



UnityPoint Health
Des Moines

**Institutional Review Board
Human Research Protection Program**

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**UnityPoint Health Des Moines IRB
Researcher User Manual
for IRBManager**



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If you need to update study team members at the time of continuing review, this can be completed within the continuing review submission. However, please note that new study team members cannot participate on the study until approval of the continuing review. Please see the Continuing Review/Administrative Update Application section on how to navigate and start the xform for this type of submission..... 35

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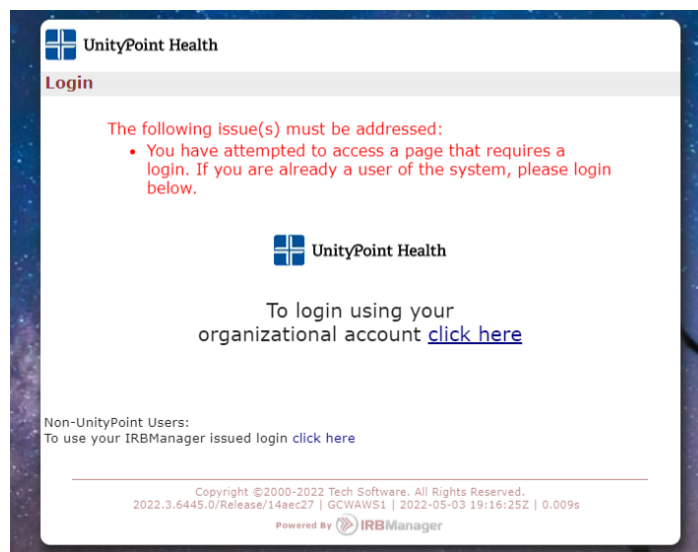
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Getting Started with IRBManager

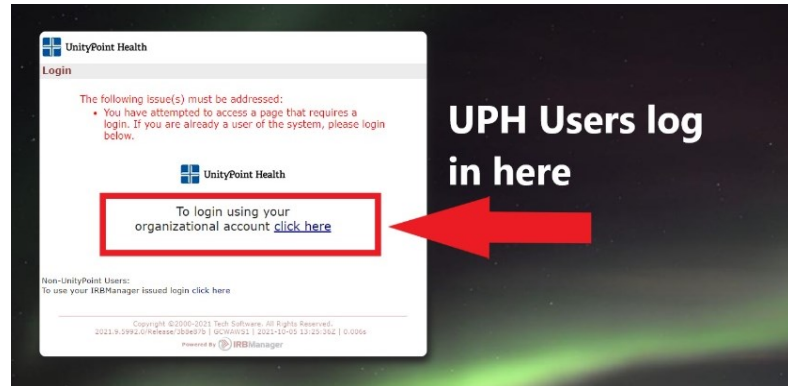
Open your web browser and go to <https://up.my.irbmanager.com/> . It is recommended to use Google Chrome or Microsoft Edge.

This should take you to the initial log in screen:

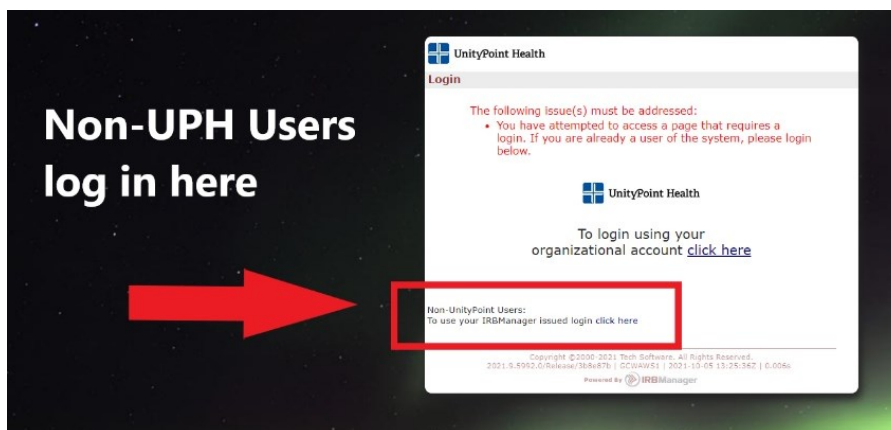


Logging in to IRBManager

- 1) New Users: Email the IRB office at IRBSubmissions@unitypoint.org to find out your log in information (username and password). Please note that you will be prompted to change your password the first time you log in to the system.
- 2) Existing Users: Use the email address affiliated with your account and your chosen password.
- 3) If your username is an UPH email address, you can use the single sign on feature by selecting this login option:



- 4) If your username is a non-UnityPoint Health email address, you will select this login option:



- 5) If you have issues logging into your IRBManager account, please email irbsubmissions@unitypoint.org explaining the issue. Please allow 24-48 business hours for a response.

IRBManager Dashboard

After logging into IRBManager, you will be taken to your IRBManager Dashboard. Your dashboard will provide you a snapshot of active studies in which you are either the primary investigator or a study team member.

The dashboard provides the status of current submissions, is the starting point for any new submissions, and returns you to a previously started xform. Hyperlinks can be used to quickly access active studies, xforms, and events.



The screenshot shows the 'My Studies' dashboard with the following sections:

- Studies (3 Active)**
 - You are associated with **3 active** Studies and **4 total** Studies.
 - You are the PI for **3 active** and **4 total** Studies.
 - Committee IRB has **385 active** and **592 total** Studies.
 - Committee test committee has **0 active** and **0 total** Studies.
- xForms (6 Active)**
 - You have **0 unsubmitted** xForms.
 - You have **6 xForms** being processed at a later stage.
- Events (29 Open)**
 - Only show events where I am: [dropdown]
 - You have **6 Closure** events.
 - You have **23 External IRB CR/Modification** events.
 - You have **29 Total Open** events
- My Studies (3 Active)** Table:

Study	Site	PI	Title	Expires	Status	Reference Doc(s)
2020-001-IMMC	Iowa Methodist Medical Center	Sample, Nicole MPA	Testing IRB forms	10/03/2022	Open Enrolling New Participants	
2020-003-IMMC	Iowa Methodist Medical Center	Sample, Nicole MPA	Expedited Test Study	03/28/2023	Open Not Enrolling New Participants	
2022-026-IMMC	Iowa Methodist Medical Center	Sample, Nicole MPA	testing expedited checklist	03/28/2023	Open Enrolling New Participants	

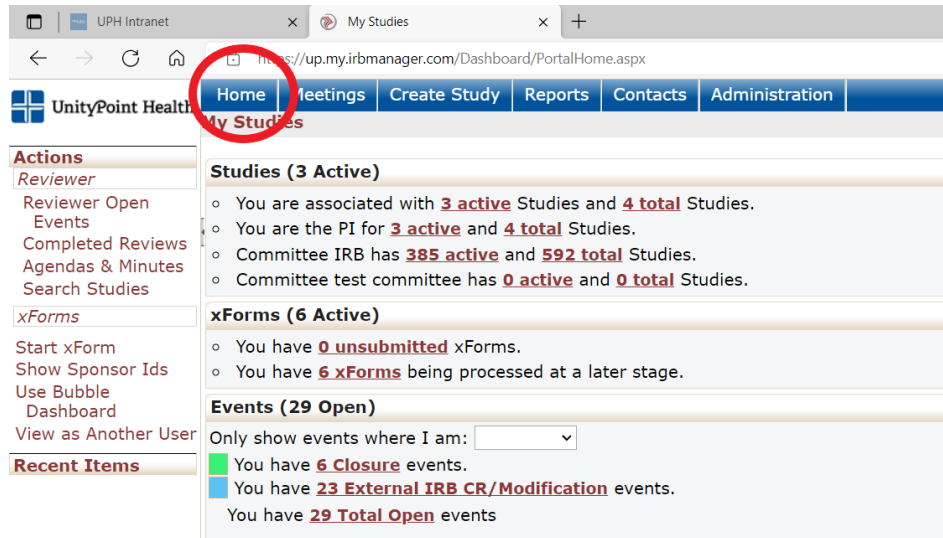
Studies- This section outlines approved studies, both active and closed. Click on the hyperlinks to view the studies. These studies will also be listed individually at the bottom of the dashboard page under “My Studies”. Here you can click on the study number link to take you directly to the study information, forms and events pertaining to that study.

xForms- This section outlines studies that have not yet been completed. There are two sections, unsubmitted xForms and being processed at a later stage.

- Unsubmitted xForms are applications that have been started but have yet to be submitted to the IRB for review. Select the link in this section to open what forms have not been submitted.
- XForms that have been submitted but are still being processed or reviewed can be found in “being processed at a later stage”. Click on the link in this section to find out what stage your application is in with the IRB.

Events- This section outlines all open events. Events such as new submissions, continuing reviews, amendments, closures, etc. are considered open until the full board is notified of the event at the next IRB meeting after approval.

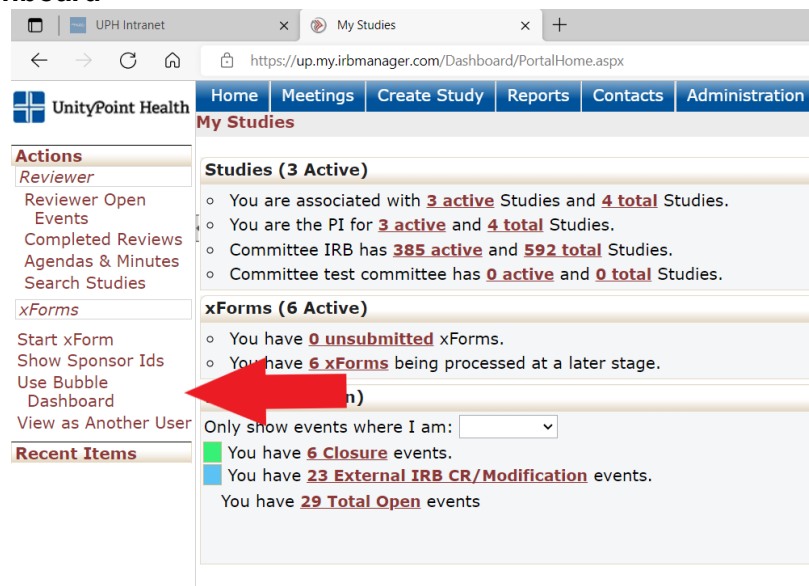
Selecting the **Home** button on any page will return you to your dashboard.



Dashboard & Profile Settings

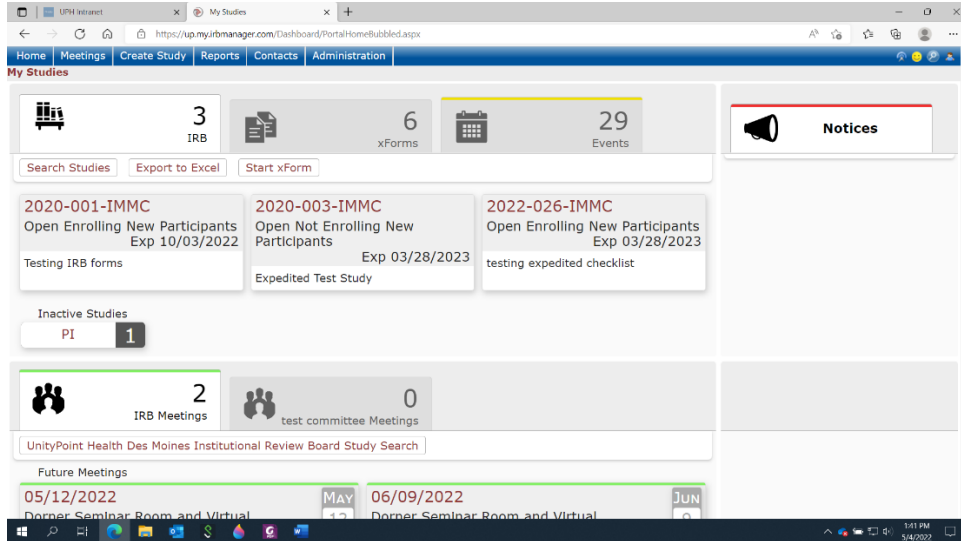
There are different setting options for your dashboard such as bubble dashboard and dark mode, as well as the ability to change your profile information and view your researcher document expiration information.

Bubble Dashboard

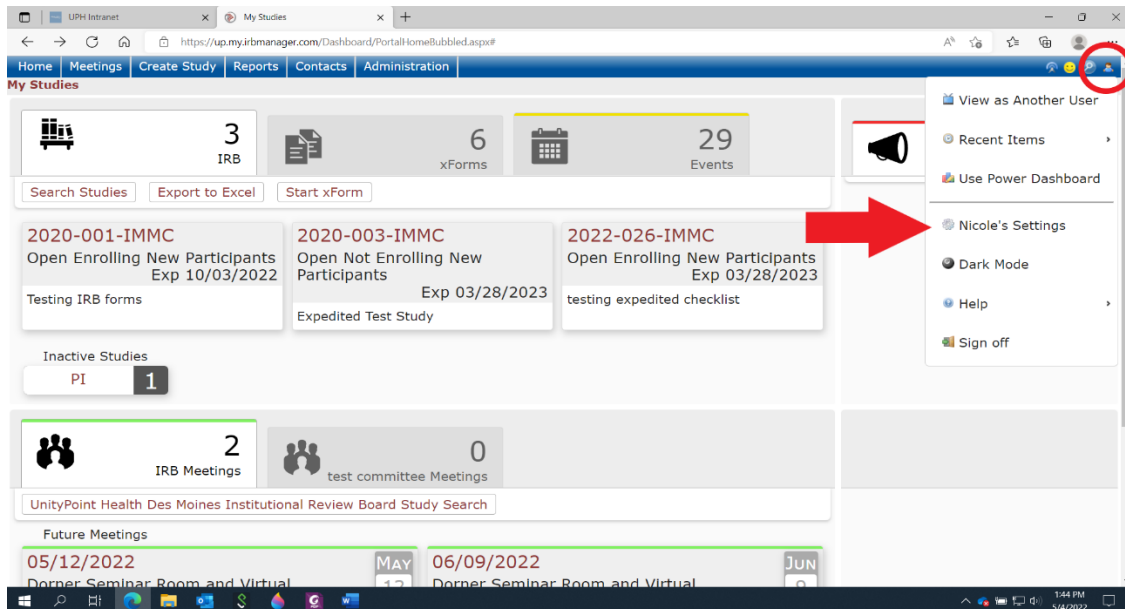




Click on “Use Bubble Dashboard”, and it will revert to this:

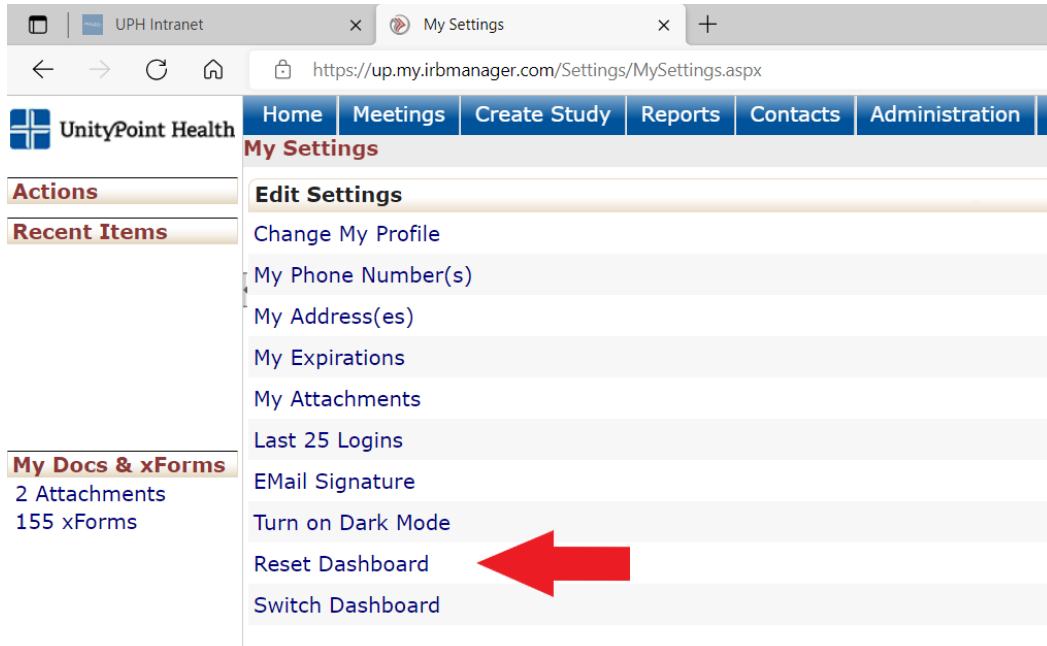


To revert to the original dashboard, click on the person in the upper right-hand corner and go to your settings:

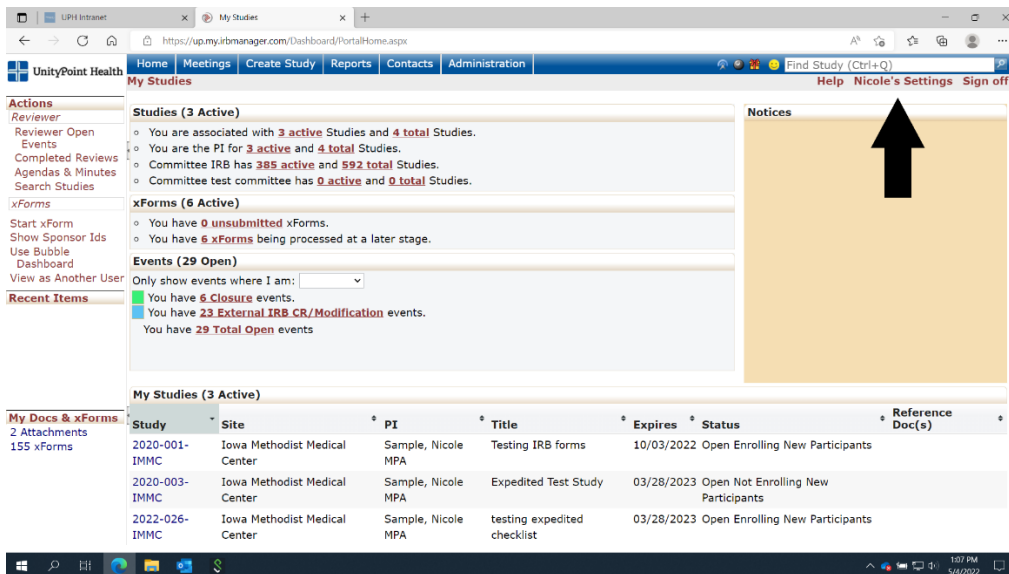




Select “Reset Dashboard” and it will return to the original dashboard view:



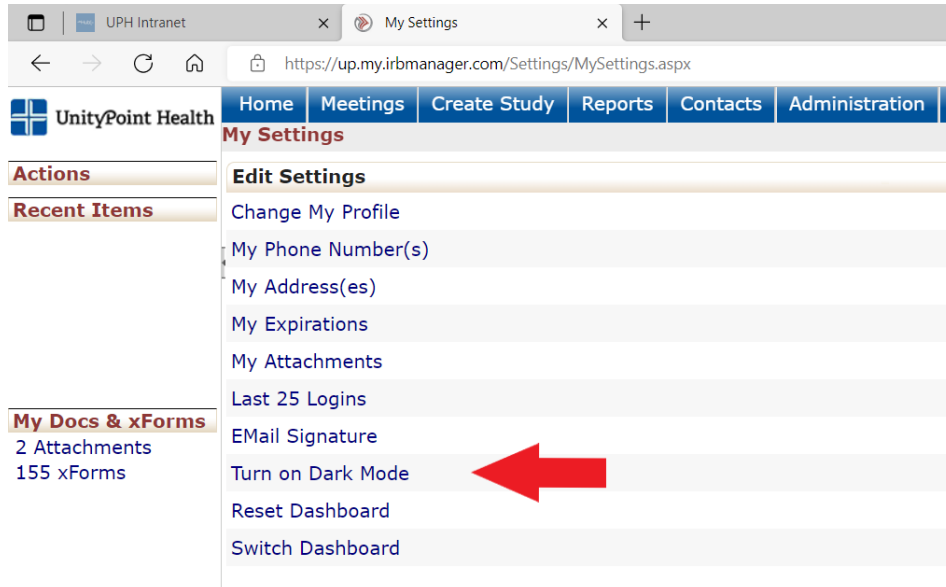
To access your settings from the original dashboard, select “(Your Name) Settings” in the upper right-hand corner:



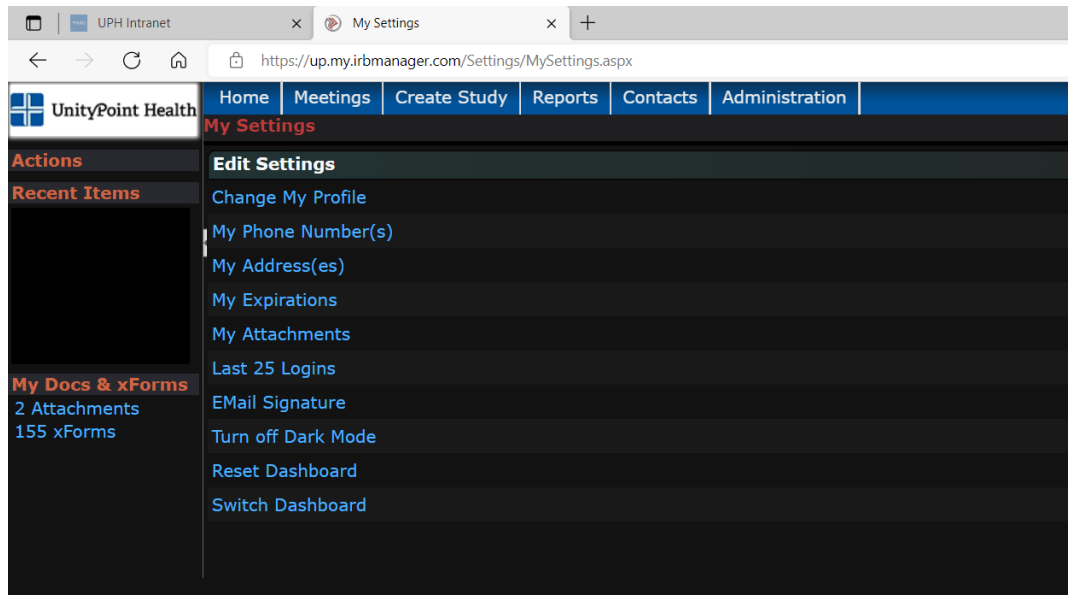


Dark Mode

Within the settings, you can change your dashboard to Dark Mode:



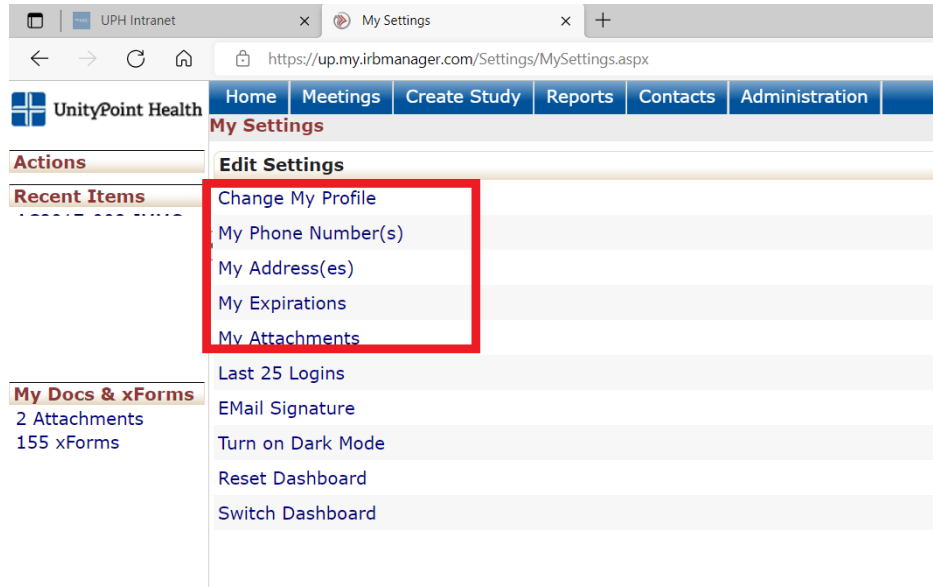
Your IRBManager screens will now look like this:





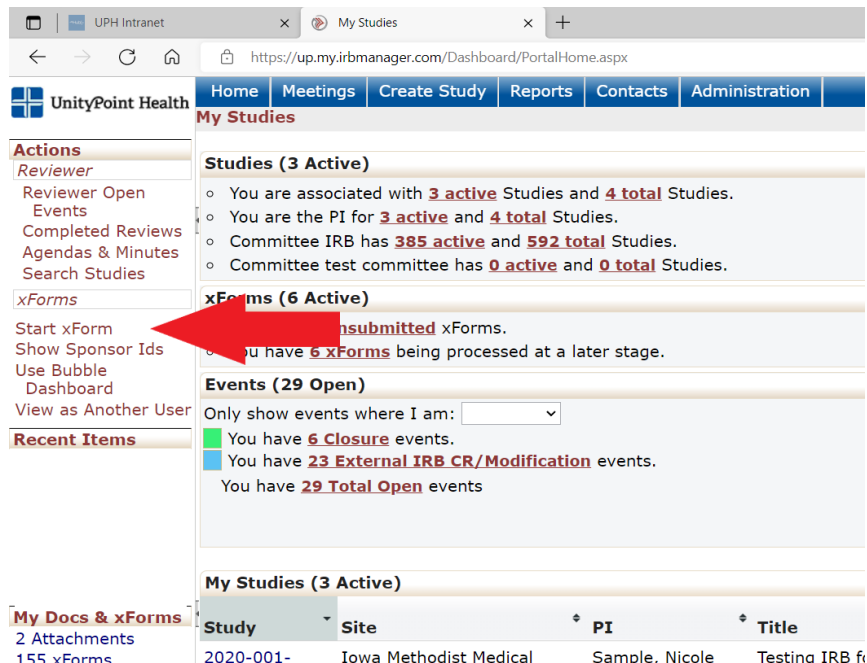
Profile Settings

To update your profile settings, go to settings and select the option you would like to update or view:



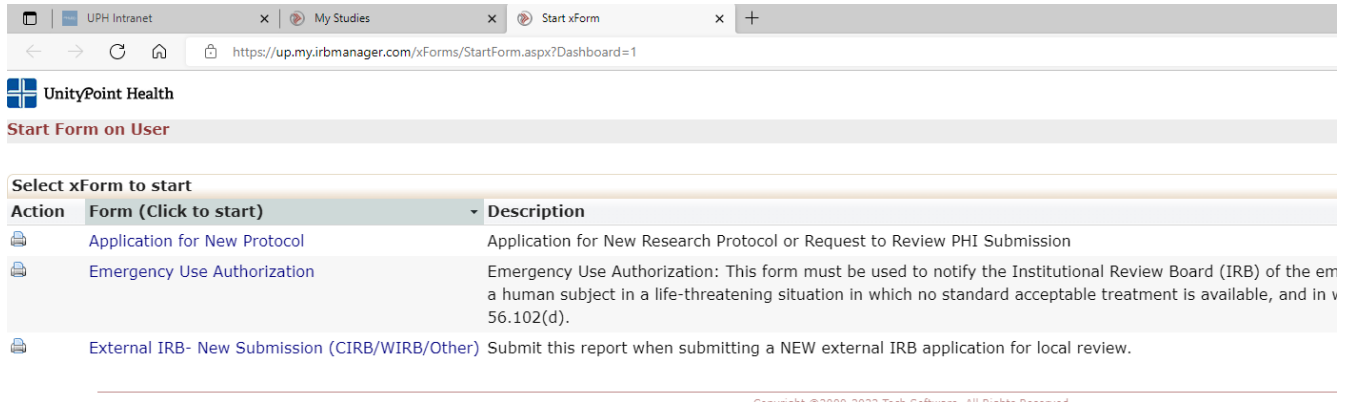
Starting a New Application

From your [IRBManager Dashboard](#), select “Start xform” on the left side under Actions:





The following menu options will appear:



Definitions

Initial submission definitions are as follows, please contact the IRB office if you have questions about which application to use for your study:

Application for New Protocol

This application is used for all new studies (full board, expedited, exempt and requests to review PHI) in which UnityPoint Health Des Moines IRB will be the IRB overseeing the study. Within the application, the “type” of study you select will guide the questions required for that application type. **Please note, if you are applying for an exempt study, you must select exempt as the study type.**

External IRB- New Submission

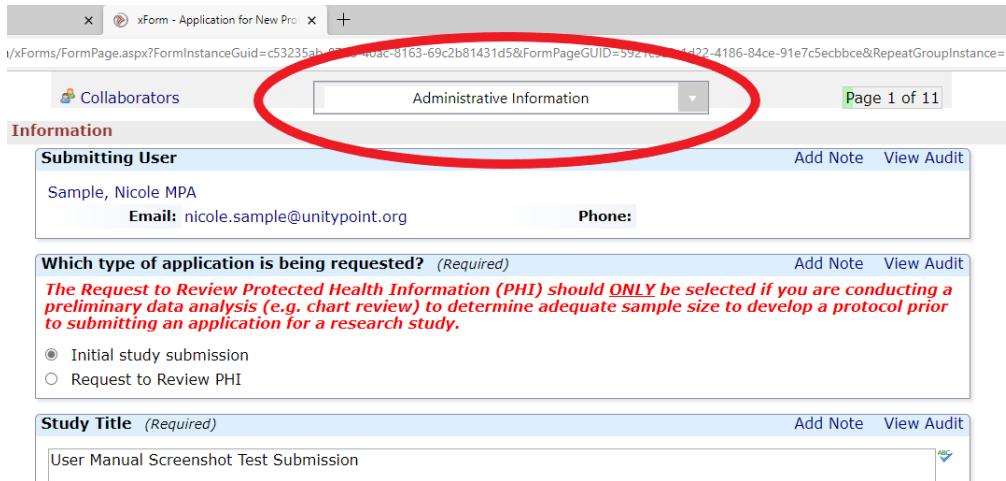
This application is used for all new studies in which another IRB (for example CIRB, WIRB, Advarra, etc.) is overseeing the study and UnityPoint Health Des Moines IRB is relying on that institutional IRB for oversight.

