



FRANCISCAN  
MISSIONARIES OF OUR LADY  
UNIVERSITY

**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

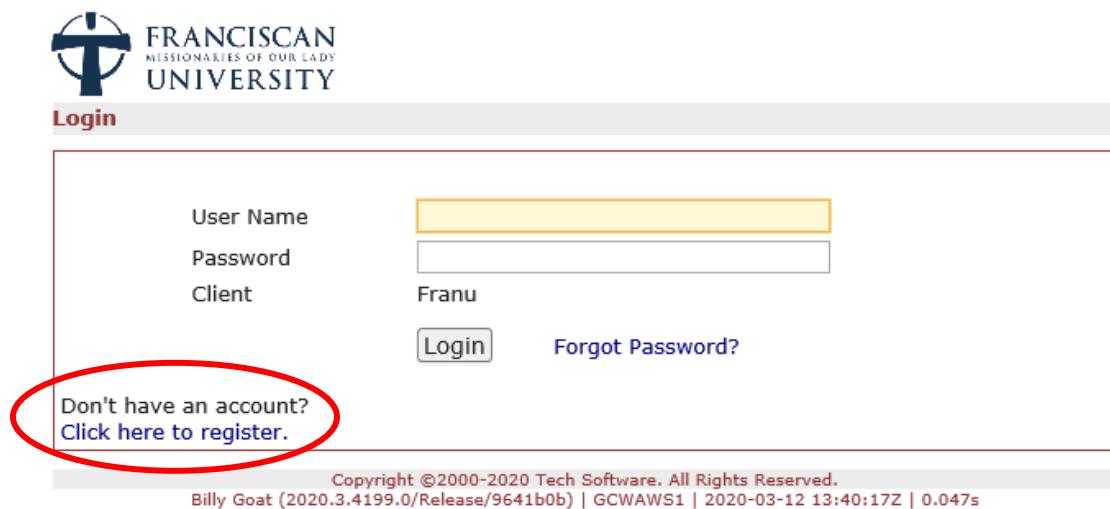
### 1.1 How to access IRBManager

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/>



FRANCISCAN  
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Login

User Name

Password

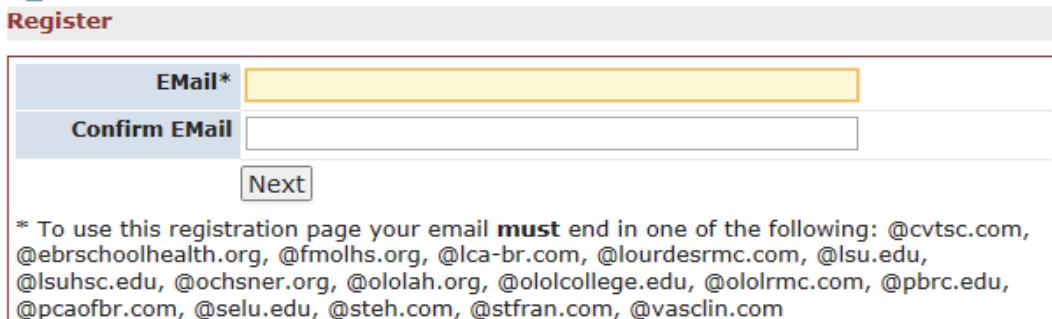
Client Franu

[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

- 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**”



Register

EMail\*

Confirm EMail

\* To use this registration page your email **must** end in one of the following: @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="text"/>
New Password:	<input type="text"/>
New Password Confirm:	<input type="text"/>
<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

