditioned on the project category of **HSR** or **NHSR** and auto populate in your form from the IRBManager contact record. If information is missing or expired, you are prompted to attach document(s) here (**red box**).
- Attach Faculty Advisor's Financial Conflict of Interest (FCOI) form (**blue arrow**).
 - FCOI template: <https://s3.franu.edu/uploads/documents/IRB-Conflict-of-Interest-Form-FranU-2017.pdf?mtime=20190724105247&focal=none>

Enter the name of faculty advisor for the Principal Investigator/Project Lead. (Required) Add Note View Audit

Newman, Betty Z x 

Newman, Betty Z


If the person you are adding is not found in the drop down list above, please click the link below to add them to the system. Once submitted you will receive an automated confirmation email and you can then use the newly added contact in your form.
Click here to add a new contact

Faculty advisor CITI expiration.
Missing CITI training is up to date if an unexpired date is shown here.

Attach Faculty Advisor's CITI certificate here
 Attach an updated CITI certificate, if training is missing or expired.

Does the Faculty Advisor have a clinical license
N/A

Is the Faculty Advisor's CV attached to the contact record
Yes


Attach Faculty Advisor's Financial Conflict of Interest (FCOI) form here. (Required)
 

6.5 Study Staff Members

Are there additional members working on this project besides the PI and Faculty Advisor?

- If “Yes” is selected (**gold arrow**) you are provided space to furnish information for each project member (**red star**). If “No” is selected the study staff section does not appear.

Besides the PI and/or Faculty Advisor are there additional study staff working on this project? (Required) Add Note View Audit

Yes 

No

DO NOT re-enter principal investigator or faculty advisor here.

Complete the information for each project member (**one card per individual**).

- Start typing the last name of the study staff member in the space provided to select from the IRBManager contact drop-down list (**purple arrow**).
- If the name is not found in the drop-down list, click the link below (**red circle**) to add new contact. For details see – **5.0 Adding New Contact to IRBManager**. After receiving the confirmation email, you can use the newly added contact by repeating the previous step.
- Details regarding CITI training, licensure and CV are conditioned on the project category of **HSR** or **NHSR** and auto populate in your form from the IRBManager contact record. If information is missing or expired, you are prompted to attach document(s) here (**red box**).
- Attach Study Staff Member’s Financial Conflict of Interest (FCOI) form where specified on their individual card (**blue arrow**).
 - FCOI template: <https://s3.franu.edu/uploads/documents/IRB-Conflict-of-Interest-Form-FranU-2017.pdf?mtime=20190724105247&focal=none>
- Click “**Save**” in the upper right corner of each card to save that entry (**red arrow**) and enter additional staff members on the next blank card if applicable.



Complete the information below for each study staff member (one card per individual). Add Note View Audit

Click “**Save**” in the upper right corner of each card to save that entry.


The pencil icon allows you to edit the card.


The paper icon allows you to duplicate the card.

The X allows you to delete the card.

Please **DO NOT** include the faculty advisor or re-enter the principal investigator here.

Save

Study staff* 

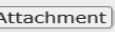
Role* 

Clinical licensure*

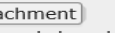
Clinical licensure expirations*

Clinical license is up to date if an unexpired date is shown here.

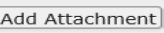

CITI Expirations*

CITI Certificate 

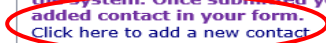
Attach an updated CITI certificate, if training is missing or expired.

Updated CV 

Attach CV, if applicable and above is 'No' or blank.

Study Staff Financial Conflict of Interest (FCOI)*  

If the person you are adding is not found in the drop down list above, please click the link below to add them to the system. Once submitted you will receive an automated confirmation email and you can then use the newly added contact in your form.


[Click here to add a new contact](#) 

6.6 Funding Source


Indicate funding source of your project


- If “Grant” or “Sponsor” is selected (**purple arrow**) the funding detail section appears (**blue arrows**).
- If “None” is selected the funding detail section does not appear.


Choose the funding source for your project. *(Required)* [Add Note](#) [View Audit](#)

Grant 
 Sponsor
 None

Please provide the federal or state agency (or sponsor company name). *(Required)*

Enter the title of the grant or contract. *(Required)* 

Enter the grant or contract number here. *(Required)* 


Enter the grant contact person including: name, address, telephone number, e-mail address. *(Required)* 

6.7 Other IRB


Has this research project been submitted for approval to another IRB?

