UnityPoint Health
Des Moines

Institutional Review Board
Human Research Protection Program
Physical Address: 1415 Woodland Avenue, Health Sciences Library
Mailing Address: 1200 Pleasant Street
Des Moines, IA 50309
515-241-8598
IRBSubmissions@unitypoint.org

UnityPoint Health Des Moines IRB Researcher User Manual for IRBManager

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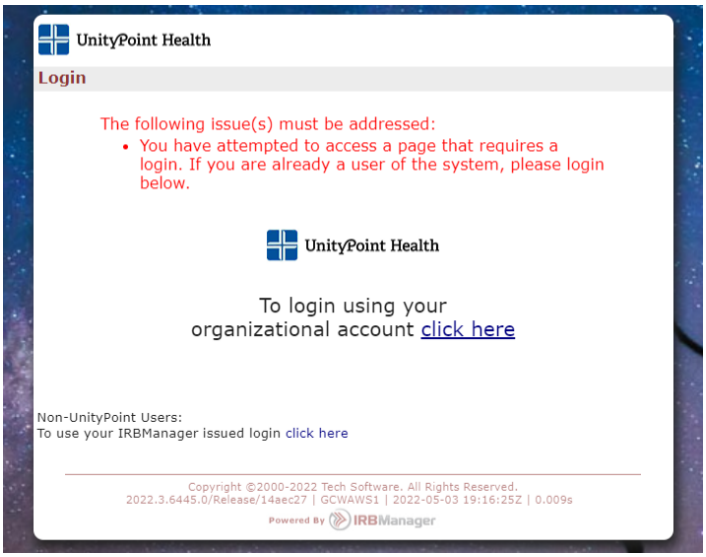
Getting Started with IRBManager

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:

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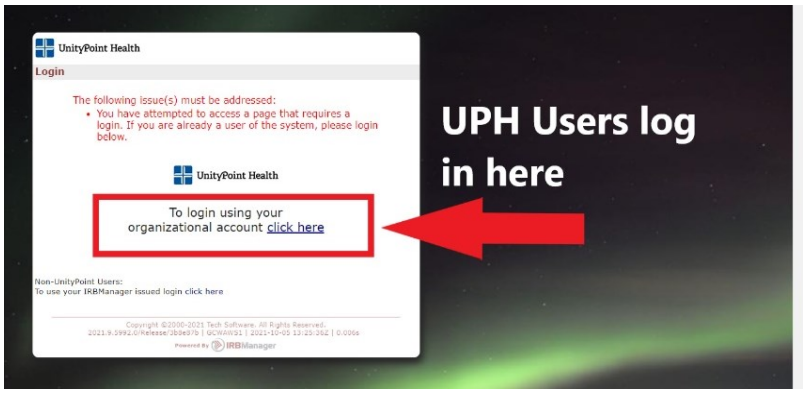
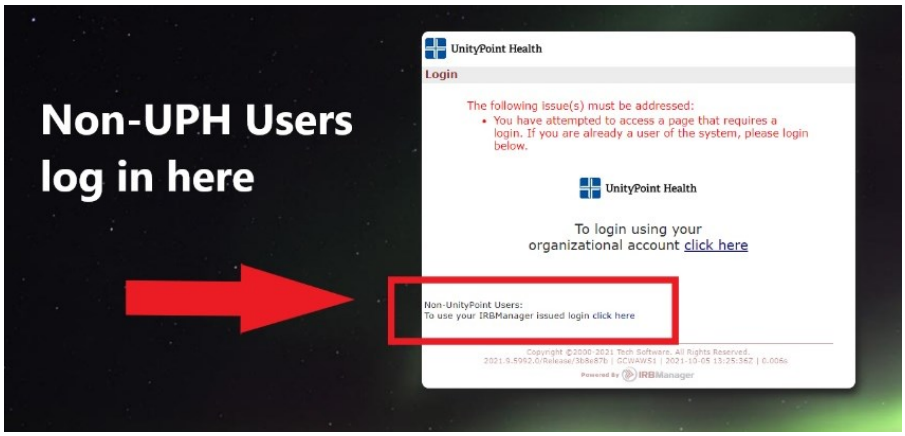


4) If your username is a non-UnityPoint Health email address, you will select this login option:



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.

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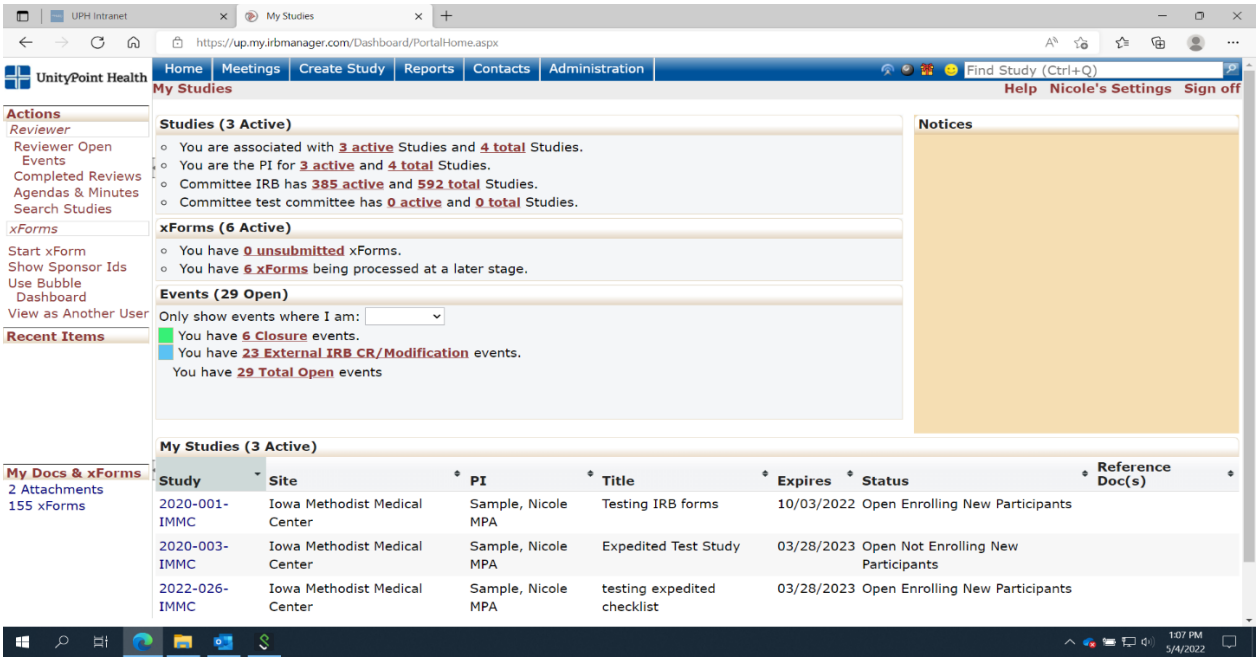

Studies- This section outlines approved studies, both active and closed. Click on the hyperlinks to view the studies. These studies will also be listed individually at the bottom of the dashboard page under “My Studies”. Here you can click on the study number link to take you directly to the study information,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

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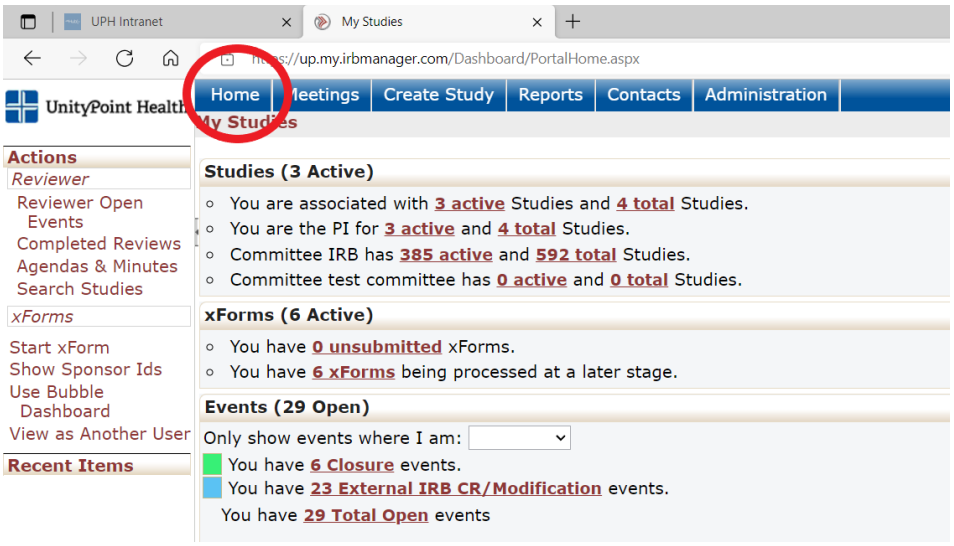
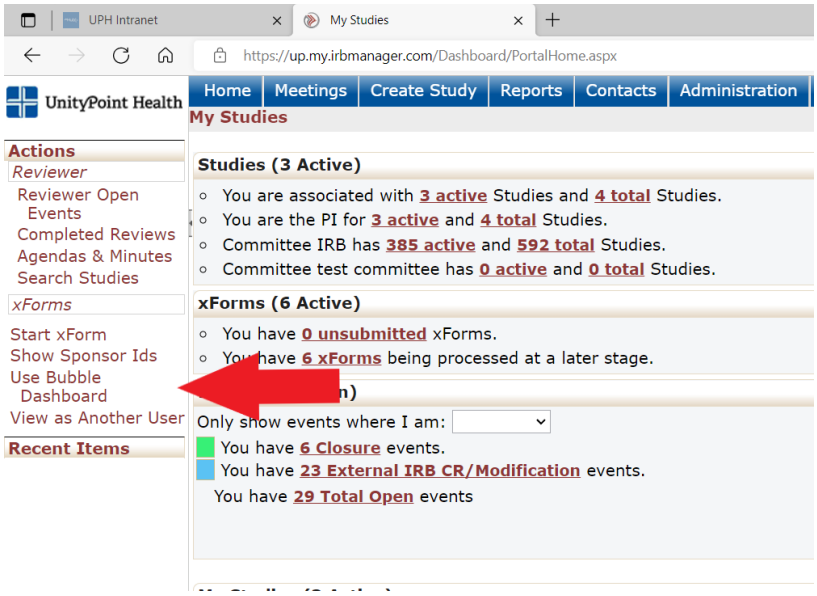
Selecting the **Home** button on any page will return you to your dashboard.



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



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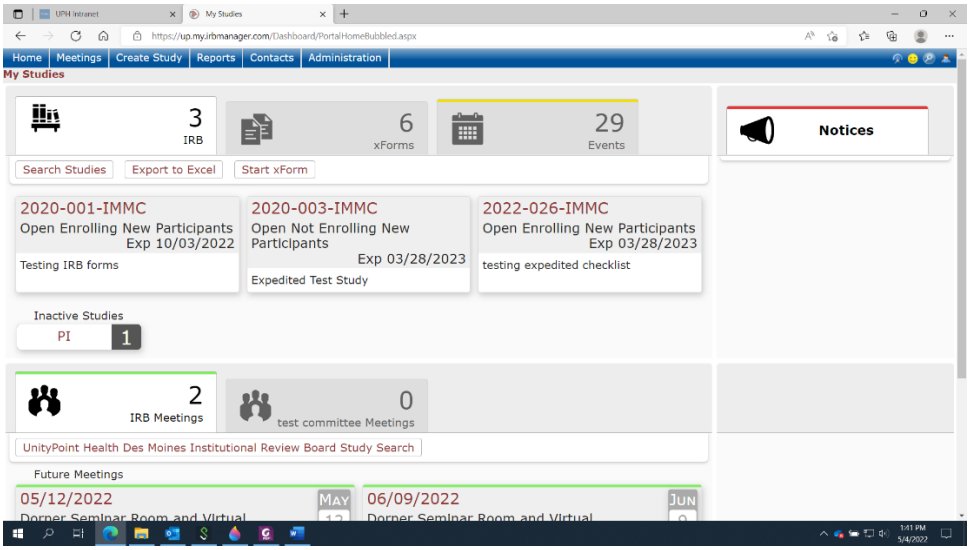
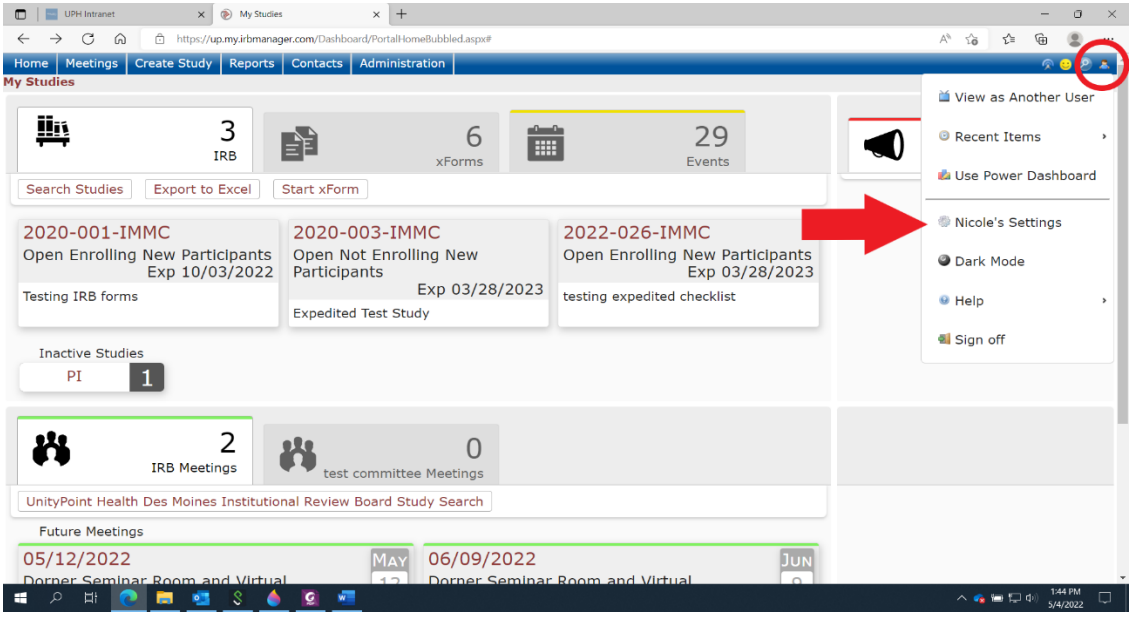
Click on “Use Bubble Dashboard”, and it will revert to this:



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



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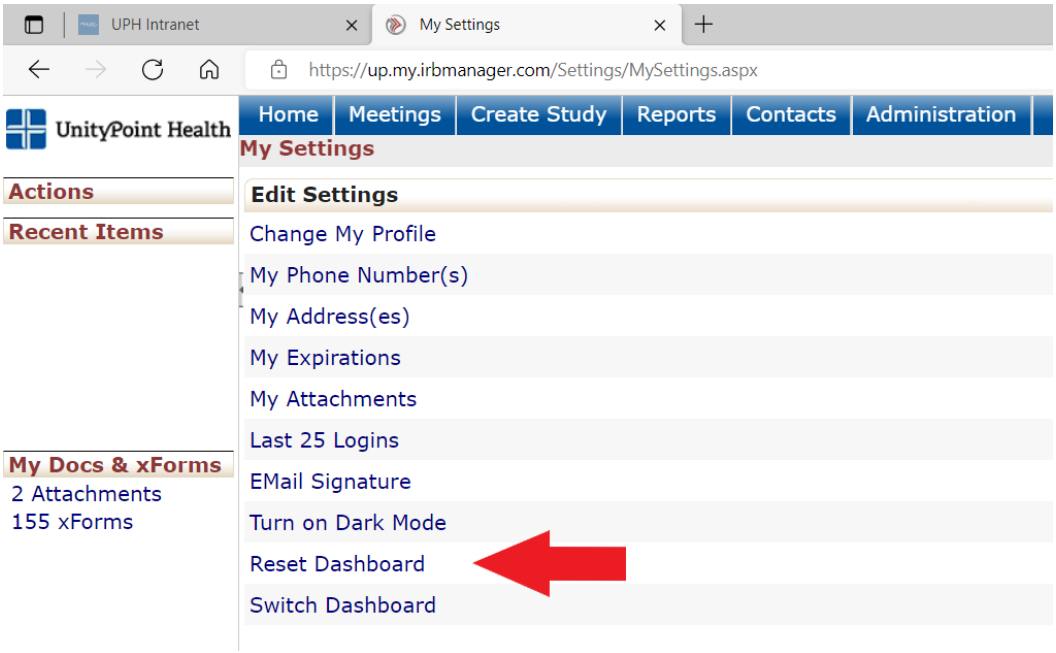
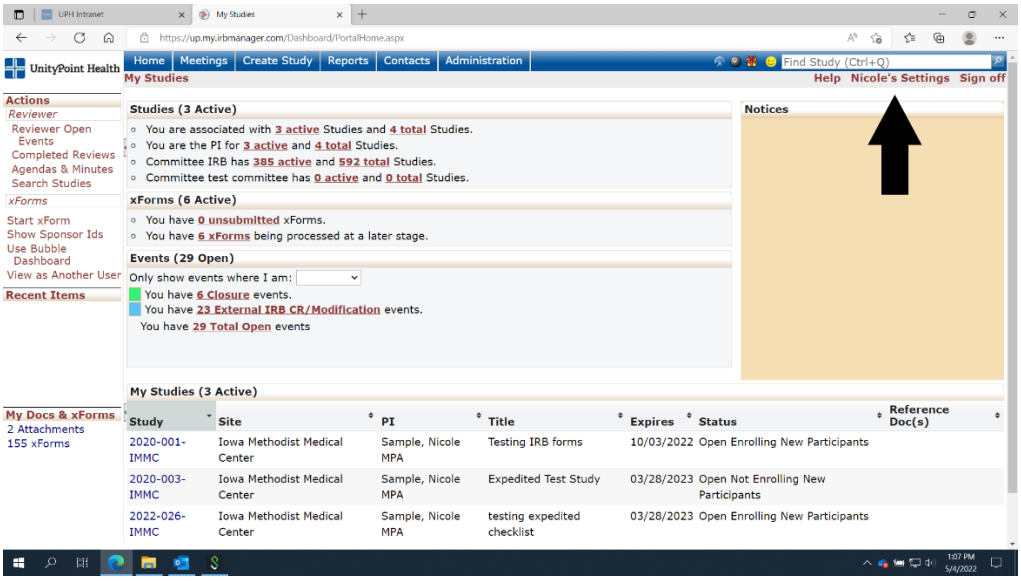
Select “Reset Dashboard” and it will return to the original dashboard view:



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



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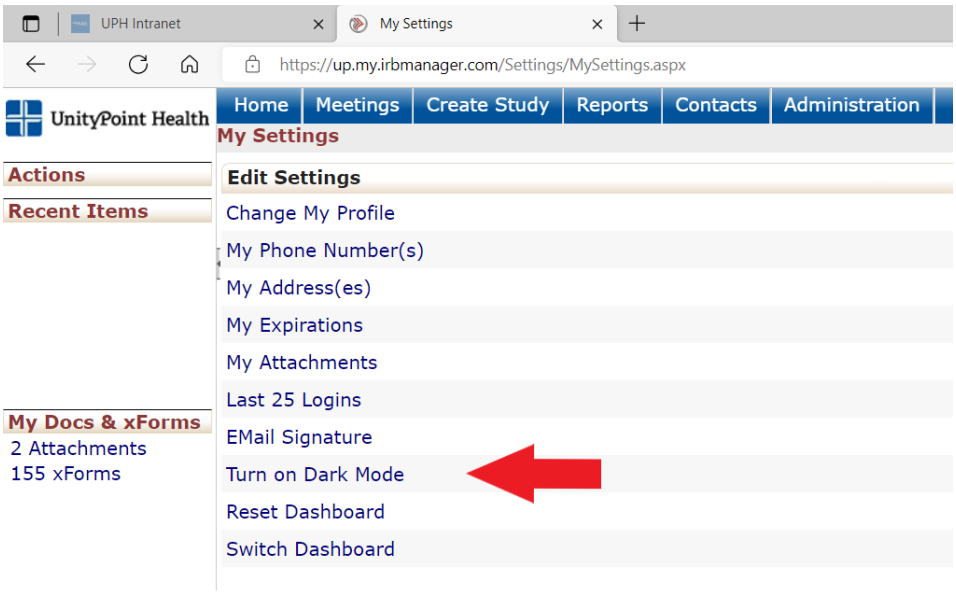
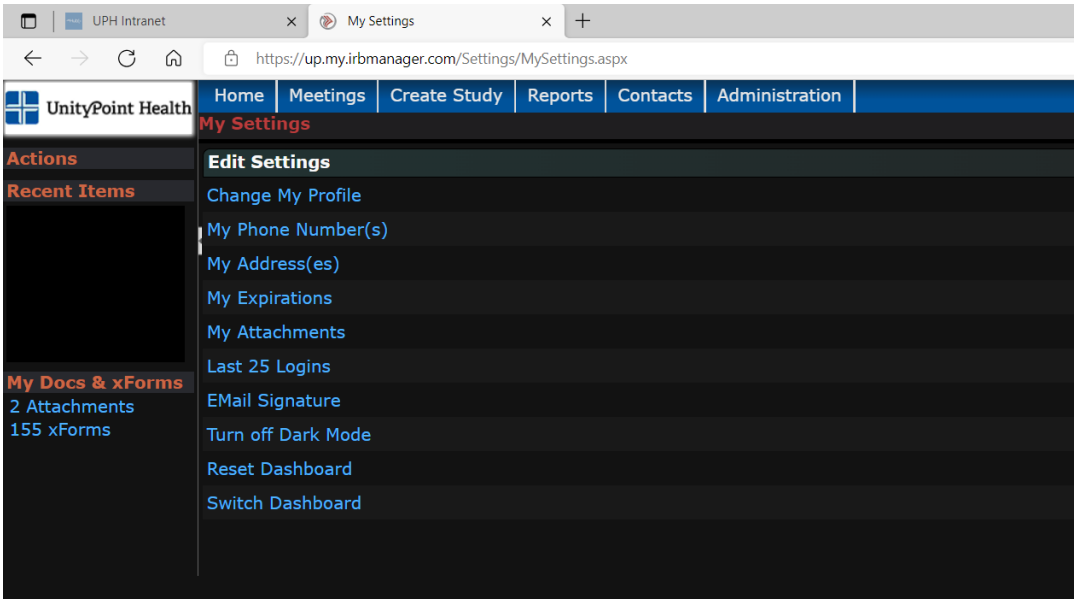
Dark Mode

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



Your IRBManager screens will now look like this:



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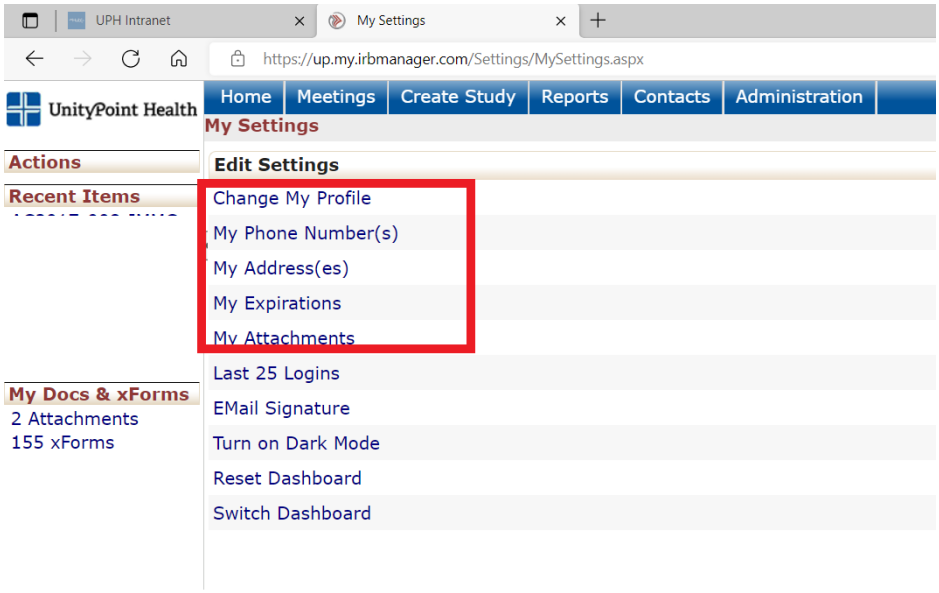
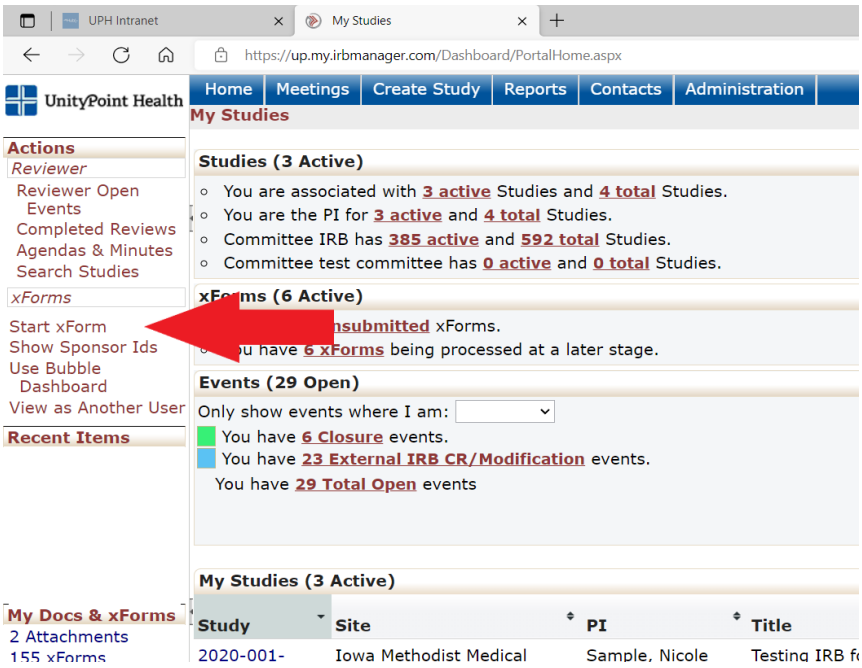
Profile Settings

