IRBManager Training for IRB Members

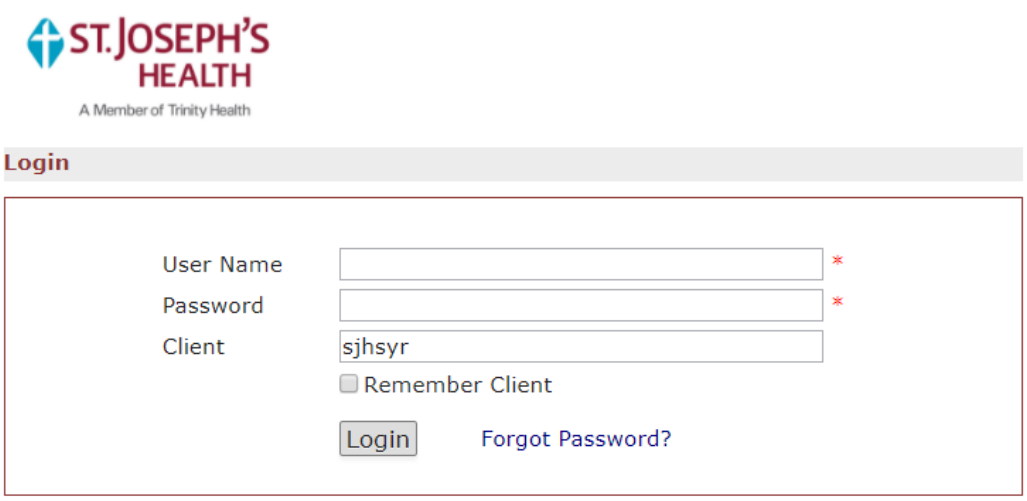
at

Trinity Health New York

(St. Joseph Hospital Health Center & St. Peter's Health Partners)

Logging into IRB Manager:

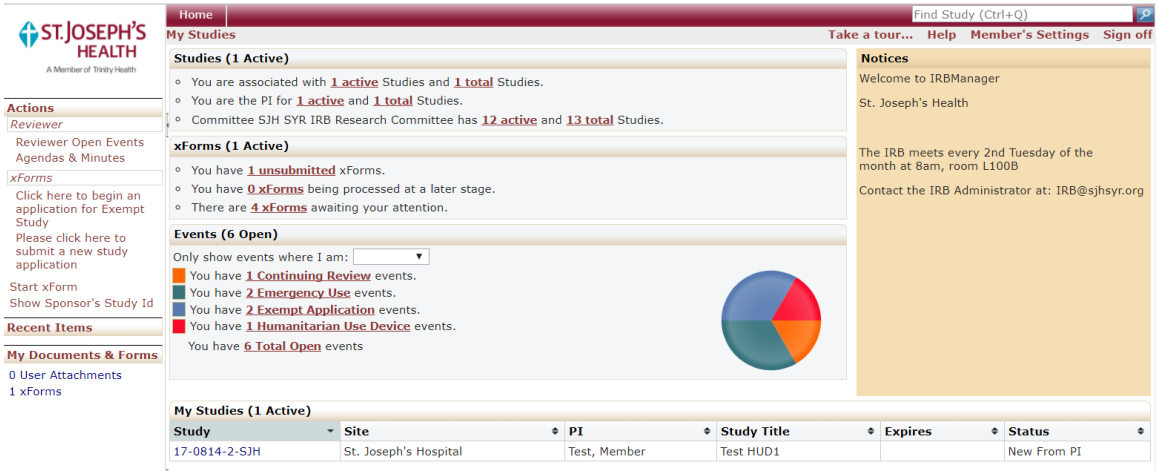
- Enter the IRB Manager URL
  https://SJHSYR.my.irbmanager.com/



- Enter your St. Joseph's Health email address and your IRBManager password.
- Select <**Login>** to continue

If you have forgotten your password, click on the Forgot Password? link to reset your account.

Once you have logged in, you will see your home screen. This is an example of how a home screen will appear to an IRB Member at St. Joseph's Health:



The IRB Member Home Page is different from the PI home page. IRB Members can view any protocol in the system and the internal information for it. We'll discuss the difference between internal and external items later.

There is one caveat about internal information while logged in as an IRB Member. If an IRB Member is also an investigator, while viewing their own protocols they will see them as if they were an investigator. None of the internal information will be revealed.

Basic Navigation

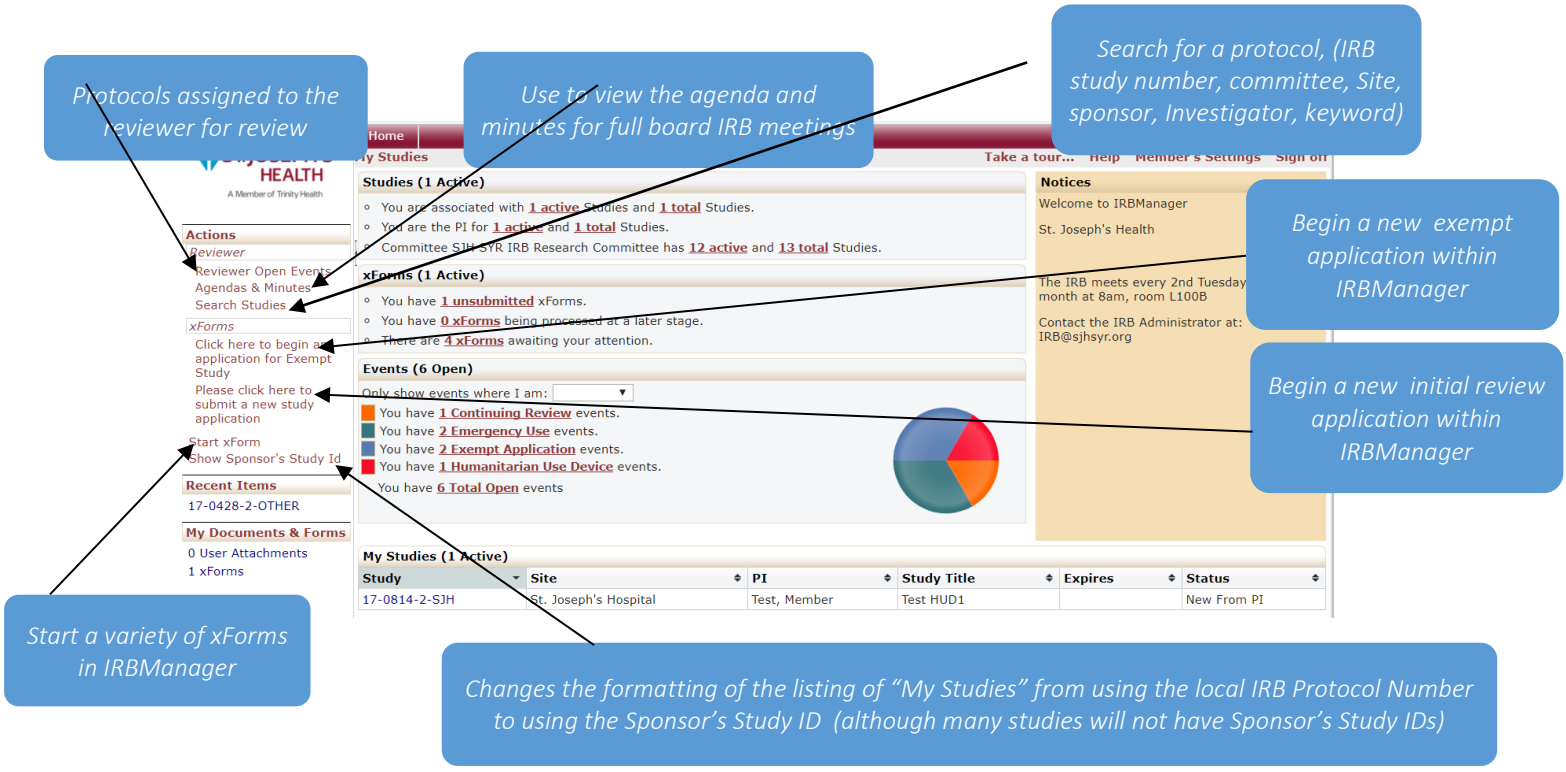
Home Screen Navigation:

Tabs at the top of the page:

- **Home** – this tab will always bring you back to your Home Page which lists all your studies.

