

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/>

ST. JOSEPH'S HEALTH
A Member of Trinity Health

Login

User Name *

Password *

Client

Remember Client

[Forgot Password?](#)

- 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:

ST. JOSEPH'S HEALTH
A Member of Trinity Health

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

My Studies (1 Active)

- You are associated with **1 active** Studies and **1 total** Studies.
- You are the PI for **1 active** and **1 total** Studies.
- Committee SJH SYR IRB Research Committee has **12 active** and **13 total** Studies.

xForms (1 Active)

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

Events (6 Open)

Only show events where I am:

- You have **1 Continuing Review** events.
- You have **2 Emergency Use** events.
- You have **2 Exempt Application** events.
- You have **1 Humanitarian Use Device** events.

You have **6 Total Open** events

My Studies (1 Active)

Study	Site	PI	Study Title	Expires	Status
17-0814-2-SJH	St. Joseph's Hospital	Test, Member	Test HUD1		New From PI

Notices

Welcome to IRBManager
St. Joseph's Health

The IRB meets every 2nd Tuesday of the month at 8am, room L100B
Contact the IRB Administrator at: IRB@sjhsyr.org

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.

The screenshot shows the IRBManager home page with several callout boxes:

- Protocols assigned to the reviewer for review**: Points to the 'My Studies' section.
- Use to view the agenda and minutes for full board IRB meetings**: Points to the 'Agendas & Minutes' link in the left sidebar.
- Search for a protocol, (IRB study number, committee, Site, sponsor, Investigator, keyword)**: Points to the 'Search Studies' link in the left sidebar.
- Begin a new exempt application within IRBManager**: Points to the 'Start xForm' link in the left sidebar.
- Begin a new initial review application within IRBManager**: Points to the 'Start xForm' link in the left sidebar.
- Start a variety of xForms in IRBManager**: Points to the 'Start xForm' link in the left sidebar.
- Changes the formatting of the listing of "My Studies" from using the local IRB Protocol Number to using the Sponsor's Study ID (although many studies will not have Sponsor's Study IDs)**: Points to the 'Show Sponsor's Study Id' link in the left sidebar.

The main content area includes:

- Studies (1 Active)**: Summary of active and total studies.
- xForms (1 Active)**: Summary of submitted and pending xForms.
- Events (6 Open)**: Summary of event types (Continuing Review, Emergency Use, Exempt Application, Humanitarian Use Device).
- My Studies (1 Active)**: Table listing active studies.

Study	Site	PI	Study Title	Expires	Status
17-0814-2-SJH	St. Joseph's Hospital	Test, Member	Test HUD1		New From PI

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.

Studies (1 Active)

- You are associated with **1 active** Studies and **1 total** Studies.
- You are the PI for **1 active** and **1 total** Studies.
- Committee SJH SYR IRB Research Committee has **12 active** and **13 total** Studies.

- **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.

xForms (3 Active)





- You have **1 unsubmitted** xForms.
- You have **2 xForms** being processed at a later stage.
- There are **1 xForms** awaiting 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.

Events (6 Open)

Only show events where I am:

-  You have **1 Continuing Review** events.
-  You have **2 Emergency Use** events.
-  You have **2 Exempt Application** events.
-  You have **1 Humanitarian Use Device** events.

You have **6 Total Open** events



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.)

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.

Click this link to view event details

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

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

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

Event Details: New Study Submission on 17-0428-2-OTHER

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: New Study Submission	Started: 04/28/2017
Instance:	Completed:
Committee: Inherited from Study	
Primary Reviewer: Test, Member	Secondary Reviewer:
Informed Consent and HIPAA Compliance:	Non Committee Reviewer:

Steps (9) Hide Skipped

Step	Planned	Actual	Complete	Minutes	Micro Note
New Study Submission Received		04/28/2017	Yes		
IRB Office Processing		04/28/2017	Yes		
Notify Expedited Reviewers		04/28/2017	Yes		
Receive Expedited Review		05/04/2017	Yes		
Notify Board of Expedited Approval	N/A	N/A	Skipped	05/09/2017	
Send for Full Board Review	05/09/2017	05/09/2017	Yes	05/09/2017	
Notify PI of Results			No		
Receive Minor Revision(s)	N/A	N/A	Skipped		
Notify PI of FINAL Approval	N/A	N/A	Skipped		

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.

