Trinity Health

IRBManager

Handbook for Researchers

Link: https://mercyhealth.my.irbmanager.com

Updated 08/22/2023

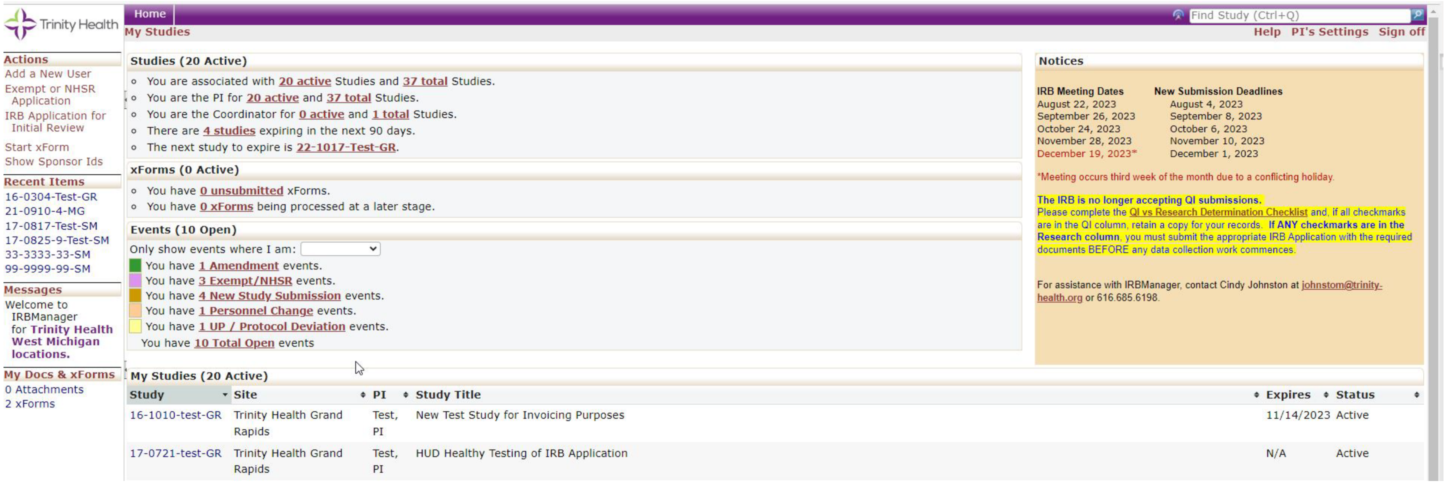
Contents

Logging into IRBManager

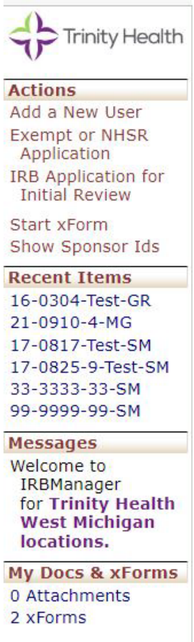
To log into IRBManager, enter the following link in your browser:
https://mercyhealth.my.irbmanager.com

Enter the *username* and *password* you were provided. Enter the Client name as **MercyHealth**, if not already displayed.

Upon logging in, you will see your dashboard.



Dashboard At-A-Glance



The left sidebar contains 4 separate sections.

Actions is where you can access xForms (electronic submission forms) for *NEW* submissions.

Recent Items allows quick access to anything you've recently viewed in IRBManager.

Messages welcomes you to IRBManager.

My Docs & xForms displays xForms and Attachments.