Emergency Use Authorization- The FDA defines this as, “the use of an investigational drug or biological product with a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval [21 CFR 56.102(d)]. The emergency use provision in the FDA regulations [21 CFR 56.104(c)] is an exemption from prior review and approval by the IRB.” (Retrieved May 5, 2022 from [Emergency Use of an Investigational Drug or Biologic | FDA](#))

Navigating pages

For new applications, the first page of the application is the administrative information page. This page must be completed before gaining access to the remaining application pages.

Amendments and continuing reviews may have required questions on the initial pages; however, they can be navigated similarly as described throughout this section.

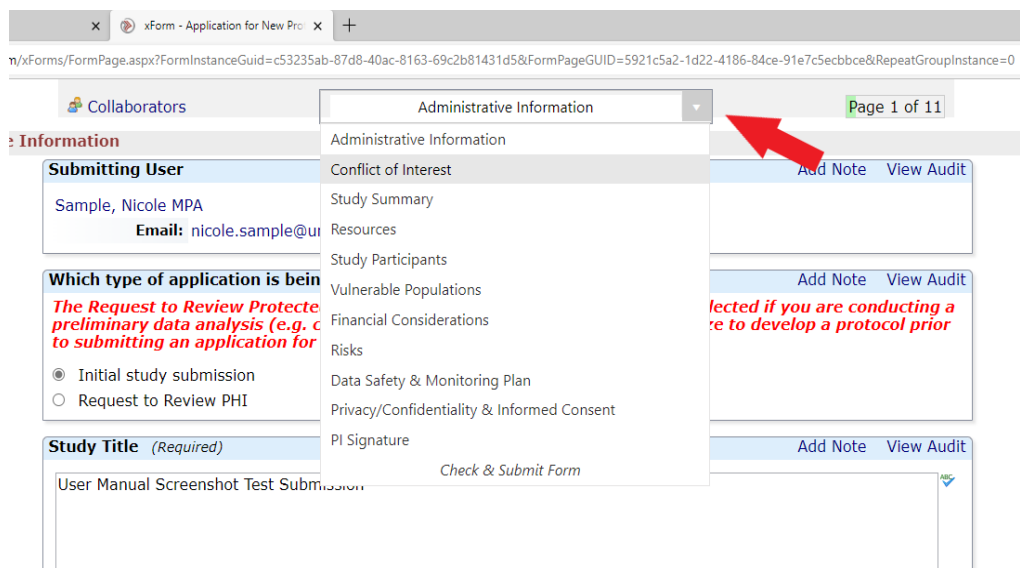


The screenshot shows a web browser window with the URL `.../xForms/FormPage.aspx?FormInstanceGuid=c53235ab-87d8-40ac-8163-69c2b81431d5&FormPageGUID=5921c5a2-1d22-4186-84ce-91e7c5ecbce&RepeatGroupInstance=0`. At the top, there is a navigation bar with a 'Collaborators' icon, a dropdown menu currently set to 'Administrative Information' (circled in red), and a 'Page 1 of 11' indicator. Below this is the 'Information' section with the following fields:

- Submitting User** (Required): Sample, Nicole MPA. Email: nicole.sample@unitypoint.org. Phone: (empty). Buttons: Add Note, View Audit.
- Which type of application is being requested?** (Required):
 - Initial study submission
 - Request to Review PHI

The Request to Review Protected Health Information (PHI) should ONLY be selected if you are conducting a preliminary data analysis (e.g. chart review) to determine adequate sample size to develop a protocol prior to submitting an application for a research study.
- Study Title** (Required): User Manual Screenshot Test Submission. Buttons: Add Note, View Audit.

Once this page is complete, the remaining application pages will become available. There are several pages to the application, and additional pages may be added based on your answers to individual questions. To skip to different application pages, use the drop-down box at the top of the page and select the page you want to skip to. Your changes will be automatically saved when you jump to a new page:



This screenshot shows the same application form as above, but the 'Administrative Information' dropdown menu is expanded, showing a list of available pages. A red arrow points to the dropdown menu. The list includes:

- Administrative Information
- Conflict of Interest
- Study Summary
- Resources
- Study Participants
- Vulnerable Populations
- Financial Considerations
- Risks
- Data Safety & Monitoring Plan
- Privacy/Confidentiality & Informed Consent
- PI Signature

At the bottom of the dropdown menu, there is a 'Check & Submit Form' button. The 'Study Title' field now contains 'User Manual Screenshot Test Submission'.

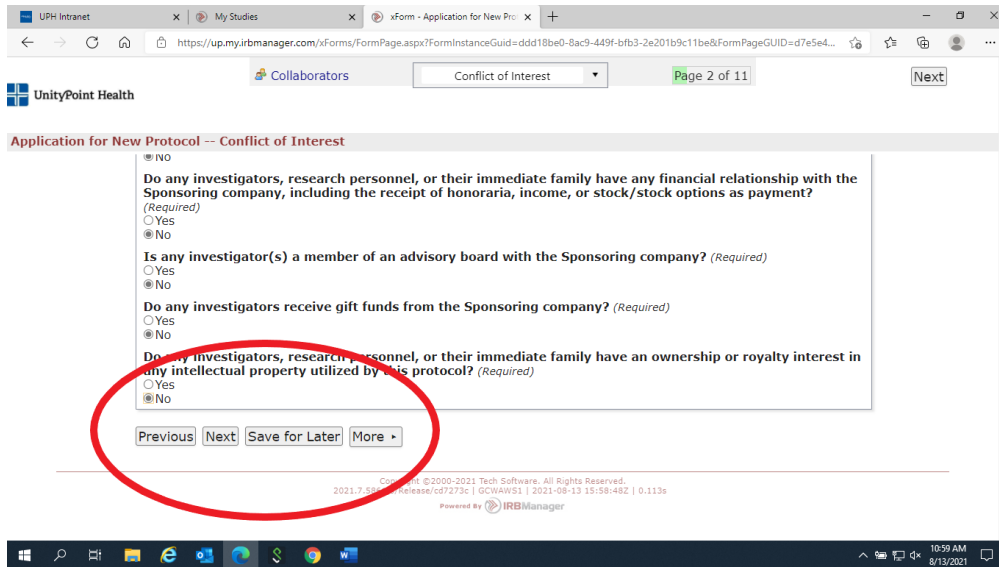
Additional Navigation Options

Next: After you complete a page, you can select the “Next” button located at the bottom of each page; additionally, there is a “Next” button located in the upper right-hand corner of each page.

Previous: You can utilize the “Previous” button located at the bottom of each page to go back to earlier pages of the application.

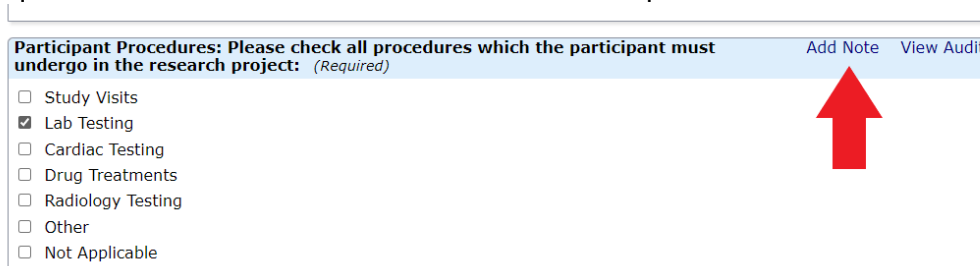
Save for Later: If you need to leave the application, but are not finished, select the “Save for Later” button located at the bottom of each page. This will save the information you have entered so you can return to the application later.

DO NOT use your browser back button as you may lose your application information.

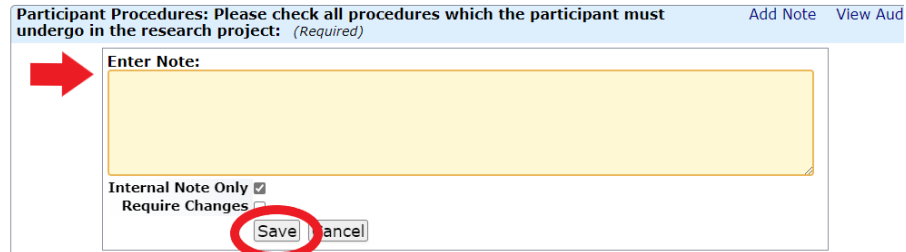


Notes

Each of the IRB forms have questions that have the “Add Note” feature which allows you to add a note for the IRB office and reviewers should you need to provide further explanation on a particular question. Click on the “Add Note” text within the question box:



Type in the text box and click “Save” when you are done:



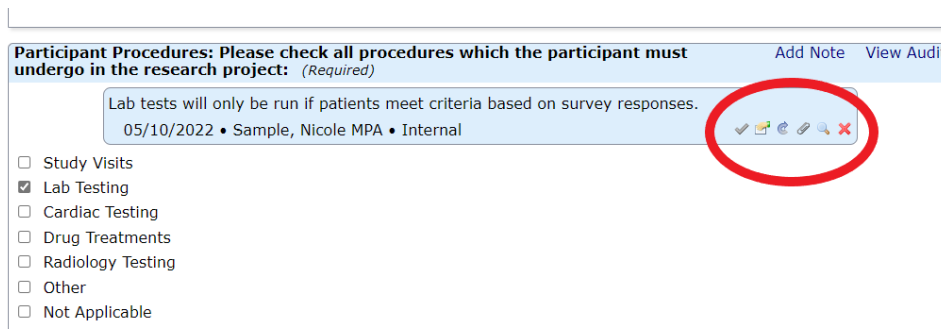
Participant Procedures: Please check all procedures which the participant must undergo in the research project: (Required) [Add Note](#) [View Audit](#)

Enter Note:

Internal Note Only
Require Changes

Save **Cancel**

After entering a note, you can edit or delete the note. You can also include additional attachments if needed.



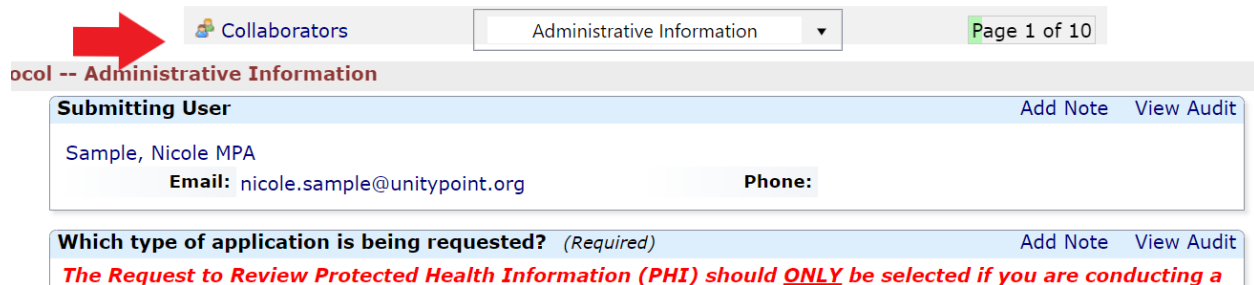
Participant Procedures: Please check all procedures which the participant must undergo in the research project: (Required) [Add Note](#) [View Audit](#)

Lab tests will only be run if patients meet criteria based on survey responses.
05/10/2022 • Sample, Nicole MPA • Internal

Study Visits
 Lab Testing
 Cardiac Testing
 Drug Treatments
 Radiology Testing
 Other
 Not Applicable

Adding Collaborators

Adding collaborators to a new submission allows other individuals the ability to view & edit the application during the data entry process. To add collaborators, have the researcher who is completing the application click on “Collaborators” at the top of the submission screen:



Collaborators Administrative Information Page 1 of 10

ocol -- Administrative Information

Submitting User [Add Note](#) [View Audit](#)

Sample, Nicole MPA
Email: nicole.sample@unitypoint.org Phone:

Which type of application is being requested? (Required) [Add Note](#) [View Audit](#)

*The Request to Review Protected Health Information (PHI) should **ONLY** be selected if you are conducting a*



In the pop-up window, begin typing the name or email address of the person you would like to add as a collaborator (note the individual must already be a user in IRBManager). Next, select the access to be given (view only, edit, edit & manage, or edit, manage & submit). Finally, click add at the bottom of the screen. Continuing adding collaborators as needed, then click the X to close out the window when you are finished.

Collaborators

Add

Email Karpowicz, Kathryn RN, MA (kathy.karpowicz@unitypoint.org)

Access Edit

Note for Collaborator View Only
Edit
Edit and manage
Edit, manage and submit

CC Me

Add

Current Collaborators

Action	Collaborator	Permission	BGR
	Sample, Nicole MPA	Author	

The individuals added to the application as collaborators will receive an email with a link to the application so they can begin utilizing the application based on the access permissions given.

Adding attachments


Throughout the various IRB forms, you may be asked to attach documents such as consents, protocols, study team member documents, other miscellaneous study documents, etc. To add an attachment, click on the “Add Attachment” button:

Collaborators Privacy/Confidentiality & Informed... Page 10 of 11


Protocol -- Privacy/Confidentiality & Informed Consent

- Complete protocol (required-a description of who, what, why, when, where of the study)
- Informed Consent/Assent Documents or Waiver of Consent form
- Investigator Brochure or Instructions for Use (if one exists)
- Final Contract with Sponsor (if not available at time of submission, please submit an "all but signed", verbally approved, version of the contract)
- All recruitment materials, including advertisements intended to be seen or heard by potential participants
- Approved DHHS sample informed consent documents (if one exists)
- Completed DHHS approved protocol (if one exists)
- Documentation of Human Subject's Protection (NIH or CITI) & COI training, if not already on file in the IRB office (required)
- Documentation of Conflict of Interest form, if not already on file in the IRB office (required)


Attach protocol here: (Required) Add Note View Audit

Add Attachment 

Please attach all Informed Consent, Assent, and Waiver of Consent Documents: (Required) Add Note View Audit

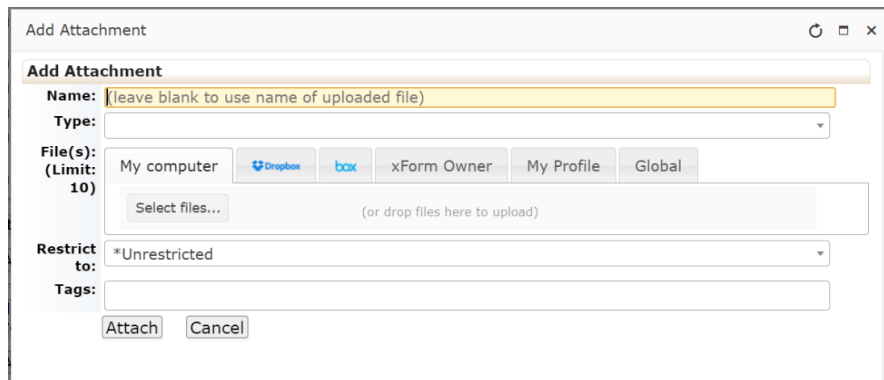
Add Attachment 

Recruitment Materials (Required) Add Note View Audit

Add Attachment 

Previous Next Save for Later More ▾

Once you have clicked the button, a window will pop-up allowing you to select the file type and choose your file destination for upload.



