



# **IRBManager User's Guide**

**Summer 2020**

Email [IRB@franu.edu](mailto:IRB@franu.edu) for questions or assistance.

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## 1.0 Access to IRBManager

### 1.1 How to access IRBManager

IRBManager is set to only allow access for FranU and FMOLHS affiliates. Your User Name is the email address you enter when registering. Professional email accounts should be used, not personal accounts like Gmail, AOL, Yahoo, etc.

- Anyone affiliated with a project needs a Contact record created in IRBManager
  - For instructions see section – **8.0 How to Submit Contact Record Forms**

### 1.2 How to log-in to IRBManager

- Go to <https://franu.my.irbmanager.com/>

The screenshot shows the login interface for Franciscan University's IRBManager. At the top left is the Franciscan University logo with the text "FRANCISCAN MISSIONARIES OF OUR LADY UNIVERSITY". Below the logo is a "Login" header. The main form area contains three input fields: "User Name" (highlighted in yellow), "Password", and "Client" (with "Franu" entered). Below these fields are a "Login" button and a "Forgot Password?" link. At the bottom left of the form, the text "Don't have an account? Click here to register." is circled in red. The footer contains copyright information: "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".

- Click “Click here to register” (red circle) if you do not have an account
- You only provide your email address the first time you log-in
- After confirming your email address, click “Next”

The screenshot shows the registration interface. It has a "Register" header. The form contains two input fields: "EMail\*" (highlighted in yellow) and "Confirm EMail". Below these fields is a "Next" button. At the bottom, there is a list of email domains that are accepted for registration: "@cvtsc.com, @ebrschoolhealth.org, @fmolhs.org, @lca-br.com, @lourdesrmc.com, @lsu.edu, @lsuhsc.edu, @ochsner.org, @ololah.org, @ololcollege.edu, @ololrmc.com, @pbrc.edu, @pcaofbr.com, @selu.edu, @steh.com, @stfran.com, @vasclin.com".

- IRBManager sends a temporary random password that allows you to log-in the first time. Then you are prompted to change your password. Subsequently, each time you log-in, enter your User Name, Password and Client ID (FranU).


## 2.0 Passwords

### 2.1 What happens at your first log-in?

When you log-in for the first time with your temporary random password, you are prompted to change your password.

### 2.2 Change your initial password and proceed


- Enter current password
- Enter new password (must meet the “Valid Password” requirements)
- Confirm new password
- Click “**Update**”



**Your Password Has Expired**

Your password has expired. You must now select a new password. A valid password must be at least 15 characters long and contain characters from at least 3 of these groups: uppercase letters, lowercase letters, numbers, special characters (!, @, #, etc).

User:	<input type="text"/>
Username:	<input type="text"/>
Current Password:	<input type="password"/>
New Password:	<input type="password"/>
New Password Confirm:	<input type="password"/>
<input type="button" value="Update"/>	

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Page generated in 0.029 seconds.  
Powered By  IRBManager

Upload the following documents after you register:

- Current CITI Training Certificate
- Current Professional License (if applicable)
- Current CV or Resume

It is important to furnish this **now** and **keep it current**. It becomes part of your IRBManager Contact record and auto-populates in IRBManager when completing forms. IRBManager sends email reminders as the expiration dates near so you can update these documents.

For instructions see section – [8.0 How to Submit Contact Record Forms](#)

## 2.3 Forgotten Password or Account Locked

Be sure to remember your User Name (your email address) and password, you will need it to log-in in the future.

- While you are logged in to IRBManager you can use your IRBManager password to provide your electronic signature

**FRANCISCAN**  
MISSIONARIES OF OUR LADY  
UNIVERSITY

**Login**

User Name

Password

Client Franu

[Forgot Password?](#)

Don't have an account?  
[Click here to register.](#)

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Billy Goat (2020.3.4199.0/Release/9641b0b) | GCWAWS1 | 2020-03-12 13:40:17Z | 0.047s

- If you forget your password, click “**Forgot Password?**” (**green circle**) from the log-in screen
- Fill in the information requested, and a new password is emailed to you and your account is unlocked

### **NOTE: IRBManager locks your account**

- If you enter the wrong User Name/Password **three times**, as a security precaution.
- If your account is inactive for 12 months.

For assistance email the IRB Office to reset your account at [IRB@franu.edu](mailto:IRB@franu.edu).

## 3.0 Dashboards

Your Dashboard is the first screen you see when you log-in to IRBManager.

**NOTE:** To return to your Dashboard from other screens, click the **“Home”** tab (green arrow).

**Power Dashboard** or **Bubble Dashboard** (see examples below). Their appearance is different, but their functionality is the same. The **NEW Bubble Dashboard** is considered more visually friendly using tabs to navigate. For instructions on how to change your dashboard see section - **3.1 Selecting Your Dashboard**.

