



# **IRBManager User's Guide**

**Summer 2020**

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

## Table of Contents

<b>1.0</b>	<b>Access to IRBManager</b> .....	<b>3</b>
<b>1.1</b>	<b>How to access IRBManager</b> .....	<b>3</b>
<b>1.2</b>	<b>How to log-in to IRBManager</b> .....	<b>3</b>
<b>2.0</b>	<b>Passwords</b> .....	<b>4</b>
<b>2.1</b>	<b>What happens at your first log-in?</b> .....	<b>4</b>
<b>2.2</b>	<b>Change your initial password and proceed</b> .....	<b>4</b>
<b>2.3</b>	<b>Forgotten Password or Account Locked</b> .....	<b>5</b>
<b>3.0</b>	<b>Dashboards</b> .....	<b>6</b>
<b>3.0a</b>	<b>Example of Power Dashboard</b> .....	<b>6</b>
<b>3.0b</b>	<b>Example of Bubble Dashboard</b> .....	<b>6</b>
<b>3.1</b>	<b>Selecting Your Dashboard</b> .....	<b>7</b>
<b>4.0</b>	<b>Navigating the Power Dashboard</b> .....	<b>8</b>
<b>4.0a</b>	<b>Power Dashboard - Headings</b> .....	<b>8</b>
<b>4.0b</b>	<b>Power Dashboard - Actions</b> .....	<b>8</b>
<b>4.0c</b>	<b>Power Dashboard - Recent Items</b> .....	<b>8</b>
<b>4.0d</b>	<b>Power Dashboard - Messages</b> .....	<b>8</b>
<b>4.0e</b>	<b>Power Dashboard - My Docs &amp; xForms</b> .....	<b>8</b>
<b>4.0</b>	<b>Navigating the Power Dashboard (continued)</b> .....	<b>9</b>
<b>4.0f</b>	<b>Power Dashboard - My Studies Section</b> .....	<b>9</b>
<b>4.0g</b>	<b>Power Dashboard - Studies</b> .....	<b>9</b>
<b>4.0h</b>	<b>Power Dashboard - xForms</b> .....	<b>9</b>
<b>4.0i</b>	<b>Power Dashboard - Events</b> .....	<b>9</b>
<b>4.0j</b>	<b>Power Dashboard - My Studies</b> .....	<b>9</b>
<b>5.0</b>	<b>Navigating the Bubble Dashboard</b> .....	<b>10</b>
<b>5.0a</b>	<b>Bubble Dashboard - My Studies Tabs</b> .....	<b>10</b>
<b>5.0b</b>	<b>Bubble Dashboard - Studies</b> .....	<b>10</b>
<b>5.0c</b>	<b>Bubble Dashboard - IRB</b> .....	<b>10</b>
<b>5.0d</b>	<b>Bubble Dashboard - xForms</b> .....	<b>10</b>
<b>5.0e</b>	<b>Bubble Dashboard - Events</b> .....	<b>10</b>
<b>5.0f</b>	<b>Bubble Dashboard - Notices</b> .....	<b>10</b>
<b>6.0</b>	<b>Update My Settings</b> .....	<b>11</b>
<b>6.0a</b>	<b>Power Dashboard Example - Update My Settings</b> .....	<b>11</b>

6.0b	Bubble Dashboard Example - Update My Settings.....	11
6.0c	Update My Settings – Edit Settings selection screen .....	11
6.1	Change My Password .....	12
6.2	Change My Profile .....	12
7.0	How to Start an xForm .....	13
7.0a	Power Dashboard Example - How to Start an xForm .....	13
7.0b	Bubble Dashboard Example - How to Start an xForm .....	13
7.1	Select xForm to Start .....	13
8.0	How to Submit - Contact Record Forms.....	14
8.1	How to Submit - IRBManager-New Contact (xForm) .....	14
8.1	How to Submit - IRBManager-New Contact (xForm) (continued) .....	15
8.2	How to Submit - Researcher Information (xForm).....	16
9.0	How to Submit - Active Study Forms.....	17
9.0a	Power Dashboard Example - Active Studies List .....	17
9.0b	Bubble Dashboard Example - Active Studies List .....	17
9.0	How to Submit - Active Study Forms (continued).....	18
9.0c	Study Detail Screen.....	18
9.0d	Study - Select xForm to Start Screen .....	18
9.1	Request for Study Amendment (xForm) .....	19
9.1a	Request for Study Amendment (xForm) - Data Entry Screen .....	19
9.1b	Request for Study Amendment (xForm) - Electronic Signature Screen .....	20
9.1c	Request for Study Amendment (xForm) - Submit Screen .....	20
9.2	Reapproval or Closure Notification (xForm) .....	21
9.2a	Reapproval or Closure Notification (xForm) - Study Status Data Entry Screen.....	21
9.2b	Reapproval or Closure Notification (xForm) - Subject Information Data Entry Screen.....	22
9.2c	Reapproval or Closure Notification (xForm) - Submit Screen.....	23

## 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**  
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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- 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**”

**i 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).

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

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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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- 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

#### 3.0b Example of Bubble Dashboard

### 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 in Bubble Dashboard view. The top navigation bar includes 'Home', a search box for 'Find Study (Ctrl+Q)', and links for 'Take a tour...', 'Help', 'Alfred's Settings', and 'Sign off'. The main content area is divided into several sections: 'My Studies' (4 Active), 'xForms' (13 Active), and 'Events' (5 Open). A pie chart is visible next to the Events section. The left sidebar contains various action links, with 'Use Bubble Dashboard' circled in red. The right sidebar contains a 'Notices' section with a welcome message and contact information.