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:



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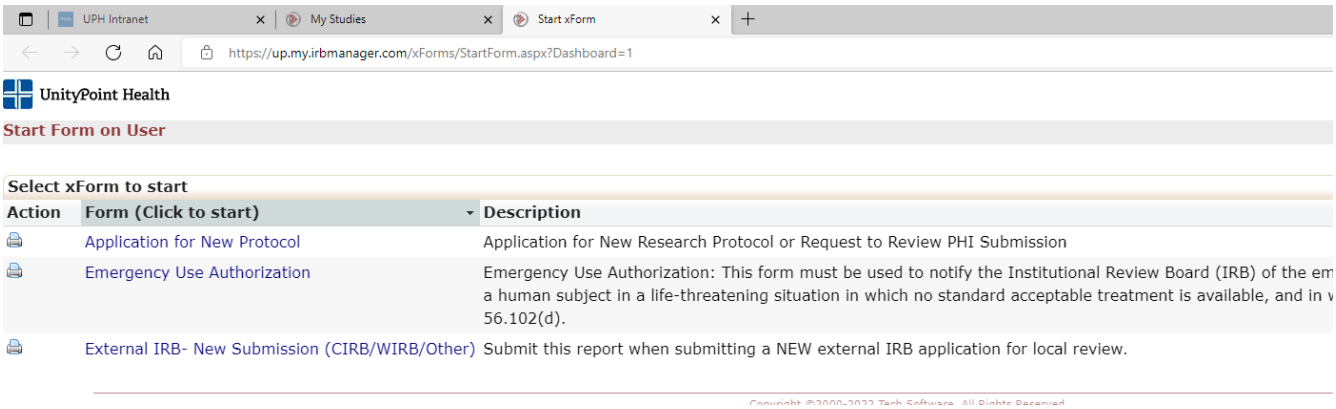
The following menu options will appear:



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.

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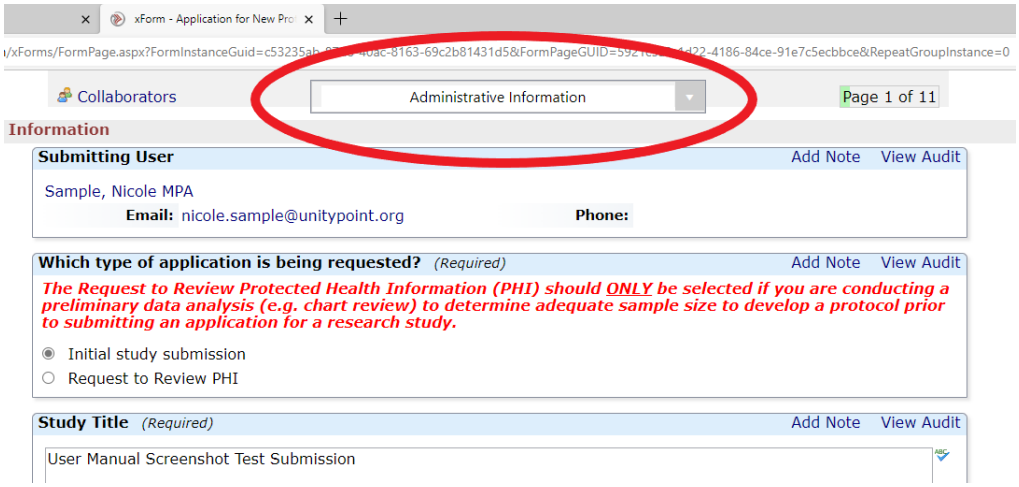
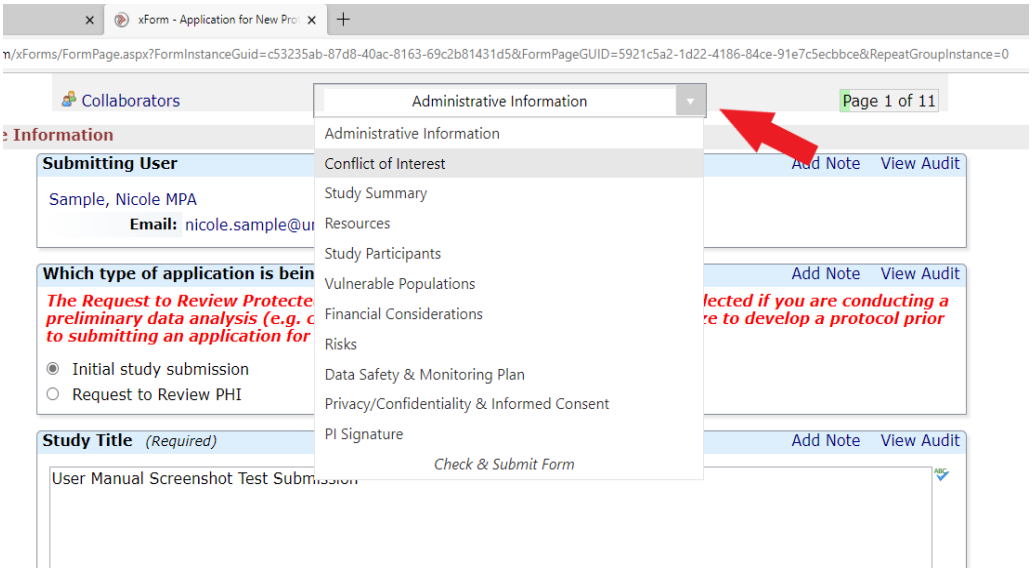
Amendments and continuing reviews may have required questions on the initial pages; however, they can be navigated similarly as described throughout this section.



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:



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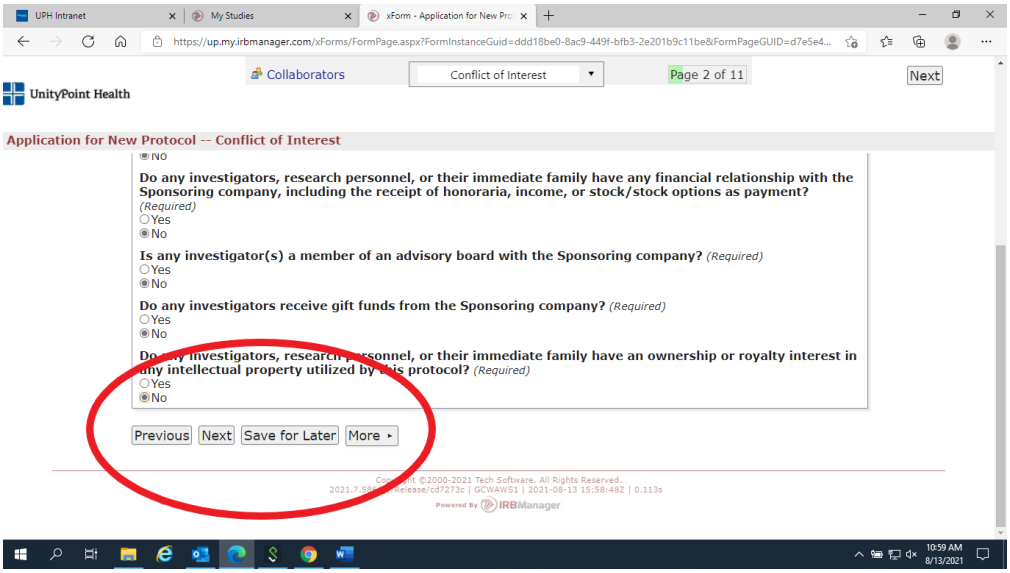
Additional Navigation Options

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.

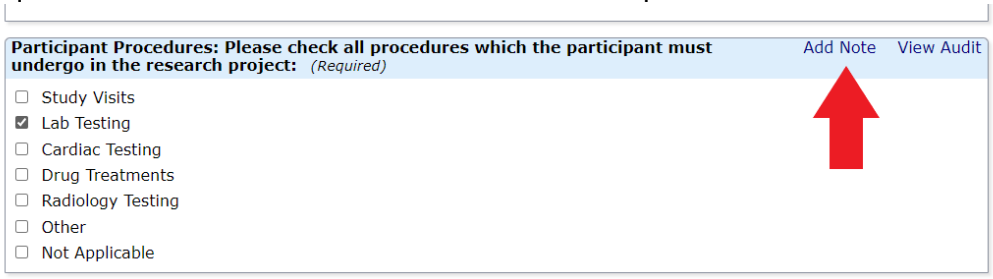
Save for Later: If you need to leave the application, but are not finished, select the "Save for Later" button located at the bottom of each page. This will save the information you have entered so you can return to the application later.

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:



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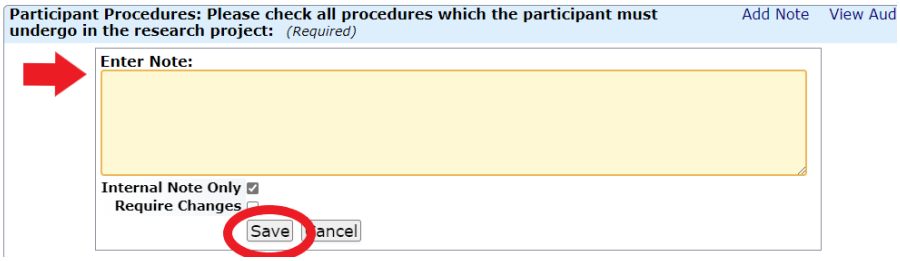
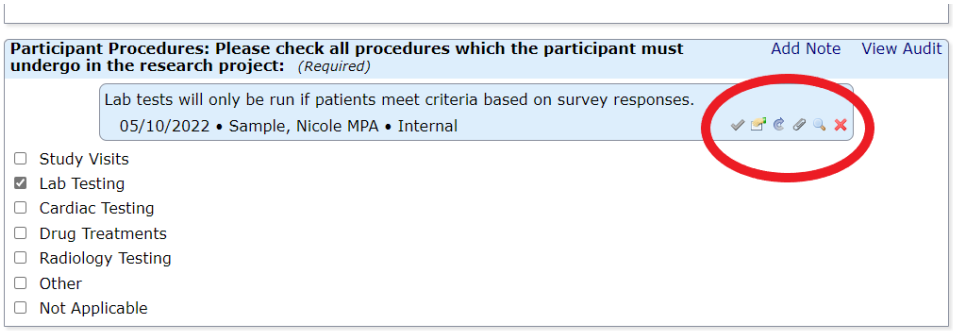
Type in the text box and click “Save” when you are done:

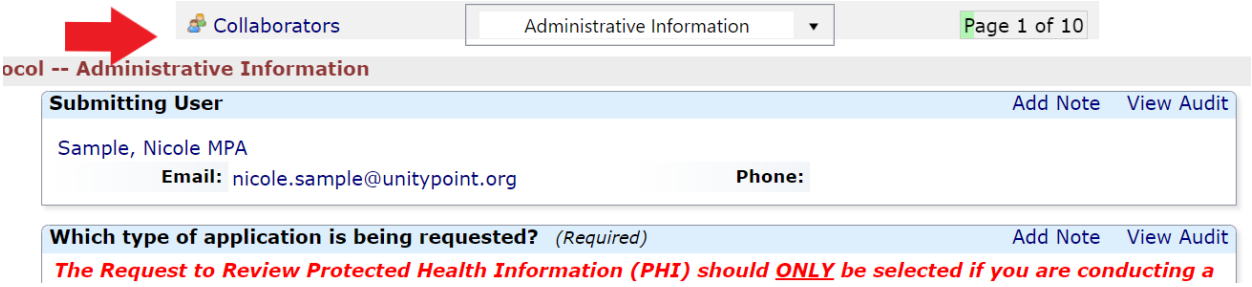


After entering a note, you can edit or delete the note. You can also include additional attachments if needed.