- If “Yes” is selected (**green arrow**) space to list other IRB (**red circle**) and place to attach their approval document (**gold arrow**) appears.
- If “No” is selected the detail section does not appear.

Has this research project been submitted for approval to another IRB? *(Required)* [Add Note](#) [View Audit](#)

Yes 
 No

Please enter the name of the other IRB where the proposal has been submitted. *(Required)*

If your proposal has been approved by another IRB please attach verification of approval. *(Required)*
 


6.8 General Purpose

- This section is conditioned on your project category of **HSR** or **NHSR** (examples follow).

6.9 Example of HSR questions

- Briefly describe the general purpose of the project, *1-2 sentence limit* (**purple arrow**).
- Choose **ALL** the study methods that describe your project (**red box**).
- Attach protocol - *12 page limit* (**blue arrow**). If you do not have a protocol document, attach a more detailed description of the project, including sufficient details about the methods.
- Attach data collection details: survey questions, interview guides, etc. (**green arrow**).
- Attach materials indicating how your sample is collected such as recruitment materials , if applicable (**gold arrow**).


Describe the general purpose of the project. Please limit to one or two sentences. (Required) [Add Note](#) [View Audit](#)

ABC


Choose all of the study methods that describe your project. (Required)


- Behavioral Observation
- Clinical Study
- Human Biological Tissue (Blood, Skin cells, Etc.)
- Intervention/Experiment
- Interview
- Prospective Review
- Public Observation
- Qualitative, Focus Group
- Qualitative, Structured/Semi-Structured Interview
- Qualitative, Unstructured Interview
- Retrospective Data Analysis (Record Review)
- Survey, In Person
- Survey, Online
- Taste or Food Quality Testing
- Venipuncture

Attach your protocol document here. Please limit to 12 pages including the title page and references. (Required)




If you do not have a protocol document, attach a more detailed description of the project, including sufficient details about the methods.

Attach any document(s) that detail your data collection (survey questions, spreadsheets, interview guide, etc.) (Required)



Attach any materials indicating how your sample will be collected (such as recruitment materials). (Required)



6.10 Example of NHSR questions

- Briefly describe the general purpose of the project, 1-2 sentence limit (purple arrow).
- Choose **ALL** the study methods that describe your project (red box).
- If you have a project document, space to attach appears (blue arrow).
- Attach data collection details: survey questions, interview guides, etc. (green arrow).
- Attach materials indicating how your sample is collected such as recruitment materials, if applicable (gold arrow).
- Provide an overview of the literature that supports your project (red arrow).

Describe the general purpose of the project. Please limit to one or two sentences. (Required) [Add Note](#) [View Audit](#)


Choose all of the study methods that describe your project. (Required)

- Behavioral Observation
- Clinical Study
- Human Biological Tissue (Blood, Skin cells, Etc.)
- Intervention/Experiment
- Interview
- Prospective Review
- Public Observation
- Qualitative, Focus Group
- Qualitative, Structured/Semi-Structured Interview
- Qualitative, Unstructured Interview
- Retrospective Data Analysis (Record Review)
- Survey, In Person
- Survey, Online
- Taste or Food Quality Testing
- Venipuncture


Do you have a Project document? (Required)

Yes
 No


Attach your Project Document here. Please limit to 12 pages including the title page and references. (Required)



Attach any document(s) that detail your data collection (survey questions, spreadsheets, interview guide, etc.)
(Required)



Attach any materials indicating how your sample will be collected (such as recruitment materials).



Provide an overview of the literature that supports your project. Please limit to 1 or 2 paragraphs. (Required) [Add Note](#) [View Audit](#)

[Previous](#) [Next](#) [Save for Later](#) [More ▸](#)

- Click “Next” at the top or bottom of the screen to proceed to the next screen.