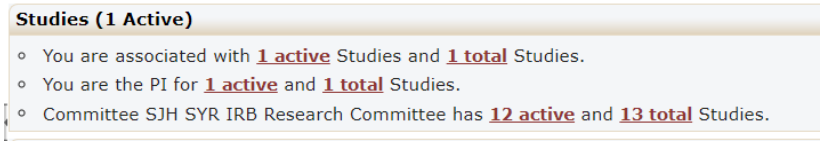
On the left side of the page:

- **Actions** – this heading allows you to perform specific actions to change the current page that is displayed. On the home page you can click **<Reviewer Open Events>, <Agendas and Minutes>,** or **<Search Studies>** as part of Reviewer actions, or **<Submit New Study>**, **<Start xForm>**, or **<Show Sponsor's Study Id>**.
- **Recent items** – the hyperlinks under this heading shows what the most recent protocol that the user has reviewed. The hyperlinks can be utilized to return to another protocol previously viewed.
- **Messages** – this heading is an area that the IRB Office may communicate to all of the users within the system. An example message would be, "All submissions are due to the IRB office by the first of every month prior to the IRB meeting."
- **My Documents & Forms** – this heading shows how many attachments and xForms the user has submitted.

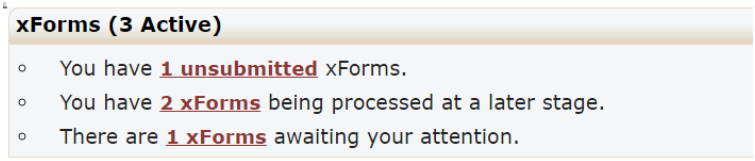


In the middle of the page:

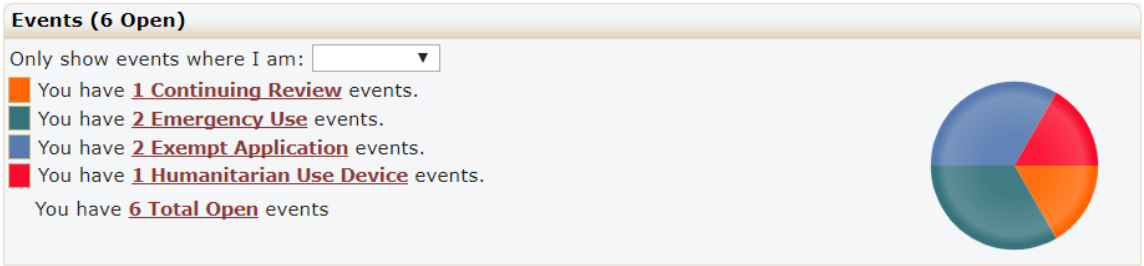
- **Studies**
  Studies are submissions within the IRBManager system that are pertinent to you. The first line will always tell you how many studies you are associated with in any role, both active and total (which includes studies have been closed or withdrawn). The next several lines afterward will break down the studies within each role that you hold. If you have any studies that will expire in the next 90 days, these will be displayed on a line. Another line item will alert you on the next study to expire. The last line in this area will let you know how many active studies the St. Joseph's Health IRB currently has, as well as how many studies in total exist within the system.



- **xForms**
  xForms are forms programmed into IRBManager with associated workflows. An xForm is generally begun and submitted by the investigator, investigative staff, or an IRB Member. It will contain either information supporting the event in the case of a continuing review or the data which created the event. The first line informs you how many xForms that you have started but have not yet been submitted. The second informs you how many of your xForms are being processed as part of the automated workflows programmed into the xForms. A third line will inform you if there are any xForms that require your attention.

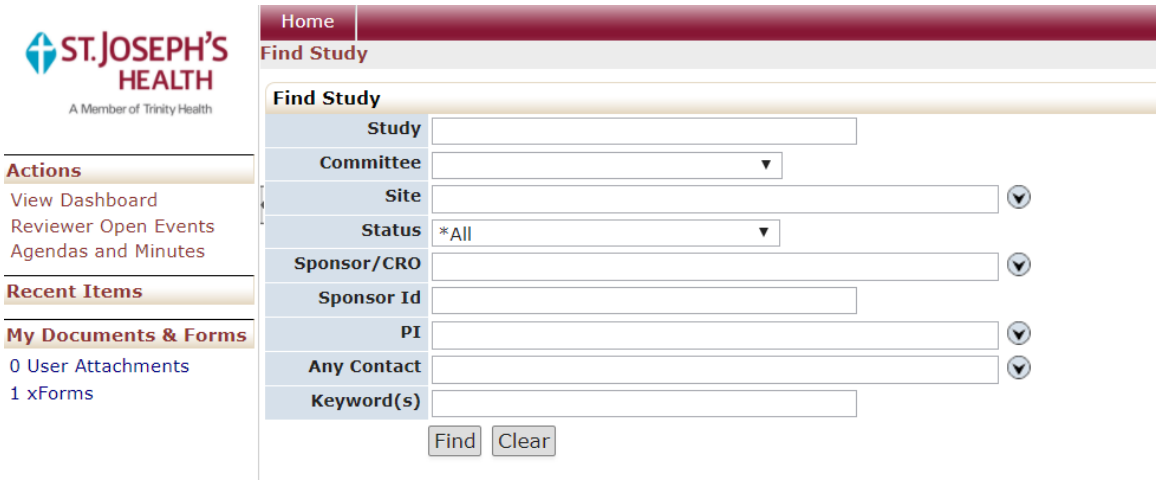


- **Events**
  Any business process happening to a protocol in IRBManager is called an event. An event can be Adverse Events, CIRB Facilitated Review for New Study, Continuing Review/ Final Closure, Emergency Use Device, Modification, New Study Submission, or Protocol Deviation. By clicking the links as shown below, you will be taken to a screen which lists all events of that particular type. On an event associated to your study you can view the status of the event as determined by the IRB. The dropdown next to "Only show events where I am:" will allow you to view this section only showing the numbers of events in the role that you chose in the dropdown. The pie chart provides a visual representation of the proportions of the open events with which you are associated.



Study Navigation:

To find a study IRB Members will need to click on the **<Search Studies>** link along the left side of the page under **Actions**. Clicking this link brings you to the following screen:



Studies can be searched using any of the listed search items or combinations. Results will be displayed on the following web page. If there is only one result matching the search criteria, the protocol will be displayed. If there are multiple studies, a list of the matching studies will be displayed and the user can then pick one.

As an example, we have searched using “test” as a search term in the **Keyword(s)** search item and found the following search results:

9 matching Studies

Study	Site	PI	Study Title	Expires	Status
17-0317-1-SJH	St. Joseph's Hospital	Szkolnik, Noreen	IRB test		New From PI
17-0317-2-SJH	St. Joseph's Hospital	Szkolnik, Noreen	IRB test		New From PI
17-0317-4-SJH	St. Joseph's Hospital	Szkolnik, Noreen	IRB test	Exempt	Closed
17-0426-1-SJH	St. Joseph's Hospital	Szkolnik, Noreen	TESTING 12345	Exempt	Active
17-0428-2-OTHER	Other	Investigator, Test	TESTSTUDY1	05/03/2019	Active
17-0525-2-OTHER	Other	Maddocks, Corinne	CMaddocks TEST	Exempt	Active
17-0814-2-SJH	St. Joseph's Hospital	Test, Member	Test HUD1		New From PI
17-0814-3-SJH	St. Joseph's Hospital	Szkolnik, Noreen	Test Emergency Use 1		New From PI
17-0821-4-SJH	St. Joseph's Hospital	Investigator, Test	Test Item HUD		New From PI

From the list a user can view the site, the PI, the title, the expiration date, and the status of the protocol. Upon clicking a chosen protocol, the study/protocol page is displayed.

Study/Protocol Details Screen

Category - The specialty in which you will be conducting this research.

Sponsor – If your study has a sponsor it will be displayed here, otherwise *None.

Agent Type - The type of procedure you will use.

Sponsor Protocol - The sponsor assigned protocol number. Not all protocols will have this.

Title – The title of the study.

Comments – The abstract or purpose or hypothesis for the study

Protocol Site Contacts – Listing of coordinators, co-investigators and research assistants

Events – Any business process in IRBManager is an event.

