

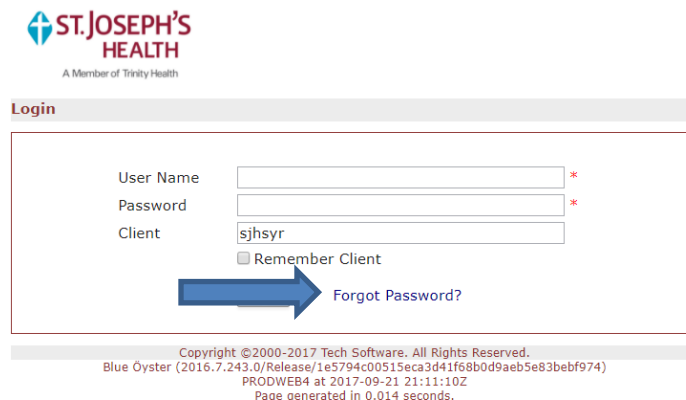


IRBManager Instructions for St. Joseph's Hospital Health Center & St. Peter's Health Partners Researchers, Coordinators or Staff

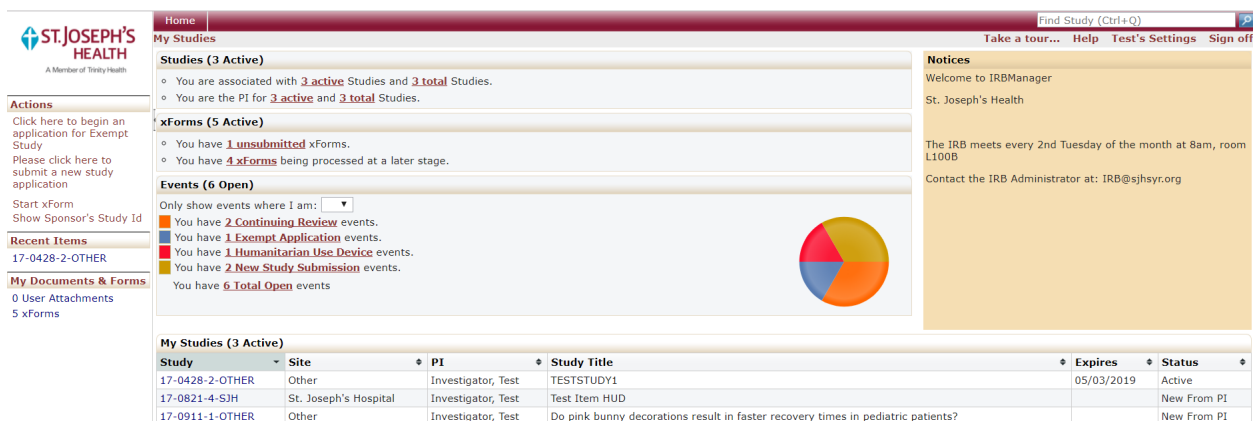
Logging into IRBManager

1. Go to this website: <https://sjhsyr.my.irbmanager.com>
2. If you have existing open studies with St. Joseph Health, Syracuse or St. Peter's Health Partners, Albany 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.



Upon logging in, your homepage will appear as below:



Study	Site	PI	Study Title	Expires	Status
17-0428-2-OTHER	Other	Investigator, Test	TESTSTUDY1	05/03/2019	Active
17-0821-4-SJH	St. Joseph's Hospital	Investigator, Test	Test Item HUD		New From PI
17-0911-1-OTHER	Other	Investigator, Test	Do pink bunny decorations result in faster recovery times in pediatric patients?		New From PI

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.

Your IRBManager Homepage is broken down into four main sections:

Studies - Summary of your studies (Studies that are not 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.

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.

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.