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



**FRANCISCAN MISSIONARIES OF OUR LADY UNIVERSITY**

**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:

**Green** You have **3 Initial Submission** events.

**Blue** You have **2 QI reports** events.

You have **5 Total Open** events

**Notices**

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

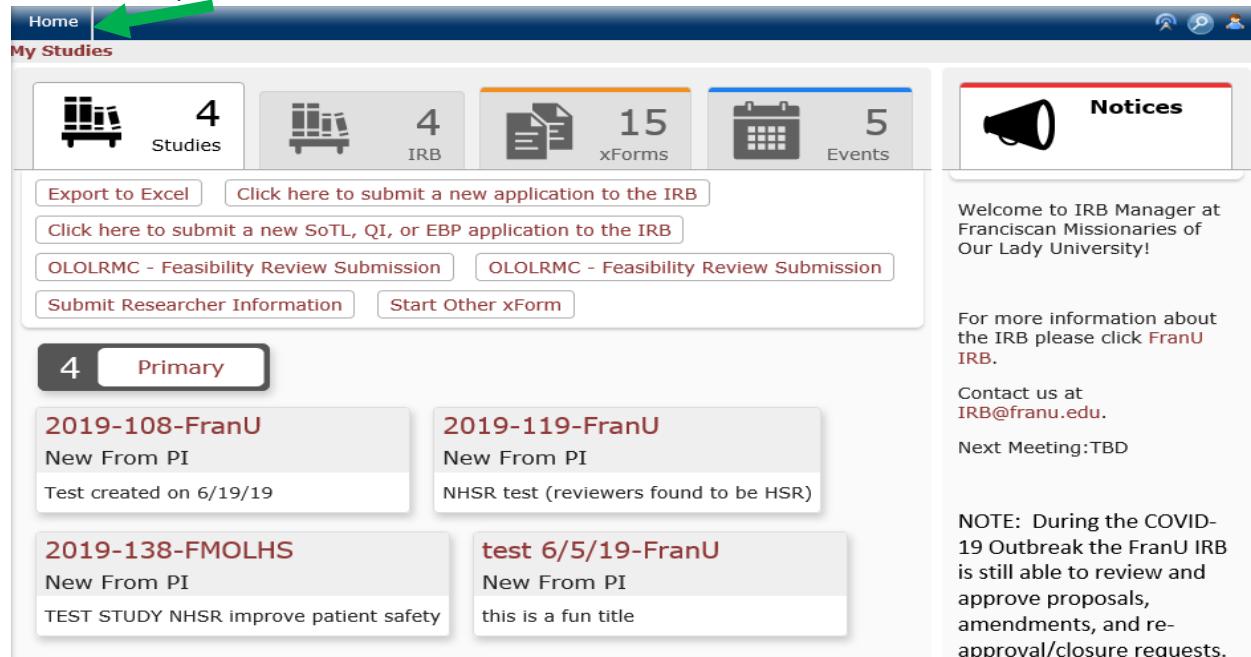
For more information about the IRB please click [FranU IRB](#).

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.

### 3.0b Example of Bubble Dashboard



**FRANCISCAN MISSIONARIES OF OUR LADY UNIVERSITY**

**My Studies**

**Studies** 4

**IRB** 4

**xForms** 15

**Events** 5

**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.

### 3.1 Selecting Your Dashboard

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

- Click “Use Bubble Dashboard” (red circle)

The screenshot shows the IRB Manager interface with a sidebar on the left and a main content area on the right.

**Left Sidebar (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 ID
- Use Bubble Dashboard** (This option is circled in red)

**Recent Items:** 2019-135-OLOLRMC

**Messages:** Welcome to IRBManager at [FranU](#)

**Right Content Area:**

- 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.

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 IRB Manager interface with a sidebar on the left and a main content area on the right.

**Left Sidebar:**

- Studies:** 4
- IRB:** 4
- xForms:** 15
- Events:** 5

**Buttons:**

- 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

**Primary Studies:** 4

**Studies:**

- 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](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.

## 4.0 Navigating the Power Dashboard

The screenshot shows the IRB Manager Power Dashboard. At the top, there is a navigation bar with links for 'Home', 'My Studies' (which is highlighted in red), 'Find Study (Ctrl+Q)', 'Take a tour...', 'Help', 'Alfred's Settings', and 'Sign off'. The main content area is divided into several sections:

- Actions:** A red box highlights a link: "Click here to submit a new application to the IRB".
- Studies (4 Active):** A list of studies associated with the user, showing 4 active and 6 total studies, and the user as PI for 4 active and 6 total studies.
- xForms (13 Active):** A list of xForms, showing 11 unsubmitted, 2 xForms being processed, and 2 xForms awaiting attention.
- Events (5 Open):** A list of events, showing 3 Initial Submission events, 2 QI reports events, and 5 Total Open events. A blue arrow points to the "5 Total Open" link.
- Recent Items:** A list of recent items: 2019-108-FranU and 2019-135-OLOLRMC.
- Messages:** A message from IRBManager: "Welcome to IRBManager at FranU". A purple arrow points to this message area.
- My Docs & xForms:** A table showing 2 Attachments and 14 xForms. A gold arrow points to the "My Docs & xForms" heading.
- Studies (4 Active):** A table showing the details of the 2 attachments, including the study number (2019-108-FranU), site (Franciscan Missionaries of Our Lady University), PI (Newman, Alfred E), title (Test created on 6/19/19), expiration date, and status (New From PI).
- Notices:** A section with a welcome message: "Welcome to IRB Manager at Franciscan Missionaries of Our Lady University!" and a note: "For more information about the IRB please click [FranU IRB](#). Contact us at [IRB@franu.edu](mailto:IRB@franu.edu). Next Meeting:TBD".
- NOTE:** A note stating: "NOTE: During the COVID-19 Outbreak the FranU IRB is still able to review and approve proposals, amendments, and re-approval/closure requests." with a pie chart showing a green and blue distribution.

### 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 Manager.**

### 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)

**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
- OLOLRM - Feasibility Review Submission**
- OLOLRM - Feasibility Review Submission**
- Submit Researcher Information
- Start xForm
- Show Sponsor Ids
- Use Bubble Dashboard

**Recent Items**

- 2019-108-FranU
- 2019-135-OLOLRM

**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

**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:
- Green** You have **3 Initial Submission** events.
- Blue** 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

### 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

Home (green arrow)

My Studies

**Studies** 4 **IRB** 4 **xForms** 10 **Events** 5 **Notices**

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 (red arrow)

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)