Attachments- Any object on a computer can be attached to a protocol or an event. We suggest attaching them directly to events.

Generated Documents – Outcome letters that are created by the St. Joseph's Health IRB.

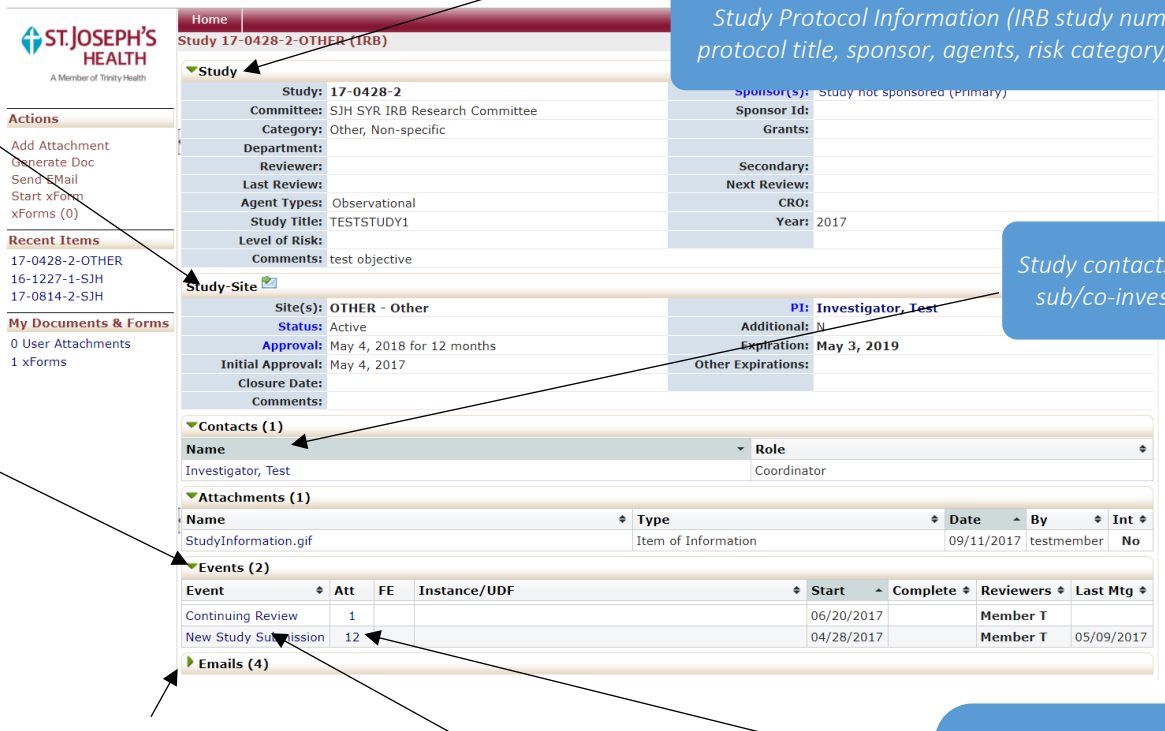
Study/Protocol Navigation:
On the study/protocol page there are several items that can be viewed.

Study sites, Investigators, status (New from PI, Exempt, Expedited, Open to Accrual, etc.). approval dates

Study Protocol Information (IRB study number, protocol title, sponsor, agents, risk category, etc.)

Study contacts (coordinators, sub/co-investigators, etc.)

Lists the study events including the number of attachments, event instance, event start date, last reviewed by IRB, etc.



Click on the green arrow beside Emails or Notes to view all emails /notes associated with this study/protocol.

Click this link to view event details

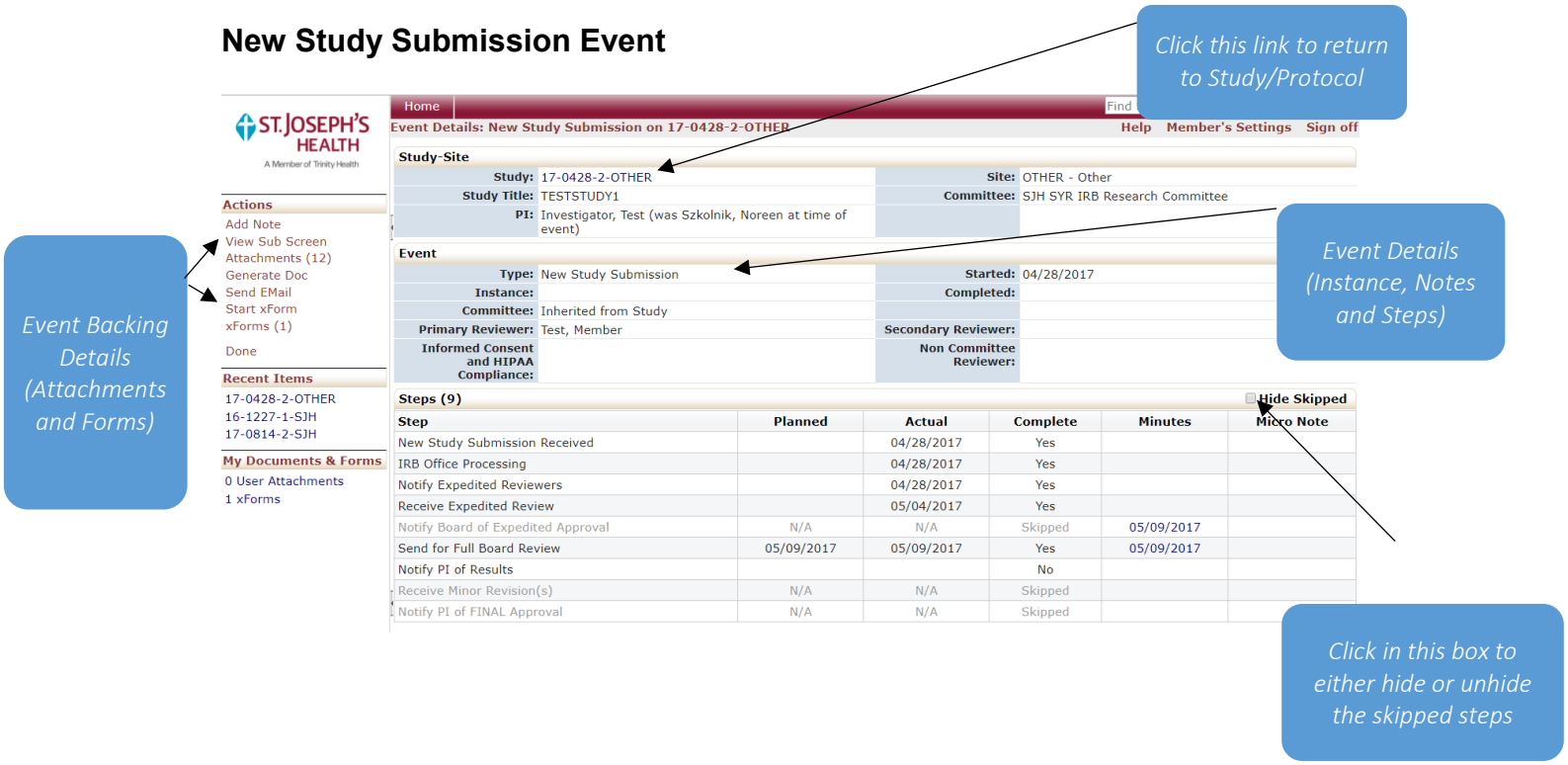
View a variety of documents that have been attached to the study. Displays the name of the document, the type of document, and when it was attached to the study.

Events in IRBManager

Any business process happening to a protocol in IRBManager is called an event. An event can be an Adverse Events, CIRB Facilitated Review for New Study, Continuing Review/ Final Closure, Emergency Use Device, Exempt Submission, Humanitarian Use Device, Modification, New Study Submission, and Protocol Deviation. By clicking on an event associated to your protocol you can view the status of the event as determined by the IRB.

Some examples are below.