### 3.0a Example of Power Dashboard

The screenshot shows the Power Dashboard interface. At the top, there is a navigation bar with the Franciscan Missionaries of Our Lady University logo, a 'Home' tab (highlighted with a green arrow), and a search bar labeled 'Find Study (Ctrl+Q)'. Below the navigation bar, the dashboard is divided into several sections:

- Actions:** A list of links for submitting applications, reviewing submissions, and submitting researcher information.
- Recent Items:** A list of recent items, including '2019-135-OLOLRMC'.
- Messages:** A welcome message from the IRBManager at FranU.
- Studies (4 Active):** A summary of active studies, including a list of studies and a pie chart showing the distribution of study types.
- xForms (13 Active):** A summary of active xForms, including a list of xForms and a pie chart showing the distribution of xForm types.
- Events (5 Open):** A summary of open events, including a list of events and a pie chart showing the distribution of event types.
- Notices:** A section for notices, including a welcome message, contact information, and a note about the COVID-19 outbreak.

### 3.0b Example of Bubble Dashboard

The screenshot shows the Bubble Dashboard interface. At the top, there is a navigation bar with the Franciscan Missionaries of Our Lady University logo, a 'Home' tab (highlighted with a green arrow), and a search bar labeled 'Find Study (Ctrl+Q)'. Below the navigation bar, the dashboard is divided into several sections:

- My Studies:** A section for managing studies, including a list of studies and a pie chart showing the distribution of study types.
- Export to Excel:** A button for exporting data to Excel.
- Click here to submit a new application to the IRB:** A button for submitting a new application.
- Click here to submit a new SoTL, QI, or EBP application to the IRB:** A button for submitting a new application.
- OLOLRMC - Feasibility Review Submission:** A button for submitting a review.
- Submit Researcher Information:** A button for submitting information.
- Start Other xForm:** A button for starting a new xForm.
- 4 Primary:** A section for primary studies, including a list of studies and a pie chart showing the distribution of study types.
- 2019-108-FranU:** A study entry with details like 'New From PI' and 'Test created on 6/19/19'.
- 2019-119-FranU:** A study entry with details like 'New From PI' and 'NHSR test (reviewers found to be HSR)'.
- 2019-138-FMOLHS:** A study entry with details like 'New From PI' and 'TEST STUDY NHSR improve patient safety'.
- test 6/5/19-FranU:** A study entry with details like 'New From PI' and 'this is a fun title'.
- Notices:** A section for notices, including a welcome message, contact information, and a note about the COVID-19 outbreak.

### 3.1 Selecting Your Dashboard

To switch from **Power Dashboard** to **Bubble Dashboard**:

- Click “Use Bubble Dashboard” (red circle)

The screenshot shows the Franciscan Missionaries of Our Lady University IRB Manager interface. The left sidebar contains a list of actions, with "Use Bubble Dashboard" circled in red. The main content area displays a summary of studies, xForms, and events, along with a pie chart. The right sidebar contains notices and a COVID-19 update.

To switch from **Bubble Dashboard** to **Power Dashboard**:

- Click **Person Icon** located in the upper right corner of the screen (red arrow)
- Select “Use Power Dashboard” from the drop-down menu

The screenshot shows the Franciscan Missionaries of Our Lady University IRB Manager interface in the Power Dashboard view. A red arrow points to the person icon in the top right corner. The main content area displays a summary of studies, IRB, xForms, and events, along with a list of recent submissions. The right sidebar contains notices and a COVID-19 update.



## 4.0 Navigating the 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

OLOLRC - Feasibility Review Submission

Submit Researcher Information

Start xForm

Show Sponsor Ids

Use Bubble Dashboard

**Recent Items**

2019-108-FranU

2019-135-OLOLRC

**Messages**

Welcome to IRBManager at FranU

**My Docs & xForms**

2 Attachments

14 xForms

**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](mailto: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.

Study	Site	PI	Title	Expires	Status
2019-108-FranU	Franciscan Missionaries of Our Lady University	Newman, Alfred E	Test created on 6/19/19		New From PI

### 4.0a Power Dashboard - Headings

On the left side of the screen, there are the following headings:

- 1) **Actions** (red arrow)
- 2) **Recent Items** (blue arrow)
- 3) **Messages** (purple arrow)
- 4) **My Docs & xForms** (gold arrow)

**NOTE: xForms refers to forms you create in IRB Manger.**

### 4.0b Power Dashboard - Actions

**Links to go directly** to frequently used xForms, "Start xForm" and other actions. In this example, there are six available actions (red box).

### 4.0c Power Dashboard - Recent Items

**Links to go directly** to the most recent items you viewed in IRBManager.

### 4.0d Power Dashboard - Messages

Area where the IRB sends communications to all system users.