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:



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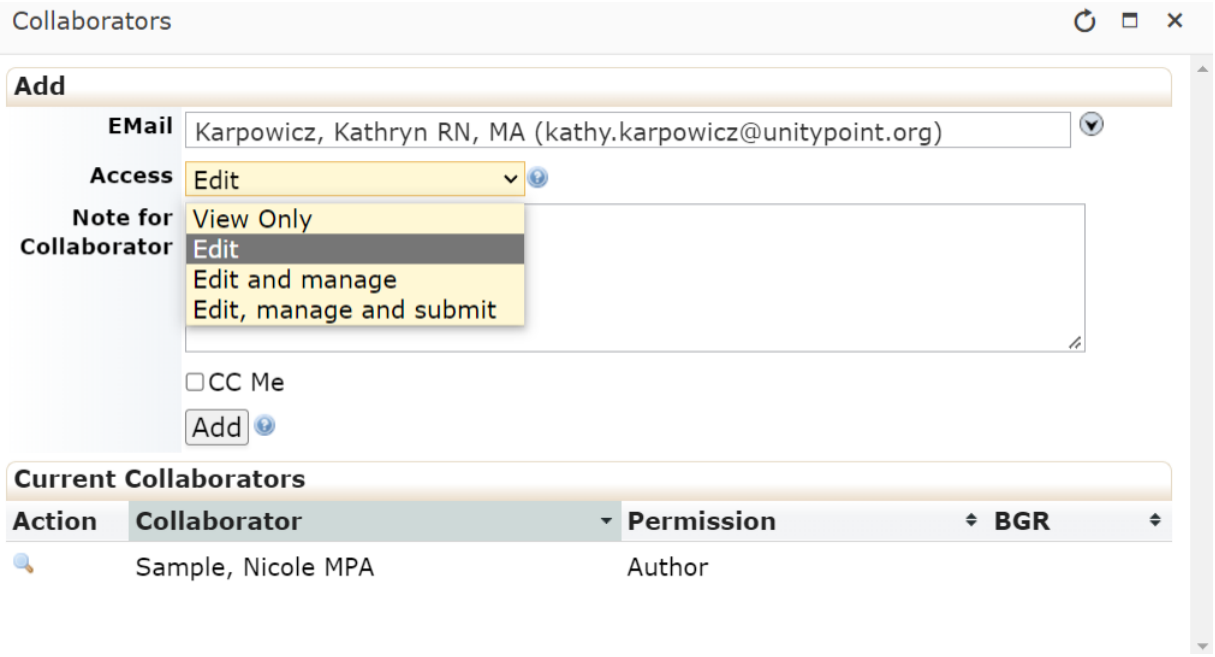
In the pop-up window, begin typing the name or email address of the person you would like to add as a collaborator (note the individual must already be a user in IRBManager). Next, select the access to be given (view only, edit, edit & manage, or edit, manage & submit). Finally, click add at the bottom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



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:

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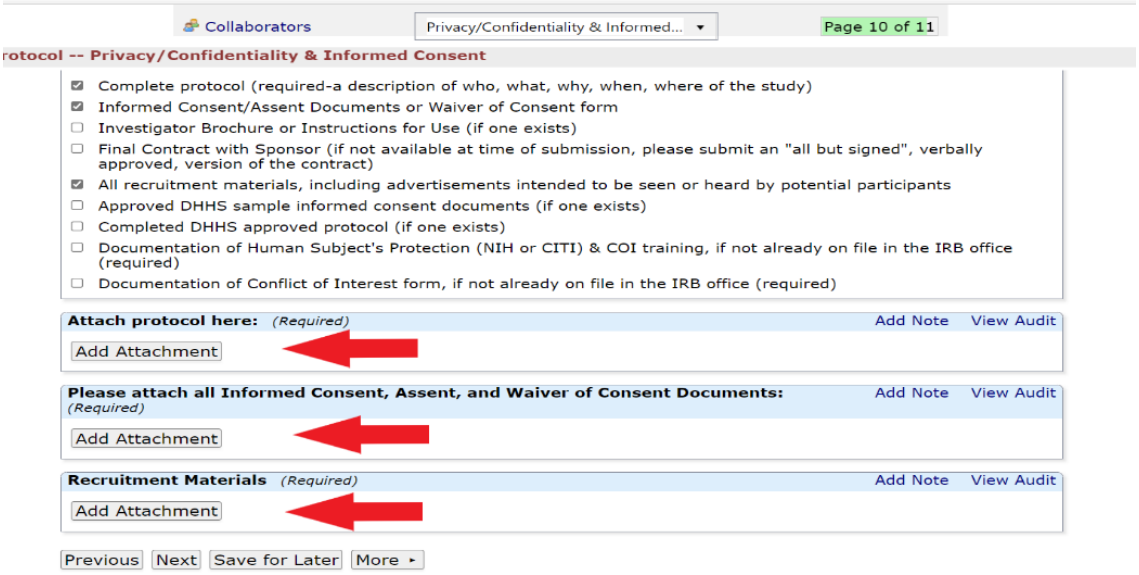
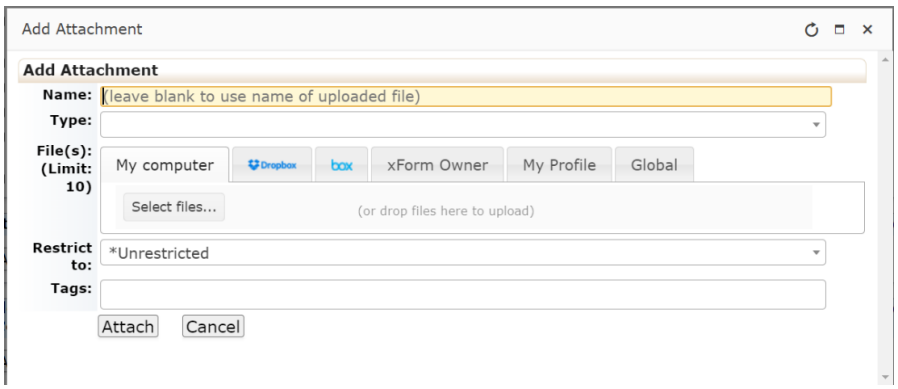


Once you have clicked the button, a window will pop-up allowing you to select the file type and choose your file destination for upload.



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.

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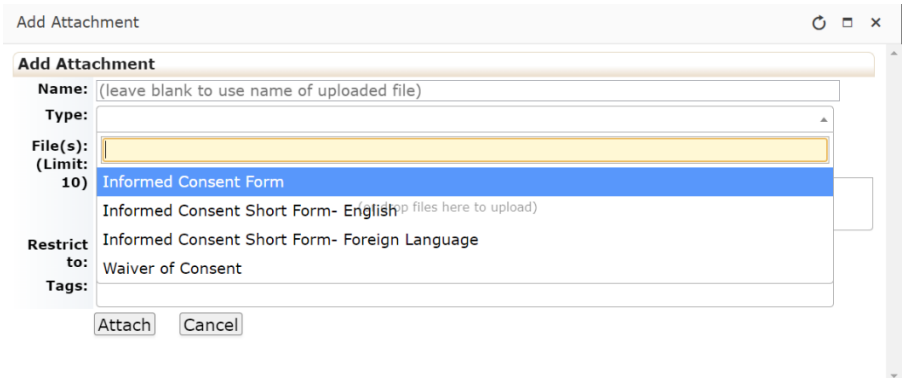
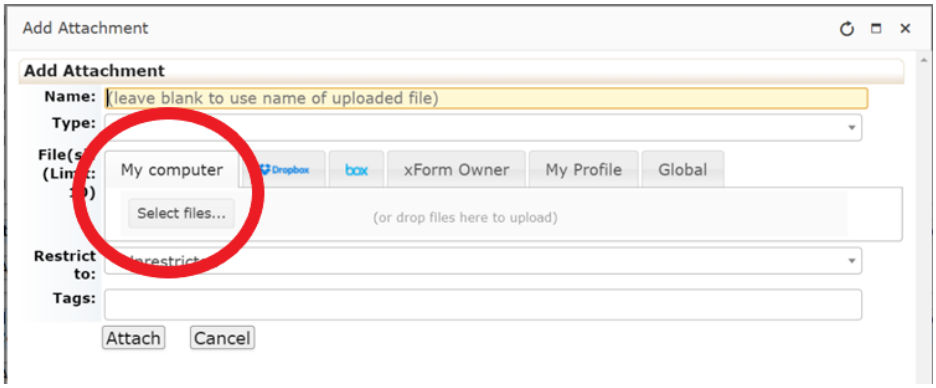
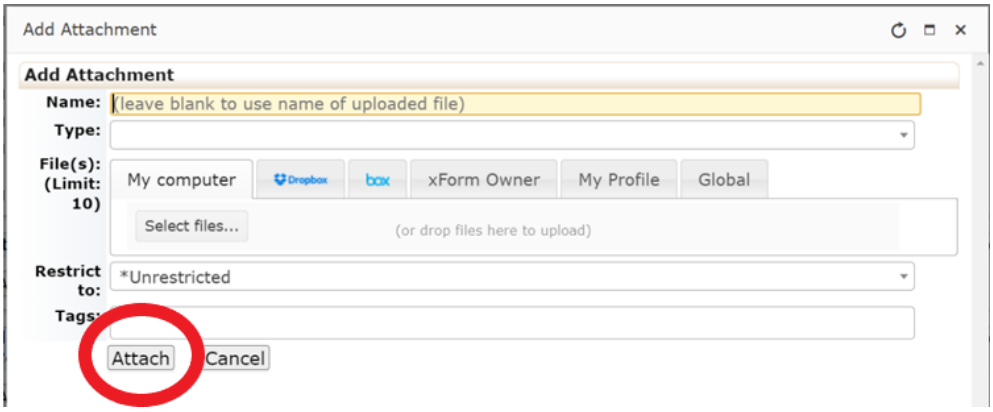


After selecting the attachment type, go to my computer to browse for your document and select the file you would like to upload and attach.



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



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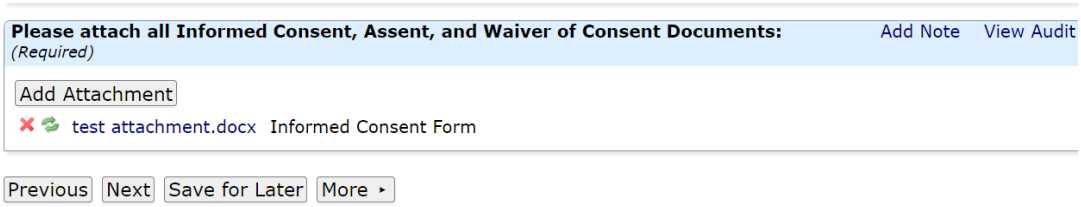
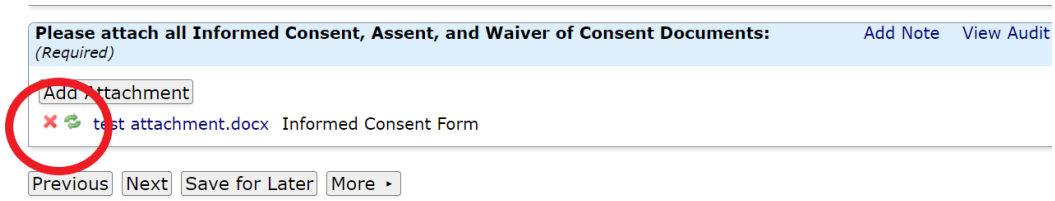
After clicking “Attach”, you will see a link to the attachment populate within the question.



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.