Inactive Studies  
PI 2

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

### 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)



FRANCISCAN MISSIONARIES OF OUR LADY UNIVERSITY

**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  
OI OI RMC - Feasibility

**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.

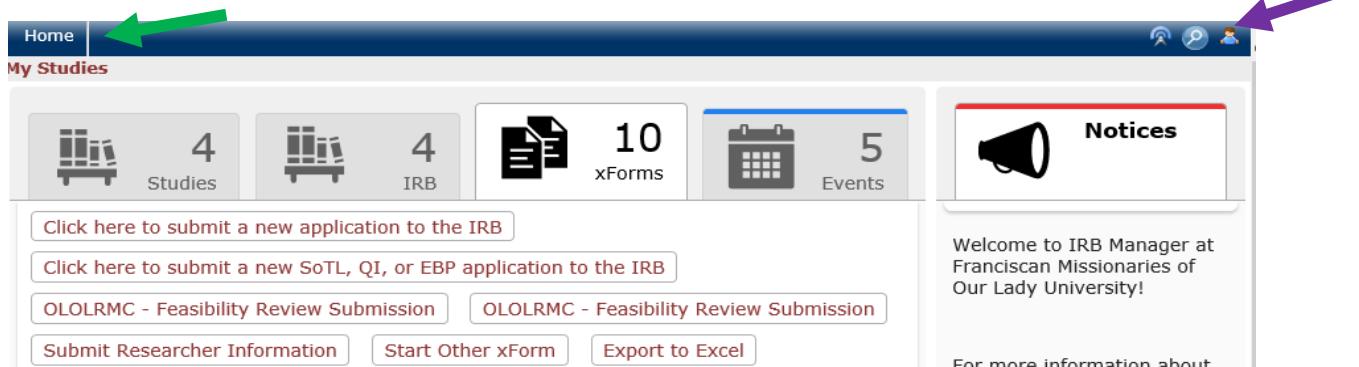
**Notices**

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

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

### 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.



Home | My Studies

**Studies** 4 **IRB** 4 **xForms** 10 **Events** 5

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  
OI OI RMC - Feasibility

Submit Researcher Information Start Other xForm Export to Excel

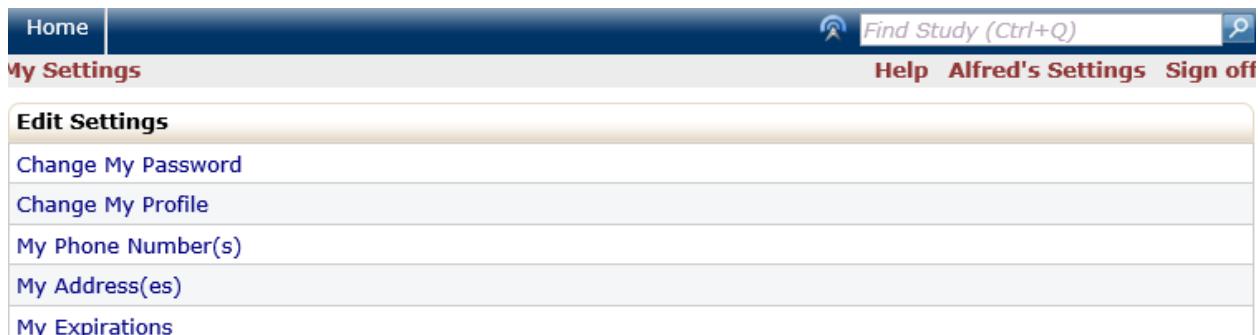
**Notices**

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

For more information about

### 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.



Home | My Settings

**Edit Settings**

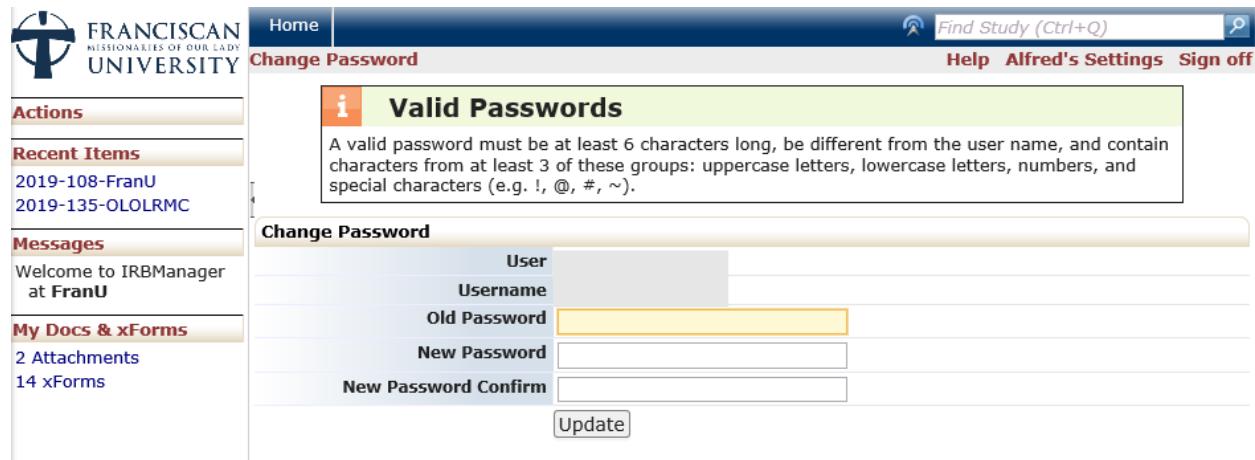
Change My Password  
Change My Profile  
My Phone Number(s)  
My Address(es)  
My Expirations

Help Alfred's Settings Sign off

- 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



**Valid Passwords**

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. !, @, #, ~).