### 4.0e Power Dashboard - My Docs & xForms

**Links to go directly** to your lists of attachments and xForms.

## 4.0 Navigating the Power Dashboard (continued)

**FRANCISCAN MISSIONARIES OF OUR LADY UNIVERSITY**

Home [Find Study \(Ctrl+Q\)](#) [Take a tour...](#) [Help](#) [Alfred's Settings](#) [Sign off](#)

**My Studies**

**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

**My Studies (4 Active)**

Study	Site	PI	Title	Expires	Status
2019-108-FranU	Franciscan Missionaries of Our Lady University	Newman, Alfred E	Test created on 6/19/19		New From PI

**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**

- [2019-108-FranU](#)
- [2019-135-OLOLRMC](#)

**Messages**

Welcome to IRBManager at **FranU**

**My Docs & xForms**

- [2 Attachments](#)
- [14 xForms](#)

**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](mailto: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.

### 4.0f Power Dashboard - My Studies Section

“My Studies” section displays headings with **links to go directly** to the studies, xForms, Events:

- 1) **Studies** (red arrow)
- 2) **xForms** (blue arrow)
- 3) **Events** (purple arrow)
- 4) **My Studies** (gold arrow)

### 4.0g Power Dashboard - Studies

**Links to go directly** to Studies you are “associated with” and/or the “PI” (active/total counts)

### 4.0h Power Dashboard - xForms

**Links to go directly** to your xForms with current disposition: unsubmitted, processing at a later stage, and awaiting your attention.

### 4.0i Power Dashboard - Events

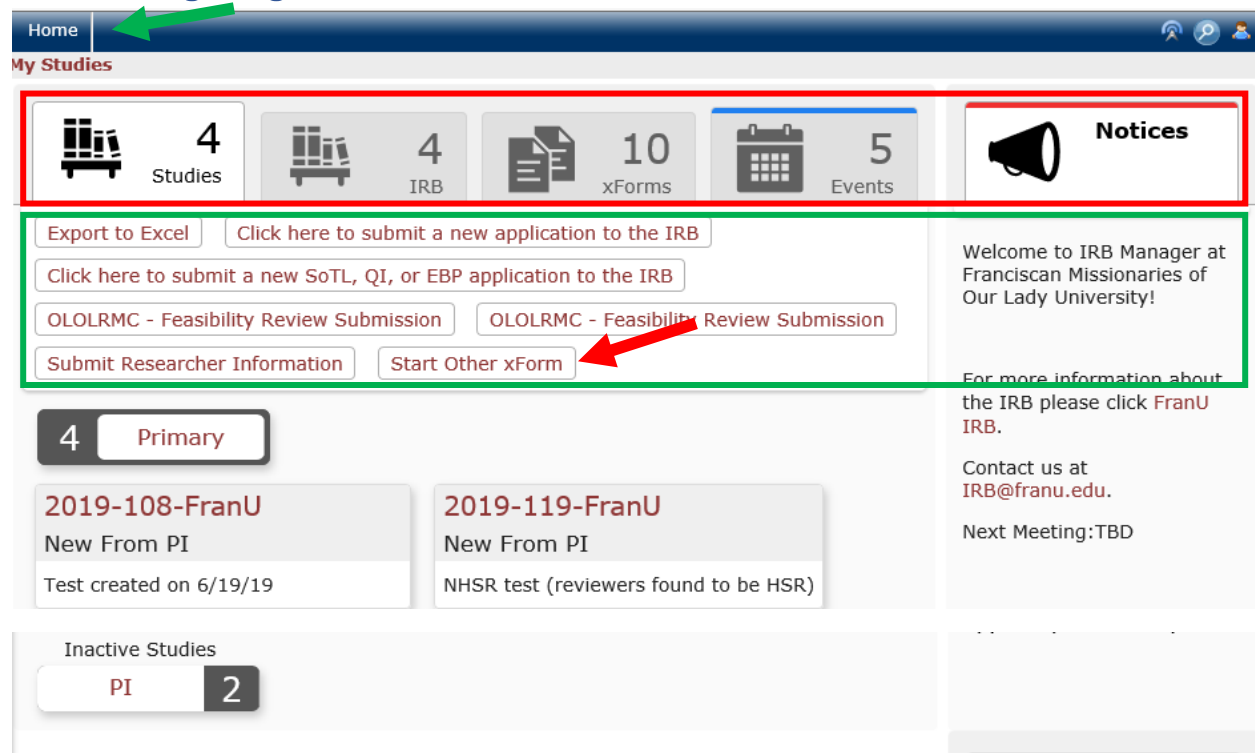
**Links to go directly** to your Events (grouped by name), such as Initial Submission events and Total Open events. *NOTE: An xForm may be complete/approved, but the Event stays open until the IRB Board is notified of the status at their next meeting.*

### 4.0j Power Dashboard - My Studies

**Links to go directly** to user’s studies (active/closed) along with sortable detail columns.

*NOTE: To return to your **Dashboard** from other screens, click the “Home” tab (green arrow).*

## 5.0 Navigating the Bubble Dashboard



### 5.0a Bubble Dashboard - My Studies Tabs

Each tab across the top of the screen (**red box**) has a section with links to *frequently used xForms* (**green box**) and a link to “**Start Other xForms**” (**red arrow**). *NOTE: xForm refers to forms you create in IRBManager*