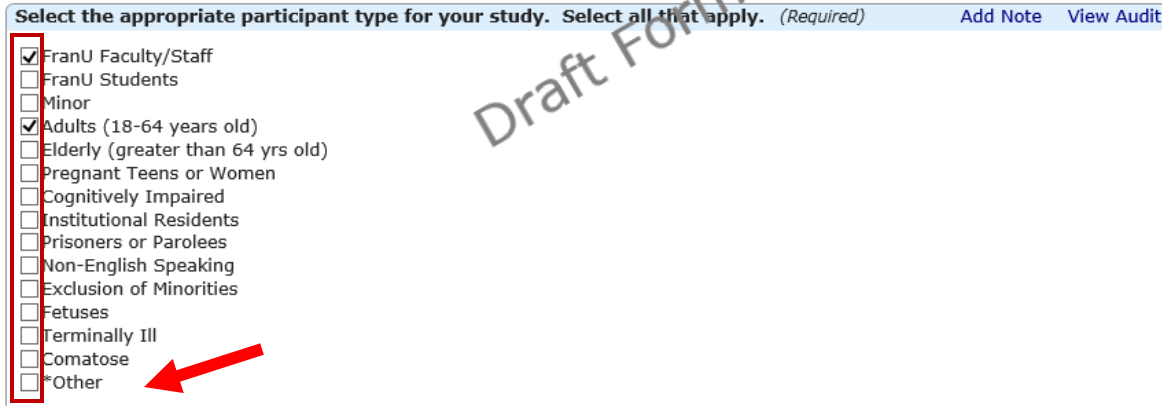
7.0 Participant Population

7.1 Participant Types

- Select ALL appropriate participant types for your project (**red box**).

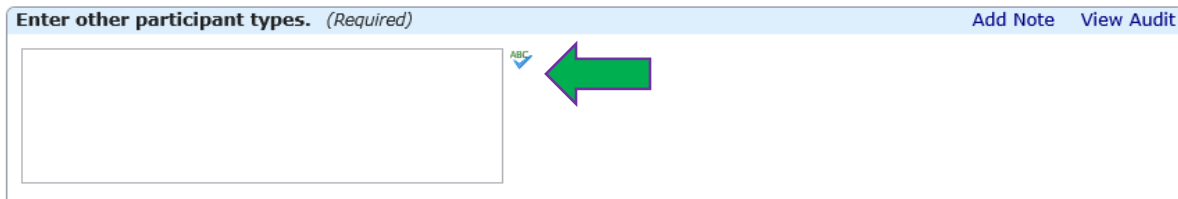
Select the appropriate participant type for your study. Select all that apply. (Required) [Add Note](#) [View Audit](#)

FranU Faculty/Staff
 FranU Students
 Minor
 Adults (18-64 years old)
 Elderly (greater than 64 yrs old)
 Pregnant Teens or Women
 Cognitively Impaired
 Institutional Residents
 Prisoners or Parolees
 Non-English Speaking
 Exclusion of Minorities
 Fetuses
 Terminally Ill
 Comatose
 *Other



- If “Other” is selected above (**red arrow**), space to list other participant types appears (**green arrow**), otherwise it does not appear.

Enter other participant types. (Required) [Add Note](#) [View Audit](#)



[Previous](#) [Next](#) [Save for Later](#) [More ▾](#)

- Click “**Next**” at the top or bottom of the screen to proceed to the next screen.

7.2 Informed Consent Methodology

For projects categorized as **HSR** choose appropriate informed consent methodology (**red box**), otherwise this section does not appear.

- Signed informed consent
- Waiver of documentation of informed consent
- Waiver of informed consent
- Implied consent (survey only)

NOTE: Click **“Show Help”** (**red circle**) for additional information on consent methodology. After selecting your methodology, you are prompted to attach information and/or answer additional questions (examples of each method follows).

Please choose the appropriate informed consent methodology. [Show Help](#) [Add Note](#) [View Audit](#)

Click 'show help' to see more information.

(Required)

Signed informed consent

Waiver of documentation of informed consent

Waiver of informed consent

Implied consent (surveys only)

7.3 Signed informed consent

- Select “Signed informed consent” (**purple arrow**)
- Attach consent form(s) here (**blue arrow**)

Please choose the appropriate informed consent methodology. [Show Help](#) [Add Note](#) [View Audit](#)

Click 'show help' to see more information.