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 in Power Dashboard view. The top navigation bar includes 'Home', a search box for 'Find Study (Ctrl+Q)', and a person icon in the upper right corner, which is highlighted by a red arrow. The main content area features a dashboard with four summary cards: '4 Studies', '4 IRB', '15 xForms', and '5 Events'. Below these cards are several action buttons, including 'Export to Excel', 'Click here to submit a new application to the IRB', and 'Start Other xForm'. The dashboard also displays a list of recent items, such as '2019-108-FranU' and '2019-119-FranU'. The right sidebar contains a 'Notices' section with a welcome message and contact information.

## 4.0 Navigating the Power Dashboard

**Actions**

Click here to submit a new application to the IRB

OLOLRCM - Feasibility Review Submission

Submit Researcher Information

Start xForm

Show Sponsor Ids

Use Bubble Dashboard

**My 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

**Recent Items**

- 2019-108-FranU
- 2019-135-OLOLRCM

**Messages**

Welcome to IRBManager at **FranU**

**My Docs & xForms**

2 Attachments  
14 xForms

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

**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.

### 4.0a 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)

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**

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

**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.

**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

### 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.

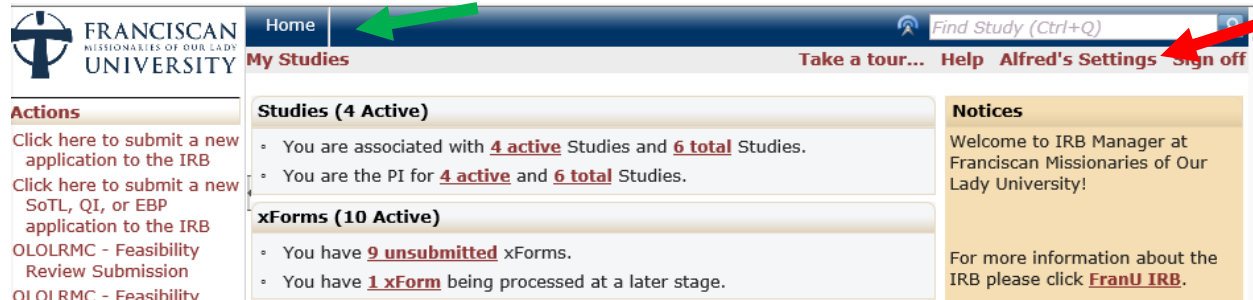
*NOTE: To return to your Dashboard from other screens, click the **“Home”** tab (**green arrow**).*

## 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

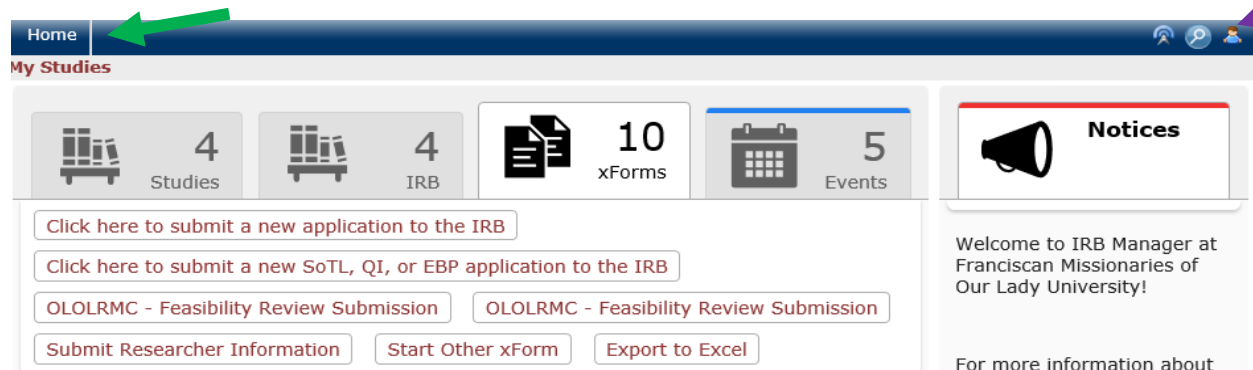
- Click “**your name Settings**” (red arrow)



The screenshot shows the Power Dashboard interface. At the top left is the Franciscan University logo. The main navigation bar includes a 'Home' tab (indicated by a green arrow) and a search bar with the text 'Find Study (Ctrl+Q)'. Below the navigation bar, the 'My Studies' section displays statistics for Studies (4 Active), xForms (10 Active), and Notices. A red arrow points to the 'Alfred's Settings' link in the top right navigation area.