**Change Password**

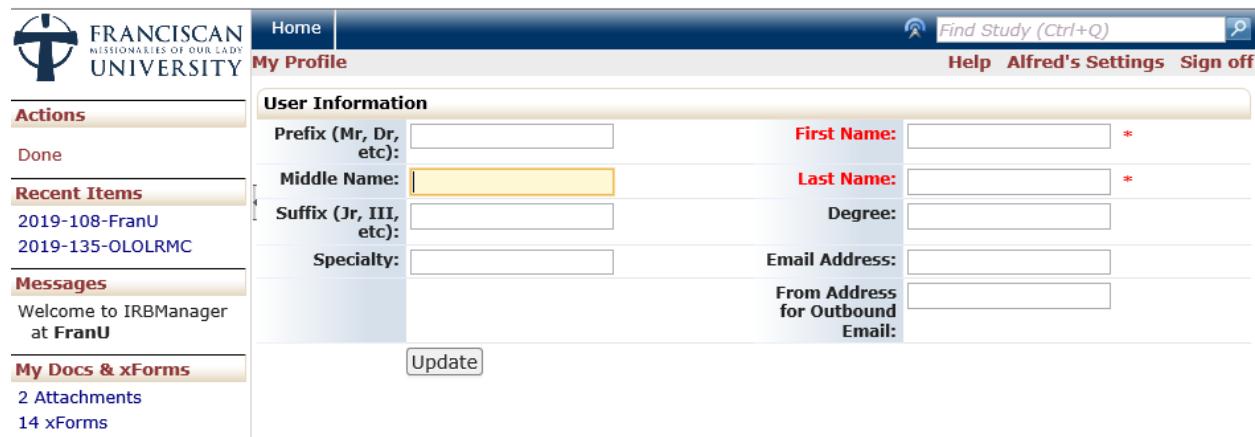
User	Username
Old Password	<input type="text"/>
New Password	<input type="text"/>
New Password Confirm	<input type="text"/>

**Update**

- 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.



**User Information**

Prefix (Mr, Dr, etc):	<input type="text"/>	First Name:	<input type="text"/> *
Middle Name:	<input type="text"/>	Last Name:	<input type="text"/> *
Suffix (Jr, III, etc):	<input type="text"/>	Degree:	<input type="text"/>
Specialty:	<input type="text"/>	Email Address:	<input type="text"/>
		From Address for Outbound Email:	<input type="text"/>

**Update**

- 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

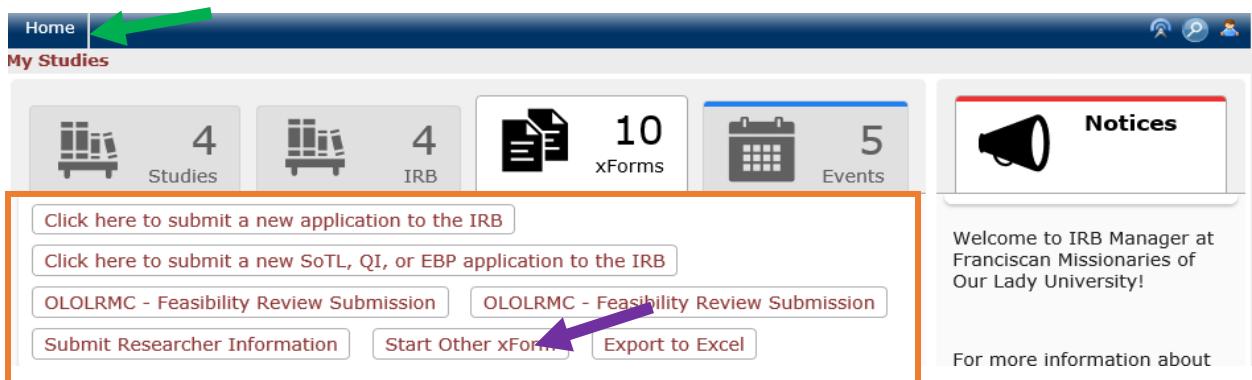
- Click any link to the *frequently used xForms* (green box) if you know the xForm name
- Or, click “Start xForm” (red arrow) under **Actions** for complete list of xForms



The screenshot shows the IRBManager Power Dashboard. The top navigation bar has a green arrow pointing to the "Home" tab. The sidebar on the left is titled "Actions" and contains links for submitting applications and researcher information, with a red arrow pointing to the "Start xForm" button. The main content area displays "Studies (4 Active)", "xForms (10 Active)", and "Events (5 Open)" sections, along with a "Notices" box containing general information and COVID-19 updates.