(Required)

Signed informed consent

Waiver of documentation of informed consent

Waiver of informed consent

Implied consent (survey only)

Please attach your consent form(s) here. (Required)

7.4 Waiver of documentation of informed consent

- Select “Waiver of documentation of informed consent” and attach consent information provided to subjects (gold arrows).
- Select ALL that apply (red box). If “45 CFR 46.117 (c)(1)” is selected (red arrow), a place to describe the potential harm/risk appears (green arrows), otherwise it does not appear.

Please choose the appropriate informed consent methodology. [Show Help](#) [Add Note](#) [View Audit](#)

Click 'show help' to see more information.

(Required)

Signed informed consent

Waiver of documentation of informed consent ←

Waiver of informed consent

Implied consent (survey only)

Please attach consent information that would be provided to subjects.

←

Check all that apply. [Add Note](#) [View Audit](#)

45 CFR 46.117(c)(1): That the only record linking the subject to the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subjects wishes will govern.

45 CFR 46.117(c)(1) ←

45 CFR 46.117(c)(2): That the research presents no more than minimal risk to subjects and involves no procedures for which a written consent is normally required outside of the research context.

45 CFR 46.117(c)(2)

Describe the potential harm/risk. (Required) [Add Note](#) [View Audit](#)

←

Describe the procedures being used in this research which present no more than minimal risk to subjects and involve no procedures for which a written consent is normally required outside of the research context. (Required)

←

The test of practicability may be met, for example by:

1. The need for a large number of subjects.
2. A presumed or demonstrated inability to contact individuals for whom contact information may not be accurate.
3. The fact that many subjects may be deceased.
4. The fact that a lack of data from a few subjects may make the number of subjects available for the study too small for make the study reliable and valid.

7.5 Waiver of informed consent

- Select “Waiver of informed consent” (purple arrow) and answer questions (blue arrows).

Please choose the appropriate informed consent methodology. Show Help Add Note View Audit

Click 'show help' to see more information.
(Required)

Signed informed consent
 Waiver of documentation of informed consent
 Waiver of informed consent
 Implied consent (surveys only)

Describe how the research will involve no more than minimal risk to subjects. (Required) Add Note View Audit

Describe how the waiver of informed consent will not adversely affect the rights and welfare of the subjects. (Required)

Describe how it is not practicable to conduct the research without the waiver of consent. (Required)

Describe additional pertinent information which will be provided to subjects after participation (if applicable).

7.6 Implied consent

- Select “Implied consent” (purple arrow) and attach consent information (blue arrow).

Please choose the appropriate informed consent methodology. Show Help Add Note View Audit

Click 'show help' to see more information.
(Required)

Signed informed consent
 Waiver of documentation of informed consent
 Waiver of informed consent
 Implied consent (survey only)

Please attach consent information that would be provided to subjects.

Previous Next Save for Later More ▾

- Click “Next” at the top or bottom of the screen to proceed to the next screen.

8.0 Research Setting

8.1 Setting for Study

- Describe the setting for your study

Research Setting

Setting for study (Required) Add Note View Audit


Examples: school labs, classroom. etc.

Draft Form

8.2 Main Site

- Choose the most appropriate main site for your project from the drop-down (**blue arrow**).

Choose the most appropriate main site for this study. (Required) Add Note View Audit




- If “other” is selected space to specify an “other” main site appears (**gold arrow**), otherwise it does not appear.

Specify the Main Site. (Required) 

8.3 Additional Sites

- Is the research taking place at additional site(s) (**green arrow**)?
- If “Yes” is selected a place to select **ALL** additional sites appears (**red box**), otherwise it does not appear.

Is the research taking place at additional sites? (Required) Add Note View Audit

Yes 
 No

Additional Sites Add Note View Audit

Choose all additional sites where your research will take place.

- FMOLHS - Franciscan Missionaries of Our Lady Health System
- FranU - Franciscan Missionaries of Our Lady University
- OLOA - Our Lady of Angels
- OLOLCC-MBP - Our Lady of the Lake Cancer Center - Mary Bird Perkins
- OLOLCH - Our Lady of the Lake Children's Hospital
- OLOLL - Our Lady of Lourdes Medical Center
- OLOLPG - Our Lady of the Lake Physician Group
- OLOLRMC - Our Lady of the Lake Regional Medical Center 
- OTH - Other Site
- PBRC - Pennington Biomedical Research Center
- St.E - St. Elizabeth Hospital
- St.F - St. Francis Medical Center

- If “OTH – Other Site” is selected from above list (**red arrow**), space to enter “other” additional site(s) appears (**purple arrow**), otherwise it does not appear.