Add Attachment

Add Attachment

Name:

Type:

File(s):

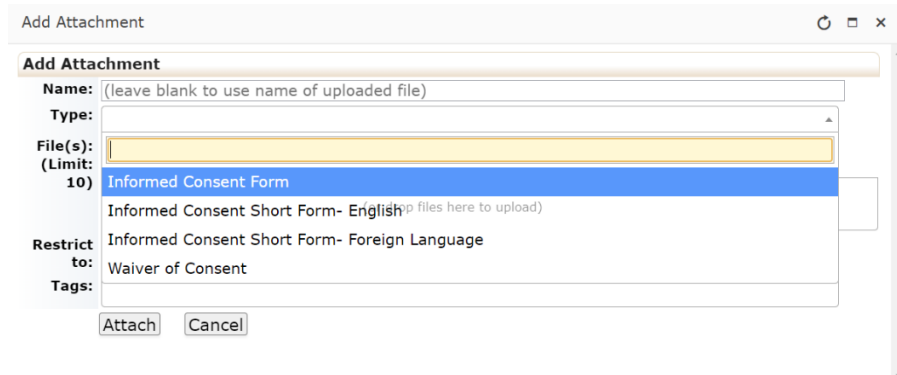
(Limit: 10)

(or drop files here to upload)

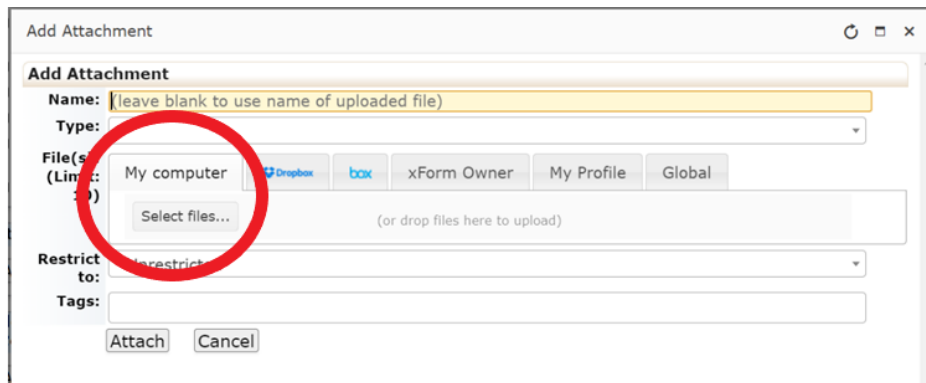
Restrict to:

Tags:

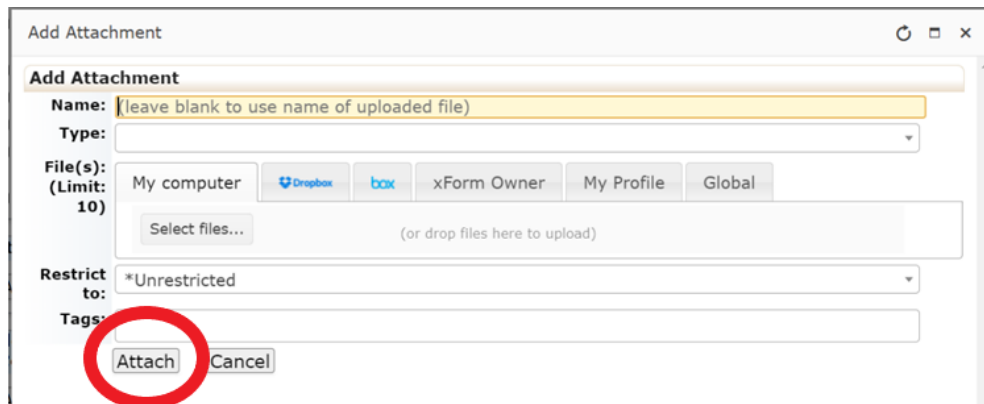
Use the drop-down box to select the type of attachment, noting the options available are dependent upon the type of attachment. For example, below shows the attachment types for consent documents.



After selecting the attachment type, go to my computer to browse for your document and select the file you would like to upload and attach.



After selecting your document, click “Attach” at the bottom of the pop-up screen:





After clicking “Attach”, you will see a link to the attachment populate within the question.

You can delete an attachment by clicking on the **X** or replace an attachment by clicking on the **double green arrows**.

During revisions, please replace the previous file with the updated version so that only the updated version is attached to the application.

Signing & Submitting Forms

Once the form is completed, the PI must electronically sign the form before submitting. Please make sure to read and understand the entire section of Investigator responsibilities before signing. Researchers and research personnel will be held accountable for these items.



Collaborators PI Signature Page 11 of 11

Signature

As principal investigator of the study being submitted for review, I accept responsibility for:

- Committing to upholding the Principles stated in the Belmont Report and to follow the HRPP Procedures with every application of research.
- Protecting the rights and welfare of human research participants and for complying with all applicable provisions of the Federal Wide Assurance between UnityPoint Health-Des Moines and the Federal Office of Human Research Protection.
- Providing a copy of the IRB approved and signed informed consent document to each participant at the time of consent, unless the IRB has specifically waived this requirement or the study is determined by the IRB to be exempt.
- Unless otherwise authorized by the IRB, obtaining and documenting informed consent in accord with applicable federal regulations at 45CFR46.111; 45CFR46.116; 45CFR46.117; 21CFR50.20; 21CFR50.23; 21CFR50.25; 21CFR50.27; 21CFR56.111.
- Promptly reporting proposed changes in previously approved research activities to the IRB. My proposed changes may not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to my participants.
- Reporting to the IRB any problems that require prompt reporting to the IRB within 7 calendar days of my first discovering it. Serious Adverse Events require reporting to the IRB within 24 hours of my first discovering it.
- Reporting to the IRB about the progress of the proposed research.
- Reporting to the IRB when all study-related activities have ceased and the study can be closed.

(Required)

To sign the form, enter your IRBManager password (same as your login credentials) in the provided box.

As principal investigator of the study being submitted for review, I accept responsibility for:

- Committing to upholding the Principles stated in the Belmont Report and to follow the HRPP Procedures with every application of research.
- Protecting the rights and welfare of human research participants and for complying with all applicable provisions of the Federal Wide Assurance between UnityPoint Health-Des Moines and the Federal Office of Human Research Protection.
- Providing a copy of the IRB approved and signed informed consent document to each participant at the time of consent, unless the IRB has specifically waived this requirement or the study is determined by the IRB to be exempt.
- Unless otherwise authorized by the IRB, obtaining and documenting informed consent in accord with applicable federal regulations at 45CFR46.111; 45CFR46.116; 45CFR46.117; 21CFR50.20; 21CFR50.23; 21CFR50.25; 21CFR50.27; 21CFR56.111.
- Promptly reporting proposed changes in previously approved research activities to the IRB. My proposed changes may not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to my participants.
- Reporting to the IRB any problems that require prompt reporting to the IRB within 7 calendar days of my first discovering it. Serious Adverse Events require reporting to the IRB within 24 hours of my first discovering it.
- Reporting to the IRB about the progress of the proposed research.
- Reporting to the IRB when all study-related activities have ceased and the study can be closed.

(Required)

To sign, enter password for jnsample@yahoo.com

After entering your password, select Next to get to the submission page. From this screen, you can go back into the form to make changes, save it for later if you are not ready to submit the

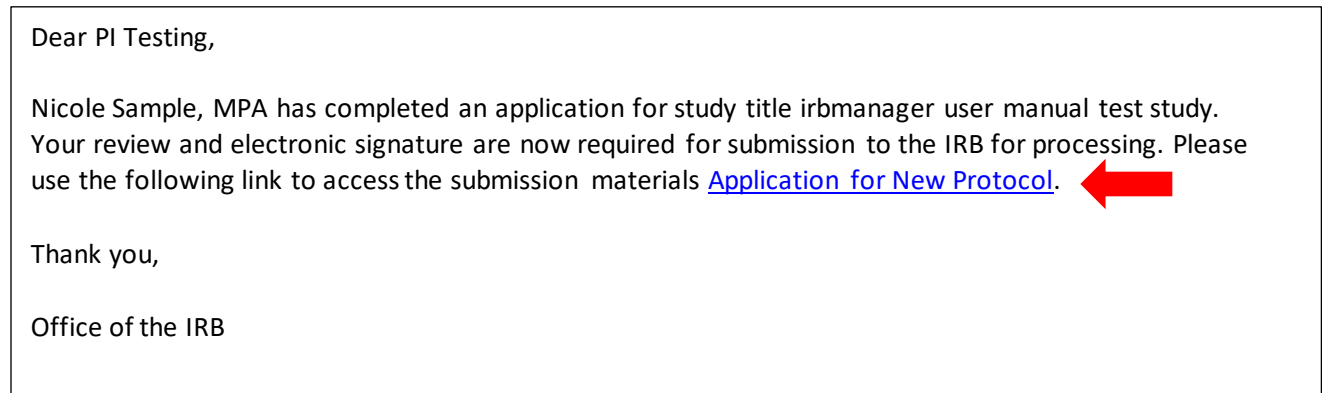


form, print, or submit the form. Once you select submit, the IRB office will be notified of your completed submission, and you will be able to track the status of the form within IRBManager from your dashboard.

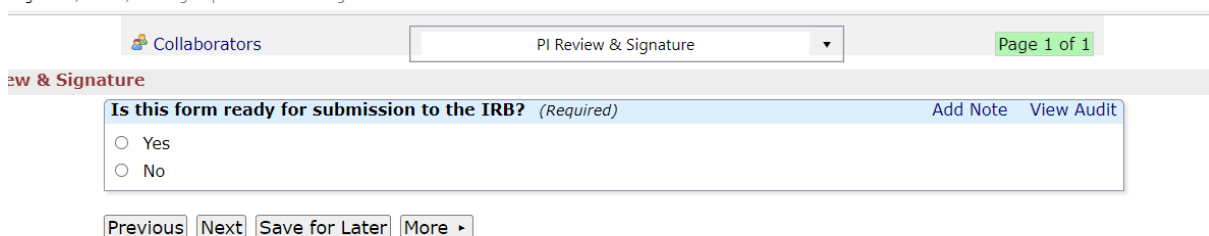


Non-PI Submissions

If the submitter is not the PI or CO-PI, they will click “Submit” on the final page of the form. There is no signature page for form submitters who are not the PI or CO-PI. Once the application has been submitted, it will be sent to the PI for approval and signature. The PI will receive an email from IRBManager with a link to the submitted form:



The PI will then be able to review the submitted form. Click next on the last form of the application, the PI will then be asked if the form is ready for submission.





Select Yes if it is ready for submission, the prompts will be the same as outlined above in the PI submission information. If revisions need to be made to the application, select No then explain what revisions are needed.

The screenshot shows a web interface for 'Collaborators' with a dropdown menu set to 'PI Review & Signature' and 'Page 1 of 1' displayed. The main heading is 'tocol -- PI Review & Signature'. The first question is 'Is this form ready for submission to the IRB? (Required)' with radio buttons for 'Yes' and 'No', where 'No' is selected. There are 'Add Note' and 'View Audit' links. Below is a text area for 'Please detail what changes are needed to the application. Your response will be emailed to the individual who completed this form. (Required)', also with 'Add Note' and 'View Audit' links. At the bottom are buttons for 'Previous', 'Next', 'Save for Later', and 'More'.

Choose Next, then click submit to return the form back to the submitting user to make the requested revisions.

Revisions to Applications

There may be occasions where the application is returned for revisions by the IRB office, a reviewer, or the PI (if PI was not the original submitter of the xForm). If you are asked to make revisions, you will receive an email like the one below. (This email will go to the individual who submitted the form and the PI if the original submitter is not the PI.)

Notification of incomplete non-compliance report



IRBManager on behalf of IRB Office <no-reply@up.my.irbmanager.com>
To Nicole Sample, MPA; Nicole Sample, MPA

Dear Nicole Sample, MPA,

The Non-compliance Report form for study title Expedited Test Study is being returned to you for the following reasons:

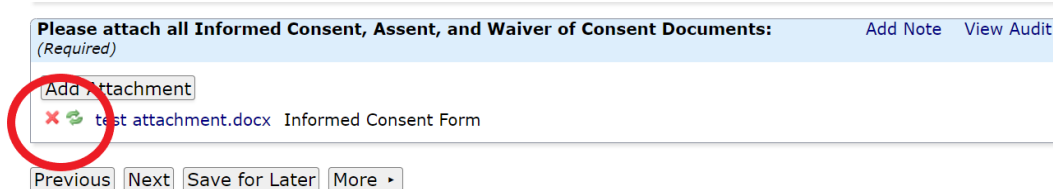
Update sponsor notification date.

Please click here to go directly to the form to make the necessary corrections and resubmit the form [Non-compliance Report form](#).

Click on the link in the email and you will be taken directly to your application (after logging in) to make the requested changes. You can edit and navigate the application just as you did on the initial submission. Navigate through the pages and make the necessary revisions.



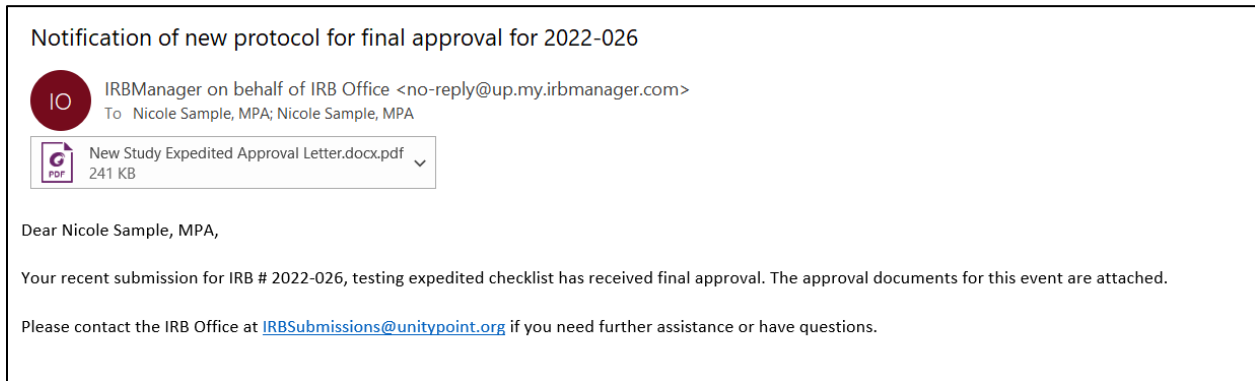
If you are attaching new versions of files, please use the replace feature (**double green arrows**). This will make it easier for your reviewer, so they do not have to figure out which file is the new file to be reviewed.



Once all revisions are complete, resubmit the form. If you are the PI, you will be asked to sign the form again. If you are a non-PI submitter, you will simply click “Submit”. The application will then be routed as it was previously for signatures and review (see [Signing & Submitting Forms](#))

Approvals

Once a submission is approved, you will receive an email notification from IRBManager, and if applicable, an approval letter and/or stamped documents will be included. (Please note some submissions only require an acknowledgement rather than an approval letter.)



You can also access approved studies, their accompanying documents, and any email correspondence through your dashboard (see [IRBManager Dashboard](#)).

Continuing Review/Administrative Update Application

A continuing review or an administrative update is a required annual review for all non-exempt studies approved by the IRB. The PI and study coordinator (if applicable) will receive a 60-day and a 30-day email reminder notification that the continuing review/administrative update is coming due.



Dear Dr. Research,

Study Title: Research Study
Principal Investigator: Dr. Research, MD
Protocol IRB #: 2022-001
Expiration Date: 6/30/2022

Except for studies determined to be exempt from IRB oversight, all human subject's studies are required to undergo continuing review based on the level of risk as assessed by the IRB. This review takes place no less than annually and may require more frequent review or reports as determined by the IRB.