### 5.0b Bubble Dashboard - Studies

**Links to go directly** to your active and inactive studies

### 5.0c Bubble Dashboard - IRB

**Links to go directly** to your active and inactive Studies.

### 5.0d Bubble Dashboard - xForms

**Links to go directly** to your xForms (grouped by disposition), unsubmitted, processing at a later stage, awaiting your attention, etc. Also, there is a **link to go directly** to list of “**All My xForms.**”

### 5.0e Bubble Dashboard - Events

**Links to go directly** to open Events (grouped by type), initial submission, continuing review, modifications, etc. *NOTE: An xForm may be complete/approved, but the Event stays open until the IRB Board is notified of the status at their next meeting.*

### 5.0f Bubble Dashboard - Notices

Area where the IRB sends communications to all system users.

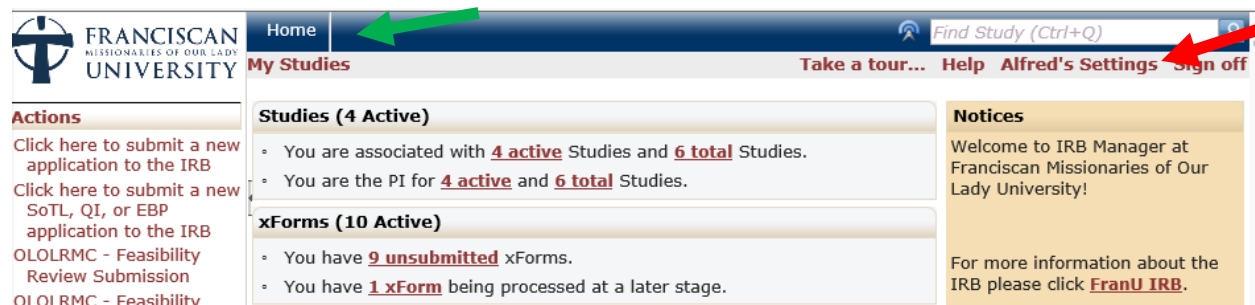
*NOTE: To return to your Dashboard from other screens, click the “**Home**” tab (**green arrow**).*

## 6.0 Update My Settings

To edit your profile settings, return to your dashboard by clicking “Home” tab (green arrows).

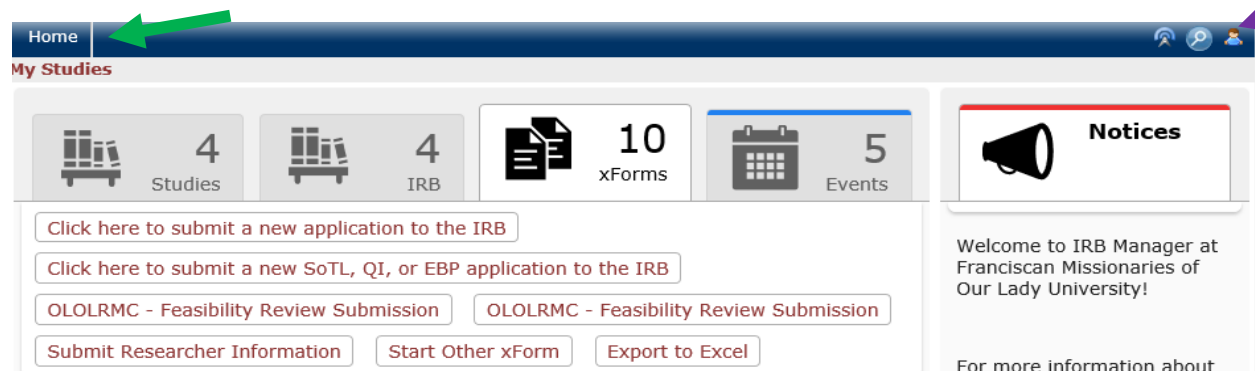
### 6.0a Power Dashboard Example - Update My Settings

- Click “your name Settings” (red arrow)



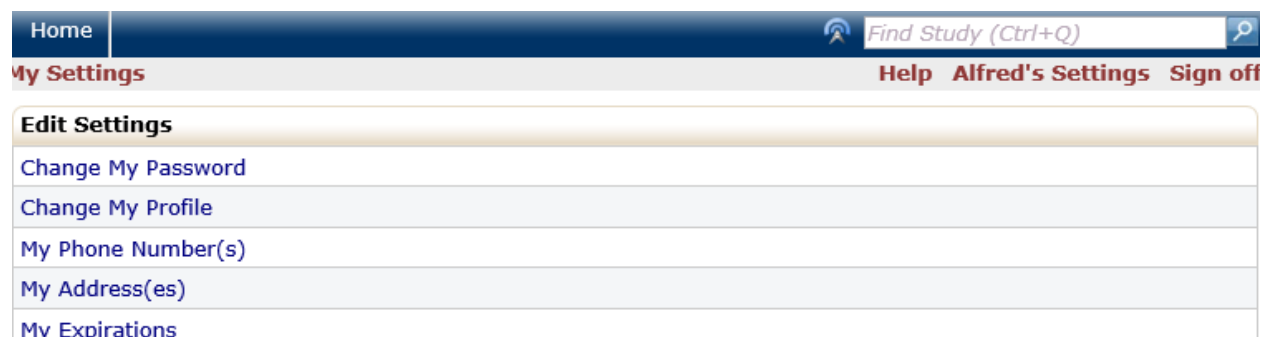
### 6.0b Bubble Dashboard Example - Update My Settings