Enter the other additional site(s). 

8.4 Site Use Approval

- Study sites off-campus or not affiliated with FranU, OLOLRMC or FMOLHS need signed authorization from the site. Attach site use approval here (if applicable).

Please attach site use approval if applicable. Add Note View Audit

Add Attachment

8.5 Feasibility Review

NOTE: If the Principal Investigator/Project Lead is a **FranU Student or Employee** the following feasibility section does NOT appear. You DO NOT NEED to request feasibility review before submitting your application to the IRB. Once your application is submitted, it is sent for feasibility review and a Letter of Endorsement is automatically attached upon approval.

- Has this study been through feasibility review process and approved?
- If “Yes” is selected a place to attach your endorsement letter is provided (**purple arrow**), otherwise it does not appear.
- Attach endorsement letter here (**blue arrow**).
- If “No” is selected the remainder of the application can be filled out using the “Navigation Drop-Down” (top of the screen), but **feasibility approval is needed before you can submit this application**. “Save for Later” at the bottom of the screen (**red arrow**) allows you to save your progress and return later from your **Dashboard**.

Has this study been through feasibility review process and approved? (Required) Add Note View Audit

No **←**

Yes

Please attach endorsement letter.

Add Attachment **←**

8.6 Video or audio recordings

- If video and/or audio recordings are used select “Yes” (**green arrow**) and provide justification (**gold arrow**). If “No” is selected the justification section does not appear.

Will video and/or audio recordings be used during the study? (Required) Add Note View Audit

Yes **←**

No

Please explain your justification for recording. (Required) Add Note View Audit

(inherited font) (inherited size) Format B I U A ↕ ↻ ↺ ↻

⌵ ⌶ ⌷ ⌸ ⌹ ⌺ ⌻ ⌼ ⌽ ⌾ ⌿ ⌿ ⌿

←

Previous **Next** Save for Later **←** More ▾

- Click “Next” at the top or bottom of the screen to proceed to the next screen.

9.0 Risks/Benefits/Alternatives

- Each of the following sections require your input (**blue arrows**).

FRANCISCAN UNIVERSITY
MISSIONARIES OF OUR L.A.D.
Collaborators

Risks/Benefits/Alternatives

Page 6 of 7

Next

IRB Application -- Risks/Benefits/Alternatives

Explain the expected or possible risks/discomforts during the study. (Required) Add Note View Audit


Explain the expected general benefits from the study and findings. (Required) Add Note View Audit

Explain the specific benefits subjects will receive by participating in the study. (Required) Add Note View Audit

Describe in detail the procedure(s) to be used to ensure confidentiality or anonymity for subjects/participants. (Required) Add Note View Audit

- Are there any alternative treatments or procedures for individuals who **do not wish to participate** (**gold arrow**)?


Are there any alternative treatments or procedures for individuals who do not wish to participate? (Required) Add Note View Audit

Yes 

No

- If “Yes” is selected a place to describe alternative treatments or procedures appears (**green arrow**), otherwise it does not appear.

Describe alternative treatments or procedures. (Required) Add Note View Audit



Previous **Next** Save for Later More ▶

- Click “**Next**” at the top or bottom of the screen to proceed to the next screen.

10.0 Waiver of authorization of HIPAA criteria

Select “Yes” if you are requesting a waiver of authorization of HIPAA (**blue arrow**) and provide the additional information related to the use of protected health information (PHI). If “No” is selected the additional information section does not appear.

- Select “Yes” (**gold arrow**) if the study involves no more than minimal risk to individuals.
- Describe your plan to protect health information identifiers from improper use and disclosure, and your plan to destroy the identifiers at the earliest opportunity or justification for retaining any identifiers (**green arrows**).
- Read statement and if you agree, select “I attest” (**red arrow**).
- Explain why it is not practical to conduct study without a waiver or alteration and without access to and use of PHI (**purple arrows**).