Associated Documents

Attachments on Event New Study Submission Started 04/28/2017 on 17-0428-2-OTHER

Attachments (4)

Action	Name	Type	Date	By	Int
	CV test	Principal Investigator CV	04/28/2017	melissa.madigan@sjhsyr.org	No
	test tool	Data Collection Tool	04/28/2017	melissa.madigan@sjhsyr.org	No
	test consent	Informed Consent Form	04/28/2017	melissa.madigan@sjhsyr.org	No
	test protocol	Protocol	04/28/2017	melissa.madigan@sjhsyr.org	No

Generated Documents (8)

Action	Name	Generated	By	Int
	NEW Full Board w_ICF.docx	06/22/2017	melissa.madigan@sjhsyr.org	No

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.

Action	Form	Identifier	Stage/Status	Started	Submitted	By
	IRB Application for Initial Review		Complete	05/04/2017	05/04/2017	Madigan, Melissa
	Expedited Reviewer Checklist - New Study		Complete	04/28/2017	05/04/2017	Madigan, Melissa

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.

ST. JOSEPH'S HEALTH
A Member of Trinity Health

Study Header

View xForm - IRB Application for Initial Review

Use this form to submit a new study application for IRB review. [Hide Help Text](#)

Application Data Entry
Submitted 4/27/2017 1:31:08 PM ET by Madigan, Melissa

Study Header

Complete this application for all study types with the exception of exempt. If you believe your study is exempt, complete the Claim of Exemption Form and submit. [Add Note](#)

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

Madigan, Melissa
Email: melissa.madigan@sjhsyr.org Phone:

Full Study Title [Add Note](#) [View Audit](#)

TESTSTUDY1

Preferred short study title: [Add Note](#) [View Audit](#)

No answer provided. Enter no more than 50 characters.

Select the name of your sponsor from the list below. [Add Note](#) [View Audit](#)

Study not sponsored *If there is no sponsor, select that option in the drop-down list and continue to the next question. If your sponsor is not listed, select that option in the drop-down list and then click on ADD NOTE and specify the name of the sponsor, address of the sponsor, and whether the sponsor is a contract research organization.*

Is there a Contract Research Organization involved that is not the listed sponsor? [Add Note](#) [View Audit](#)

No answer provided.

Study Type(s): (Select all that apply to this study.) [Add Note](#) [View Audit](#)

Observational

Indicate all departments where you expect to use St. Joseph's Health staff, recruit participants, review medical records, or use other resources. (Select all that apply) [Add Note](#) [View Audit](#)

Other

Will you require cooperation or support of another department for this study? [Add Note](#) [View Audit](#)

No answer provided.

Please indicate the level of review that this study requires. [Add Note](#) [View Audit](#)

Full Board

Other Recruitment Location

You indicated "Other" as a location where you expect to use St. Joseph's Health staff, recruit participants or review medical records. Please specify. [Add Note](#) [View Audit](#)

test location

Principal Investigator

Principal Investigator (After entering the email address, touch TAB on your keyboard to reveal the investigator name.) [Add Note](#) [View Audit](#)

Emergency Use Event



[Home](#)

Event Details: Emergency Use on 17-0804-1-SJH

[Help](#)
[Member's Settings](#)
[Sign off](#)

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



[Home](#)

Event Details: Continuing Review on 17-0428-2-OTHER

[Help](#)
[Member's Settings](#)
[Sign off](#)

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.

The screenshot shows the IRB Manager interface for St. Joseph's Health. The sidebar on the left contains navigation options: 'Reviewer Open Events', 'Agendas & Minutes', 'Search Studies', 'xForms', and 'My Documents & Forms'. The main content area is divided into several sections: 'My Studies (1 Active)' with a list of study details, 'xForms (1 Active)' showing the number of submitted and awaiting forms, and 'Events (7 Open)' with a breakdown of event types (Continuing Review, Emergency Use, Exempt Application, Humanitarian Use Device, New Study Submission) and a total count. A pie chart is also present in the Events section. A search bar and navigation links are at the top.