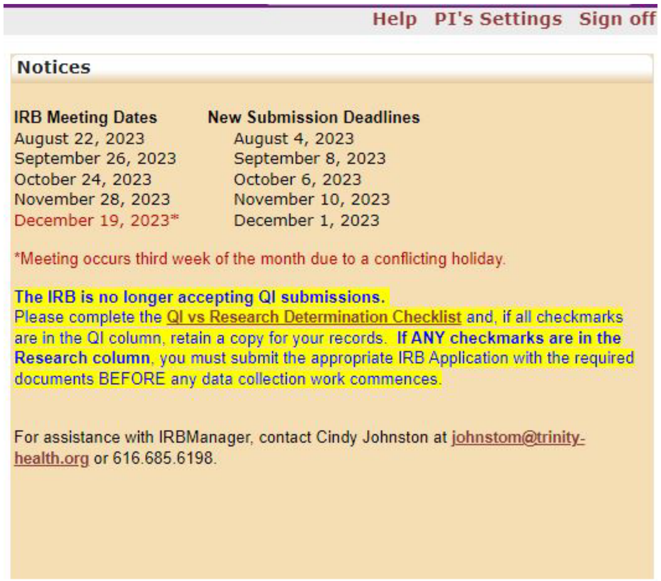
The center of your dashboard also contains 4 sections.

Studies displays the number of studies you are associated with, your role, and the next study due to expire.

xForms will display the number of unsubmitted xForms, those being processed at a later stage, and those **awaiting your attention**.

Events specifies the number and type of open study events.

My Studies lists all studies you are associated with, the PI, the expiry date, and the study status. **Click on the study number to open a study.**



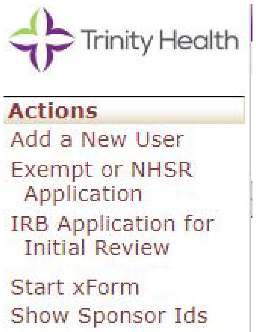
Notices is where the IRB Administrator can post information that may be of help to research staff, including meeting and submission deadline dates, special notices, and contact information.

Changing Your Password and more

To change your password or contact information (i.e., email address), click on your **settings** at the top right side of your landing page.

It is important to keep your contact information current, especially your email address, as all communication generated in IRBManager is sent via email.

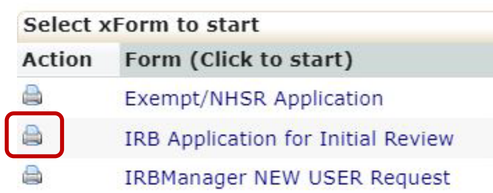
Creating a New Study Submission



To submit a new application for review, click on the form name, if listed, on the left sidebar of your dashboard or select *Start xForm* and make your selection from the list of the available xForms.

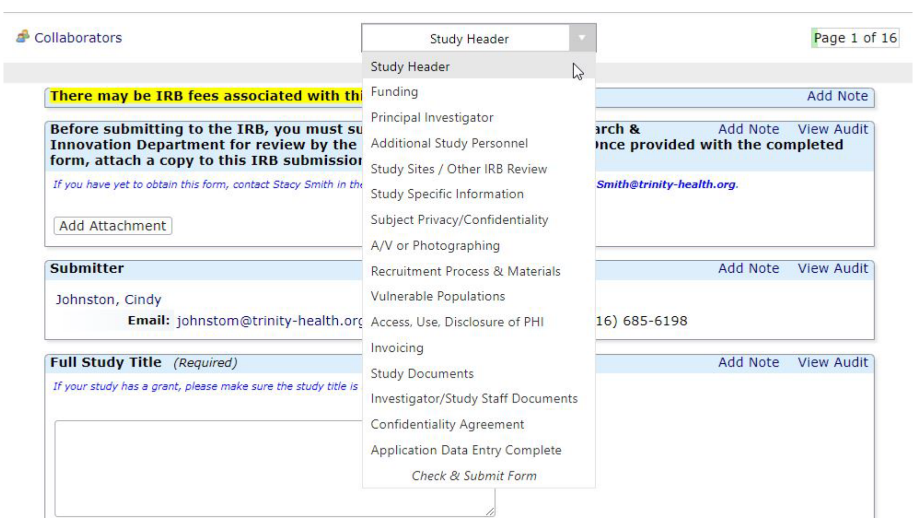
Previewing a Form

To preview a form, click on the printer icon next to the form name. Please note that all questions may not be applicable to your study.