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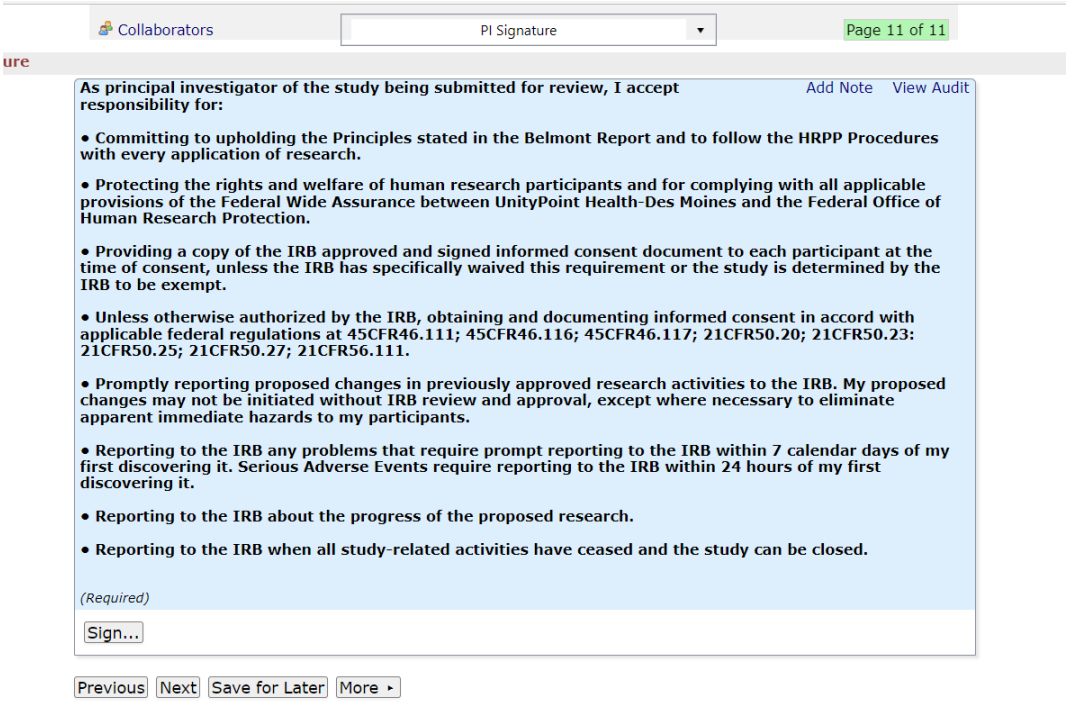
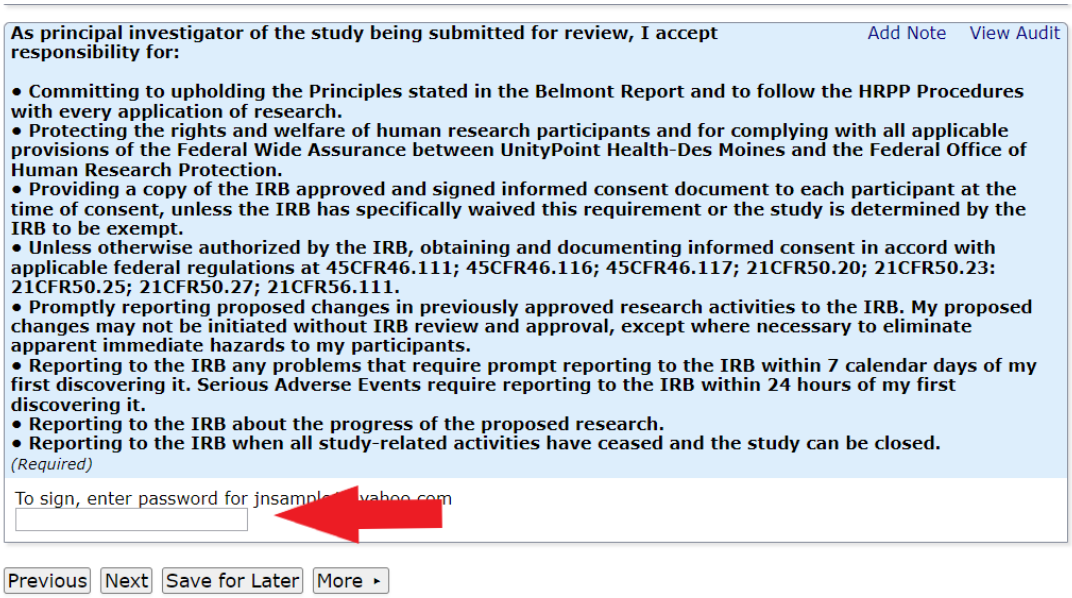


To sign the form, enter your IRBManager password (same as your login credentials) in the provided box.



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

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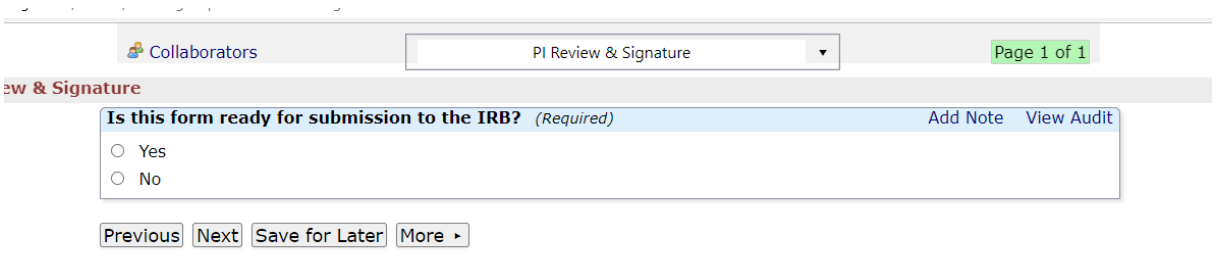
form, print, or submit the form. Once you select submit, the IRB office will be notified of your completed submission, and you will be able to track the status of the form within IRBManager from your dashboard.

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:

> Dear PI Testing,
>
> Nicole Sample, MPA has completed an application for study title irbmanager user manual test study. Your review and electronic signature are now required for submission to the IRB for processing. Please use the following link to access the submission materials Application for New Protocol.
>
> Thank you,
>
> Office of the IRB

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.



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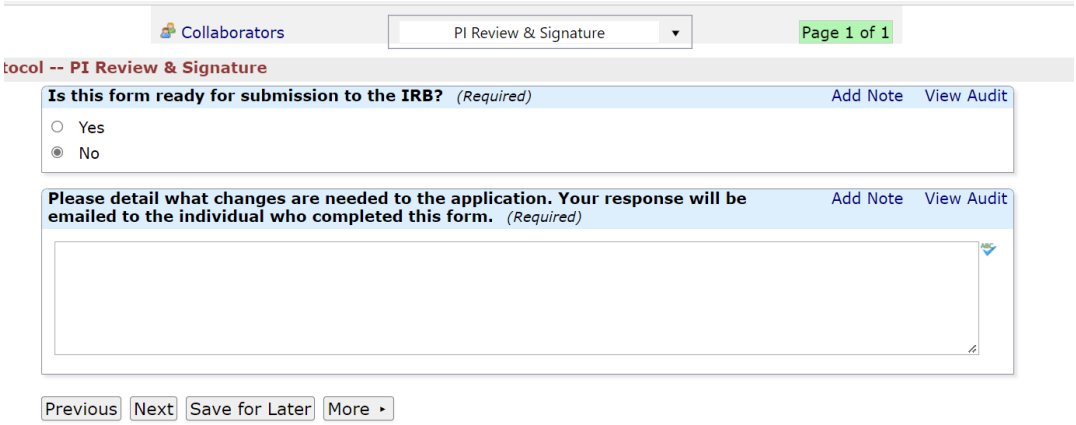
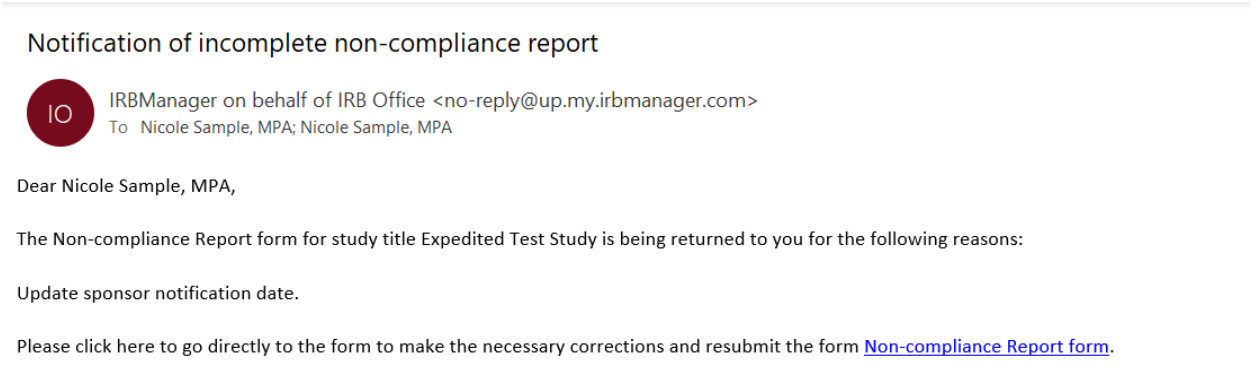
Select Yes if it is ready for submission, the prompts will be the same as outlined above in the PI submission information. If revisions need to be made to the application, select No then explain what revisions are needed.



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.)



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.

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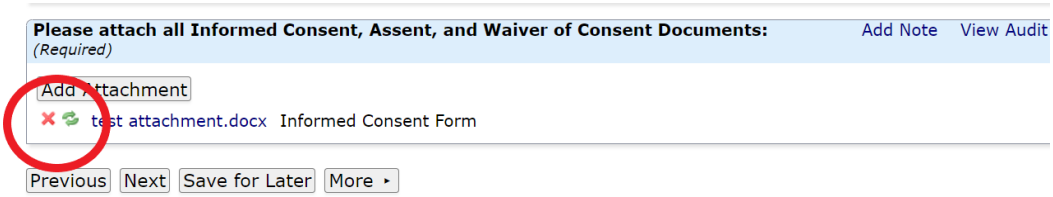
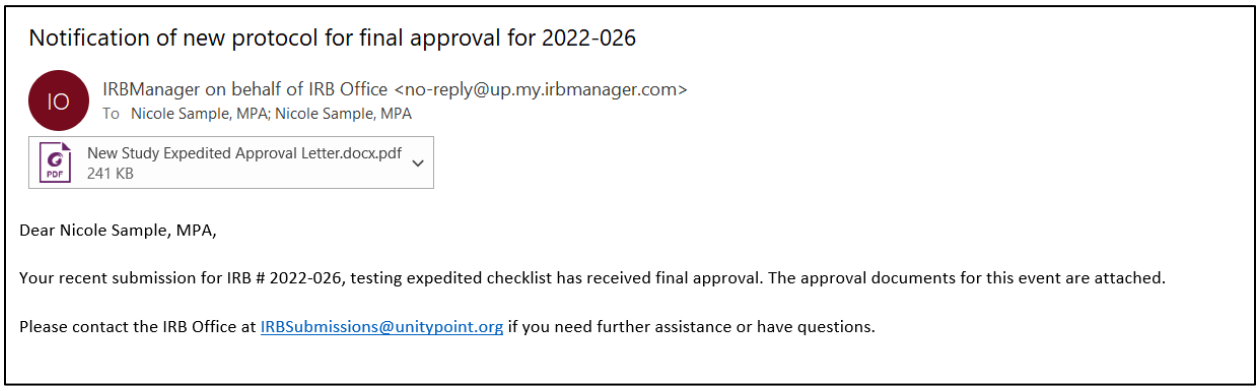
If you are attaching new versions of files, please use the replace feature (**double green arrows**). This will make it easier for your reviewer, so they do not have to figure out which file is the new file to be reviewed.



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.

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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.

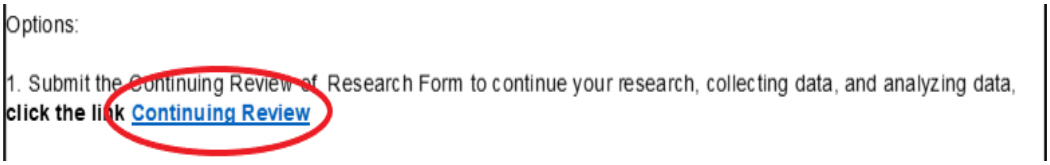
If you have any questions or concerns, please contact the IRB office at irbsubmission@unitypoint.org.