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 (6 Open)

Only show events where I am:

- You have **2 Continuing Review** events.
- You have **1 Exempt Application** events.
- You have **1 Humanitarian Use Device** events.
- You have **2 New Study Submission** events.
- You have **6 Total Open** events

My Studies - Listing of your studies

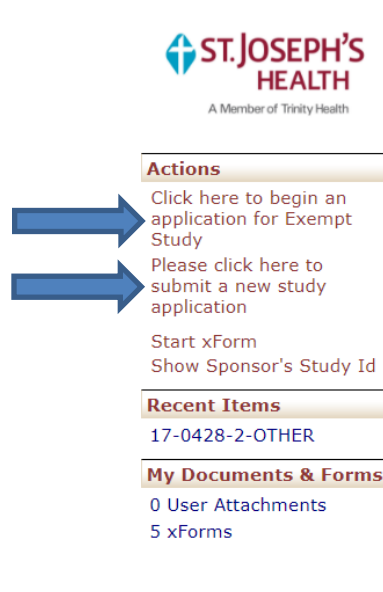
You can filter your list of studies on the particular item you choose to filter (i.e.; PI Name, Expiration Date, etc.). When the filter feature is turned on, a yellow dashed box surrounds the data. To remove the filter, click again on your original filter item.

My Studies (3 Active)						
Study	Site	PI	Study Title	Expires	Status	
17-0428-2-OTHER	Other	Investigator, Test	TESTSTUDY1	05/03/2019	Active	
17-0821-4-SJH	St. Joseph's Hospital	Investigator, Test	Test Item HUD		New From PI	
17-0911-1-OTHER	Other	Investigator, Test	Do pink bunny decorations result in faster recovery times in pediatric patients?		New From PI	

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 begin an application for Exempt Study> or <Please click here to submit a new study>.



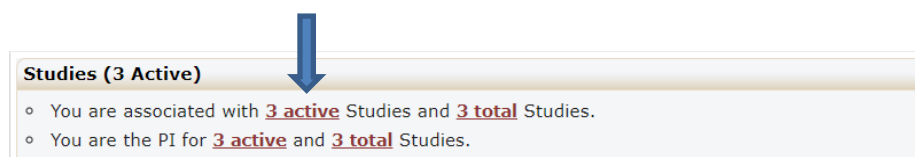
Clicking on <Start xForm> will provide a list of additional forms that can be submitted:

The screenshot shows the St. Joseph's Health logo at the top, with the text 'A Member of Trinity Health' below it. Below the logo is a table titled 'Select xForm to start'. The table has three columns: 'Action', 'Form (Click to start)', and 'Description'. There are five rows of data, each with a printer icon in the 'Action' column.


Action	Form (Click to start)	Description
	Add a New Contact to IRB Manager Form	Use this form to add a new contact that is not currently in IRB Manager.
	Claim of Exemption Form	Complete this form if you believe your study is eligible for exempt review.
	Emergency Use Reporting Form	Emergency Use Reporting Form
	Humanitarian Use Device Application (HUD)	Humanitarian Use Device Application (HUD)
	IRB Application for Initial Review	Use this form to submit a new study application for IRB review.

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	Study Title	Expires	PI	Status
17-0428-2-OTHER	Other	TESTSTUDY1	05/03/2019	Investigator, Test	Active
17-0428-2-OTHER	Other	TESTSTUDY1	05/03/2019	Investigator, Test	Active
17-0821-4-SJH	St. Joseph's Hospital	Test Item HUD		Investigator, Test	New From PI
17-0911-1-OTHER	Other	Do pink bunny decorations result in faster recovery times in pediatric patients?		Investigator, Test	New From PI

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



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Home | Find Study (Ctrl+Q) | Help | Test's Settings

Study 17-0428-2-OTHER (IRB)

Study

Study: 17-0428-2 | Sponsor(s): Study not sponsored (Primary)
 Committee: SJH SYR IRB Research Committee | Sponsor Id:
 Category: Other, Non-specific | Grants:
 Department: | Secondary:
 Reviewer: | Next Review:
 Last Review: | CRO:
 Agent Types: Observational | Year: 2017
 Study Title: TESTSTUDY1
 Level of Risk: |
 Comments: test objective

Study-Site

Site(s): OTHER - Other | PI: Investigator, Test
 Status: Active | Additional: N
 Approval: May 4, 2018 for 12 months | Expiration: May 3, 2019
 Initial Approval: May 4, 2017 | Other Expirations:
 Closed to Patient | Closure Date:
 Accrual Date:
 Comments:

Actions

- Add Attachment
- Generate Doc
- Send EMail
- Start xForm
- xForms (0)
- Done

Recent Items

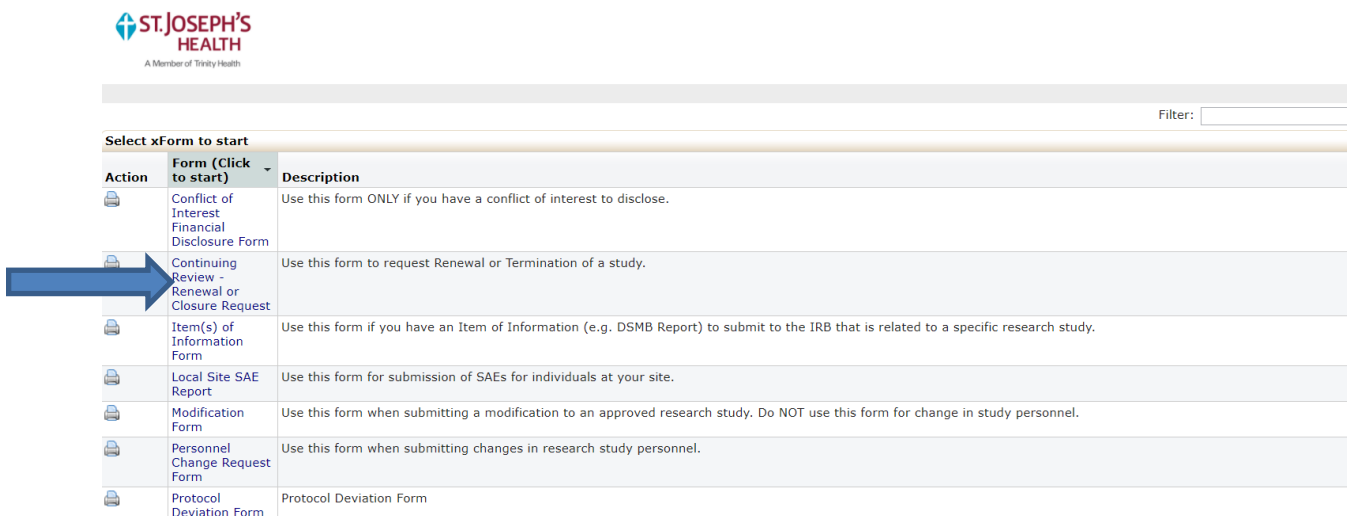
- 17-0428-2-OTHER
- 17-0911-1-OTHER

My Documents & Forms

- 0 User Attachments
- 5 xForms

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

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



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Filter:

Select xForm to start

Action	Form (Click to start)	Description
	Conflict of Interest Financial Disclosure Form	Use this form ONLY if you have a conflict of interest to disclose.
	Continuing Review - Renewal or Closure Request	Use this form to request Renewal or Termination of a study.
	Item(s) of Information Form	Use this form if you have an Item of Information (e.g. DSMB Report) to submit to the IRB that is related to a specific research study.
	Local Site SAE Report	Use this form for submission of SAEs for individuals at your site.
	Modification Form	Use this form when submitting a modification to an approved research study. Do NOT use this form for change in study personnel.
	Personnel Change Request Form	Use this form when submitting changes in research study personnel.
	Protocol Deviation Form	Protocol Deviation Form

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.

The screenshot shows a web interface titled "Studies (1 Active)". It contains a bulleted list of information:

- You are associated with **1 active** Studies and **1 total** Studies.
- You are the PI for **1 active** and **1 total** Studies.
- There are **1 studies** expiring in the next 90 days.
- The next study to expire is **00023-BPoly**.

Two callouts are present: an orange callout box labeled "Expiring in 90 days" with an arrow pointing to the third bullet point, and a blue callout box labeled "Next to expire" with an arrow pointing to the fourth bullet point.

If you have any questions about IRBManager please contact the St. Joseph Health Syracuse IRB Coordinator at:
IRB@sjhsyr.org or PHONE NUMBER