- Click **Person Icon** located in the upper right corner of the screen (purple arrow)
- Select “your name Settings” from the drop-down menu.



### 6.0c Update My Settings – Edit Settings selection screen

- Both dashboards open the “My Settings” Edit Settings selection screen.
- Click on your selection and follow the prompts.



- For instructions to “Change My Password” or “Change My Profile” see sections:
  - 6.1 Change My Password
  - 6.2 Change My Profile

## 6.1 Change My Password

After selecting “**Change My Password**” from the **My Settings “Edit Settings”** screen, “**Change Password**” data entry screen opens

The screenshot shows the 'Change Password' screen. On the left is a sidebar with the Franciscan University logo and navigation links: Actions, Recent Items (2019-108-FranU, 2019-135-OLOLRMC), Messages (Welcome to IRBManager at FranU), and My Docs & xForms (2 Attachments, 14 xForms). The main content area has a top bar with 'Home', 'Find Study (Ctrl+Q)', and links for 'Help', 'Alfred's Settings', and 'Sign off'. Below the top bar is a 'Valid Passwords' warning box stating: 'A valid password must be at least 6 characters long, be different from the user name, and contain characters from at least 3 of these groups: uppercase letters, lowercase letters, numbers, and special characters (e.g. !, @, #, ~)'. Below this is the 'Change Password' form with fields for 'User' (Username), 'Old Password', 'New Password', and 'New Password Confirm', followed by an 'Update' button.

- Enter your old password
- Enter new password
- Enter new password again to confirm
- Your password must meet the “Valid Password” requirements shown
- Click “**Update**”

## 6.2 Change My Profile

After selecting “**Change My Profile**” from the **My Settings “Edit Settings”** screen, “**User Information**” data entry screen opens.

The screenshot shows the 'User Information' screen. On the left is a sidebar with the Franciscan University logo and navigation links: Actions (Done), Recent Items (2019-108-FranU, 2019-135-OLOLRMC), Messages (Welcome to IRBManager at FranU), and My Docs & xForms (2 Attachments, 14 xForms). The main content area has a top bar with 'Home', 'Find Study (Ctrl+Q)', and links for 'Help', 'Alfred's Settings', and 'Sign off'. Below the top bar is the 'User Information' form with fields for 'Prefix (Mr, Dr, etc):', 'First Name:', 'Middle Name:', 'Last Name:', 'Suffix (Jr, III, etc):', 'Degree:', 'Specialty:', 'Email Address:', 'From Address for Outbound Email:', and an 'Update' button.

- Update User Information fields
- Click “**Update**”

## 7.0 How to Start an xForm

Forms you create using IRBManager are called xForms. To start an xForm, return to your dashboard by clicking “Home” tab (green arrows).

### 7.0a Power Dashboard Example - How to Start an xForm

- Click any link to the *frequently used xForms* (green box) if you know the xForm name
- Or, click “Start xForm” (red arrow) under **Actions** for complete list of xForms

**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

**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 (10 Active)**

- You have **9 unsubmitted** xForms.
- You have **1 xForm** being processed at a later stage.

**Events (5 Open)**

Only show events where I am: ☐ You

- You have **3 Initial Submission** events.
- You have **2 QI reports** 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](mailto:IRB@franu.edu).

Next Meeting:TBD

NOTE: During the COVID-19

### 7.0b Bubble Dashboard Example - How to Start an xForm

- Click any link to the *frequently used xForms* (gold box) if you know the xForm name
- Or, click “Start Other xForm” (purple arrow) on xForms tab for complete list of xForms

**Home**

**My Studies**

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**

Export to Excel

**Notices**

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

For more information about

## 7.1 Select xForm to Start

Both dashboards open the “Select xForm to Start” selection screen.

Select xForm to start		
Action	Form (Click to start)	Description
	<a href="#">Submit CITI, License and C.V. or Resume</a>	For faculty and researchers to load their CITI, License and C.V. or Resume
	<a href="#">IRB Application for Human Subjects Research</a>	FranU IRB Application for Human Subjects Research
	<a href="#">IRB Manager-New Contact</a>	IRB Manager-New Contact

- Click the xForm you wish to start (red box)


## 8.0 How to Submit - Contact Record Forms

- New Contact (xForm)
- Researcher Information (xForm)

Anyone affiliated with a project needs a Contact record in IRBManager.