FRANCISCAN UNIVERSITY COLLABORATORS
Waiver of authorization of HIPAA crit... Page 7 of 9 **Next**

IRB Application -- Waiver of authorization of HIPAA criteria

Are you requesting a waiver of authorization of HIPAA? (Required) Add Note View Audit

Yes **←**

According to the HIPAA Privacy Rule, there are a limited number of conditions under which individuals' protected health information (PHI) can be disclosed without their authorization for research purposes. Researchers who are using individuals' PHI must request a HIPAA waiver in order to document that they are properly handling this information, and risk is minimized. The FranU IRB is authorized to grant this waiver.

Will the use or disclosure of protected health information (PHI) involve no more than minimal risk to individuals? (Required)

Yes **←**

Please describe your plan to protect the health information identifiers from improper use and disclosure. (Required) **←**

Please describe your plan to destroy the identifiers at the earliest opportunity consistent with the conduct of research. If there is a research justification for retaining the identifiers, please explain. (Required) **←**

By clicking "I attest," the researchers attest that the PHI will not be used or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted by the Privacy Rule. (Required)

I attest **←**

Please explain why it is not practicable to conduct the research without the waiver or alteration. (Required) **←**

***The test of practicability may be met, for example by: 1. The need for a large number of subjects. 2. A presumed or demonstrated inability to contact individuals for whom contact information may not be accurate. 3. The fact that many subjects may be deceased. 4. The fact that a lack of data from a few subjects may make the number of subjects available for the study too small for make the study reliable and valid.*

Please explain why it is not practicable to conduct the research without access to and use of PHI. (Required) **←**

Previous **Next** Save for Later More ▶

- Click “**Next**” at the top or bottom of the screen to proceed to the next screen.

11.0 Last Essentials

11.1 Other materials not previously attached

- This section allows you to attach other material you feel is important to your study but was not previously attached (**red arrow**).

FRANCISCAN UNIVERSITY
MISSIONARIES OF OUR L.A.E. Collaborators

Last essentials Page 6 of 7

Next

IRB Application -- Last essentials

Please attach any other materials not previously attached. Add Note View Audit

Add Attachment

Previous Next Save for Later More >

- Click “**Next**” at the top or bottom of the screen to proceed to the next screen.

12.0 PI Signature for self-submission

This section shows how the PI signs for self-submission.

- Read and agree to Investigator Agreement (**gold arrow**)
- Electronically sign application using your IRBManager password (**green arrow**).

FRANCISCAN UNIVERSITY
MISSIONARIES OF OUR L.A.E. Collaborators

PI Signature for self submission Page 9 of 9

Next

IRB Application -- PI Signature for self submission

Investigator Agreement Add Note View Audit

1. No subjects will be recruited or entered into a protocol until an approval notification is received from the IRB;
2. Changes or modifications in the research protocol during the period for which IRB approval has been granted shall not be initiated without prior IRB review and approval, except where necessary to eliminate immediate hazards to the subjects.
3. Written reports will be submitted to the FranU IRB regarding any deviation from the protocol and/or consent form, adverse events that are serious, unanticipated, and related to the study, or a death occurring during the study.
4. No human being will be involved as a research subject unless legally effective informed consent of the subject has been obtained, unless this requirement is waived.
5. The IRB will be notified within 60 days of a change in the principal investigator or the closure of the study.
6. The proposed research protocol will be conducted by me or under my close supervision.
7. The IRB shall have the authority to suspend or terminate approval of the research project if it is not being conducted in accordance with the IRB's decision, conditions, and requirements.

I hereby agree that I will comply with the rules and regulations of the FranU IRB and the Office of Human Research Protections. (Required)

Yes

No

Please enter your IRBManager password in order to electronically sign this submission. (Required)

To sign, enter password for marick953

Previous Next Save for Later More >


- Click “**Next**” at the top or bottom of the screen to proceed to **check and submit form** screen.

12.1 How will the PI sign when submitted by others?

NOTE: Coordinators and Research Directors - When the submitter is NOT the PI the application routes to the PI for review and signature. If submitter is the PI, these steps will not appear.

- Select the appropriate option for the PI’s signature (**red arrow**).

How will the PI be signing this submission? (Required) [Add Note](#) [View Audit](#)

Electronic signature 

Print, wet signature, scan, and attach.