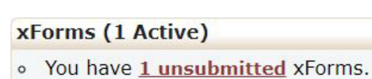


Jumping Between Pages in a Form

The submission forms are built so that you cannot move forward to the next page until all questions on the current page are answered. However, you do have the ability to jump between pages of any form by clicking on the down arrow next to the title of the page you are on and selecting another page to jump to. You can select *Save for Later* at the bottom of any page and return to the form later to resume completion.

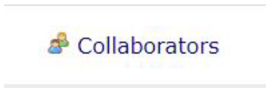


You will find your unsubmitted form on your dashboard.

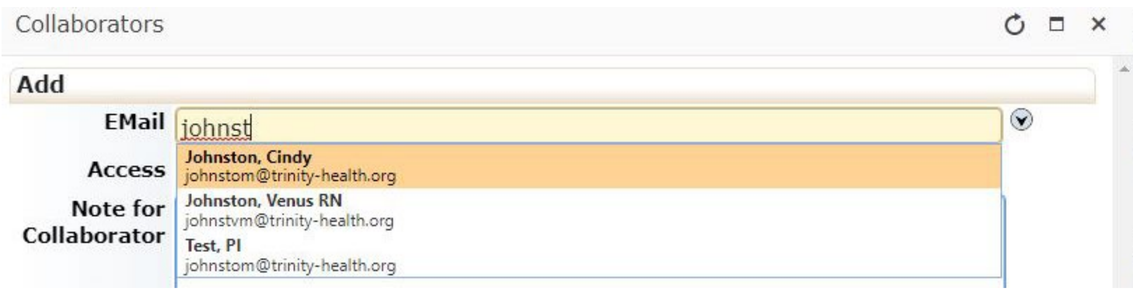


Adding Collaborators to a Submission Form

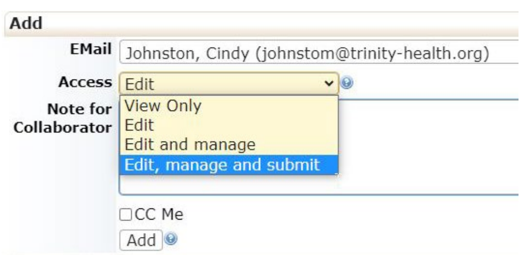
A collaborator can be added to *any form*. If you initiate a form and want to allow another individual access to review, edit, and/or submit the form, simply click on the Collaborators link at the top of any page of your form.



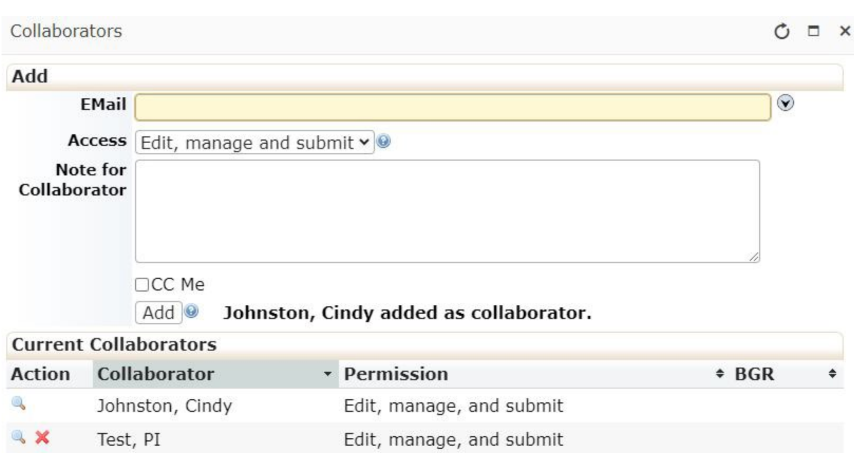
A new window will open. As you begin to enter the email address, the name of the individual should appear. Click on the name of the individual to add as a collaborator.



Next, select the type of access you would like to grant that individual. Add any specific notes for the collaborator if applicable, and click on the **Add** button. An email will be sent to the individual notifying them they have been added as a collaborator to your form.