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:

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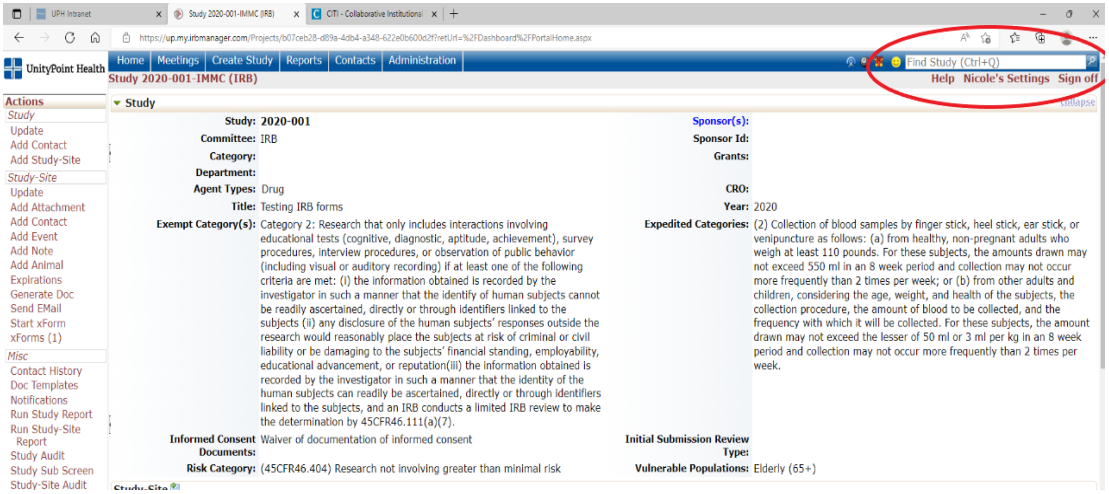
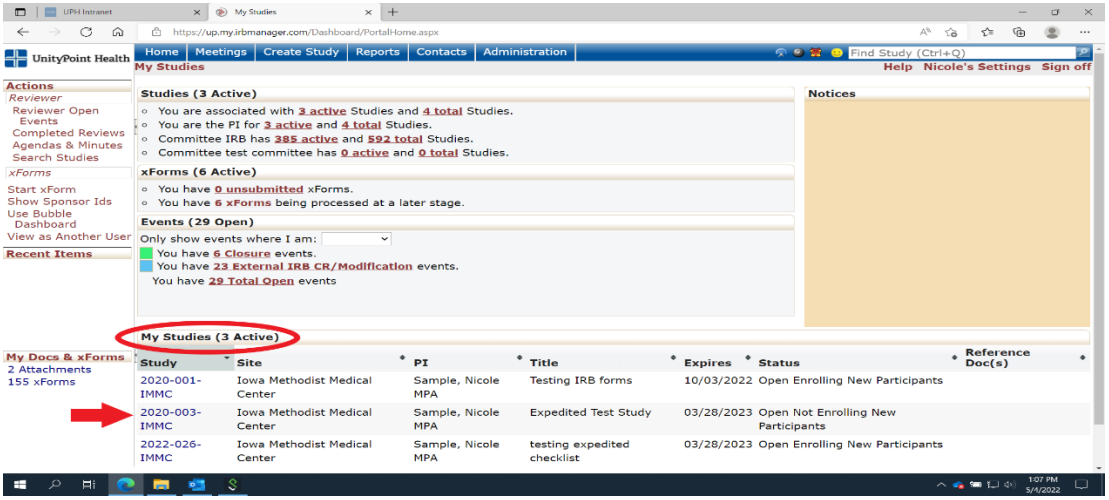
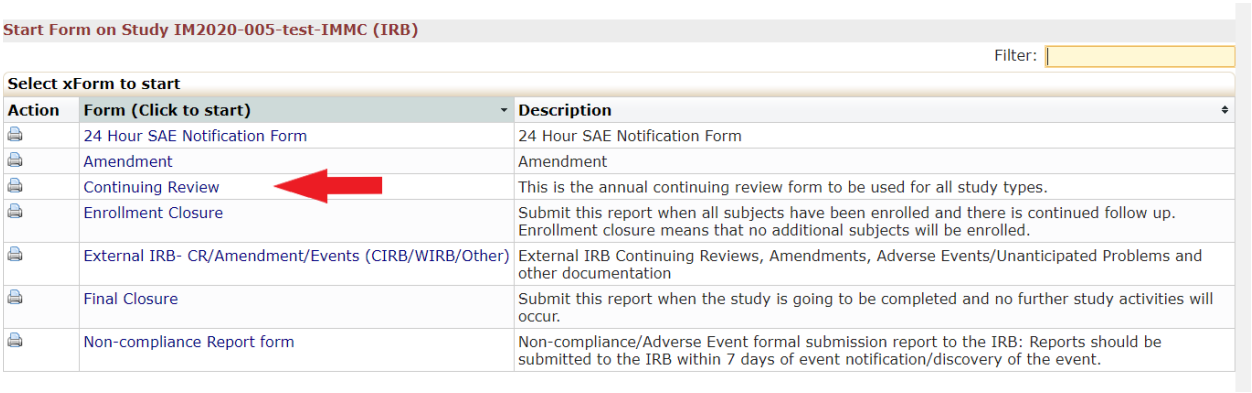


3) OR from your dashboard, go the "My Studies" located at the bottom of your screen and select the study you would like to begin the continuing review on:



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

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



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:

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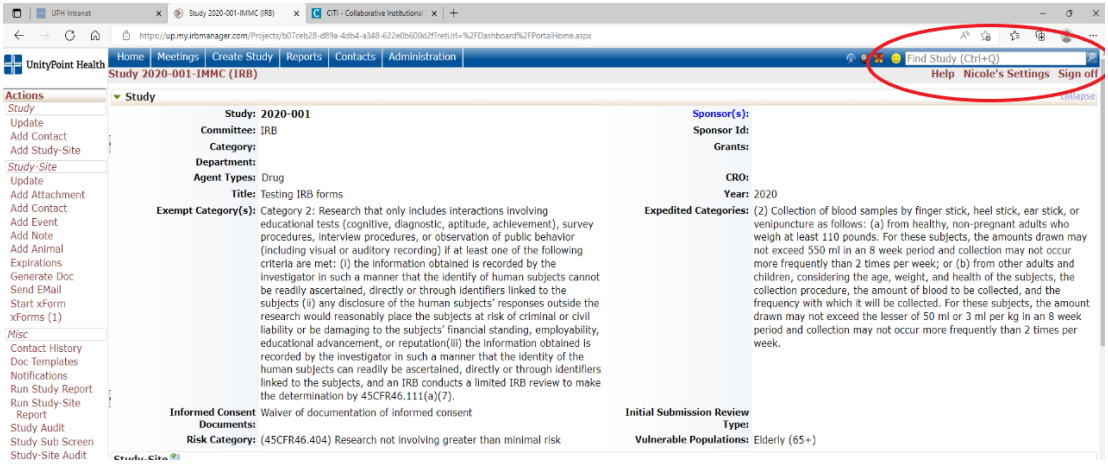
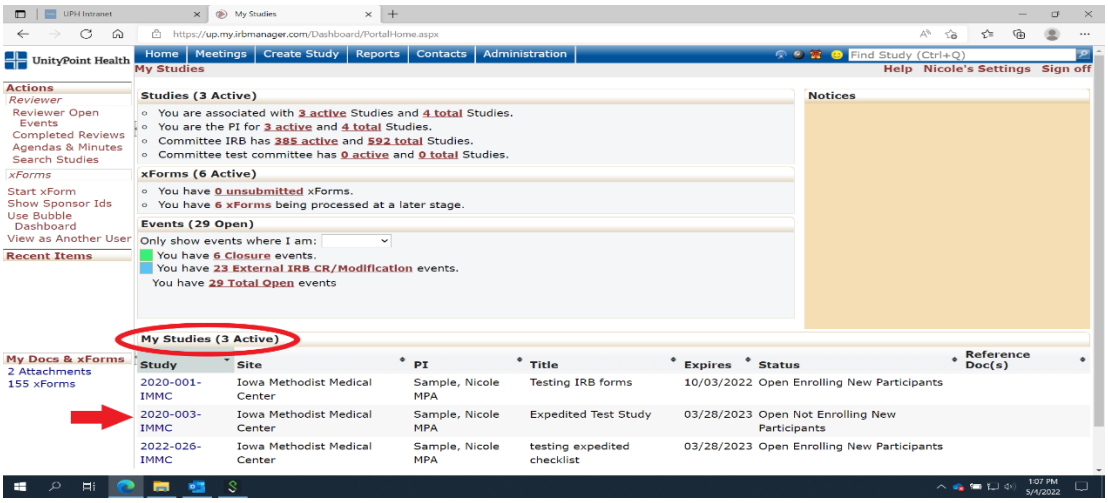
1) Log into IRBManager, type the study number into the “Find a Study” field in the upper right of the screen:



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:



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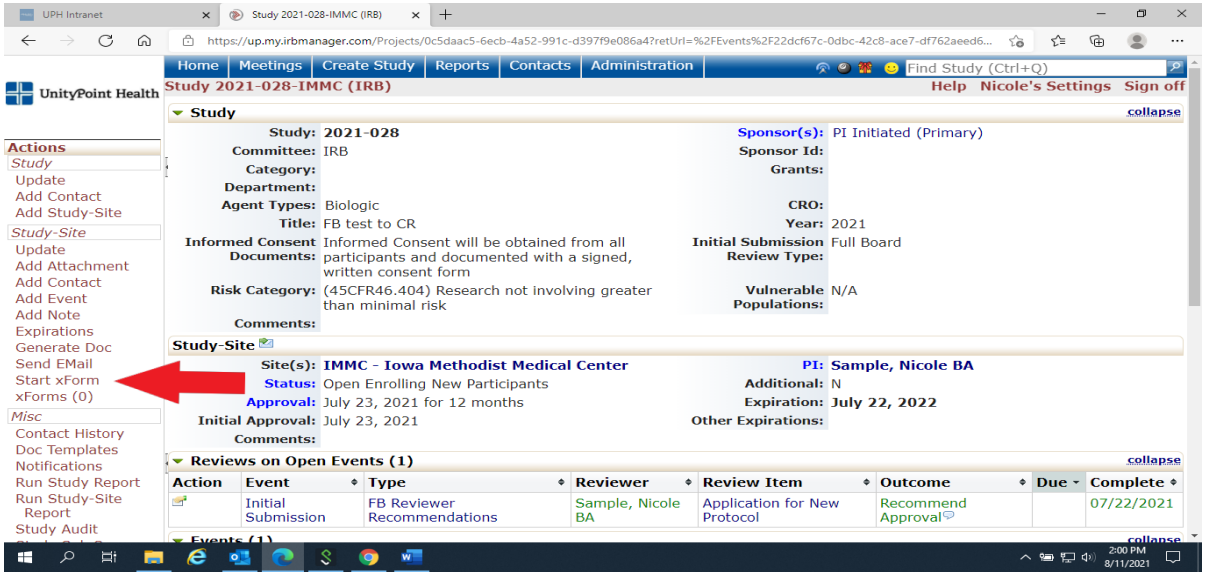
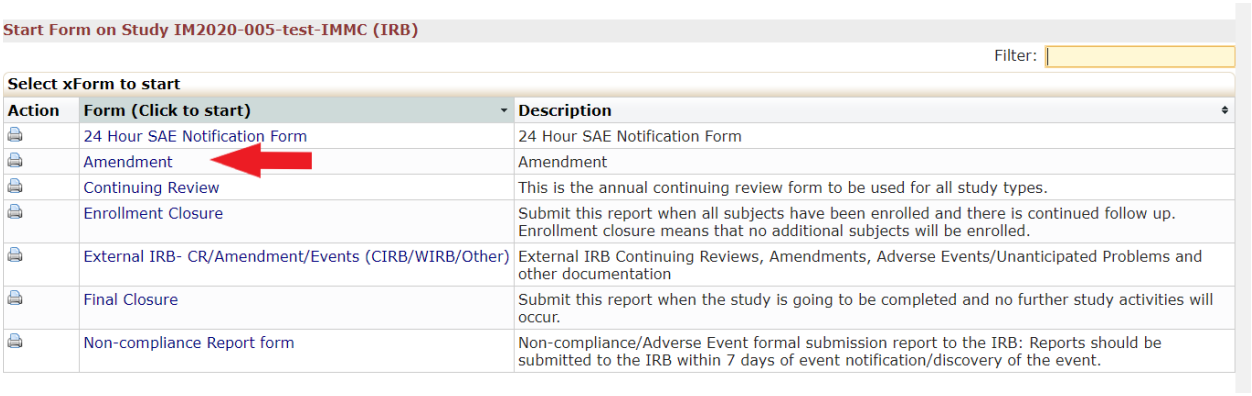
Once you are in the study, navigate to the “Actions” panel on the left of the screen and select “Start xForm”.



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).