On 7/1/2021 the IRB approved the protocol referenced above.

Options:

1. Submit the Continuing Review of Research Form to continue your research, collecting data, and analyzing data, **click the link [Continuing Review](#)**
2. Submit the Study Closure Final report to close your protocol (subject recruitment, subject visits, data collection and analysis are complete), click the link [Final Closure](#)

Note: To ensure adequate time for the UnityPoint Health Des Moines IRB to process the Continuing Review and to avoid study expiration, the information should be submitted as soon as possible.

If continuing review approval is not granted before the approval expires, all research activities must stop. This includes recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection or analysis of private identifiable information. Advertisements must be pulled.

If you have any questions or concerns, please contact the IRB office at irbsubmission@unitypoint.org.

Sincerely,
Office of the IRB

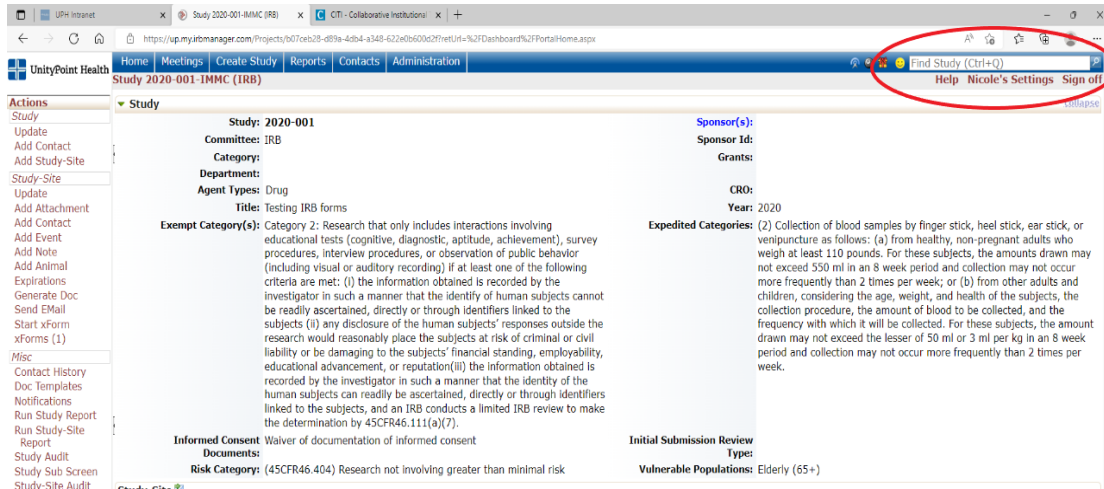
Starting a continuing review submission- There are several ways to navigate to the continuing review form within IRBManager.

- 1) Use the link provided in the email reminder notifications labeled “Continuing Review”:

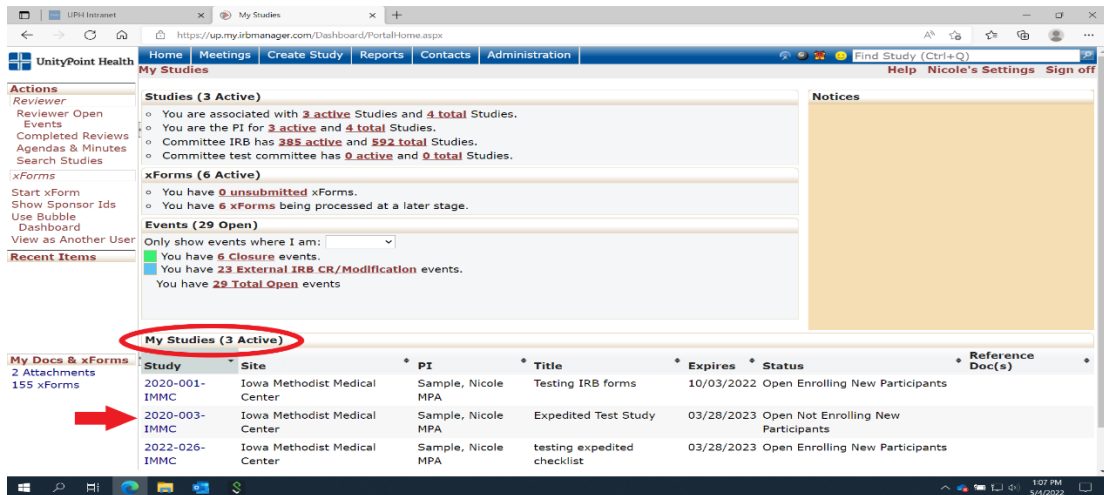
Options:

1. Submit the ~~Continuing Review~~ of Research Form to continue your research, collecting data, and analyzing data, **click the link [Continuing Review](#)**

- 2) OR Log into IRBManager, type in the study number into the “Find a Study” field in the upper right of the screen:



3) OR from your dashboard, go the “My Studies” located at the bottom of your screen and select the study you would like to begin the continuing review on:



Once you are in the study, navigate to the “Actions” panel on the left of the screen and select “Start xForm”.



The screenshot shows the UPH Intranet interface for a study. The left sidebar contains a menu with 'Actions' expanded, showing options like 'Update', 'Add Contact', and 'Start xForm'. A red arrow points to 'Start xForm'. The main content area displays study details for 'Study 2021-028-IMMC (IRB)', including sponsor information, agent types, informed consent documents, risk category, and site information. A red arrow also points to the 'Start xForm' link in the 'Study-Site' section.

Next, select “Continuing Review” from the menu options:

Start Form on Study IM2020-005-test-IMMC (IRB) Filter:

Action	Form (Click to start)	Description
	24 Hour SAE Notification Form	24 Hour SAE Notification Form
	Amendment	Amendment
	Continuing Review	This is the annual continuing review form to be used for all study types.
	Enrollment Closure	Submit this report when all subjects have been enrolled and there is continued follow up. Enrollment closure means that no additional subjects will be enrolled.
	External IRB- CR/Amendment/Events (CIRB/WIRB/Other)	External IRB Continuing Reviews, Amendments, Adverse Events/Unanticipated Problems and other documentation
	Final Closure	Submit this report when the study is going to be completed and no further study activities will occur.
	Non-compliance Report form	Non-compliance/Adverse Event formal submission report to the IRB: Reports should be submitted to the IRB within 7 days of event notification/discovery of the event.

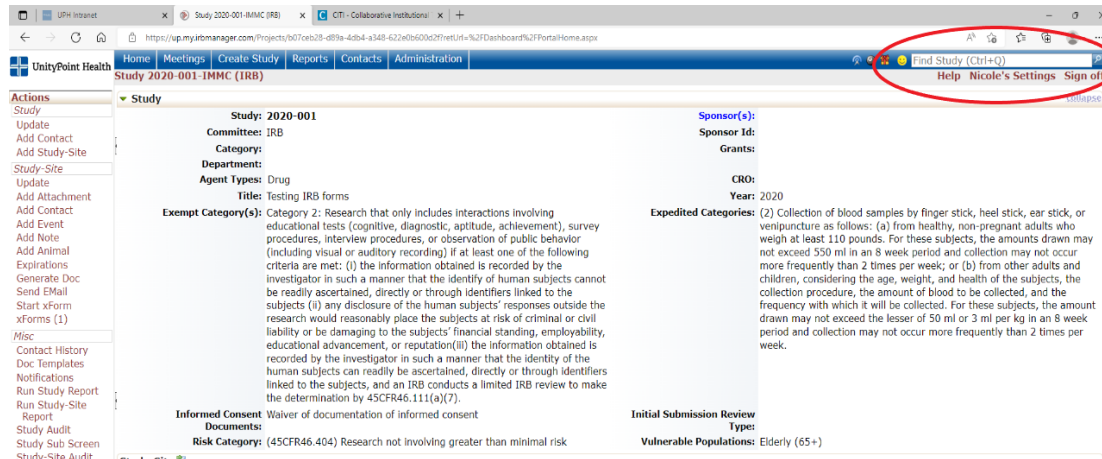
Finally, complete the continuing review xform using the same navigation processes outlined previously (see [Navigating pages](#)). For additional instructions on adding or removing study team members, see [Adding/Removing Study Team Personnel](#).

*Continuing Reviews for external IRB/CIRB/WIRB studies have a different submission process, please see the separate instructions for these studies below ([Continuing Reviews/Amendments for External IRB Studies](#)).

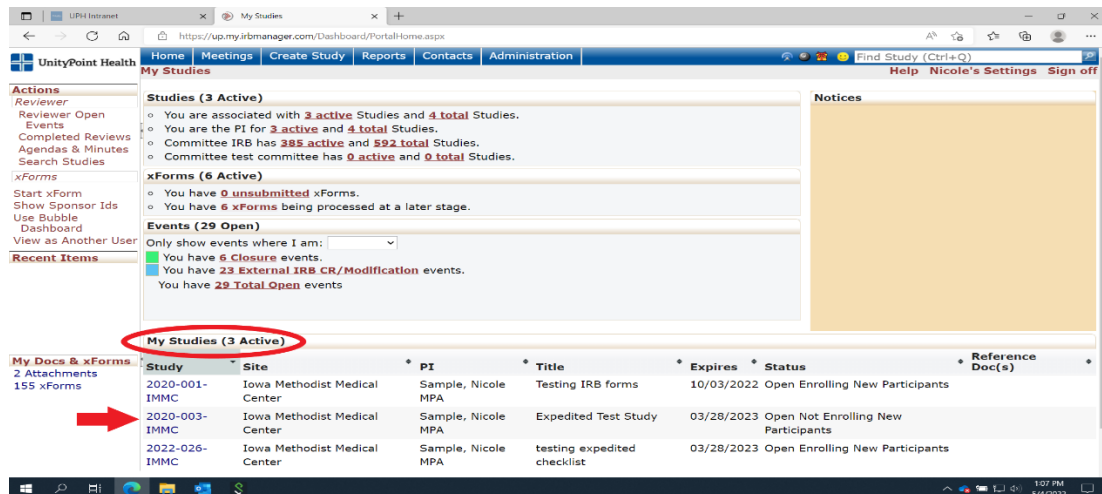
Amendment Application

If you need to make a revision to your approved study, please submit an amendment request. Starting an amendment request is like that of starting a continuing review, you have similar options to navigate to the amendment form:

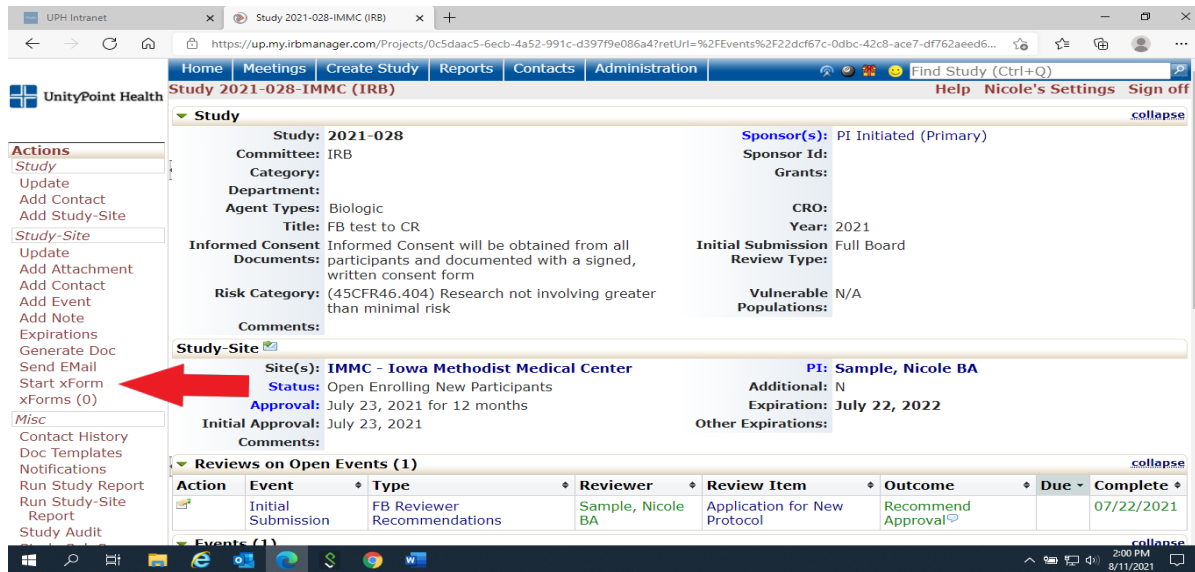
- 1) Log into IRBManager, type the study number into the “Find a Study” field in the upper right of the screen:



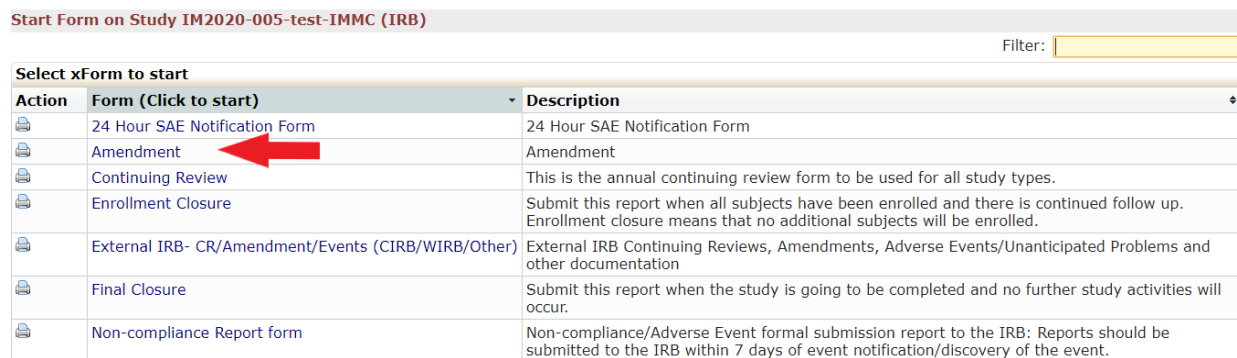
- 2) OR from your dashboard, go to the “My Studies” located at the bottom of your screen and select the study you would like to begin the amendment on:



Once you are in the study, navigate to the “Actions” panel on the left of the screen and select “Start xForm”.



Next, select “Amendment” from the menu options:



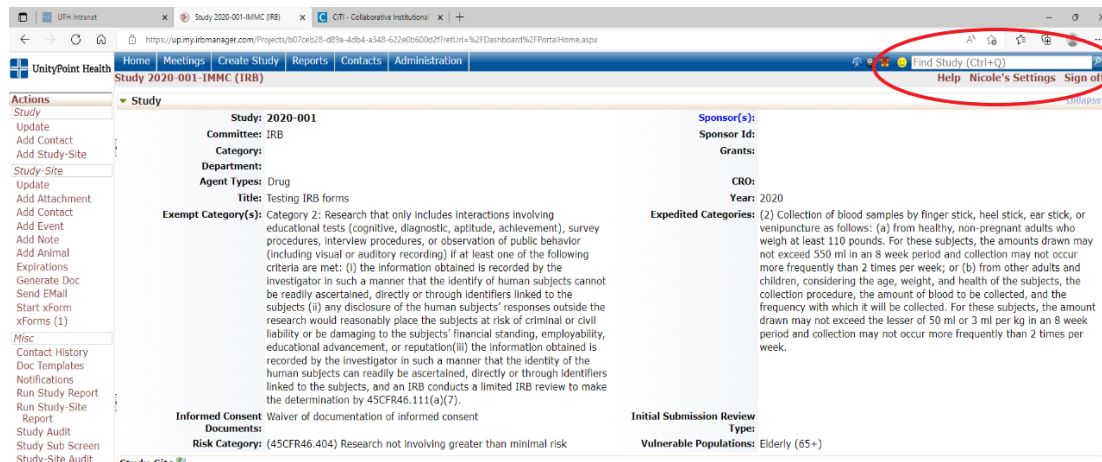
Finally, complete the amendment xform using the same navigation processes outlined previously (see [Navigating pages](#)). For additional instructions on adding or removing study team members, see [Adding/Removing Study Team Personnel](#).