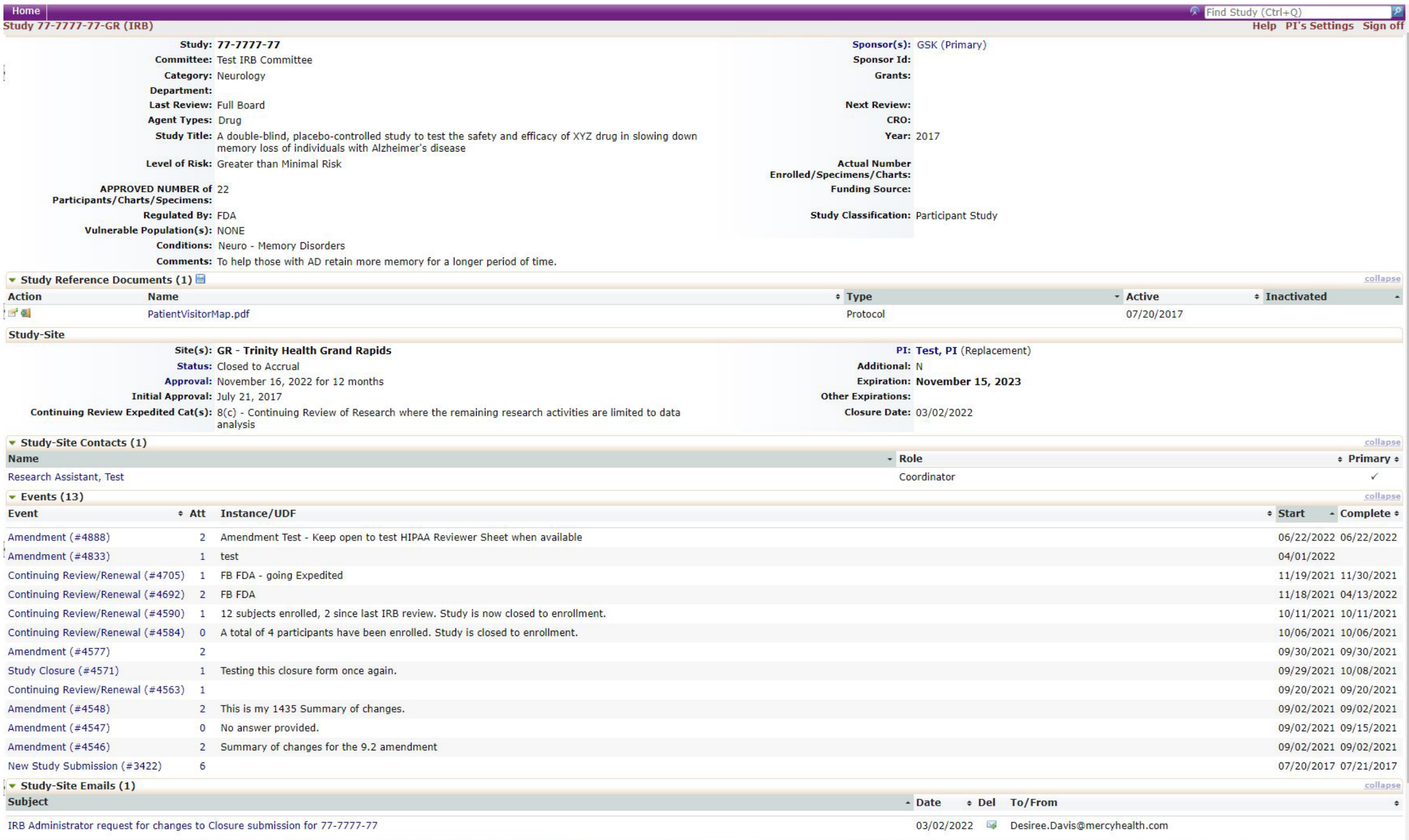
You will see the individual has been added to the form and their level of access. The list of current collaborators is also updated.



