



IRBManager Instructions for Researcher/Staff

Logging into IRBManager

1. Go to this website: <https://flhealth.my.irbmanager.com>
2. If you have existing open studies with the Florida Department of Health and this is your first time using the IRBManager system, click the **<Forgot Password>** link. You will then be asked to enter your email address and a code to ensure you are a human. IRBManager will then send a temporary password to your email address.
3. Enter the **User Name** (usually your email address) and **Password** that you were provided (*you will be given the option to change your password*).
4. Select **<Login>** to continue.

If you do not have an existing user name, please use the "Click here to register" link, which will direct you to a form to register as a new user.

The screenshot shows the login interface for IRBManager. At the top left is the Florida Health logo. Below it is the word "Login" in red. The main form area contains the following elements:

- User Name: A text input field with a red asterisk to its right.
- Password: A text input field with a red asterisk to its right.
- Client: A text input field containing "FLHealth".
- Remember Client: A checkbox.
- Login: A button.
- Forgot Password?: A link with a blue arrow pointing to it from the right.
- Don't have an account? Click here to register.: A link with a blue arrow pointing to it from the left.

At the bottom of the page, there is a copyright notice: "Copyright ©2000-2018 Tech Software. All Rights Reserved. Steampunk (2017.11.133.0) Release/3d900d6fe343e42ac8bb02bc3fb6e9e442c1bcc TP-WE801 at 2018-02-19 21:29:26Z Page generated in 0.003 seconds."

Upon logging in, your homepage will appear as below:

The screenshot shows the Florida Health IRB Manager homepage. The left sidebar contains navigation links for Actions, Recent Items, Messages, and My Documents & Forms. The main content area is titled 'My Studies' and includes a search bar, a 'Take a tour...' link, and a 'Sign off' button. The 'My Studies' section is divided into several sub-sections: 'Studies (3 Active)', 'xForms (1 Active)', and 'Events (4 Open)'. The 'Studies (3 Active)' section lists three studies with their respective sites, PIs, titles, expiration dates, and statuses. The 'Events (4 Open)' section includes a pie chart and a list of event types. The right sidebar contains a 'Notices' section with a welcome message and contact information for Rotanya Bryan, Gavin Grigg, and Bonnie Gaughan-Bailey.

My Studies (3 Active)

Study	Site	PI	Title	Expires	Status
2018-002-UF	University of Florida	Researcher, Test	The Effect of Obesity on Immune Responses to the Yellow Fever Vaccine	02/28/2018	Open to enrollment
2018-003-HIV	HIV Clinics	Coordinator, Test	Opioid misuse, overdose and access to behavioral health services in Orange County, Florida		New From PI
2018-004-DFT	Default Site	Researcher, Test	Yellow Fever - Testing for Levels of Exposure	02/12/2019	Open to enrollment

To Change Your Password and other Settings

After logging in select <settings> at the top right hand side of the page; you will then have the option to change your password, contact information, update your profile, etc.

The screenshot shows the 'My Settings' page in the Florida Health IRB Manager. The left sidebar is identical to the previous screenshot. The main content area is titled 'My Settings' and includes a search bar and a 'Sign off' button. The 'My Settings' section is divided into several sub-sections: 'Edit Settings', 'My Phone Number(s)', 'My Address(es)', 'My Expirations', 'Last 25 Logins', 'EMail Signature', and 'Linked Clients'. The 'Edit Settings' section includes links to 'Change My Password', 'Change My Profile', and 'My Phone Number(s)'. The 'My Address(es)' section includes a link to 'My Address(es)'. The 'My Expirations' section includes a link to 'My Expirations'. The 'Last 25 Logins' section includes a link to 'Last 25 Logins'. The 'EMail Signature' section includes a link to 'EMail Signature'. The 'Linked Clients' section includes a link to 'Linked Clients'.