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:

Study	Event	Started	Instance	PI
17-0426-1-SJH	Exempt Application	04/26/2017		Szkolnik, Noreen
17-0428-2-OTHER	New Study Submission	04/28/2017		Investigator, Test (was Szkolnik, Noreen at time of event)
17-0428-2-OTHER	Continuing Review	06/20/2017		Investigator, Test (was Szkolnik, Noreen at time of event)
17-0525-2-OTHER	Exempt Application	05/25/2017		Maddocks, Corinne
17-0804-1-SJH	Emergency Use	08/04/2017	Emergency Use of Graftmaster Rx Coronary Stent Graft System	Szkolnik, Noreen
17-0814-3-SJH	Emergency Use	08/14/2017	Test Emergency Use 1	Szkolnik, Noreen
17-0911-1-OTHER	Exempt Application	09/11/2017		Investigator, Test

Click on links in this column to view overall study information

Click on links in this column to view the event currently requiring review

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):

Event Details: Exempt Application on 17-0911-1-OTHER

Study-Site	
Study: 17-0911-1-OTHER	Site: OTHER - Other
Study Title: Do pink bunny decorations result in faster recovery times in pediatric patients?	Committee: SJH SYR IRB Research Committee
PI: Investigator, Test	

Event	
Type: Exempt Application	Started: 09/11/2017
Instance:	Completed:
Committee: Inherited from Study	
Primary Reviewer: Test, Member	Secondary Reviewer:
Exemption Categories:	Non Committee Reviewer:

Actions: Add Note, View Sub Screen, Attachments (4), Generate Doc, Send EMail, Start xForm, xForms (1), Done

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.

Action	Form	Identifier	Stage/Status	Started	Submitted	By
	Claim of Exemption Form	Investigator, Test	Exempt Review	13 minutes ago		Investigator, Test

Click on *Claim of Exemption Form* to view the form submitted by the researcher

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.

Click here to be provided with a dropdown menu that will allow you to navigate from page to page of the xForm

ASPIRUS
 Collaborators [Details] [Next]

View xForm - Modification Form

Complete this form for Protocol Amendments/Revisions/Updates Hide Help Text

Data Entry for Modifications
 - Submitted 1/24/2017 2:25:57 PM ET by Block, Deb B.S., CCRC

Details

Submitting User Add Note View Audit
 Block, Deb B.S., CCRC
 Email: deb.block@aspirus.org Business: 715.847.2569

PI Add Note View Audit
 Block, Deb B.S., CCRC
 Email: deb.block@aspirus.org Business: 715.847.2569

Review Type Add Note View Audit
 Expedited

IRB Number Add Note View Audit
 16.04.1

Study Name Add Note View Audit
 Cat Scratch Fever Treatments

Click here to view an audit of all changes that have taken place within this question.

If you have been assigned as a reviewer for this particular form, you will have the option to click on an Add Note link just before the View Audit link, which will allow you to add your thoughts to individual questions. The default setting makes your notes be internal only, which means only IRB reviewers for this event and IRB staff and administrators can view the notes.

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:

ST. JOSEPH'S HEALTH
A Member of Trinity Health

Collaborators Exempt Review Page 1 of 1 Next

Claim of Exemption Form -- Exempt Review

IRB Number Add Note View Audit
17-0911-1

Please click on the following link to begin your review of this claim of exemption form. Add Note
Click here to begin exempt review form

Primary Reviewer Instructions Add Note
The Primary Reviewer (typically the IRB Chair) will need to click NEXT and then submit this Exempt Review form to forward it to the Primary Reviewer stage.

Previous Next Save for Later View Attachment Questions View Questions with Notes PDF

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.