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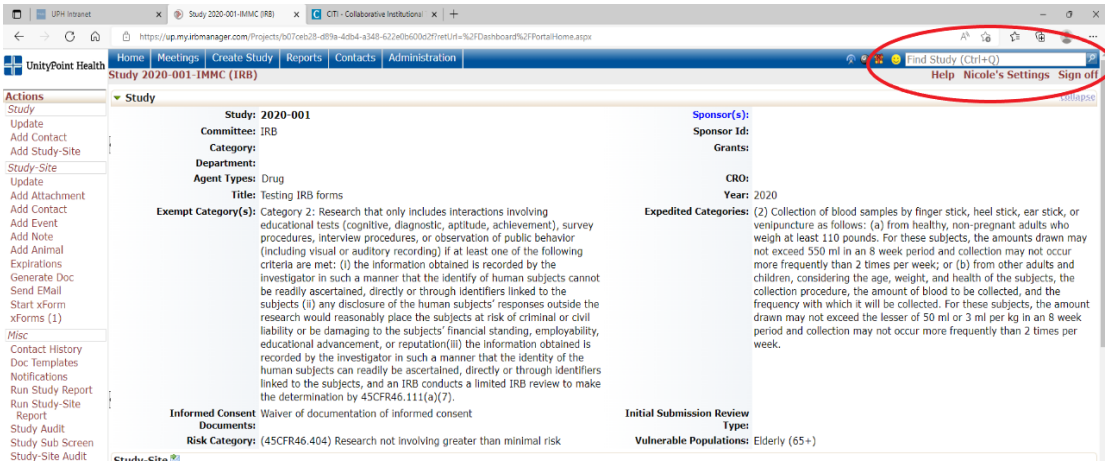
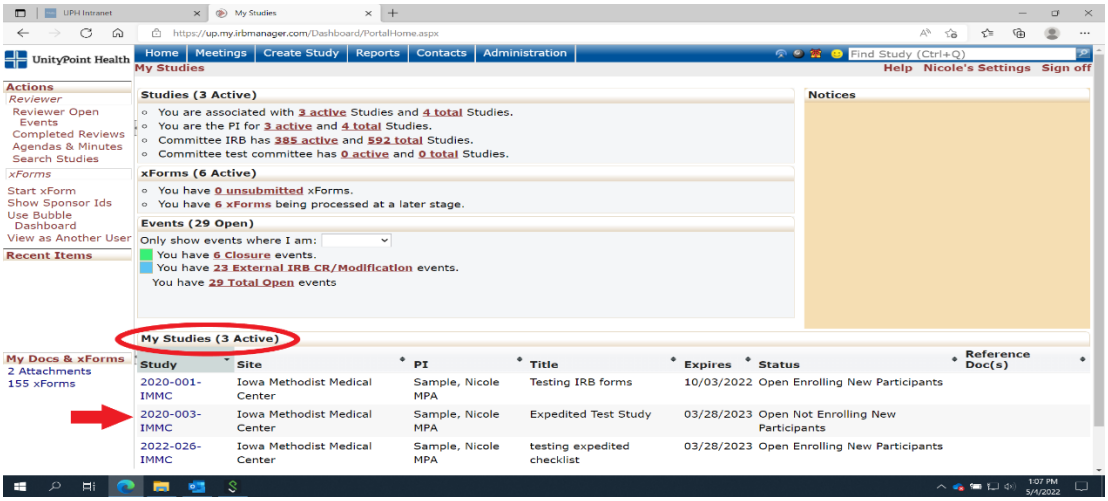
Continuing Reviews/Amendments for External IRB Studies

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:



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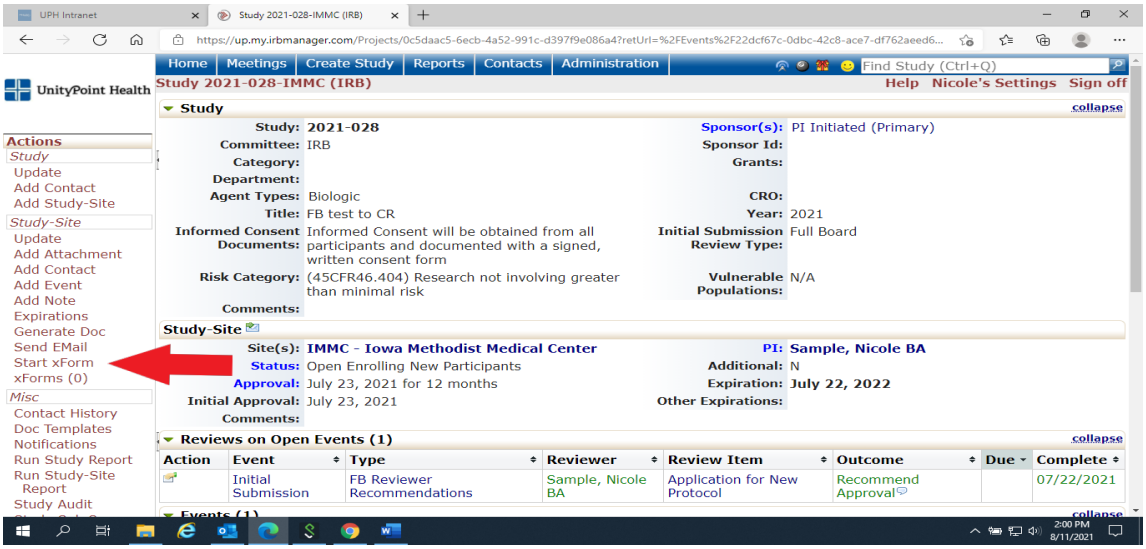
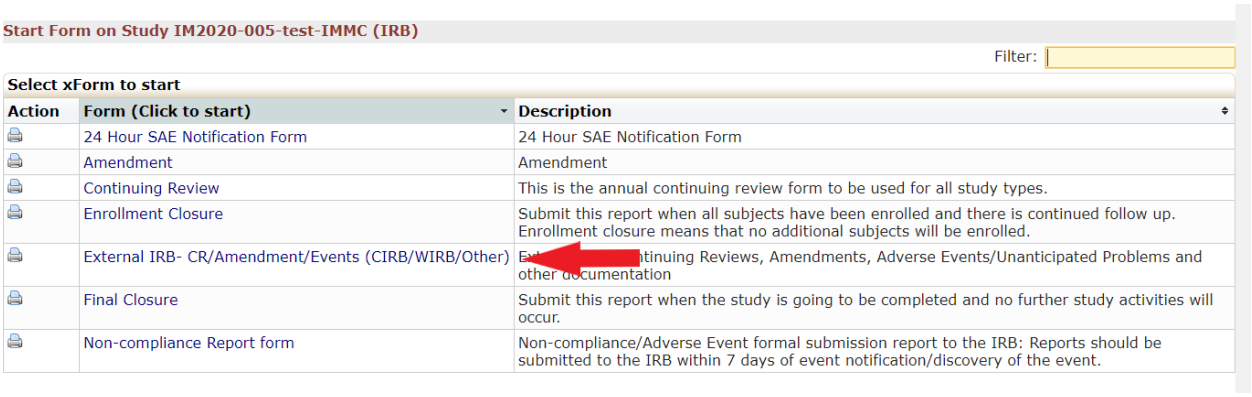
Once you are in the study, navigate to the “Actions” panel on the left of the screen and select “Start xForm”.



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

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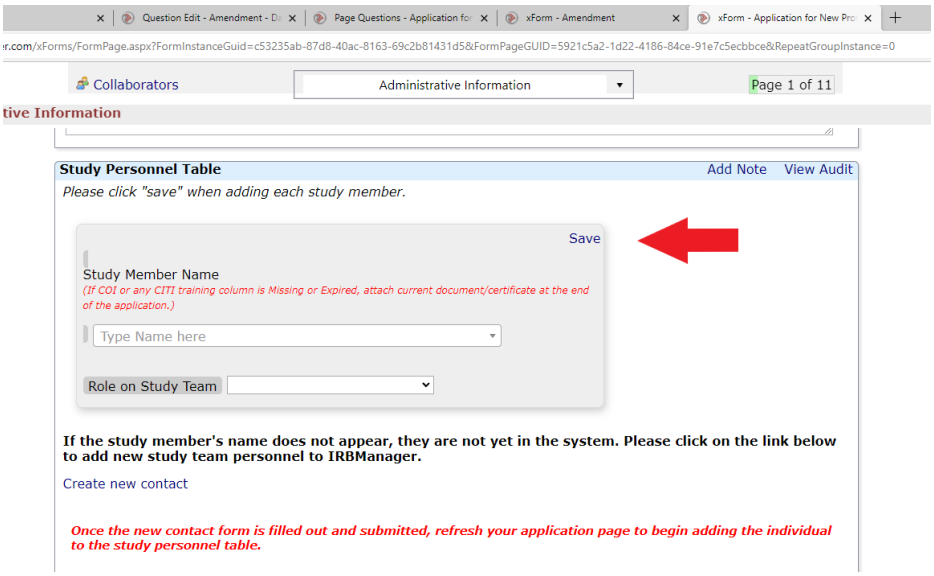
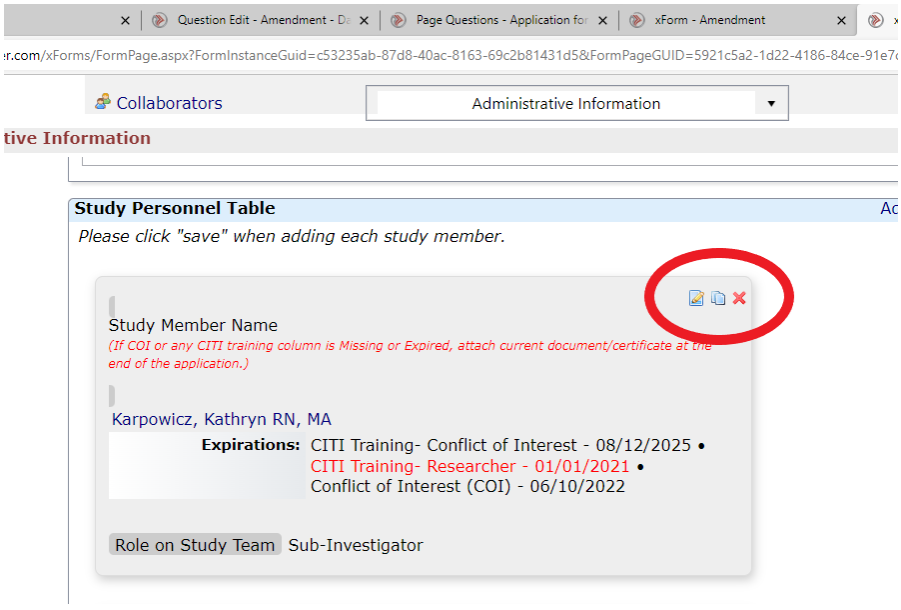
study team member until their name comes up, then click on their name. Next, select their role on the study team. Finally, select “Save” after each entry or the information will not be added to the application:

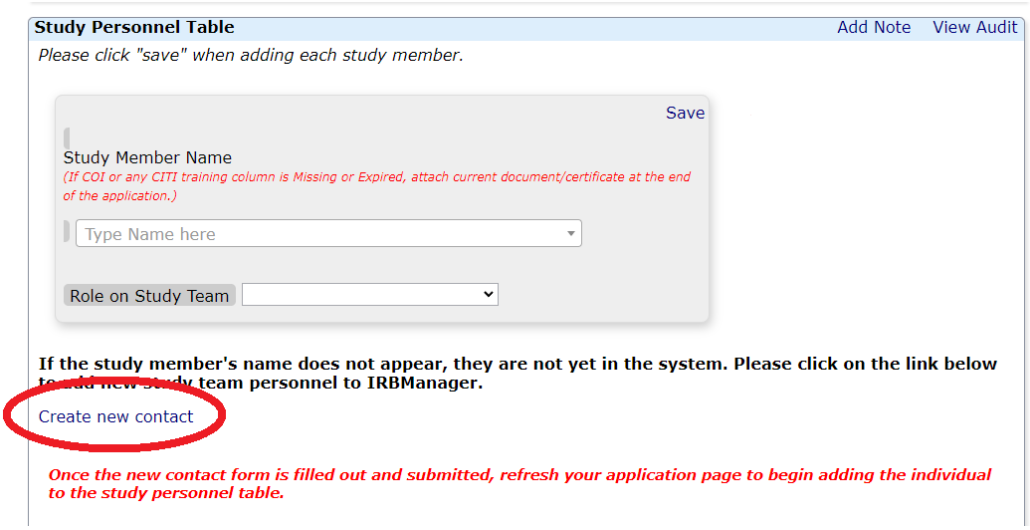


Once it is saved, it will appear like this which gives you the ability to edit, duplicate, or delete the information if needed:



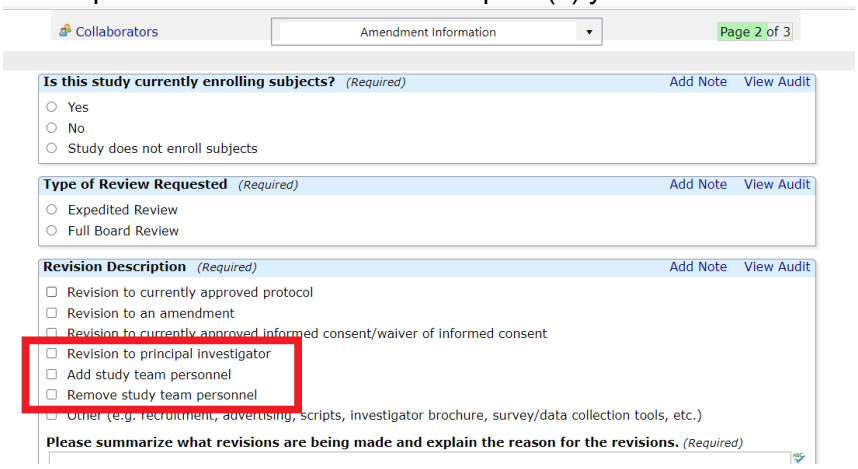
Continue adding additional study team members as needed. If an individual is not currently listed in IRBManager you will need to create a new contact first (see red circle in picture below).