*Amendments for external IRB/CIRB/WIRB studies have a different submission process, please see the separate instructions for these studies below ([Adding/Removing Study Team Personnel](#)).

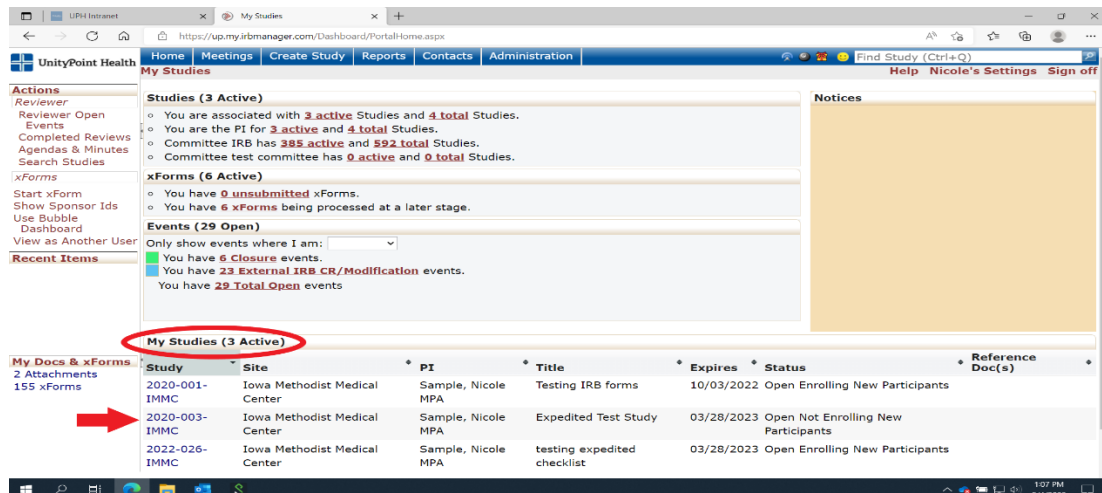
Continuing Reviews/Amendments for External IRB Studies

Navigating to the External IRB- CR/Amendment xForm is like that of the regular continuing review and amendment:

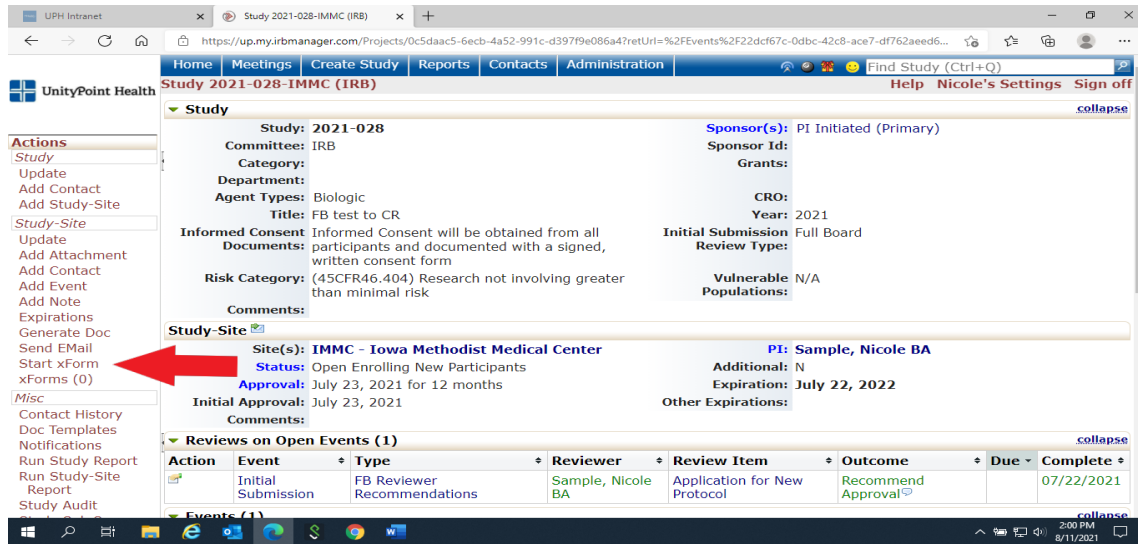
- 1) Log into IRBManager, type the study number into the “Find a Study” field in the upper right of the screen:



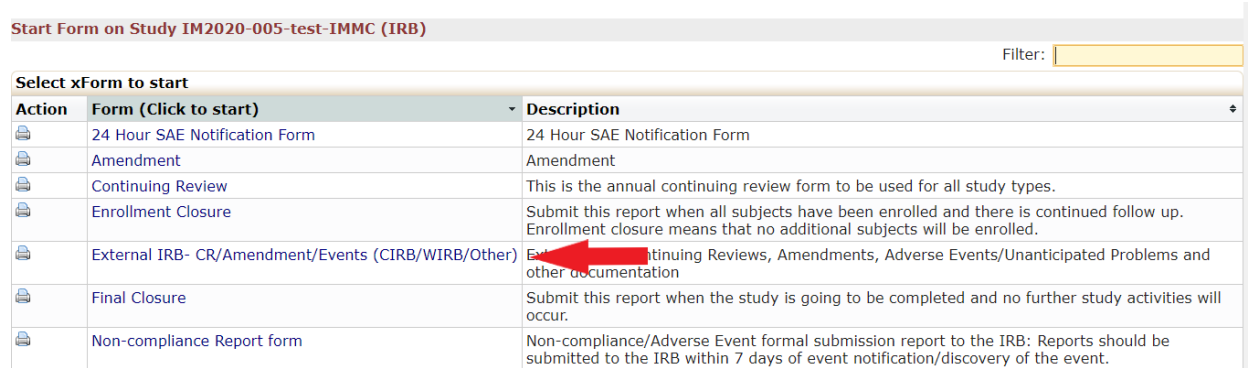
- 2) OR from your dashboard, go the “My Studies” located at the bottom of your screen and select the study you would like to begin the xform on:



Once you are in the study, navigate to the “Actions” panel on the left of the screen and select “Start xForm”.



Next, select “External IRB-CR/Amendment/Events” from the menu options:



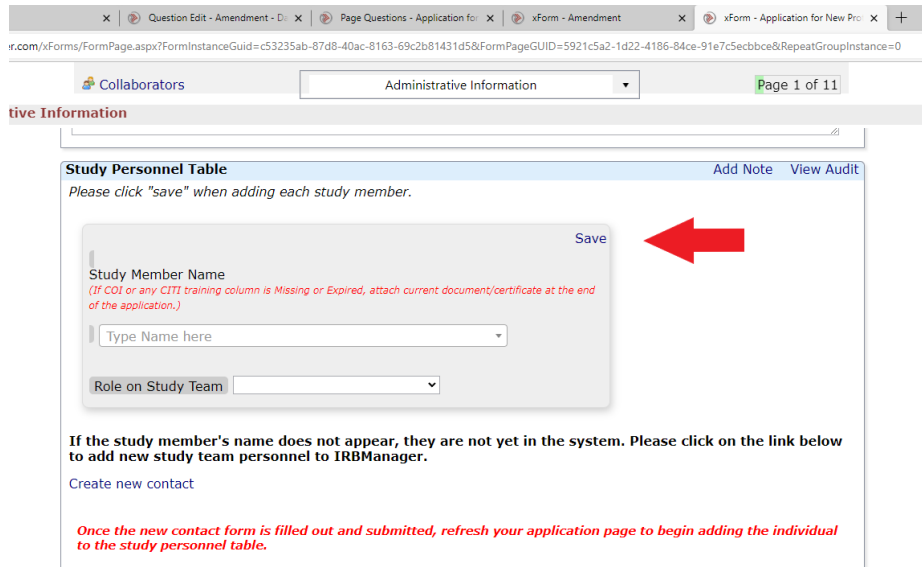
Finally, complete the External IRB CR/Amendment xform using the same navigation processes outline previously (see [Navigating pages](#)). External IRB CR and Amendment submissions do not receive approval letters, but rather you will receive an email notification of review and the stamped external IRB letter for your records.

Adding/Removing Study Team Personnel

New Applications

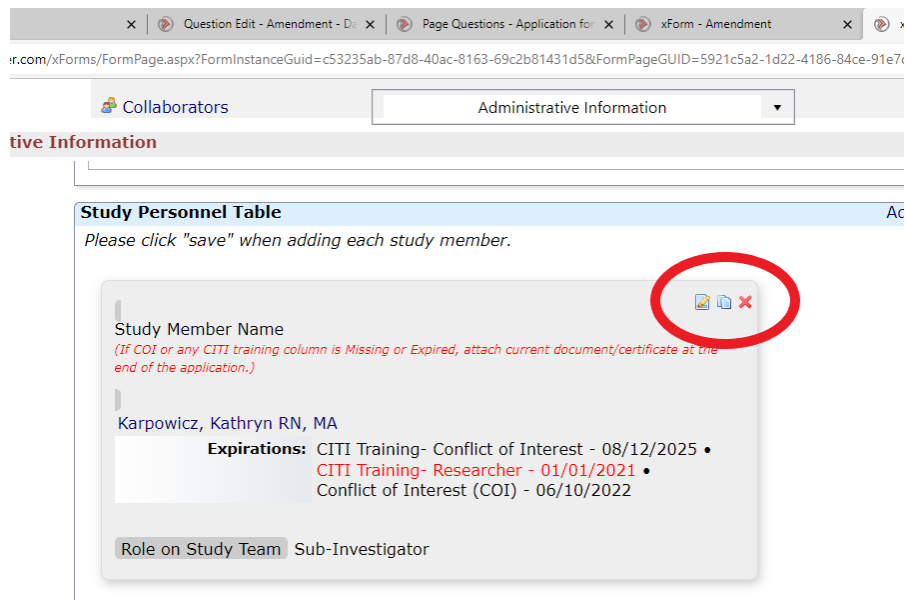
Please see the [Starting a New Application](#) section on how to navigate and start the xform for this type of submission. Begin typing the last name of the individual you would like to add as a

study team member until their name comes up, then click on their name. Next, select their role on the study team. Finally, select “Save” after each entry or the information will not be added to the application:



The screenshot shows a web browser window with several tabs open. The main content area is titled 'Administrative Information' and 'Collaborators'. Below this is the 'Study Personnel Table' section. A form is displayed with a 'Save' button highlighted by a red arrow. The form contains a 'Study Member Name' field with a dropdown menu and a 'Role on Study Team' dropdown menu. Below the form, there is a note: 'If the study member's name does not appear, they are not yet in the system. Please click on the link below to add new study team personnel to IRBManager.' and a link 'Create new contact'.

Once it is saved, it will appear like this which gives you the ability to edit, duplicate, or delete the information if needed:



The screenshot shows the same web browser window as the previous one, but now the 'Study Personnel Table' section is populated with a study member. The study member's name is 'Karpowicz, Kathryn RN, MA'. Below the name, there are 'Expirations' listed: 'CITI Training- Conflict of Interest - 08/12/2025', 'CITI Training- Researcher - 01/01/2021', and 'Conflict of Interest (COI) - 06/10/2022'. The 'Role on Study Team' is 'Sub-Investigator'. A red circle highlights the edit, duplicate, and delete icons in the top right corner of the study member's entry.

Continue adding additional study team members as needed. If an individual is not currently listed in IRBManager you will need to create a new contact first (see red circle in picture below).



Once this is done, you can go back into your amendment, refresh the page, and add the individual as explained above.

Study Personnel Table Add Note View Audit

Please click "save" when adding each study member.

Save

Study Member Name
(If COI or any CITI training column is Missing or Expired, attach current document/certificate at the end of the application.)

Type Name here

Role on Study Team

If the study member's name does not appear, they are not yet in the system. Please click on the link below to add new study team personnel to IRBManager.

[Create new contact](#)

Once the new contact form is filled out and submitted, refresh your application page to begin adding the individual to the study personnel table.

Amendments

If you need to change the primary investigator on a study or add/remove study team personnel, this can be done through an amendment. Please see the [Amendment Application](#) section on how to navigate and start the xform for this type of submission. Once in the amendment form, go to the "Revision Description" section and select the option(s) you would like to do:

Collaborators Amendment Information Page 2 of 3

Is this study currently enrolling subjects? *(Required)* Add Note View Audit

Yes
 No
 Study does not enroll subjects

Type of Review Requested *(Required)* Add Note View Audit

Expedited Review
 Full Board Review

Revision Description *(Required)* Add Note View Audit

Revision to currently approved protocol
 Revision to an amendment
 Revision to currently approved informed consent/waiver of informed consent
 Revision to principal investigator
 Add study team personnel
 Remove study team personnel
 Other (e.g. recruitment, advertising, scripts, investigator brochure, survey/data collection tools, etc.)

Please summarize what revisions are being made and explain the reason for the revisions. *(Required)*

Amendment Change to Principal Investigator

Select "Revision to principal investigator", explain the change the in PI then go to the drop-down box and type in the name of the PI. The researcher documents they have on file will auto populate. If there are any missing or are listed in red, you can attach them



here. Any outdated or missing documents must be attached to make the amendment request.

The screenshot shows a web-based form for an amendment request. At the top, there are tabs for 'Collaborators' and 'Amendment Information', and a page indicator 'Page 2 of 3'. The main section is titled 'Amendment Information' and contains a 'Revision Description' section. This section has a list of checkboxes for different types of revisions: 'Revision to currently approved protocol', 'Revision to an amendment', 'Revision to currently approved informed consent/waiver of informed consent', 'Revision to principal investigator' (which is checked), 'Add study team personnel', 'Remove study team personnel', and 'Other (e.g. recruitment, advertising, scripts, investigator brochure, survey/data collection tools, etc.)'. Below this list is a text area for summarizing the revisions. A red box highlights the 'New Principal Investigator' section, which includes a dropdown menu, a note about attaching conflict of interest forms, and a note about attaching CITI training certificates, both with 'Add Attachment' buttons.

Adding Study Team Members for an Amendment

Select “Add study team personnel”, explain the addition of the study team member then go to the drop-down box and add the new study team member. The researcher documents they have on file will auto populate. If there are any missing or are listed in red, you can attach them here. Any outdated or missing documents must be attached to make the amendment request. Finally, select “Save” after each entry or the information will not be added to the amendment form.

If an individual is not currently listed in IRBManager you will need to create a new contact first (see red circle in picture below). Once this is done, you can go back into your amendment, refresh the page, and add the individual as explained above.



Collaborators Amendment Information Page 2 of 3

Amendment Information

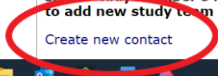
Add study team personnel
 Remove study team personnel
 Other (e.g. recruitment, advertising, scripts, investigator brochure, survey/data collection tools, etc.)

Please summarize what revisions are being made and explain the reason for the revisions. (Required)

Add study team members (Required)
 After filling in all applicable information make sure to click **SAVE** on the right hand side of the row.