### 8.1 How to Submit - IRBManager-New Contact (xForm)

- To begin see section [7.0 - How to Start an xForm](#)
- Click “**IRBManager-New Contact**” from the list of xForms
- Contact data entry screen opens
- Enter the email address for the user to add to IRBManager. Use professional email addresses (i.e., @franu.edu, @fmoths.org, @lsuhsc)
- **Warning** appears if the email is already assigned to another contact (**red arrow**)
- Fill in required field(s), enter expiration date(s) and attach backup document(s)

Enter the email address for the user to add. Use professional email address (i.e., @franu.edu, @fmoths.org, @lsuhsc, etc.). (Required)	<a href="#">Add Note</a>	<a href="#">View Audit</a>
<input type="text"/>		
E-Mail already assigned to another contact.		

<b>New Contact Information</b>	<a href="#">Add Note</a>	<a href="#">View Audit</a>
<b>Prefix (Required)</b> <input type="text"/>		
<b>First Name (Required)</b> <input type="text"/>		
<b>Last Name (Required)</b> <input type="text"/>		
<b>Degree(s)</b> <input type="text"/>		
<b>Telephone Number (Required)</b> <input type="text"/>		
<b>Institutional Affiliation (Required)</b> <input type="text"/>		

Enter CITI training expiration date.	<a href="#">Add Note</a>	<a href="#">View Audit</a>
<input type="text"/>		

Attach CITI training document here.	<a href="#">Add Note</a>	<a href="#">View Audit</a>
<input type="text"/>		

Attach CV here.	<a href="#">Add Note</a>	<a href="#">View Audit</a>
<input type="text"/>		

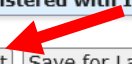
Enter licensure expiration date.	<a href="#">Add Note</a>	<a href="#">View Audit</a>
<input type="text"/>		

Attach licensure here.	<a href="#">Add Note</a>	<a href="#">View Audit</a>
<input type="text"/>		

## 8.1 How to Submit - IRBManager-New Contact (xForm) (continued)


- Click “**Next**” if you are ready to submit this xForm (**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 [Add Note](#) contact information and a notification email is sent to the new contact and submitter confirming the information is registered with IRB Manager.



- If your form is complete, 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)**.*



## 8.2 How to Submit - Researcher Information (xForm)

By submitting researcher information and keeping it current it becomes part of the Contact record and the data auto-populates in your xForms in IRBManager.

- To begin see section [7.0 - How to Start an xForm](#)
- Select “**Submit CITI, License and C.V. or Resume**” from the xForm list.
- **Researcher Information** data entry screen opens.

The screenshot shows the 'Researcher Information' xForm in IRBManager. The header includes the Franciscan University logo, the title 'Submit CITI, License and C.V. or Resume -- Researcher Information', a dropdown menu set to 'Researcher Information', 'Page 1 of 1', and a 'Next' button. The form contains several sections: 'Researcher' with fields for name (Newman, Alfred E), email, and phone; 'CITI Expiration Date' with a date picker; 'CITI Attachments' with an 'Add Attachment' button; 'Clinical Licensure Expiration Date (if applicable)' with a date picker; 'Clinical Licensure (Required)' with an 'Add Attachment' button; and 'Resume or C.V.' with an 'Add Attachment' button. At the bottom, there are three buttons: 'Next', 'Save for Later', and 'More >'. A red arrow points to the 'Next' button.

- Enter expiration date(s) and attach backup document(s).
- 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.

The screenshot shows a 'Form Completed' message box. It contains the text: 'You've completed the form. You can now either save the form for later revision, or submit it.' Below the text are four buttons: 'Go Back', 'Save for Later', 'Print', and 'Submit'. A purple arrow points to the 'Submit' button.

- If your form is complete, click “**Submit**” (**purple arrow**) and close window.

## 9.0 How to Submit - Active Study Forms

- Request for Study Amendment (xForm)
- Reapproval Application or Closure Notification Form (xForm)

*You must be a study staff member and **first find the study on your dashboard** before you can start a request to amend, extend or close an active study.*

- Start from your dashboard by clicking “Home” tab (**green arrows**).

### 9.0a Power Dashboard Example - Active Studies List

The screenshot shows the Franciscan Missionaries of Our Lady University IRB Manager dashboard. The 'Home' tab is selected at the top. The 'My Studies' section displays a table of active studies. A red arrow points to the study '2019-108-FranU'.

Study	Site	PI	Title	Expires	Status
2019-108-FranU	Franciscan Missionaries of Our Lady University	Newman, Alfred E	Test created on 6/19/19		New From PI

- In the “My Studies” section (**red arrow**), click the link to your Study Number.

### 9.0b Bubble Dashboard Example - Active Studies List

The screenshot shows the Franciscan Missionaries of Our Lady University IRB Manager dashboard. The 'Home' tab is selected at the top. The 'Studies' section displays a list of active studies. A purple arrow points to the study '2019-108-FranU'.