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

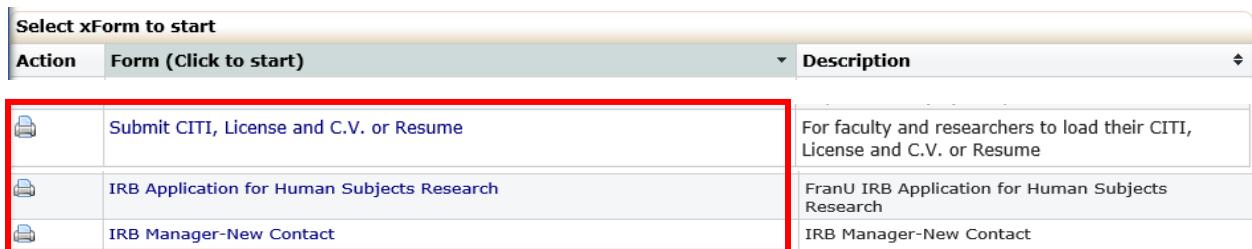
- Click any link to the *frequently used xForms* (gold box) if you know the xForm name
- Or, click “Start Other xForm” (purple arrow) on xForms tab for complete list of xForms



The screenshot shows the IRBManager Bubble Dashboard. The top navigation bar has a green arrow pointing to the "Home" tab. The main content area features a grid of summary cards: "Studies (4)", "IRB (4)", "xForms (10)", and "Events (5)". Below this, a box contains links for submitting applications and researcher information, with a purple arrow pointing to the "Start Other xForm" button. A "Notices" box on the right provides general information.

### 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)
	Submit CITI, License and C.V. or Resume
	IRB Application for Human Subjects Research
	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, @fmolhs.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, @fmolhs.org, @lsuhsc, etc.). (Required)

EMail already assigned to another contact.

[Add Note](#) [View Audit](#)

**New Contact Information**

**Prefix (Required)**  
 Dr., Mr., Ms., etc.

**First Name (Required)**

**Last Name (Required)**

**Degree(s)**  
 Ph.D., M.D., M.S., B.S.,

**Telephone Number (Required)**

**Institutional Affiliation (Required)**

**Enter CITI training expiration date.**



**Attach CITI training document here.**

[Add Attachment](#)

**Attach CV here.**

[Add Attachment](#)

**Enter licensure expiration date.**



**Attach licensure here.**

[Add Attachment](#)

[Add Note](#) [View Audit](#)

## 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.

**Next** **Save for Later** **More ▶**

- 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.