NOTE: PI signature only required on initial submission, not on the revisions requested by the IRB. However, PI is still responsible for implementing all required revisions requested by the IRB.

- If “electronic signature” is selected the PI receives an email with a link to the form to review and electronically sign using IRBManager password.
- If “Print, wet signature, scan and attach” is selected follow the steps in 12.2 below.

12.2 Print, wet signature, scan and attach.

Use this option when the PI does not have access to electronically sign. This allows PI’s wet signature to be scanned and attached.

- Create PDF of form using “More” button below (**blue arrow**), print and have PI sign.
- Scan signed form and attach in the space provided (**green arrow**).

FRANCISCAN UNIVERSITY MISSIONARIES OF OUR L.A.E. [Collaborators](#) PI attestation and signature Page 1 of 1 Next

IRB Application -- **PI attestation and signature**

Coordinator instructions [Add Note](#)


Please create PDF of form, print and have PI sign. After signing, scan form and attach in the space below.


PI attestation [Add Note](#)

I agree to conduct this research consistent with what was included in this IRB application and also with any changes required by the IRB during the review process.

Investigator *Signing as Principal*

Signed application (Required) [Add Note](#) [View Audit](#)

Add Attachment 

Previous Next Save for Later More 

- Click “**Next**” at the top or bottom of the screen to proceed to **check and submit form** screen.

13.0 Form Complete and Submit

Once you reach the submission screen you have several options (**red square**).

- **Go Back** – return to prior screen(s).
- **Save for Later** – save and exit your form. You may return later from your **Dashboard**.
- **Print** – print a PDF of your form.
- **Submit** – submit your form.

After selecting “**Submit**” the system checks for all required elements.

- If you provided all required elements your form is sent to IRB for review. You may close this window.
- If you missed any required elements a list of issues is created to correct before you can submit your form (**green box**).
- Click on the page name link to jump to that screen and correct issues (**blue arrow**).
- After correcting all issues, select “**Submit**” again and your form is sent to IRB for review. You may close this window.



Form Completed

You've completed the form. You can now either save the form for later revision, or submit it.

[Go Back](#) [Save for Later](#) [Print](#) [Submit](#)



Your progress to this point *has been saved*, however you must address the following issues before you can submit this form. Click on a page name to go to issues on that page.

[Project Details](#)

- Attach clinical licensure - Required.
- Attach PI CV - Required.
- Display study staff table - One or more errors exist in the table:
 - You must supply at least one row of data.

[PI Signature for self submission](#)

- Assurance compliance agreement - Required.
- PI Signature - Required.

14.0 What's Next?

- After your application is submitted, an automated email is generated to the owner of each stage with a link to the form as it advances.
 1. Application data entry
Stage Owner - **Submitter/PI**
 2. Faculty Advisor Review (if applicable)
Stage Owner - **Faculty Advisor**
 3. IRB Office Review
Stage Owner – **FranU IRB Office** (IRB@franu.edu)
 4. FranU Feasibility Review (if applicable)
Stage Owner - **FranU Research & Scholarship Council Chair** (RSC@franu.edu)
 5. IRB Chair Review
Stage Owner – **FranU IRB Chair** (IRB@franu.edu)
 6. IRB Member Review
Stage Owner(s) – **FranU IRB Committee Member(s)** assigned by IRB Chair
 7. IRB Full Board Review (if applicable)
Stage Owner – **FranU IRB Office**
 8. Post Review Processing
Stage Owner – **FranU IRB Office** (IRB@franu.edu)
 9. Notify PI of Approval
Stage Owner – **FranU IRB Office** (IRB@franu.edu)
- Once your application is submitted, you can see the “initial submission” link on your **Dashboard**. To check the progress of your application in IRBManager return to your **Dashboard** and click on your application.
- Access to update applications is restricted to the owner of each stage (see above). In other words, no one can make changes or add notes to the form unless they are the owner of the current/active stage.
- Forms may be returned to the Submitter/PI during any review stage if additional information or further explanation is needed. In the event this happens, an automated email is generated to the PI/Submitter with a link to the form. A link to your form is also available on your **Dashboard**. Once the form is resubmitted it routes back through all stages again.
- The usual turnaround from submission to assigning reviewers is five business days with most decisions rendered within 30 days.

Email IRB@franu.edu for questions or assistance.