Study	Status
2019-108-FranU	New From PI
2019-119-FranU	New From PI

- From the “Studies” tab, click the link to your Study Number (**purple arrow**)

## 9.0 How to Submit - Active Study Forms (continued)

- Both Dashboards open the **Study Detail Screen**

### 9.0c Study Detail Screen

**Franciscan University** Home Find Study (Ctrl+Q) Study 2019-108-FranU (IRB) Help Alfred's Settings Sign off

**Actions**

- Send Email
- Start xForm
- xForms (0)
- Done

**Recent Items**

- 2019-108-FranU
- test 6/5/19-FranU
- 2019-138-FMOLHS
- 2019-135-OLLRMC

**Messages**

Welcome to IRBManager at FranU

**My Docs & xForms**

- 2 Attachments
- 12 xForms

**Study**

Study: 2019-108 Sponsor(s):  
Committee: IRB Sponsor Id:  
Category: Grants:  
Department: Next Review:  
Last Review: CRO:  
Agent Types: Behavioral Observation  
Title: Test created on 6/19/19 Year: 2019  
Financial Feasibility: Professional Practice Research Director:  
Comments: test proposal

**Study-Site**

Site(s): FranU - Franciscan Missionaries of Our Lady University PI: Newman, Alfred E  
Status: New From PI Additional: N  
Approval: Expiration: Other Expirations:  
Initial Approval: Comments: classroom

**Events (1)**

Event	Att	FE	Instance/UDF	Start	Complete	Last Mtg
Initial Submission	1			06/24/2019		

- Click **"Start xForm"** under Actions ().

### 9.0d Study - Select xForm to Start Screen

**Franciscan University** Start Form on Study 2019-108-FranU (IRB) Filter:

Select xForm to start

Action	Form (Click to start)	Description
	Big combo IRB Application (Copy) (Draft)	UPDATE BEFORE LAUNCH
	IRB Application for Human Subjects Research	FranU IRB Application for Human Subjects Research
	IRB Manager-New Contact	IRB Manager-New Contact
	Re-Approval Application or Closure Notification Form	Re-Approval Application or Closure Notification Form
	Remote Submit CITI, License and C.V. or Resume	For Research Directors to submit for their faculty and researchers to load their CITI, License and C.V. or Resume
	Request for amendment	Request for amendment

- Make your selection form the list of available xForms (
- For instructions to amend, extend or close see sections –
  - 9.1a-c Request Study Amendment (xForm)
  - 9.2a-c Reapproval application of Closure Notification Form (xForm)

## 9.1 Request for Study Amendment (xForm)

“Request for Amendment” form is required for any substantial change to your IRB-approved study. Do not implement any changes unless you submit this form and receive approval from the IRB.

- Click “Request an amendment” from [9.0b Select xForm to Start Screen](#)
- Amendment data entry screen opens.

### 9.1a Request for Study Amendment (xForm) - Data Entry Screen

**FRANCISCAN UNIVERSITY** Collaborators Amendment header Page 1 of 2 Next

**Request for amendment -- Amendment header**

**submitter** Add Note View Audit  
Newman, Alfred E  
Email: marick953@gmail.com Phone:

**Principal investigator** Add Note View Audit  
Newman, Alfred E  
Email: marick953@gmail.com Phone:

**study title** Add Note View Audit  
Test created on 6/1

**study number** Add Note View Audit  
2019-108

**study status** Add Note View Audit  
New From PI

**agent type** Add Note View Audit  
Behavioral Observation

**approval period** Add Note View Audit  
N/A

**Please describe the proposed amendment(s) to your study. (Required)** Add Note View Audit  
ABC

**Is this amendment only for the removal of study personnel? (Required)** Add Note View Audit  
☐

**Are you requesting a waiver of authorization of HIPAA? (Required)** Add Note View Audit  
☐  
According to the HIPAA Privacy Rule, there are a limited number of conditions under which individuals' private 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. FranU IRB is authorized to grant this waiver.

**According to the HIPAA Privacy Rule, there are a limited number of conditions under which individuals' private 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. (Required)** Add Note View Audit  
☐ Waiver of informed consent  
☐ Waiver of documentation of informed consent  
☐ No waiver requested

Next Save for Later More >

- The top of the form auto-populates with your study detail information
- Enter the *Required* information and supporting document(s) (red arrows)
- Click “Next” (green arrow) to advance to the Signature screen

### 9.1b Request for Study Amendment (xForm) - Electronic Signature Screen

The screenshot shows the 'Request for amendment -- Submitter Signature' screen. At the top left is the Franciscan University logo and name. To the right is a 'Collaborators' link and a 'Submitter Signature' dropdown menu. Further right is a 'Page 2 of 2' indicator and a 'Next' button. Below the header, a blue box contains the instruction: 'Please enter your password to electronically sign this form. (Required)'. Below this is a text input field with the placeholder 'To sign, enter password for'. A red arrow points to this field. Below the input field are four buttons: 'Previous', 'Next', 'Save for Later', and 'More'. A green arrow points to the 'Next' button. On the right side of the blue box are links for 'Add Note' and 'View Audit'.