Your IRBManager Homepage is broken down into four main sections:

Studies - Summary of your studies (Studies that are complete or have not been submitted will NOT appear in "Active")

Under "Studies" you will see the number of active and the total studies you are associated with. By clicking on either **#active** or **#total** will show a list of your studies you are associated with. This section lists the specific roles you have for each study (PI, Sub-I, Coordinator; etc.). This section also provides you with the next study to expire and all of the studies expiring in the next 90 days.

Studies (3 Active)

- You are associated with **3 active** Studies and **3 total** Studies.
- You are the PI for **2 active** and **2 total** Studies.
- You are the Co-Investigator for **1 active** and **1 total** Studies.
- There are **1 studies** expiring in the next 90 days.
- The next study to expire is **2018-002-UF**.

xForms - Summary of your xForms

Forms you are currently working on will be listed under **# unsubmitted xforms**. You can work on multiple forms at the same time, and save them for completing at a later time. If you click on this link, you will find a list of the forms you are working on but have not yet been submitted.

xForms (12 Active)

- You have **0 unsubmitted** xForms.
- You have **12 xForms** being processed at a later stage.
- You have **1 xForm** in error.
- There are **4 xForms** awaiting your attention.

Once a form is submitted, it will be listed under **# xForms being processed**. You will be able to check on the status of a form after you have submitted it by clicking on this link. The current stage the form is in will be listed under the Stage column. For example, **"Under Review"** means that the form is under review by the IRB.

xForms (12 Active)

- You have **0 unsubmitted** xForms.
- You have **12 xForms** being processed at a later stage.
- You have **1 xForm** in error.
- There are **4 xForms** awaiting your attention.

Forms that require your sign off will be listed under **# xForms awaiting your attention**. After you click on the link, it will bring up a list of forms. If you click on the box on the upper right corner next to "Show forms requiring approvals ONLY", the list will be sorted and display only the forms you need to sign off on.

xForms (12 Active)

- You have **0 unsubmitted** xForms.
- You have **12 xForms** being processed at a later stage.
- You have **1 xForm** in error.
- There are **4 xForms** awaiting your attention.

NOTE: If you notice a form designated as "You have #xForm in error," please contact your IRB Administrator for assistance.

Events


Once a form has been submitted and accepted into IRBManager, an event is created. To see what events are open (i.e.; Modifications, New Study Submissions, etc.) look under the events section and you will be able to check the status of that event.

Events (4 Open)

Only show events where I am:

- You have **2 Adverse event/noncompliance** events.
- You have **1 Initial Submission** events.
- You have **1 Modification** events.

You have **4 Total Open** events



My Studies - Listing of your studies

You can filter your list of studies on the particular item you choose to filter (i.e.; PI Name, Expiration Date, etc.). When the filter feature is turned on, a yellow dashed box surrounds the data. To remove the filter, click again on your original filter item.

My Studies (3 Active)					
Study	Site	PI	Title	Expires	Status
2018-002-UF	University of Florida	Researcher, Test	The Effect of Obesity on Immune Responses to the Yellow Fever Vaccine	02/28/2018	Open to enrollment
2018-003-HIV	HIV Clinics	Coordinator, Test	Opioid misuse, overdose and access to behavioral health services in Orange County, Florida		New From PI
2018-004-DFT	Default Site	Researcher, Test	Yellow Fever - Testing for Levels of Exposure	02/12/2019	Open to enrollment

TO SUBMIT FORMS TO THE IRB – SELECT FORM THE FOLLOWING OPTIONS

1. Creating a New IRB Submission

If you want to create a new study submission form, click on **<Click here to determine if IRB review is required>** or **<Submit a new IRB Application>**.