ST. JOSEPH'S HEALTH
A Member of Trinity Health

Collaborators Exemption Checklist Page 2 of 2 Next

Reviewer Checklist- Exempt -- Exemption Checklist

Is the selection of subjects equitable? (Required) Add Note View Audit
 Yes
 No

Are the provisions for the protection of confidentiality appropriate? (Required) Add Note View Audit
 Yes
 No

Are the materials & recruitment process appropriate? (Required) Add Note View Audit
 Yes
 No
 Not Applicable

Are the provisions for the protection of privacy appropriate? (Required) Add Note View Audit
 Yes
 No
 Not applicable

Are the provisions for the consent of subjects appropriate? (Required) Add Note View Audit
 Yes
 No
 Not applicable

Have the removal of subject HIPPA Identifiers been addressed? (Required) [Add Note](#) [View Audit](#)

- Yes
- No
- Not Applicable

1. Names;
2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
4. Phone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social Security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)

Please indicate the most appropriate selection describing this research (Required) [Add Note](#) [View Audit](#)

- Research determined Exempt
- Research not eligible for Exemption
- Additional information or modifications required
- Not Human Subjects Research

By entering your password, you are providing an electronic signature for this determination. (Required) [Add Note](#) [View Audit](#)

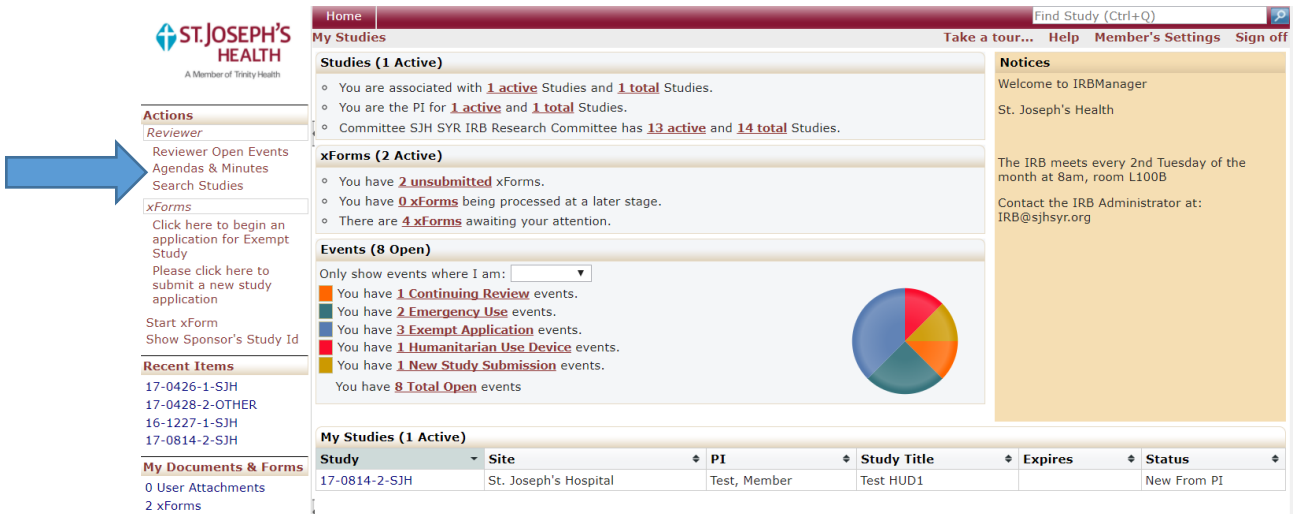
To sign, enter password for testmember

[Previous](#) [Next](#) [Save for Later](#) [View Attachment Questions](#) [View Questions with Notes](#) [PDF](#)

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.

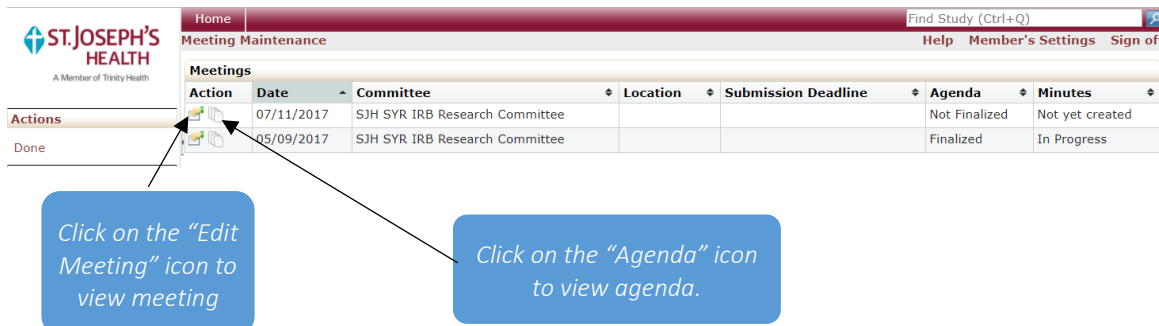
Full Board Meetings

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.