- Enter your IRBManager password (**red arrow**) to electronically sign this form
- Click “**Next**” (**green arrow**) to advance to the “**Submit**” screen

### 9.1c Request for Study Amendment (xForm) - Submit Screen

The screenshot shows the 'Form Completed' screen. At the top left is the Franciscan University logo and name. Below the header, a blue box contains the text: 'Form Completed' and 'You've completed the form. You can now either save the form for later revision, or submit it.' Below this text are four buttons: 'Go Back', 'Save for Later', 'Print', and 'Submit'. A purple arrow points to the 'Submit' button. At the bottom of the screen, there is a copyright notice: 'Copyright ©2000-2020 Tech Software. All Rights Reserved. Billy Goat (2020.6.4702.0/Release/0dc645e) | GCWAWS1 | 2020-07-02 19:23:44Z | 0.052s' and a 'Powered By IRBManager' logo.

- Click “**Save for Later**” to save your revisions and access from your Dashboard later
- Or, if your form is complete, click “**Submit**” (**purple arrow**) and close window

## 9.2 Reapproval or Closure Notification (xForm)

This form is used to **either extend or close** your study. You will need to submit the “Reapproval or Closure Notification” form **prior** the expiration date of your IRB-approved study. You have the option to request a one-year renewal or to close your study if it is complete. IRBManager sends email reminders as the expiration date approaches.

- Click “**Reapproval Application or Closure Notification Form**” from **9.0b Study - Select xForm to Start Screen**
- Study Status data entry screen opens

### 9.2a Reapproval or Closure Notification (xForm) - Study Status Data Entry Screen

**FRANCISCAN UNIVERSITY** MISSIONARIES OF OUR LAC Collaborators Study Status Page 1 of 2 Next

**Re-Approval Application or Closure Notification Form -- Study Status**

**Submitter** View Audit  
Newman, Alfred E  
Email: Phone:

**Principal Investigator**  
Newman, Alfred E  
Email: Phone:

**Study Personnel**

Name	Role	Primary
Newman, Alfred E	Investigator	✓

**IRB Study Number**  
2019-108

**Protocol Title**  
Test created on 6/19/19

**Provide a brief description of the study.** (Required) View Audit

**Is this study still in progress?** (Required) View Audit

☐ Yes, the study is active and still accruing  
☐ Yes, the study is active but closed to accrual  
☐ No, the study is complete and can be closed

*If you choose either of the YES answers you will be requesting renewal for one year of the study.*


**Please select the appropriate status of your data collection.** (Required) View Audit

☐ Data collection is ongoing  
☐ Collecting follow-up data only  
☐ Data collection is completed, data analysis only (Study may be closed if the data is de-identified)

Next Save for Later More ▶

- The top of the form auto-populates with your study detail information
- Enter the *Required* information (**red arrows**)
- Click “**Next**” (**green arrow**) to advance to the “**Subject Information Data Entry**” Screen

## 9.2b Reapproval or Closure Notification (xForm) - Subject Information Data Entry Screen



FRANCISCAN  
UNIVERSITY

Collaborators

Subject Information

Page 2 of 2

Next

Re-Approval Application or Closure Notification Form -- Subject Information

How many subjects were enrolled in the past approval period? (Required)
View Audit

How many subjects were enrolled since the beginning of the study? (Required)
View Audit

Please enter the approximate number who voluntarily withdrew in the last approval period. (Required)
View Audit

Please enter the approximate number of subjects who voluntarily withdrew since the beginning of the study. (Required)
View Audit

What is the age range of the subjects enrolled in the study. (Required)
View Audit

Please provide a brief summary of the results so far. (Required)
View Audit

Have you had any complaints related to the study thus far? (Required)
View Audit

Have there been any adverse events during the study thus far? (Required)
View Audit

Submitter Instructions

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

By signing this document, I agree to the following:

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 90 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.

By signing below I agree to conduct the research protocol according to the above conditions.

Please enter your password to electronically sign this form. (Required)
View Audit

To sign, enter password for

Previous
Next
Save for Later
More

- Enter the *Required* information
- Electronically sign using your IRBManager password (**red arrow**)
- Click “Next” (**green arrow**) to advance to the “Submit” screen

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## 9.2c Reapproval or Closure Notification (xForm) - Submit Screen



**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](#)



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Billy Goat (2020.6.4702.0/Release/0dc645e) | GCWAWS1 | 2020-07-02 20:08:31Z | 0.043s

Powered By  IRBManager

- Click “**Save for Later**” to save your revisions and access from your Dashboard later
- Or, if your form is complete click “**Submit**” (**purple arrow**) and close window