NOTE: The author of the form can also REMOVE any collaborator by simply clicking on the red **X** next to the individual's name.

Study Home Page At-A-Glance

To view a specific study, click on the study number under "My Studies" on your dashboard.


Home | Find Study (Ctrl+Q)

Study 77-7777-77-GR (IRB) | Help | PI's Settings | Sign off

Study:	77-7777-77	**Sponsor(s):**	GSK (Primary)
Committee:	Test IRB Committee	**Sponsor Id:**	
Category:	Neurology	**Grants:**	
Department:			
Last Review:	Full Board	**Next Review:**	
Agent Types:	Drug	**CRO:**	
Study Title:	A double-blind, placebo-controlled study to test the safety and efficacy of XYZ drug in slowing down memory loss of individuals with Alzheimer's disease	**Year:**	2017
Level of Risk:	Greater than Minimal Risk	**Actual Number Enrolled/Specimens/Charts:**	
APPROVED NUMBER of Participants/Charts/Specimens:	22	**Funding Source:**	
Regulated By:	FDA	**Study Classification:**	Participant Study
Vulnerable Population(s):	NONE		
Conditions:	Neuro - Memory Disorders		
Comments:	To help those with AD retain more memory for a longer period of time.		

Study Reference Documents (1) collapse

Action	Name	Type	Active	Inactivated
	PatientVisitorMap.pdf	Protocol	07/20/2017	

Study-Site

Site(s):	GR - Trinity Health Grand Rapids	**PI:**	Test, PI (Replacement)
Status:	Closed to Accrual	**Additional:**	N
Approval:	November 16, 2022 for 12 months	**Expiration:**	November 15, 2023
Initial Approval:	July 21, 2017	**Other Expirations:**	
Continuing Review Expedited Cat(s):	8(c) - Continuing Review of Research where the remaining research activities are limited to data analysis	**Closure Date:**	03/02/2022

Study-Site Contacts (1) collapse

Name	Role	Primary
Research Assistant, Test	Coordinator	✓

Events (13) collapse

Event	Att	Instance/UDF	Start	Complete
Amendment (#4888)	2	Amendment Test - Keep open to test HIPAA Reviewer Sheet when available	06/22/2022	06/22/2022
Amendment (#4833)	1	test	04/01/2022	
Continuing Review/Renewal (#4705)	1	FB FDA - going Expedited	11/19/2021	11/30/2021
Continuing Review/Renewal (#4692)	2	FB FDA	11/18/2021	04/13/2022
Continuing Review/Renewal (#4590)	1	12 subjects enrolled, 2 since last IRB review. Study is now closed to enrollment.	10/11/2021	10/11/2021
Continuing Review/Renewal (#4584)	0	A total of 4 participants have been enrolled. Study is closed to enrollment.	10/06/2021	10/06/2021
Amendment (#4577)	2		09/30/2021	09/30/2021
Study Closure (#4571)	1	Testing this closure form once again.	09/29/2021	10/08/2021
Continuing Review/Renewal (#4563)	1		09/20/2021	09/20/2021
Amendment (#4548)	2	This is my 1435 Summary of changes.	09/02/2021	09/02/2021
Amendment (#4547)	0	No answer provided.	09/02/2021	09/15/2021
Amendment (#4546)	2	Summary of changes for the 9.2 amendment	09/02/2021	09/02/2021
New Study Submission (#3422)	6		07/20/2017	07/21/2017

Study-Site Emails (1) collapse

Subject	Date	Del	To/From
IRB Administrator request for changes to Closure submission for 77-7777-77	03/02/2022		Desiree.Davis@mercyhealth.com

The top section is the **Study** section containing basic study information including the study title, assigned study #, name of the reviewing IRB, sponsor, type of review, level of risk and more.

Study Reference Documents will list the current approved protocol.

The **Study-Site** section primarily reflects the study site, study status, approval dates and name of the PI.