The screenshot shows the IRBManager dashboard for St. Joseph's Health. A blue arrow points to the 'Agendas & Minutes' link in the left sidebar menu. The main content area displays 'My Studies (1 Active)', 'xForms (2 Active)', and 'Events (8 Open)'. A table at the bottom lists the active study: 17-0814-2-SJH at St. Joseph's Hospital, PI: Test, Member, Study Title: Test HUD1, Expires: , Status: New From PI.

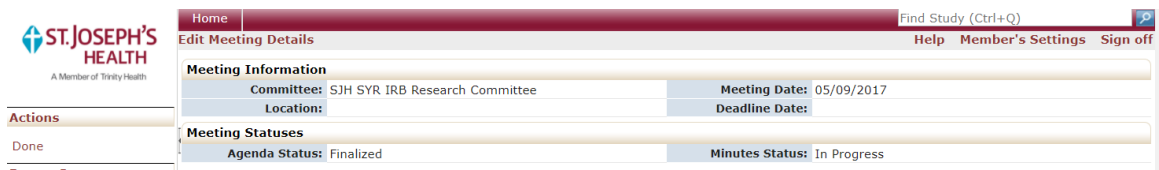
Once you click on **<Agenda & Minutes>**, you will find the following view. For meeting details, click the hand holding the piece of paper located next to the meeting date. For the agenda, click on the three sheets of paper. Once minutes have been created, they can be accessed by clicking a clock icon.



The screenshot shows the 'Meeting Maintenance' page with a table of meetings. Two callout boxes provide instructions: one pointing to the hand icon for 'Edit Meeting' and another pointing to the three sheets icon for 'Agenda'.

Action	Date	Committee	Location	Submission Deadline	Agenda	Minutes
	07/11/2017	SJH SYR IRB Research Committee			Not Finalized	Not yet created
	05/09/2017	SJH SYR IRB Research Committee			Finalized	In Progress

Meeting Details




The screenshot shows the 'Edit Meeting Details' page. It displays the following information:

- Meeting Information:** Committee: SJH SYR IRB Research Committee, Meeting Date: 05/09/2017, Location: , Deadline Date:
- Meeting Statuses:** Agenda Status: Finalized, Minutes Status: In Progress

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.



ST. JOSEPH'S HEALTH
A Member of Trinity Health

Home Find Study (Ctrl+Q)

Member Agenda

Meeting

Committee: SJH SYR IRB Research Committee Meeting Date: May-09-2017

Meeting Opening

Call to Order

Approval of Minutes

General Discussion (2)

16-1227-1-SJH

Event	Study Title	PI	Instance	Step	Reviewer
(Event)	A Prospective, Post-Market, Multi-Center Evaluation of the Clinical Outcomes of the Restoration Anat (hover for more...)	Samson, Ari		Modification/Revision	

17-0428-2-OTHER

Event	Study Title	PI	Instance	Step	Reviewer
(Event)	TESTSTUDY1	Investigator, Test		Expedited Approval of New Study Submission	Test, Member

Exempt Studies (2)

17-0317-4-SJH

Event	Study Title	PI	Instance	Step	Reviewer
(Event)	IRB test	Szkolnik, Noreen		Notify Board of Exempt review of Exempt Application	

17-0426-1-SJH

Event	Study Title	PI	Instance	Step	Reviewer
(Event)	TESTING 12345	Szkolnik, Noreen		Notify Board of Exempt review of Exempt Application	Test, Member

Help Member's Settings Sign off

Click on an [\(Event\)](#) to view event submission details.