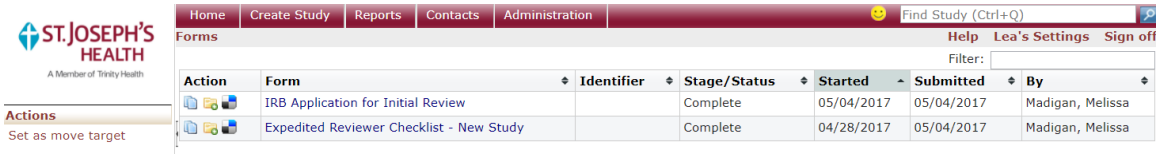
New Study Submission Event



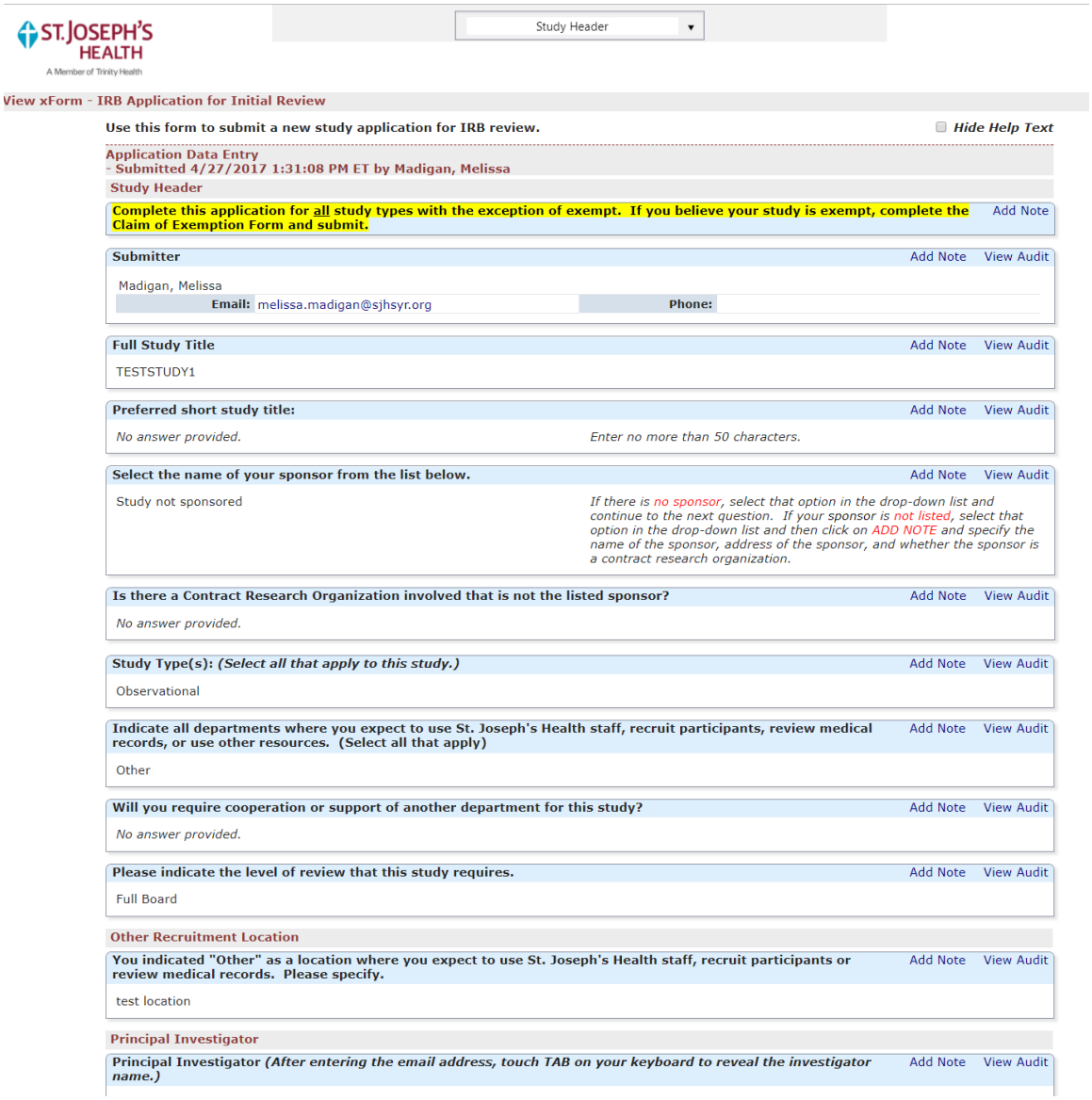
IRB Members can view the steps that are to be completed by the IRB as part of a New Study Submission event and view which steps are complete, not complete, skipped, and not applicable (N/A). You can also view the date each of these steps were planned and actually completed, the date of the meeting where the protocol will be acknowledged or approved
and any short notes added by administrators or staff.

When you click the **<Attachments>** link on the Event Details page, a different page will be displayed with a listing of both Attachments and Generated Documents.

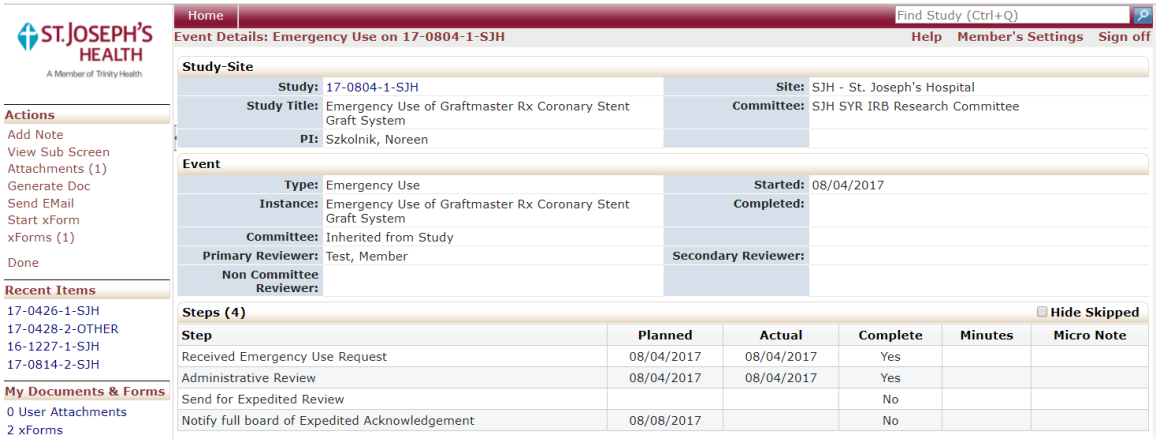
When you click on the **<xForms>** link on the Event Details page, you will find a listing of all xForms associated with that particular event.



An xForm is submitted by the investigative staff or an IRB Member. It will contain either information supporting the event, in the case of a continuing review, or the data which created the event. In this case the New Study Submission Form will hold all the details of a new study.



Emergency Use Event



ST. JOSEPH'S HEALTH
A Member of Trinity Health

Home | Find Study (Ctrl+Q)

Event Details: Emergency Use on 17-0804-1-SJH | Help | Member's Settings | Sign off

Actions
Add Note
View Sub Screen
Attachments (1)
Generate Doc
Send EMail
Start xForm
xForms (1)
Done

Recent Items
17-0426-1-SJH
17-0428-2-OTHER
16-1227-1-SJH
17-0814-2-SJH

My Documents & Forms
0 User Attachments
2 xForms

Study-Site

Study:	17-0804-1-SJH	**Site:**	SJH - St. Joseph's Hospital
Study Title:	Emergency Use of Graftmaster Rx Coronary Stent Graft System	**Committee:**	SJH SYR IRB Research Committee
PI:	Szkolnik, Noreen		