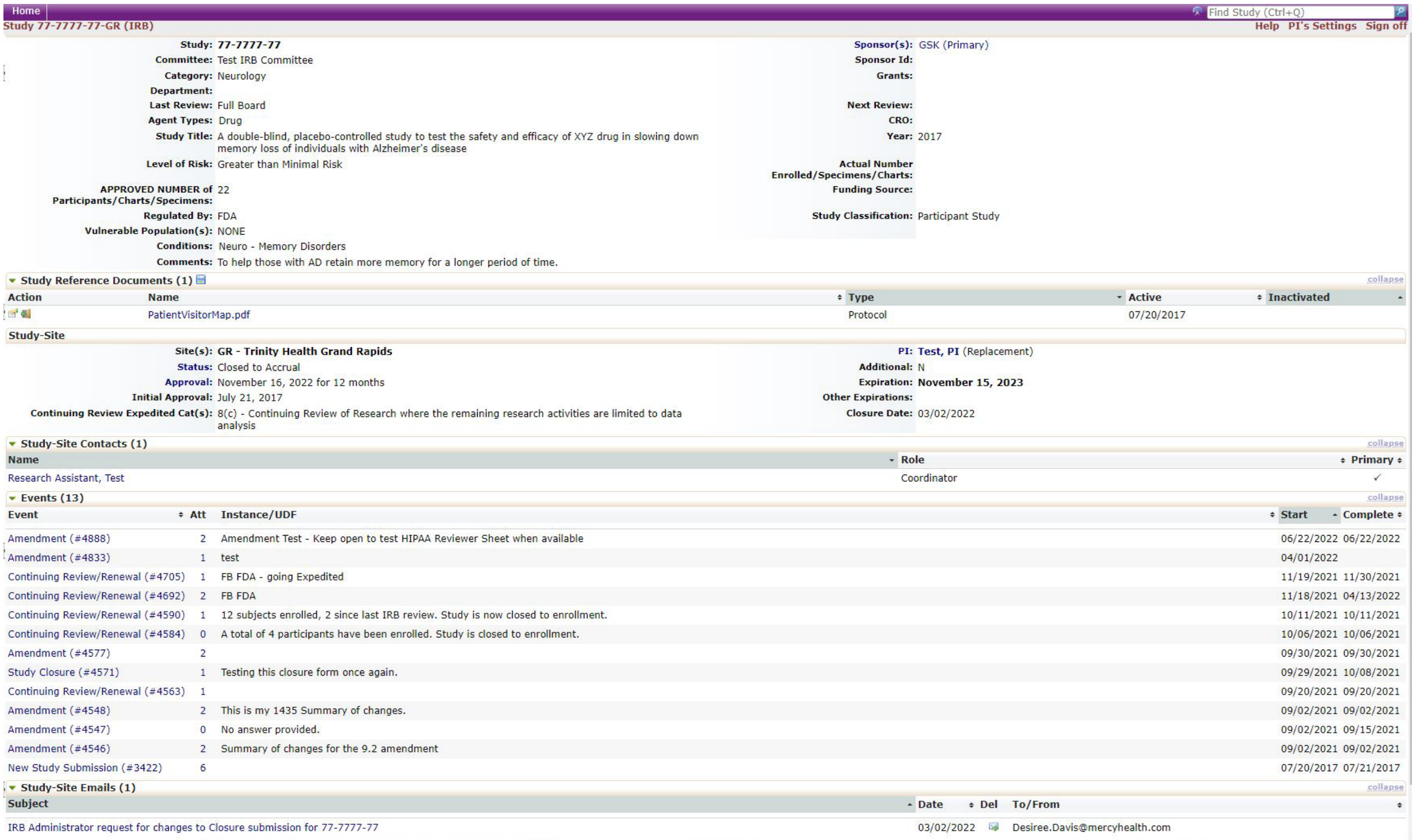
The **Study-Site Contacts** section lists all additional research study staff associated with the study.

The **Events** section lists every event submitted and reviewed by the IRB. The most recent submission is listed at the top with all other events listed in reverse chronological order. To the right of the event column is "**ATT**" where you will find all attachments associated with that specific event.