Study Team Member Name* Save
 Study Team Member Role*
 CITI Conflict of Interest certificate. Add Attachment
 CITI (researcher) training certificate. Add Attachment
 Conflict of Interest. Add Attachment

If the study member's name does not appear, they are not yet in the system. Please click on the link below to add new study team personnel to IRBManager.
[Create new contact](#)



Removing Study Team Members for an Amendment

Select "Remove study team personnel", explain the removal of the study team member then go to the drop-down box and type in the study team member you would like to remove along with their role. Finally, select "Save" after each entry or the information will not be added to the amendment form.

Collaborators Amendment Information Page 2 of 3

Amendment Information

Revision to currently approved protocol
 Revision to an amendment
 Revision to currently approved informed consent/waiver of informed consent
 Revision to principal investigator
 Add study team personnel
 Remove study team personnel
 Other (e.g. recruitment, advertising, scripts, investigator brochure, survey/data collection tools, etc.)

Please summarize what revisions are being made and explain the reason for the revisions. (Required)

Remove study team members (Required)
 After filling in all applicable information make sure to click **SAVE** on the right hand side of the row.

Study Team Member Name* Save
 Study Team Member Role*





Continuing Reviews

If you need to update study team members at the time of continuing review, this can be completed within the continuing review submission. However, please note that new study team members cannot participate on the study until approval of the continuing review. Please see the [Continuing Review/Administrative Update Application](#) section on how to navigate and start the xform for this type of submission.

If you need to make changes to the study team, answer “No” to the question whether the current list of study team members is correct, then select add or remove (or both) study team personnel.

Collaborators Report of Activity Page 2 of 5

Report of Activity

Yes
 No

Current Study Team Members Add Note View Audit

Name	Role
Sample, Nicole MPA	Principal Investigator

Is the list of study team members above accurate? (Required)

Yes
 No

Please select the changes to the study team that need to occur. (Required) Add Note View Audit

Add study team members
 Remove study team members (Select all that apply)

Adding Study Team Members during Continuing Review

Select “Add study team members”, then go to the drop-down box and add the new study team member. The researcher documents they have on file will auto populate. If there are any missing or are listed in red, you can attach them here. Any outdated or missing documents must be attached to add them to the study. Finally, select “Save” after each entry or the information will not be added to the continuing review form.



Collaborators Report of Activity Page 2 of 5

Report of Activity

No

Current Study Team Members Add Note View Audit

Name	Role
Sample, Nicole MPA	Principal Investigator

Is the list of study team members above accurate? (Required)

Yes

No

Please select the changes to the study team that need to occur. (Required) Add Note View Audit

Add study team members (Select all that apply)

Remove study team members

Add study team members (Required)

Study Team Member Name* Save

Study Team Member Role*

CITI COI Training Certificate Add Attachment

CITI Researcher Training Certificate Add Attachment

Conflict of Interest Form Add Attachment

*After filling in all applicable information make to click **SAVE** on the right hand side of the row.*

Removing Study Team Members during Continuing Review

Select "Remove study team personnel", then go to the drop-down box and type in the study team member you would like to remove along with their role. Finally, select "Save" after each entry or the information will not be added to the continuing review form.

Collaborators Report of Activity Page 2 of 5

Report of Activity

No

Current Study Team Members Add Note View Audit

Name	Role
Sample, Nicole MPA	Principal Investigator

Is the list of study team members above accurate? (Required)

Yes

No

Please select the changes to the study team that need to occur. (Required) Add Note View Audit

Add study team members (Select all that apply)

Remove study team members

Remove Study Team Members (Required)

Study Team Member Name Save

Study Team Member Role



Enrollment/Final Closures

If your study is closing its enrollment or if you need to close the study entirely, please complete the appropriate form. Navigating to the forms are like that of the continuing review and amendments; however, when you get to the select xForm to start screen, select the “Enrollment Closure” if you are only closing enrollment to your study but keeping it active for follow up and data analysis. Select “Final Closure” if you are closing out the study to make it inactive.

Start Form on Study IM2020-005-test-IMMC (IRB) Filter:

Select xForm to start		
Action	Form (Click to start)	Description
	24 Hour SAE Notification Form	24 Hour SAE Notification Form
	Amendment	Amendment
	Continuing Review	This is the annual continuing review form to be used for all study types.
	Enrollment Closure	Submit this report when all subjects have been enrolled and there is continued follow up. Enrollment closure means that no additional subjects will be enrolled.
	External IRB- CR/Amendment/Events (CIR)	External IRB Continuing Reviews, Amendments, Adverse Events/Unanticipated Problems and other documentation
	Final Closure	Submit this report when the study is going to be completed and no further study activities will occur.
	Non-compliance Report form	Non-compliance/Adverse Event formal submission report to the IRB: Reports should be submitted to the IRB within 7 days of event notification/discovery of the event.

OR

Complete the xform using the same navigation processes outline previously (see [Navigating pages](#)). Please note that enrollment closures do not receive a formal letter but rather an email acknowledging the enrollment closure. Final Closures must be reported to the full board, so any final closure submissions will be finalized after the next IRB meeting following the submission date. The PI will receive a formal closure letter for the study at that time.

Unanticipated Events and Deviations

24-Hour Serious Adverse Event (SAE) Reporting

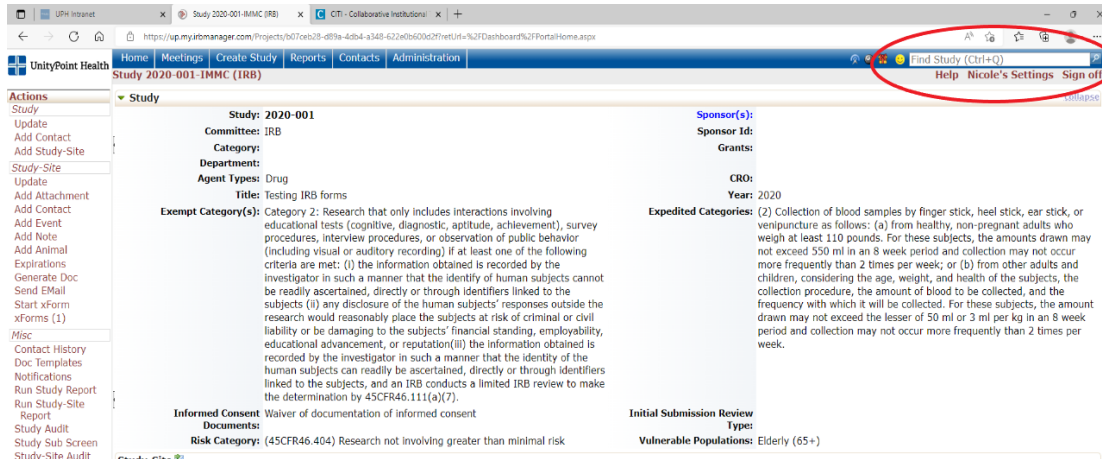
The 24-Hour Serious Adverse Event Notification is to be used to notify the IRB of any Serious Adverse Event that occurs that is unexpected, related to research and poses risk to subject or others. This form is also used to report the death of a subject.

Non-compliance Reporting

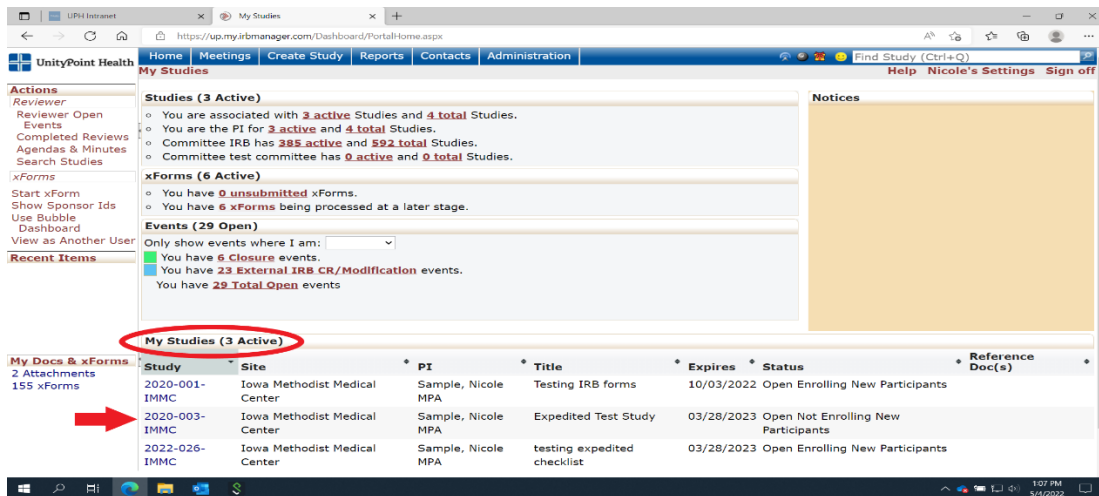
The Non-Compliance Form is to be used to report all internal unanticipated problems and protocol deviations and violations with the protocol, board requirements or regulations. This form also serves as a follow up report to the 24-Hour SAE Reporting form.

To access these forms:

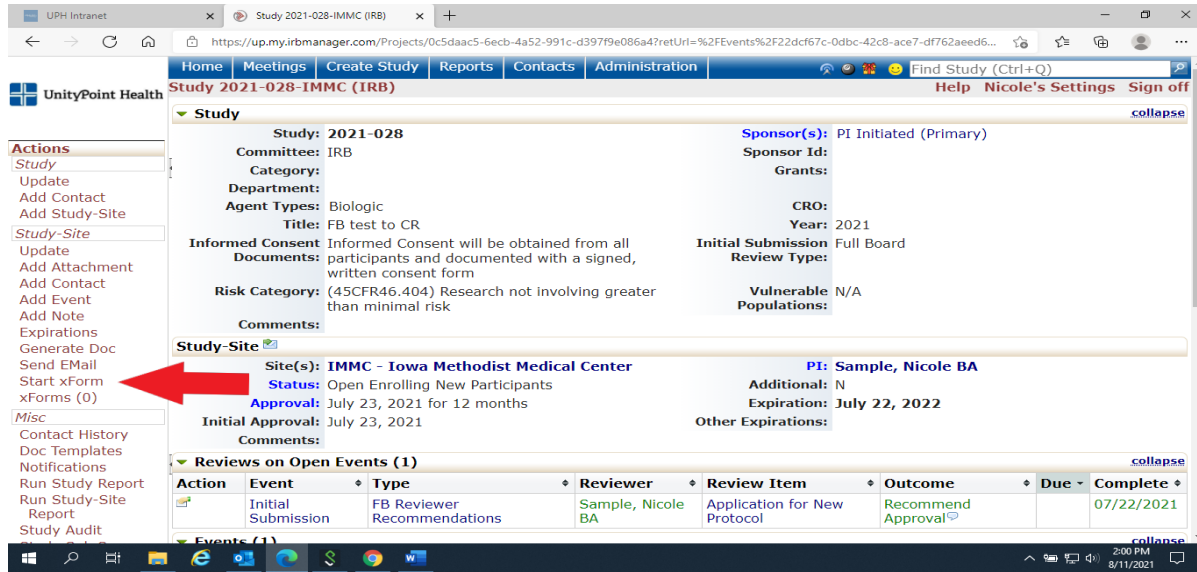
- 1) Log into IRBManager, type the study number into the “Find a Study” field in the upper right of the screen:



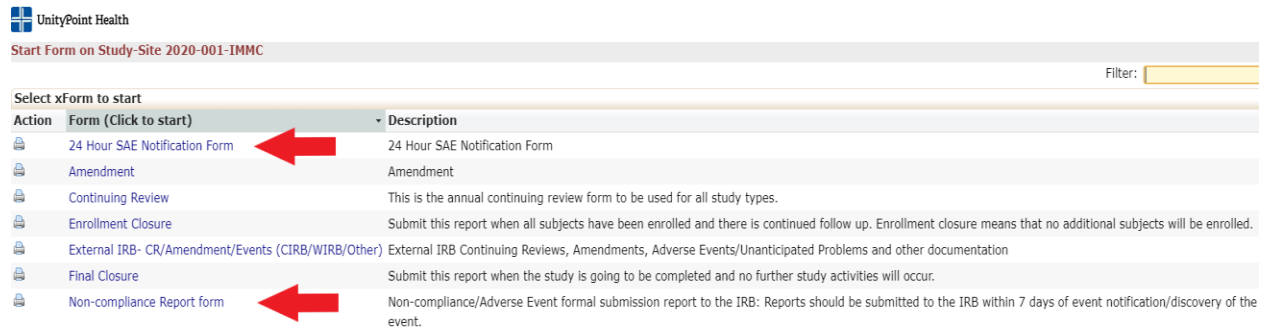
2) OR from your dashboard, go the “My Studies” located at the bottom of your screen and select the study you would like to begin the xform on:



Once you are in the study, navigate to the “Actions” panel on the left of the screen and select “Start xForm”.



Next, select either “24 Hour SAE Notification” or “Non-compliance Report” from the menu options:



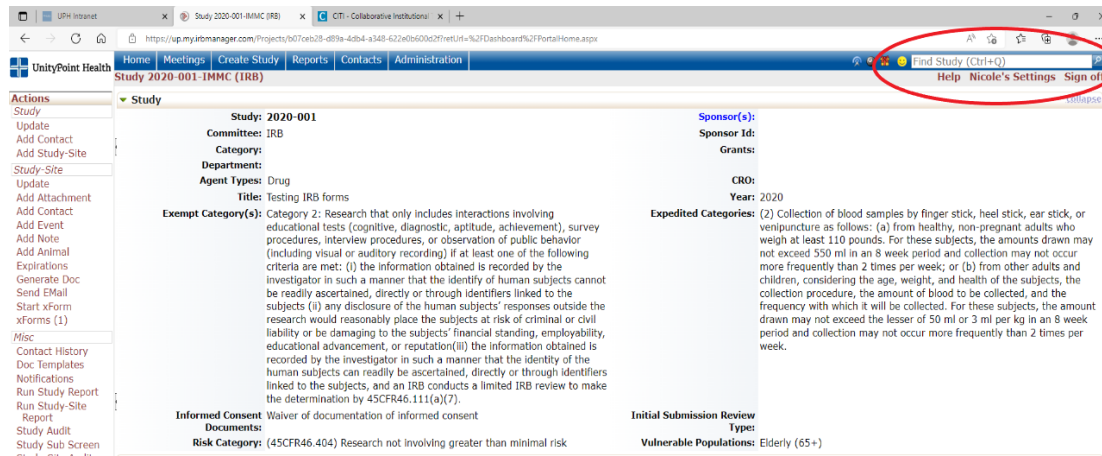
Finally, complete the xform(s) using the same navigation processes outlined previously (see [Navigating pages](#)).