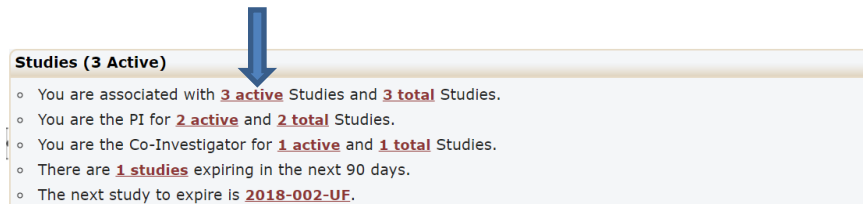


Clicking on **<Start xForm>** will provide a list of additional forms that can be submitted:


Select xForm to start		
Action	Form (Click to start)	Description
	Determination of whether IRB review is required	Determination of whether IRB review is required
	New IRBMANAGER Contact End User	This form will allow you to add a new user to IRBManager at Florida Health.
	Research Outline - Application for Initial Review by the IRB	Research Outline - Application for Initial Review by the IRB

2. Creating forms for Active Studies

To submit a request on an active study, click on **# active** Studies,



then click on any **Study #** under the "**Study**" column.



Study	Site	Title	Expires	PI	Status
2018-002-UF	University of Florida	The Effect of Obesity on Immune Responses to the Yellow Fever Vaccine	02/28/2018	Researcher, Test	Open to enrollment
2018-003-HIV	HIV Clinics	Opioid misuse, overdose and access to behavioral health services in Orange County, Florida		Coordinator, Test	New From PI
2018-004-DFT	Default Site	Yellow Fever - Testing for Levels of Exposure	02/12/2019	Researcher, Test	Open to enrollment

Once in the study, click on **<Start xForm>** on the left side of your screen under "Actions."





Actions

- Send EMail
- Start xForm
- xForms (0)

Done

Recent Items

- 2018-002-UF
- 2018-004-DFT

Messages

Welcome to IRBManager at FLDOD

My Documents & Forms

- 0 User Attachments
- 2 xForms

Home Find Study (Ctrl+Q)

Study 2018-002-UF (IRB) Help Test's Settings Sign off

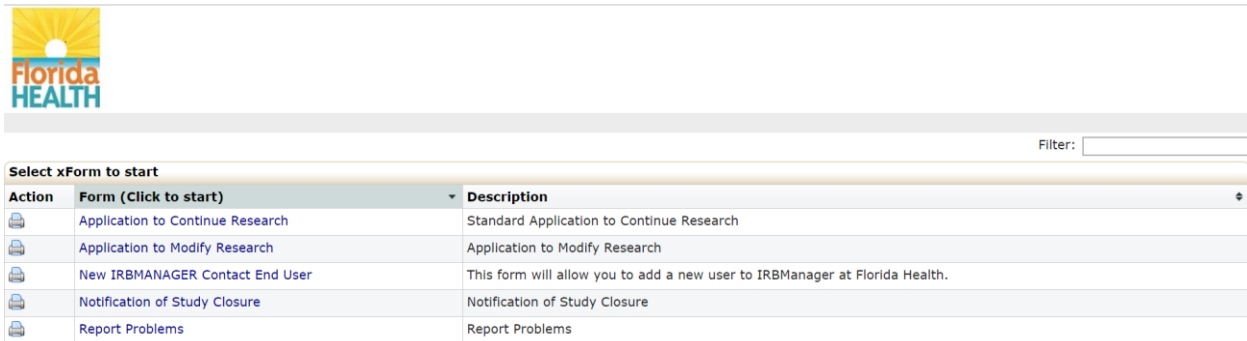
Study

Study: 2018-002	Sponsor(s): Not applicable (Primary)
Committee: IRB 1	Sponsor Id:
Category:	Grants:
Department:	Next Review:
Last Review:	CRO:
Agent Types: Data analysis - no interaction	Year: 2018
Title: The Effect of Obesity on Immune Responses to the Yellow Fever Vaccine	Fees required:
Fee for continuing review:	
Vulnerable populations:	
Comments: fgjfrj	