The **Study-Site Emails** section contains emails generated in IRBManager specific to the study.

Submitting Forms on Active Studies

To submit an amendment, continuing review report, unanticipated problem, item of information, etc. for an active study, you must be in that specific study, so the system knows which study to associate your request with. To open an active study, click on the study number under "**My Studies**" on your dashboard.



Once the study is open, select *Start xForm* under **"Actions"** on the left sidebar**,** and select the appropriate form from the list of available options.

Electronic Signatures

When a submitter, who is not the PI, submits a form, the PI will receive an email notification that a form was submitted and requires their electronic signature. The PI can go directly to the form by clicking on the link contained in the email (example below). They may also open the form by clicking on "1 xForms awaiting your attention" displayed on their dashboard.

> Dear PI Test,
>
> An Amendment request for 17-0721-test has been prepared for submission to the IRB by Cindy Johnston. As Principal Investigator for this study, you are required to review the submission for accuracy and completeness and sign the form to forward the submission to the IRB. Click here to access the form Amendment Request.
>
> Thank you for your prompt attention to this matter.

On new study submissions and continuing review reports, two (or more) signatures are required. The initial signature verifies the information in the form and the signing off on PI Assurance. If a Waiver of HIPAA is requested, the PI will be required to sign off on that as well.

After the PI has provided the required electronic signatures on the submitted form, they may wait 30 seconds or so and refresh their dashboard and the Forms Section should again reflect there is "1 xForms awaiting your attention" or they may wait until they receive an email notification advising their signature is required on financial conflict of interest (FCOI). Click on the link to open the form and provide your electronic signature on FCOI or to complete the FCOI disclosure form. An email is also sent to all research personnel requiring their electronic signature on FCOI as well (see example below).

> A new exempt submission was submitted to the Mercy Health Regional Institutional Review Board (IRB). Before this submission can go to the IRB, all research study staff are required to disclose any conflicts of interest and provide their electronic signature. This submission cannot move forward until all signatures are obtained.
>
> If you **do NOT** have any conflicts to disclose, sign off next to your name at the bottom of the Conflicts of Interest page.
>
> If you **DO have a conflict to disclose**, please click on the link below to complete the Conflicts of Interest Disclosure form.
>
> Click Exempt/NHSR Application to go directly to the form.
>
> If you have questions or require assistance with IRBManager, please contact the IRB Administrator at 616.685.6198.

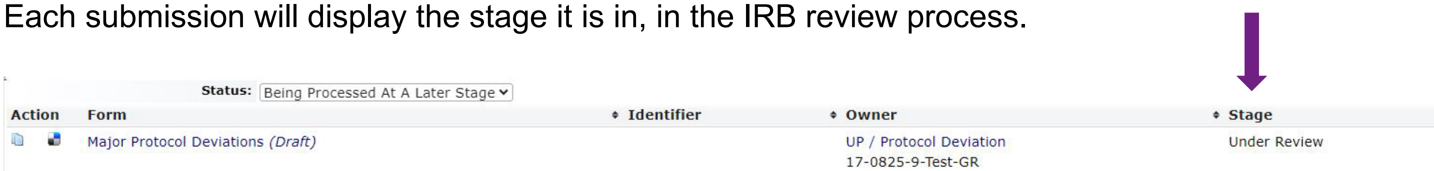
If any research staff are not affiliated with Trinity Health, the submitter should note this where indicated in the application and those individuals will receive an additional email requesting their electronic signature on a Confidentiality Agreement.

NOTE: A study is not fully submitted until ALL research staff have provided the required signatures and the status of the submission is in the "NOTIFY IRB" stage.

Checking on Submission Status

To check on the status of a submission, click on the link of xForms being processed at a later stage found on your dashboard.

Each submission will display the stage it is in, in the IRB review process.



NEED HELP?

Contact the IRB Administrator, Cindy Johnston, at johnstom@trinity-health.org or 616.685.6198.