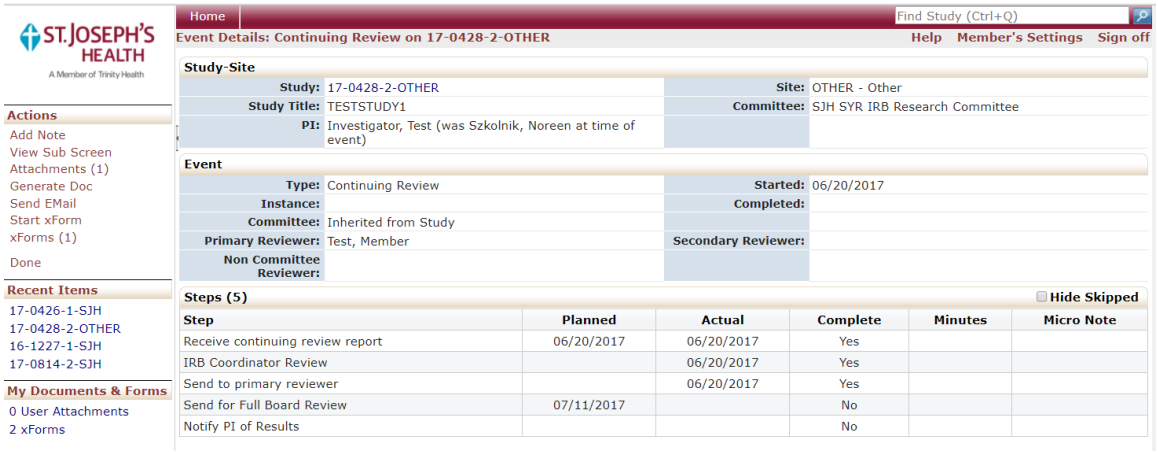
Event

Type:	Emergency Use	**Started:**	08/04/2017
Instance:	Emergency Use of Graftmaster Rx Coronary Stent Graft System	**Completed:**	
Committee:	Inherited from Study		
Primary Reviewer:	Test, Member	**Secondary Reviewer:**	
Non Committee Reviewer:			

Steps (4) Hide Skipped

Step	Planned	Actual	Complete	Minutes	Micro Note
Received Emergency Use Request	08/04/2017	08/04/2017	Yes		
Administrative Review	08/04/2017	08/04/2017	Yes		
Send for Expedited Review			No		
Notify full board of Expedited Acknowledgement	08/08/2017		No		

Continuing Review/Final Closure Event



ST. JOSEPH'S HEALTH
A Member of Trinity Health

Home | Find Study (Ctrl+Q)

Event Details: Continuing Review on 17-0428-2-OTHER | Help | Member's Settings | Sign off

Actions
Add Note
View Sub Screen
Attachments (1)
Generate Doc
Send EMail
Start xForm
xForms (1)
Done

Recent Items
17-0426-1-SJH
17-0428-2-OTHER
16-1227-1-SJH
17-0814-2-SJH

My Documents & Forms
0 User Attachments
2 xForms

Study-Site

Study:	17-0428-2-OTHER	**Site:**	OTHER - Other
Study Title:	TESTSTUDY1	**Committee:**	SJH SYR IRB Research Committee
PI:	Investigator, Test (was Szkolnik, Noreen at time of event)		

Event

Type:	Continuing Review	**Started:**	06/20/2017
Instance:		**Completed:**	
Committee:	Inherited from Study		
Primary Reviewer:	Test, Member	**Secondary Reviewer:**	
Non Committee Reviewer:			

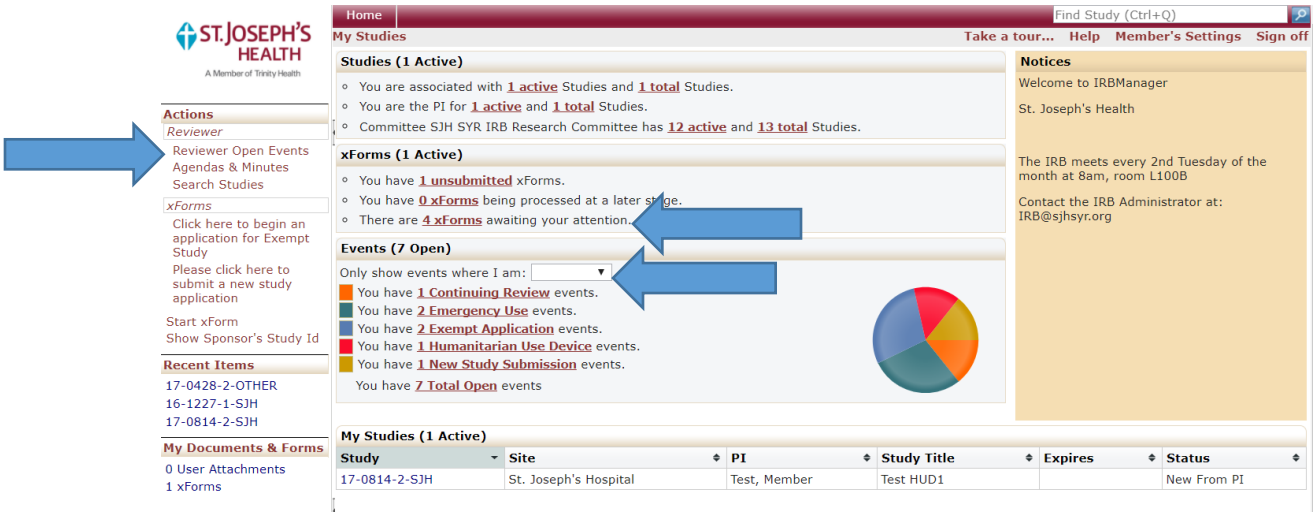
Steps (5) Hide Skipped

Step	Planned	Actual	Complete	Minutes	Micro Note
Receive continuing review report	06/20/2017	06/20/2017	Yes		
IRB Coordinator Review		06/20/2017	Yes		
Send to primary reviewer		06/20/2017	Yes		
Send for Full Board Review	07/11/2017		No		
Notify PI of Results			No		

Member Reviews

There are four ways to know you have an event to review:

1. Email sent automatically with a link to go directly to the form.
2. Clicking **<Reviewer Open Events>**
3. Under xForms heading where it states “There are # xForms awaiting your attention.”
4. Under Events heading after selecting “Reviewer” as the dropdown.



1. Email sent automatically with a link to go directly to the form.

The emails will provide a link that will take you directly to the form where you will be able to view all data provided by the submitter, the Principal Investigator signature, and the IRB office administrative review. By clicking <Next> you will either be taken to a series of review questions that you will then need to submit, or you will be provided with a link to a review form to be completed and submitted.

2. Clicking <Reviewer Open Events>

Clicking <Reviewer Open Events> will open a page displaying all open events where the user is listed as the reviewer. This will display all the business processes where the user is the expedited reviewer or studies that are still open where the reviewer is the full board reviewer.

3. Under xForms heading where it states “There are # xForms awaiting your attention.”

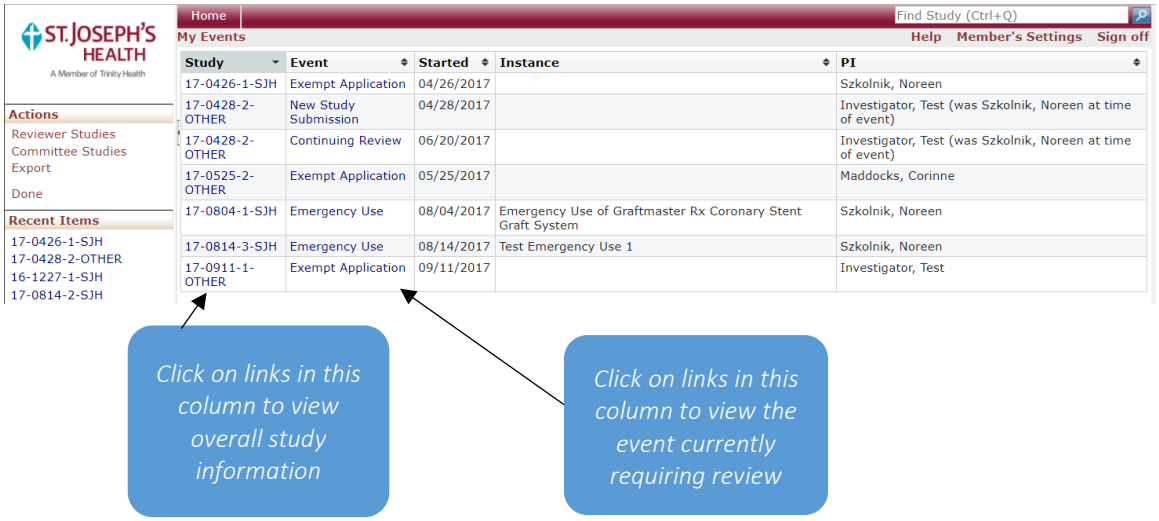
Clicking the link within “There are # xForms awaiting your attention” will produce a list of xForms that require some action on your part- possibly IRB reviews, but some could be requesting your signature as principal investigator.