Study-Site

Site(s): UF - University of Florida	PI: Researcher, Test
Status: Open to enrollment	Additional: N
Approval: March 1, 2017 for 12 months	Expiration: February 28, 2018
Initial Approval: March 1, 2017	Other Expirations:
Comments:	

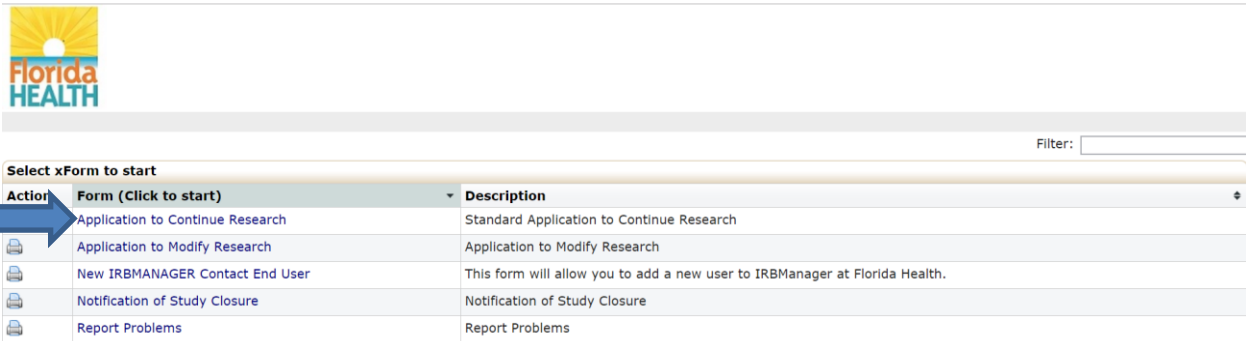
After clicking **<Start xForm>** you will see a screen similar to the below image.



Action	Form (Click to start)	Description
	Application to Continue Research	Standard Application to Continue Research
	Application to Modify Research	Application to Modify Research
	New IRBMANAGER Contact End User	This form will allow you to add a new user to IRBManager at Florida Health.
	Notification of Study Closure	Notification of Study Closure
	Report Problems	Report Problems

Note: The screen above represents **SOME** of the available forms. (screenshot is for example only). To complete one of forms above, you must be in the specific study for which you want to complete the form.

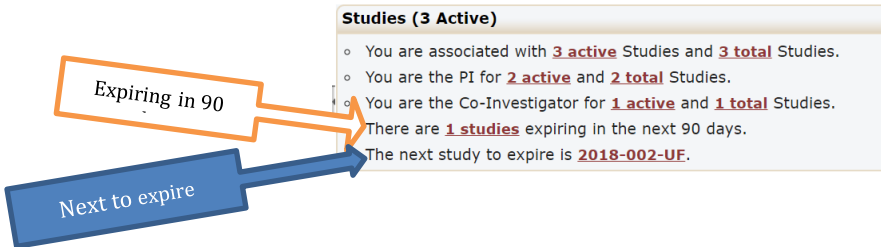
Select the xForm needed by clicking on the form's title.



Action	Form (Click to start)	Description
	Application to Continue Research	Standard Application to Continue Research
	Application to Modify Research	Application to Modify Research
	New IRBMANAGER Contact End User	This form will allow you to add a new user to IRBManager at Florida Health.
	Notification of Study Closure	Notification of Study Closure
	Report Problems	Report Problems

Studies about to Expire

This section will list the next study to expire as well as all studies that will be expiring in the next 90 days. You will continue to receive reminder emails until a continuing review report is signed off and submitted.



Studies (3 Active)

- You are associated with **3 active** Studies and **3 total** Studies.
- You are the PI for **2 active** and **2 total** Studies.
- You are the Co-Investigator for **1 active** and **1 total** Studies.

There are **1 studies** expiring in the next 90 days.
The next study to expire is **2018-002-UF**.

If you have any questions about IRBManager please contact the Florida Department of Health IRB Coordinator at:

IRB@flhealth.gov or 850-245-4585