**Go Back** **Save for Later** **Print** **Submit** 

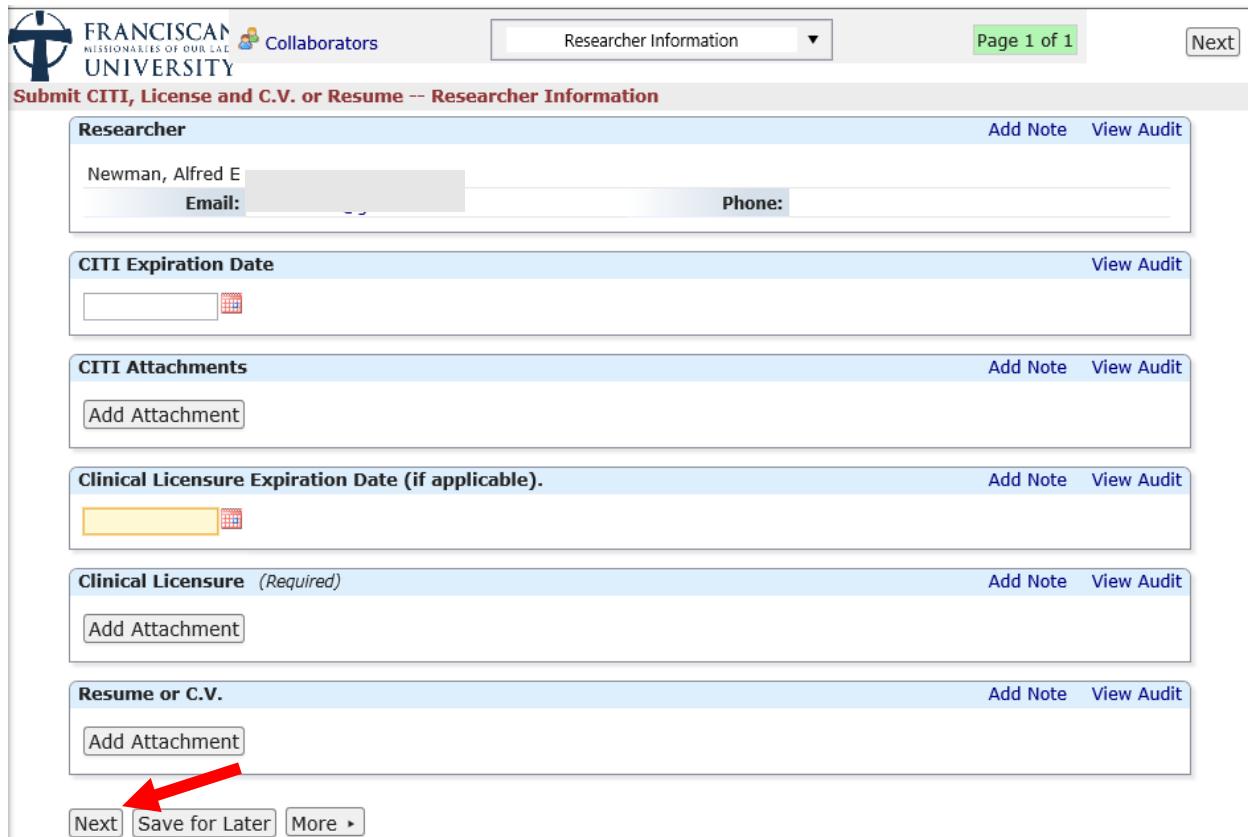
*NOTE: After you click “**Submit**” IRBManager processes the new contact information and a notification email is sent to you (the submitter) and the new contact just entered confirming the information is registered with IRBManager.*

*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.



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Researcher Information

Page 1 of 1

Next

Submit CITI, License and C.V. or Resume -- Researcher Information

**Researcher**

Newman, Alfred E

Email:

Phone:

**CITI Expiration Date**



**CITI Attachments**

**Clinical Licensure Expiration Date (if applicable).**



**Clinical Licensure (Required)**



**Resume or C.V.**



- 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.



Form Completed

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

- 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



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

**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  
OOLRMC - Feasibility Review Submission  
Submit Researcher Information

**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 (12 Active)**

- You have **11 unsubmitted** xForms.
- You have **1 xForm** being processed at a later stage.

**Events (5 Open)**

Only show events where I am:

**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

**Messages**

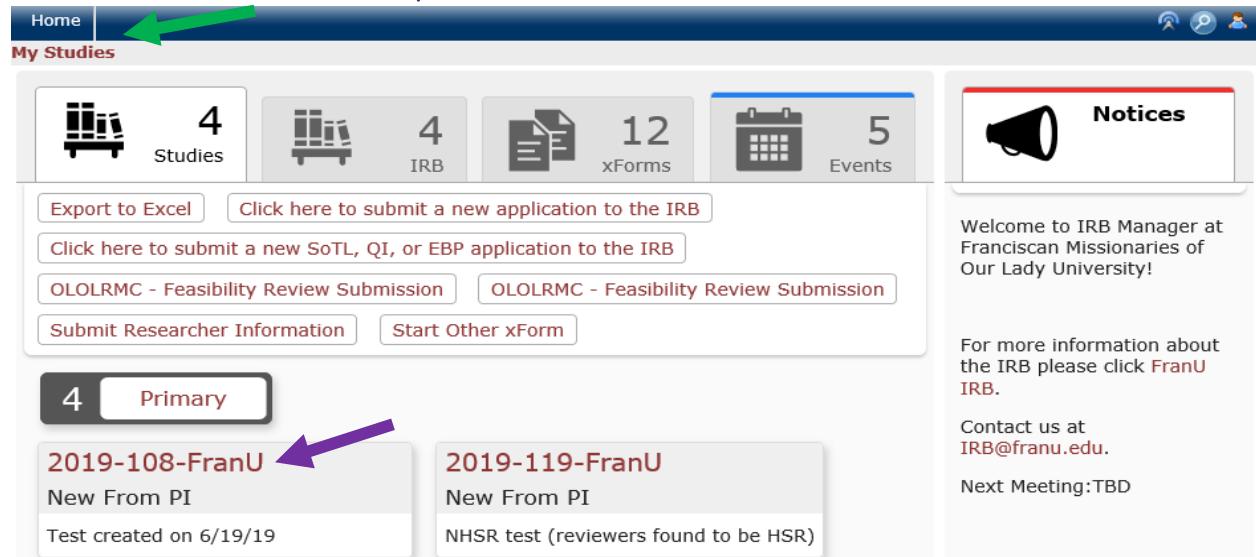
Welcome to IRBManager at FranU

**My Docs & xForms**  
2 Attachments

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



Home My Studies

**Studies** 4 Studies **IRB** 4 IRB **xForms** 12 xForms **Events** 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 OOLRMC - 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 NHR test (reviewers found to be HSR)

**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

- 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

Action	Value
Study:	2019-108
Committee:	IRB
Category:	
Department:	
Last Review:	
Agent Types:	Behavioral Observation
Title:	Test created on 6/19/19
Financial Feasibility:	
Comments:	test proposal
Site(s):	FranU - Franciscan Missionaries of Our Lady University
Status:	New From PI
Approval:	
Initial Approval:	
Comments:	classroom
PI:	Newman, Alfred E
Additional:	N
Expiration:	
Other Expirations:	

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

- Click “Start xForm” under Actions (red arrow).

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

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 from the list of available xForms (red box)
- 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

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Request for amendment -- Amendment header

Amendment header Page 1 of 2 Next

**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

**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.

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



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Submitter Signature

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Next

**Request for amendment -- Submitter Signature**

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

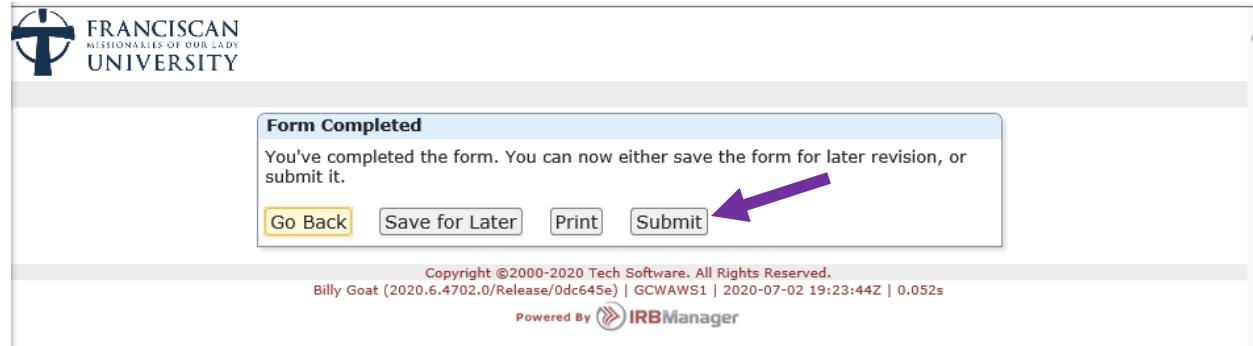
To sign, enter password for

Add Note View Audit

Previous Next Save for Later More ▶

- 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



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**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

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  
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

## 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

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Study Status Page 1 of 2 Next

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

**Submitter** View Audit

Newman, Alfred E

Email: [redacted] Phone: [redacted]

**Principal Investigator**

Newman, Alfred E

Email: [redacted] Phone: [redacted]

**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

ABC

**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

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Subject Information ▼

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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

## 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](#) 

Copyright ©2000-2020 Tech Software. All Rights Reserved.  
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