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

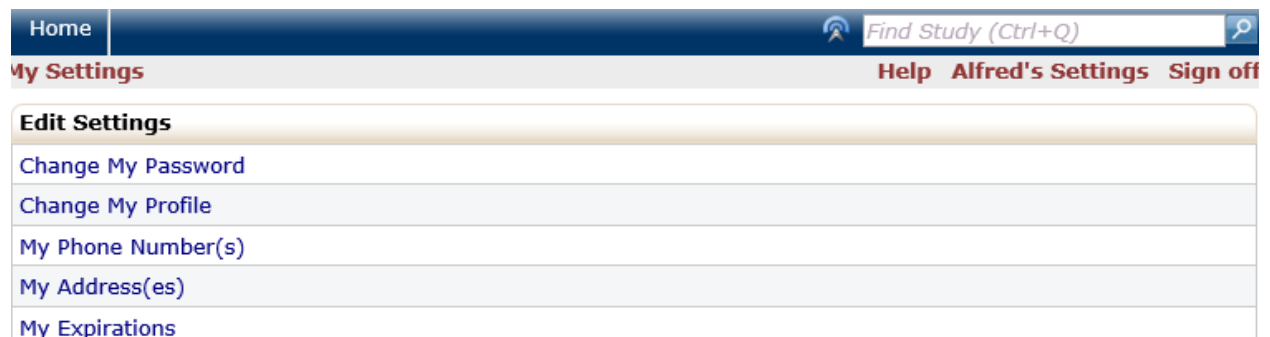
- Click **Person Icon** located in the upper right corner of the screen (purple arrow)
- Select “**your name Settings**” from the drop-down menu.



The screenshot shows the Bubble Dashboard interface. At the top left is the 'Home' tab (indicated by a green arrow). The main navigation bar includes a search bar with the text 'Find Study (Ctrl+Q)'. Below the navigation bar, the 'My Studies' section displays statistics for Studies (4), IRB (4), xForms (10), and Events (5). A purple arrow points to the person icon in the top right corner of the dashboard.

### 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.



The screenshot shows the 'Edit Settings' selection screen. At the top left is the 'Home' tab. The main navigation bar includes a search bar with the text 'Find Study (Ctrl+Q)'. Below the navigation bar, the 'My Settings' section is active, displaying a list of settings options: Change My Password, Change My Profile, My Phone Number(s), My Address(es), and My Expirations.

- 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

New Password

New Password Confirm

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):

Middle Name:

Suffix (Jr, III, etc):

Specialty:

First Name:

Last Name:

Degree:

Email Address:

From Address for Outbound Email:

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

### 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

## 7.1 Select xForm to Start

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

Action	Form (Click to start)	Description
	Submit CITI, License and C.V. or Resume	For faculty and researchers to load their CITI, License and C.V. or Resume
	IRB Application for Human Subjects Research	FranU IRB Application for Human Subjects Research
	IRB Manager-New Contact	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) [Add Note](#) [View Audit](#)

EEmail already assigned to another contact. 

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

**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.** [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](#)

## 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 text 'FRANCISCAN UNIVERSITY' and 'COLLEAGUES OF OUR CARE Collaborators', a dropdown menu set to 'Researcher Information', 'Page 1 of 1', and a 'Next' button. The main content area is titled 'Submit CITI, License and C.V. or Resume -- Researcher Information' and 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. The text reads: '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 University IRB Manager dashboard. The 'Home' tab is highlighted with a green arrow. The 'My Studies' section displays a table with the following data:

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 University IRB Manager dashboard with a bubble-style layout. The 'Home' tab is highlighted with a green arrow. The 'Studies' tab is active, showing a summary of 4 studies, 4 IRB applications, 12 xForms, and 5 events. A purple arrow points to the '2019-108-FranU' study bubble, which is labeled 'New From PI' and 'Test created on 6/19/19'.

- 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

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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-OLOLRMC

**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:  
Initial Approval: Other Expirations:  
Comments: classroom

**Events (1)**

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

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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 (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

FRANCISCAN MISSIONARIES OF OUR LADY 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

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Submitter Signature

Page 2 of 2

Next

**Request for amendment -- Submitter Signature**

Please enter your password to electronically sign this form. (Required) [Add Note](#) [View Audit](#)

To sign, enter password for

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

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Billy Goat (2020.6.4702.0/Release/0dc645e) | GCWAWS1 | 2020-07-02 19:23:44Z | 0.052s

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- 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

**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.** [View Audit](#)  
(Required)

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

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.** [View Audit](#)  
(Required)

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

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


## 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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- 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