4. Under Events heading after selecting “Reviewer” as the dropdown.

Using the “Reviewer” choice in the dropdown under **Events** will result in a list of the types of events for which you have been selected as a reviewer. Clicking any link produced under the Events heading will provide a list of the studies of that particular event type with you selected as a reviewer.

Reviewer Actions

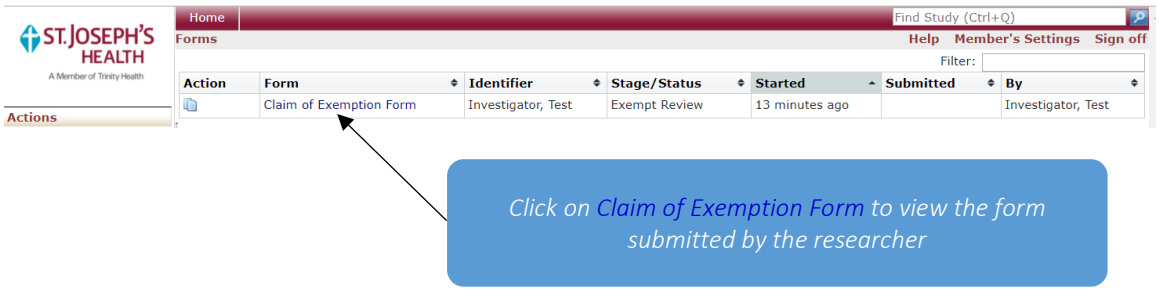
When you click on **<Reviewer Open Events>** you will see a screen as follows:



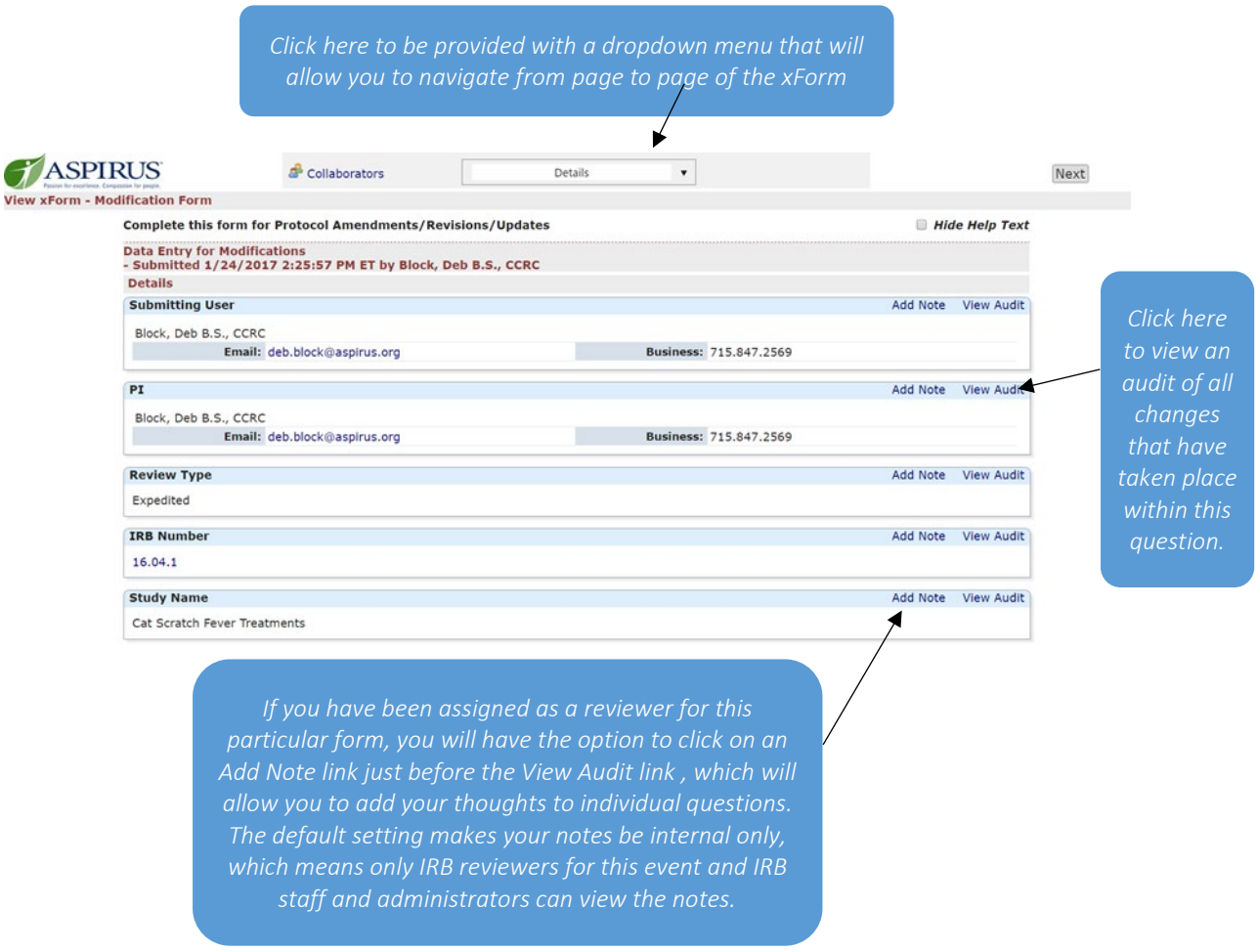
Once the IRB Member knows which protocol and event (or process) they want to view, they will click on event. In this example, the member would either click on one of the Exempt Application links, the New Study Submission, Continuing Review, or one of the Emergency Use. By clicking the top Exempt Application event in this example, the following screen is produced (only top portion shown):

To view the form associated with this event, you will click **<xForm (1)>.** This will be found under actions in the upper left of the screen.

Clicking on **<xForm (1)>** will provide a list of xForms associated with this particular Continuing Review/Final Closure event.

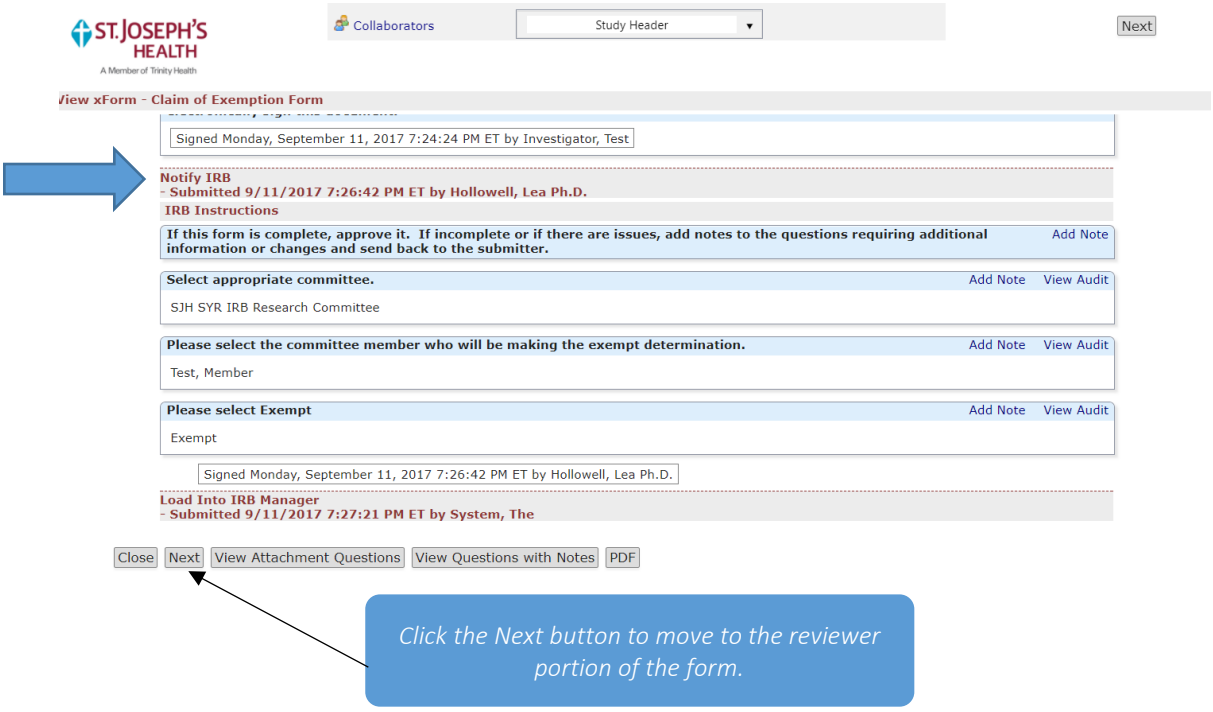


Click on the xForm name that you wish to view. Please make certain to scroll all the way to the bottom of the form, and click the "Next" button to view every page.