Event Pages

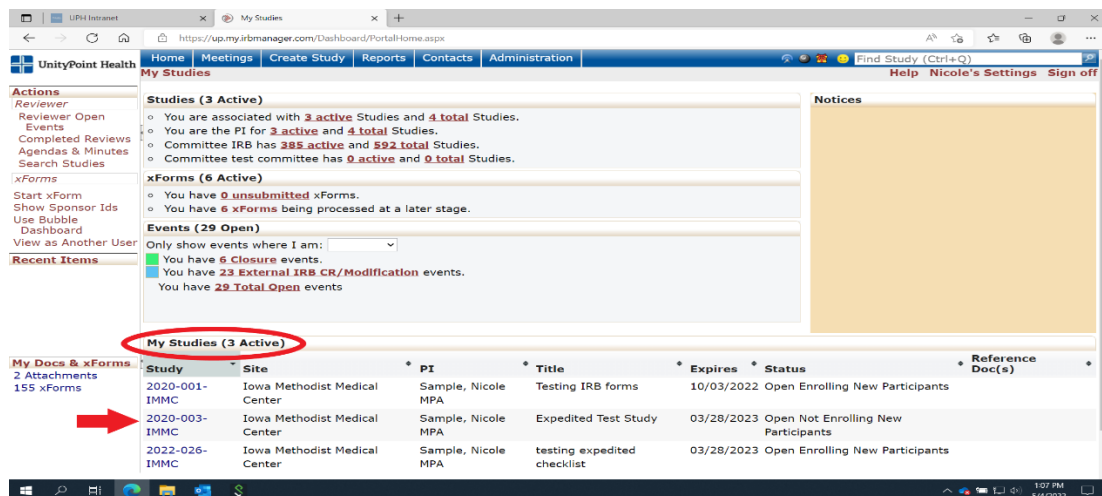
Any time you submit an xform to the IRB (new application, continuing review, amendment, etc.) it creates an event for that submission. It is within the event page(s) that you can obtain more detail for each submission such as attachments to the xform/event, viewing the approved xform, approval letters and emails sent.

To access the events for an approved study:

- 1) Log into IRBManager, type the study number into the “Find a Study” field in the upper right corner of the screen:



- 2) OR from your dashboard, go the “My Studies” located at the bottom of your screen and select the study you would like to view:



Once you are in the study, scroll to the bottom of the page to “Events”:

▼ Events (13)						
Action	Event	Att	Instance/UDF	Start	Complete	
	Continuing Review	2		06/03/2022		
	SAE/Non-compliance related to Research	0		05/24/2022		
	SAE/Non-compliance related to Research	1		05/18/2022	06/09/2022	
	Amendment	2		10/28/2021	10/29/2021	
	Amendment	2		12/03/2020	12/10/2020	
	Amendment	2		12/03/2020	12/03/2020	
	Amendment	2		12/03/2020	01/07/2021	
	Amendment	2		12/01/2020	12/10/2020	
	Amendment	2		11/19/2020	07/16/2021	
	Continuing Review	4		10/22/2020	10/12/2021	
	Continuing Review	11		10/13/2020	07/16/2021	
	Continuing Review	3		09/21/2020	10/12/2021	
	Initial Submission	13		06/04/2020	01/18/2022	
▼ Study-Site Emails (17)						

From here, you can select the event you want:

▼ Events (13)						
Action	Event	Att	Instance/UDF	Start	Complete	
	Continuing Review	2		06/03/2022		
	SAE/Non-compliance related to Research	0		05/24/2022		
	SAE/Non-compliance related to Research	1		05/18/2022	06/09/2022	
	Amendment	2		10/28/2021	10/29/2021	
	Amendment	2		12/03/2020	12/10/2020	
	Amendment	2		12/03/2020	12/03/2020	
	Amendment	2		12/03/2020	01/07/2021	
	Amendment	2		12/01/2020	12/10/2020	
	Amendment	2		11/19/2020	07/16/2021	
	Continuing Review	4		10/22/2020	10/12/2021	
	Continuing Review	11		10/13/2020	07/16/2021	
	Continuing Review	3		09/21/2020	10/12/2021	
	Initial Submission	13		06/04/2020	01/18/2022	
▼ Study-Site Emails (17)						



Once you have clicked on the event, it will open the event details page:



The screenshot shows the 'Event Details' page for a 'Continuing Review on 2020-001-IMMC'. The page is divided into several sections:

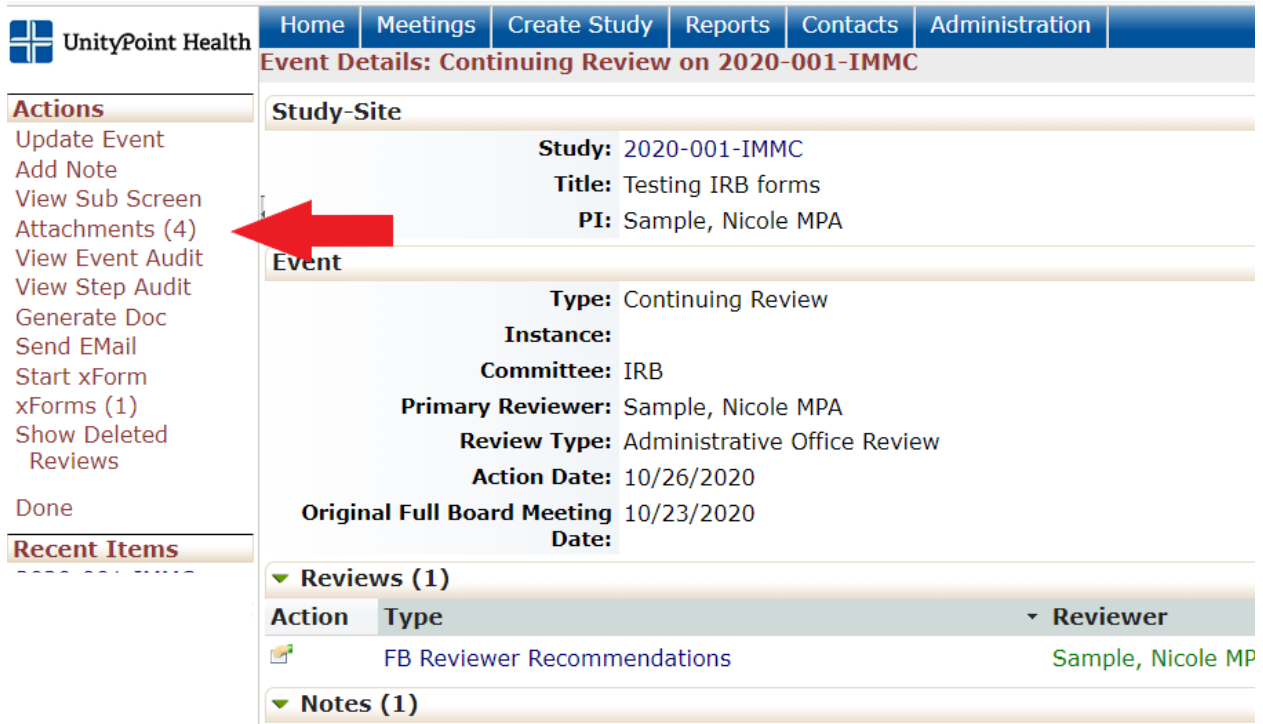
- Study-Site:** Study: 2020-001-IMMC, Title: Testing IRB forms, PI: Sample, Nicole MPA, Site: IMMC - Iowa Methodist Medical Center, Committee: IRB, Sponsor Id.
- Event:** Type: Continuing Review, Instance: IRB, Committee: IRB, Primary Reviewer: Sample, Nicole MPA, Review Type: Administrative Office Review, Action Date: 10/26/2020, Original Full Board Meeting Date: 10/23/2020, Started: 10/22/2020, Completed: 10/12/2021, Assigned: Sample, Nicole MPA, Secondary Reviewer: Sample, Nicole MPA, Changes Requested: Update protocol.
- Reviews (1):** A table with columns: Action, Type, Reviewer, Review Item, Outcome, Due, Complete. One entry: FB Reviewer Recommendations, Reviewer: Sample, Nicole MPA, Review Item: Continuing Review, Outcome: Recommend Approval, Due: 10/22/2020, Complete: 10/22/2020.
- Notes (1):** One note: 'Event Date Completed was set to the latest actual step date by TheSystem when all the steps were marked as completed.' Entered: 01/18/2022, By: nicole.sample@unitypoint.org, Type: Automation, Int: Yes.
- Emails (13):** A table with columns: Action, Subject, Date, Del, To/From, Int. Multiple entries for notifications and approvals.

To access the full approved xform for the event, select "xforms" under Actions on the left side of the page:



This screenshot shows the same 'Event Details' page, but with the 'xForms (1)' option in the 'Actions' menu on the left highlighted by a red arrow. The 'xForms (1)' option is located between 'Start xForm' and 'Show Deleted Reviews'.

To access attachments for the event, select “Attachments” under Actions on the left side of the page:



UnityPoint Health | Home | Meetings | Create Study | Reports | Contacts | Administration

Event Details: Continuing Review on 2020-001-IMMC

Study-Site

Study: 2020-001-IMMC
Title: Testing IRB forms
PI: Sample, Nicole MPA

Event

Type: Continuing Review
Instance:
Committee: IRB
Primary Reviewer: Sample, Nicole MPA
Review Type: Administrative Office Review
Action Date: 10/26/2020
Original Full Board Meeting Date: 10/23/2020

Actions

- Update Event
- Add Note
- View Sub Screen
- Attachments (4) ←
- View Event Audit
- View Step Audit
- Generate Doc
- Send EMail
- Start xForm
- xForms (1)
- Show Deleted Reviews
- Done

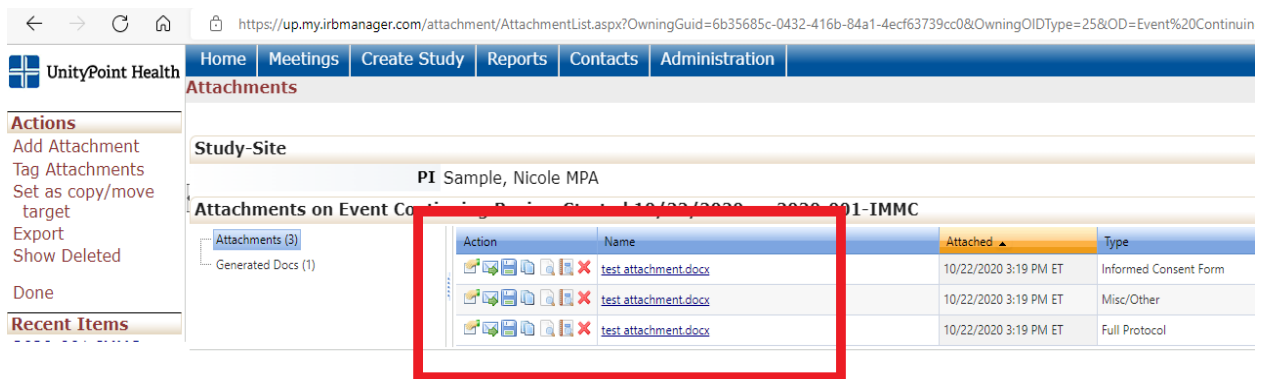
Recent Items

Reviews (1)

Action	Type	Reviewer
	FB Reviewer Recommendations	Sample, Nicole MP

Notes (1)

The attachments page will open, from here you can select, open, and download attachments.



← → ↻ 🏠 <https://up.my.irbmanager.com/attachment/AttachmentList.aspx?OwningGuid=6b35685c-0432-416b-84a1-4ecf63739cc0&OwningOIDType=25&OD=Event%20Continuin>

UnityPoint Health | Home | Meetings | Create Study | Reports | Contacts | Administration

Attachments

Study-Site

PI: Sample, Nicole MPA

Attachments on Event Continuing Review on 10/23/2020 - 2020-001-IMMC

Action	Name	Attached	Type
	test attachment.docx	10/22/2020 3:19 PM ET	Informed Consent Form
	test attachment.docx	10/22/2020 3:19 PM ET	Misc/Other
	test attachment.docx	10/22/2020 3:19 PM ET	Full Protocol

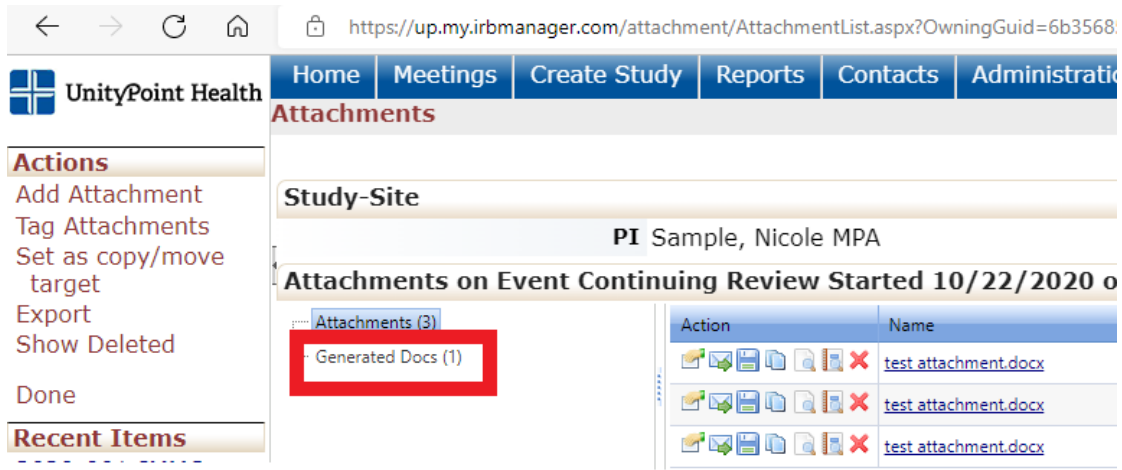
Actions

- Add Attachment
- Tag Attachments
- Set as copy/move target
- Export
- Show Deleted
- Done

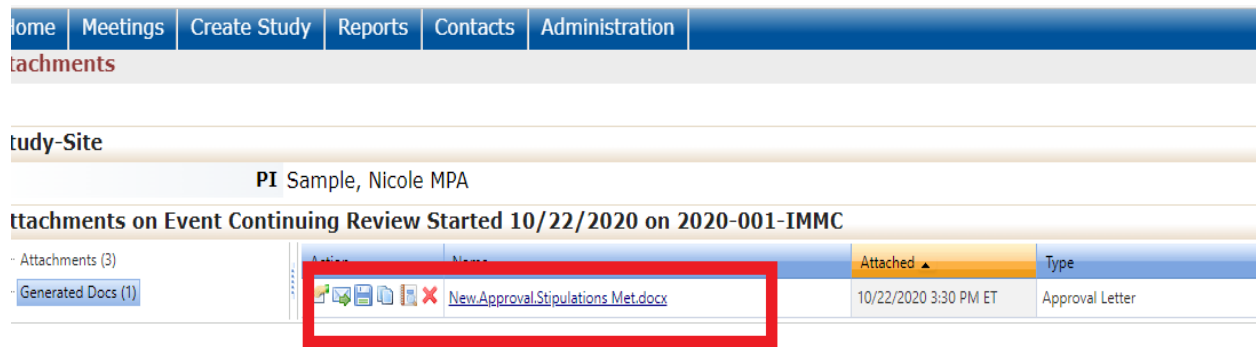
Recent Items

Attachments (3)
Generated Docs (1)

To view and/or download the approval letter, within the attachments page, select Generated Docs:



Any documentations generated by IRBManager for this event can be found here. From within the Generated Docs screen, you can select the document you would like to view or download:



Additional Information & Assistance

To access additional submission guidelines, forms, or the policies and procedures of the IRB/HRPP, please go to our website: [Institutional Review Board | UnityPoint Health - Des Moines](#)

Should you have additional questions regarding IRBManager, please contact the IRB office via email (IRBSubmission@unitypoint.org) or call our office at 515-241-8598. Please allow 24-48 business hours for a response.