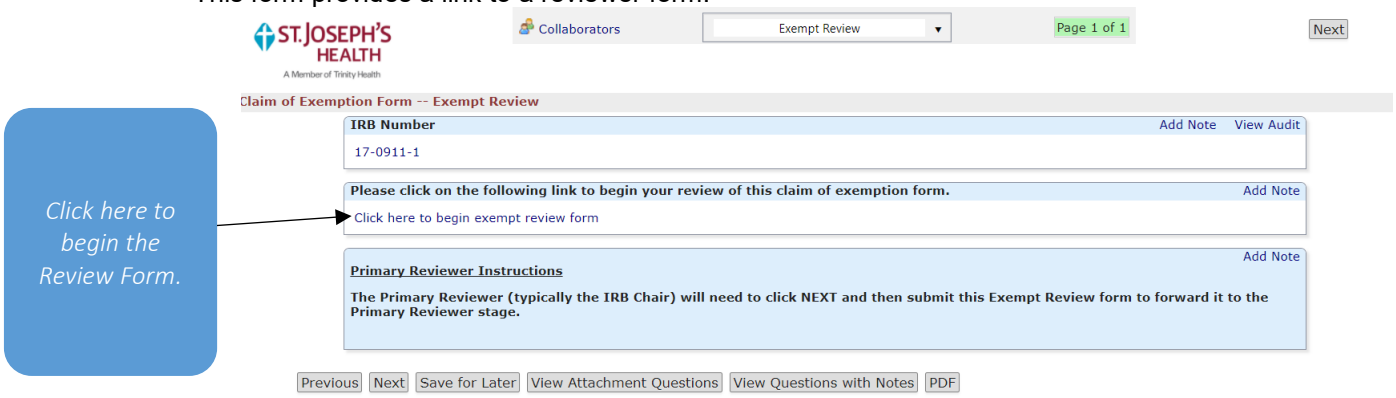
If you want to add reviewer notes to the xForm, click the Add Note link on the form. The default setting checks the “Internal Note Only” checkbox, which makes the note be internal and ONLY viewable by other IRB Members and the IRB Staff. The Investigative teams will not be able to view it, UNLESS you uncheck the “Internal Note Only” checkbox. You can also check the “Requires Changes” checkbox to indicate that the submitter needs to make changes to that particular question.

You will notice a section titled “Notify IRB” (or something similar) where your IRB office staff has answered some questions that to verify the study is ready for review and to move it forward into the review process.

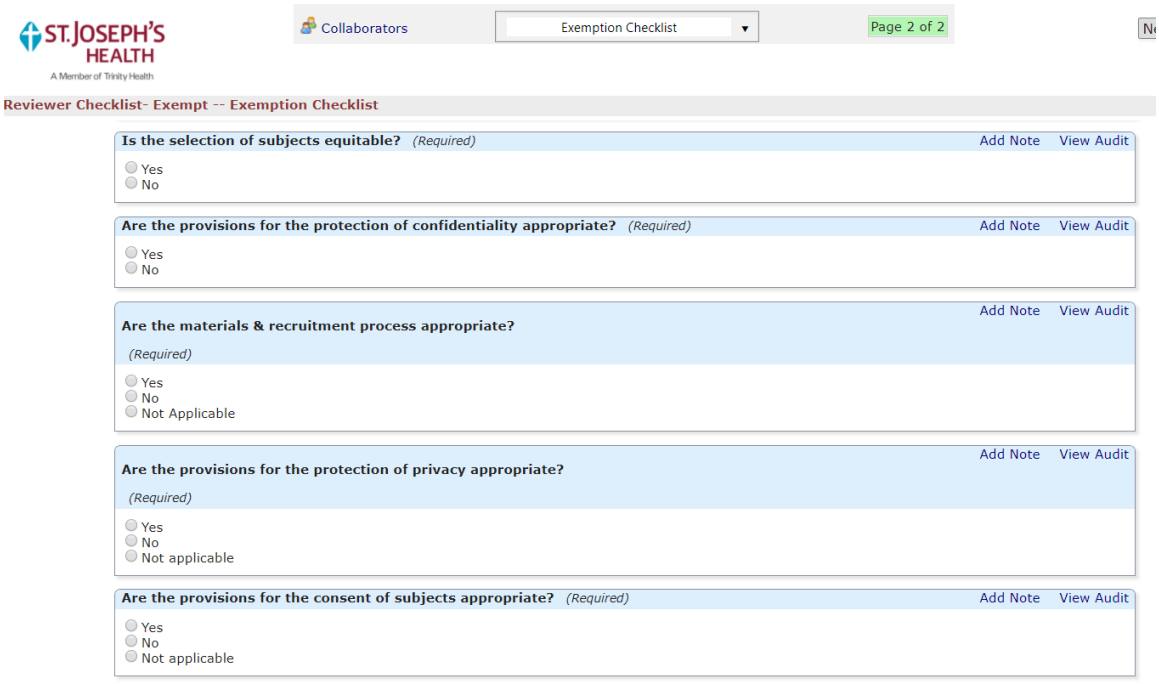


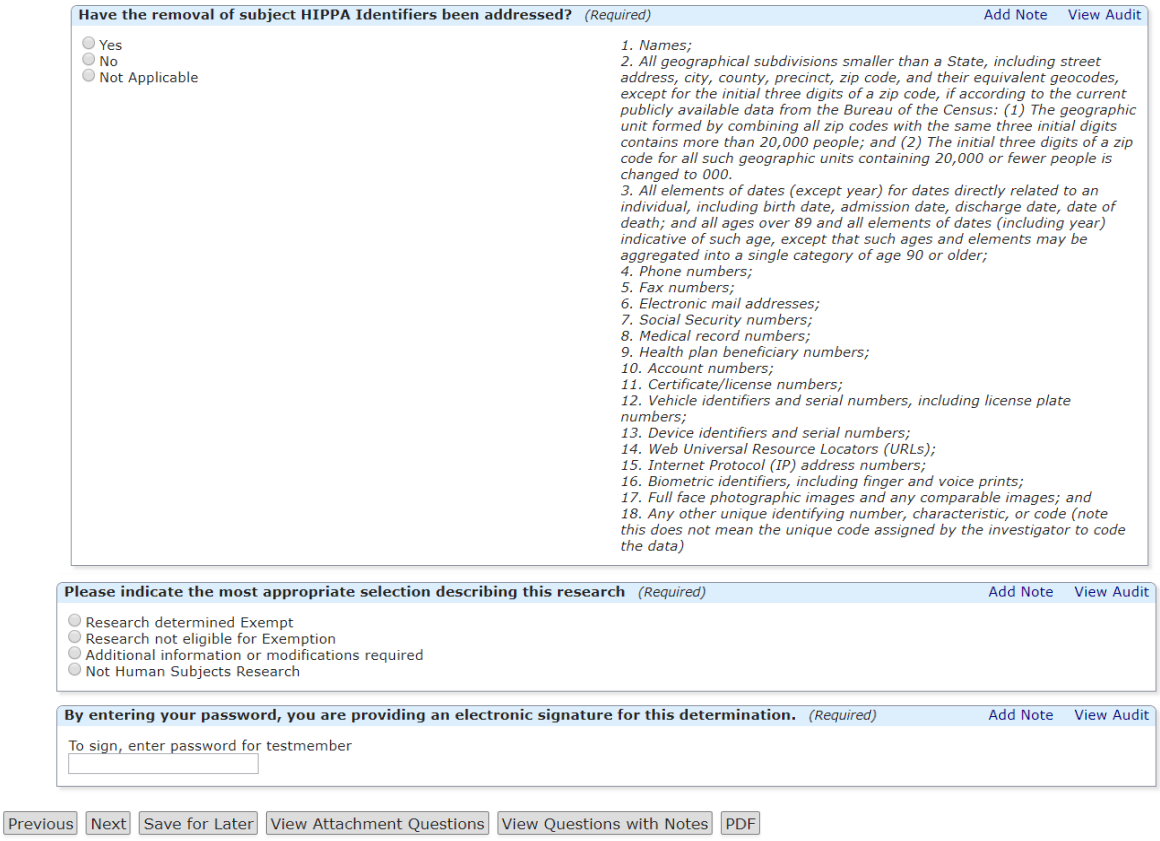
Finally, you’ll be asked to either answer a series of questions within the original form, which you will then submit, or you will be provided with a link to a separate reviewer form (stored within the event that only IRB members and administration can view) to give your thoughts on the study, which will vary depending on the event being reviewed and the type of review you have been asked to provide.

This form provides a link to a reviewer form:



Once in the review form, there are several review questions. The questions may be on multiple pages, requiring you to click “Next” several times to navigate between the pages. Alternately, you can use the dropdown menu at the top of the page to navigate between the pages of review questions. Once you have completed all questions, you will need to click “Next” one last time. This will take you to a page where you will need to click “Submit,” which will forward the xForm on to complete processing.

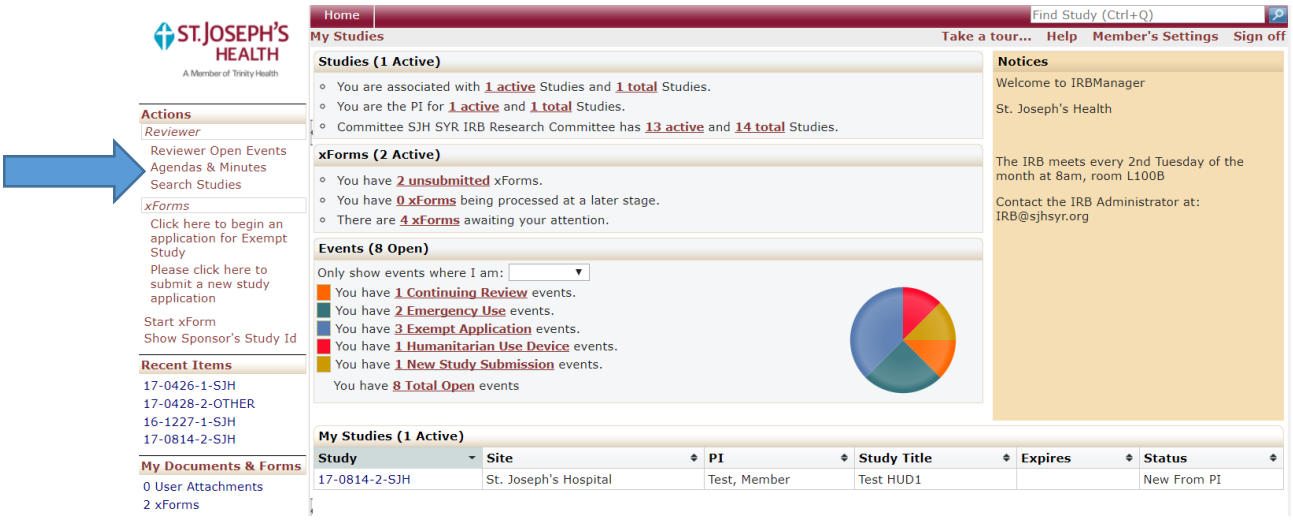




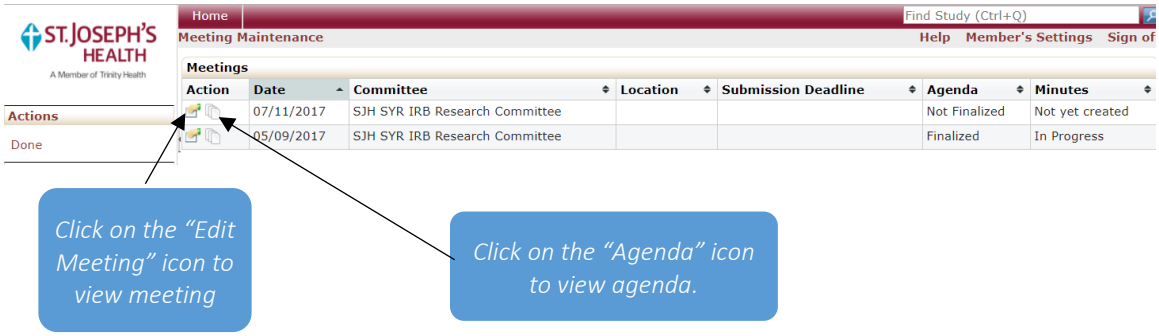
In some cases, the form will be reviewed by the primary reviewer, who will use all reviewers responses to make the final determination. In other cases, the form will be forwarded to complete the approval processing, or, when you have required changes, the xForm will be returned to the submitter and, once the changes have been completed, it will be returned to you for your final review.

Full Board Meetings

Clicking on **<Agendas & Minutes>** will take you to a list of meetings and allow you to view the Word Documents created by IRBManager for each one.



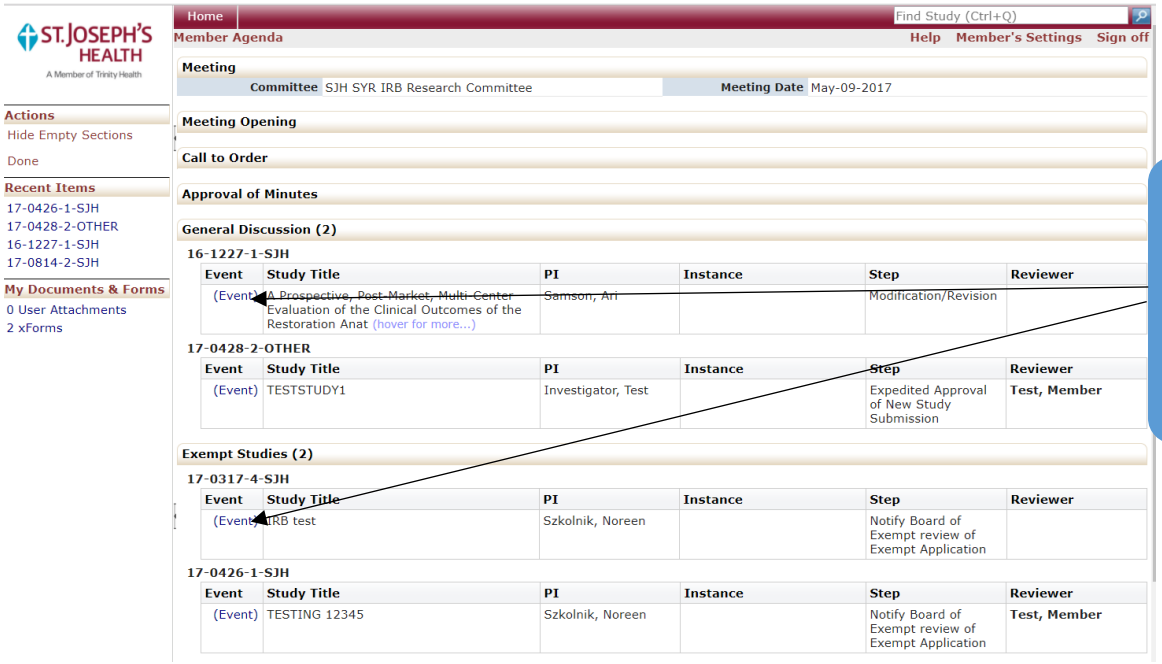
Once you click on **<Agenda & Minutes>**, you will find the following view. For meeting details, click the hand holding the piece of paper located next to the meeting date. For the agenda, click on the three sheets of paper. Once minutes have been created, they can be accessed by clicking a clock icon.



Meeting Details

Agenda

If you click on the agenda icon, which is the three pieces of paper, you'll see an online view of the agenda. Any studies that you are the reviewer for will have your name in bold on the right. You can either click on the study number to go directly to the study or click (Event) to go to the event that brought the study to the agenda.



Click on an (Event) to view event submission details.