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



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:



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

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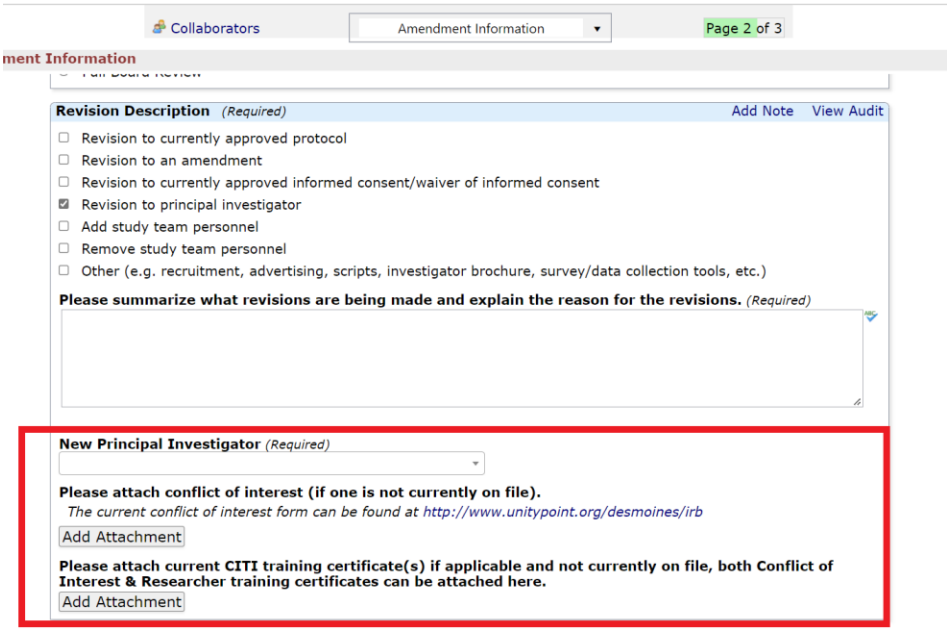
here. Any outdated or missing documents must be attached to make the amendment request.



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.

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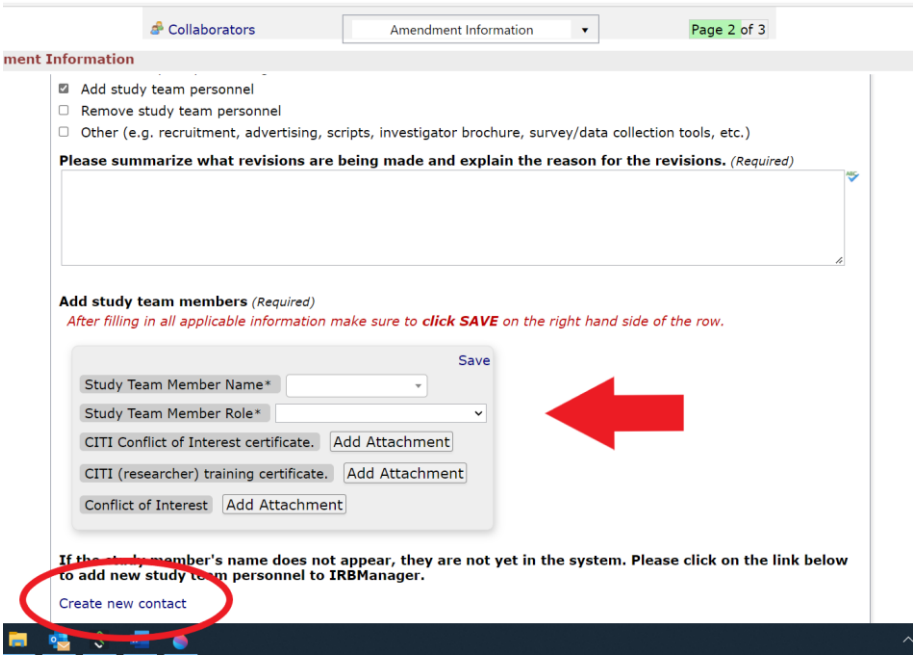
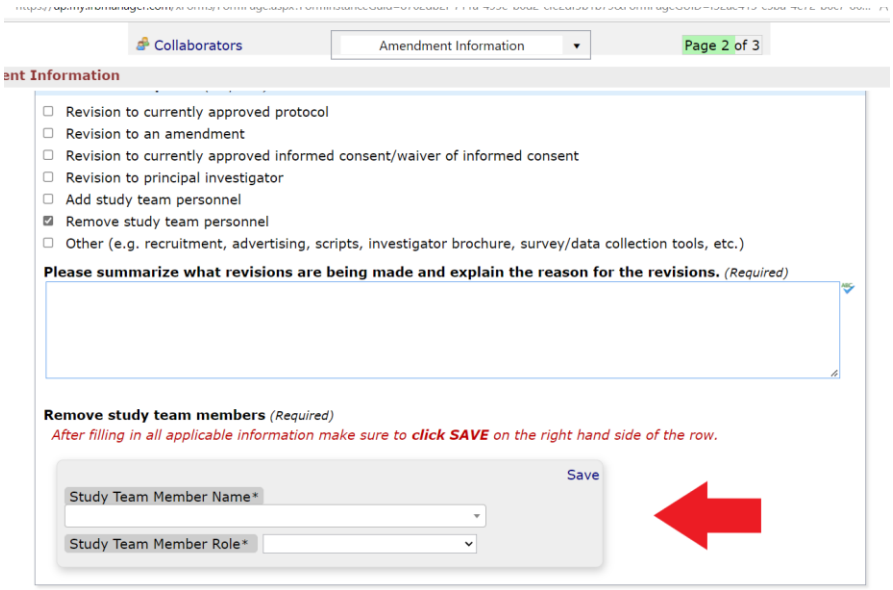


Removing Study Team Members for an Amendment

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.



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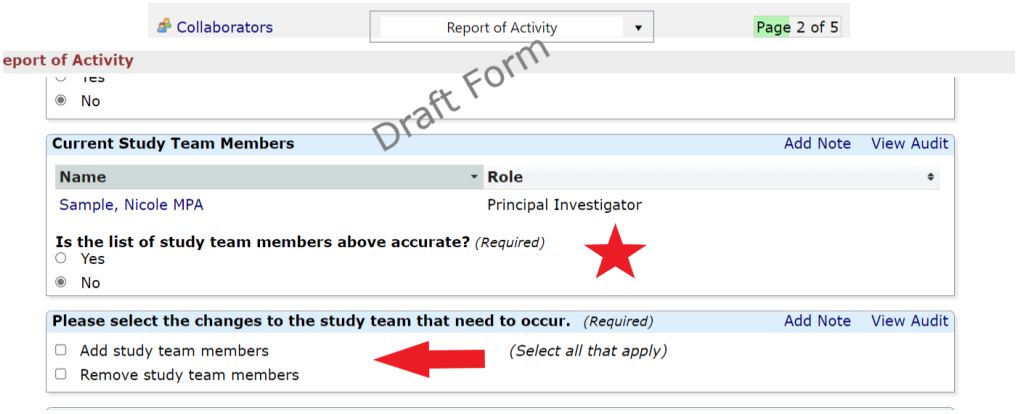
Continuing Reviews

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.



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.

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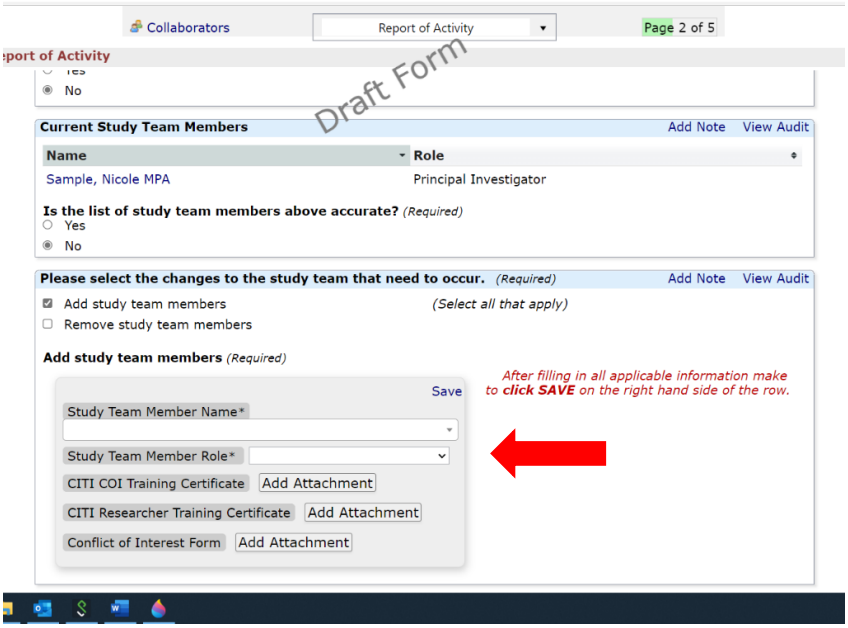
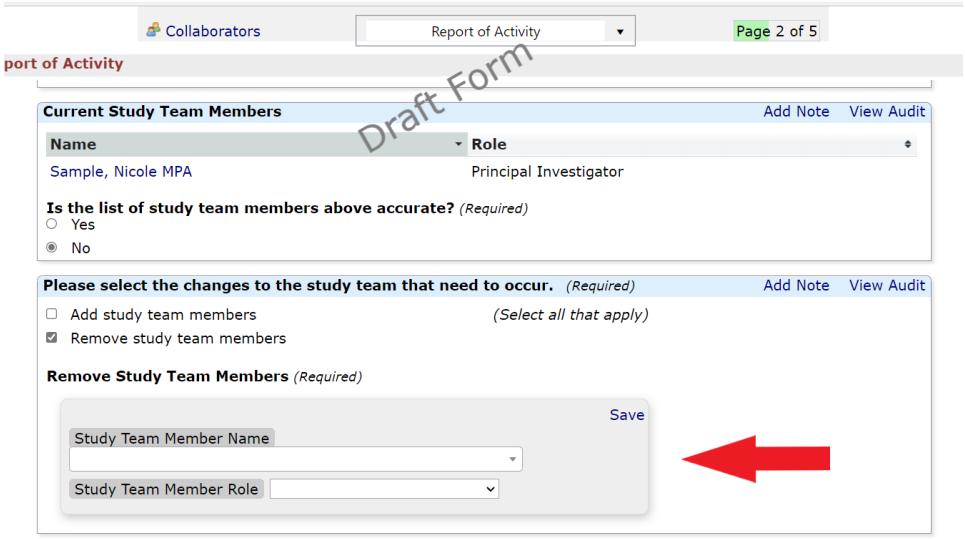


<u>Removing Study Team Members during Continuing Review</u>
Select “Remove study team personnel”, then go to the drop-down box and type in the study team member you would like to remove along with their role. Finally, select “Save” after each entry or the information will not be added to the continuing review form.



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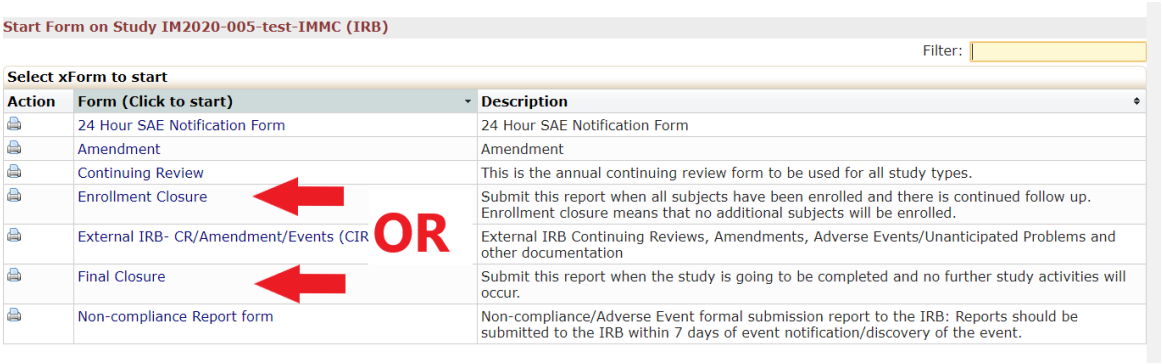
Enrollment/Final Closures

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.



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:

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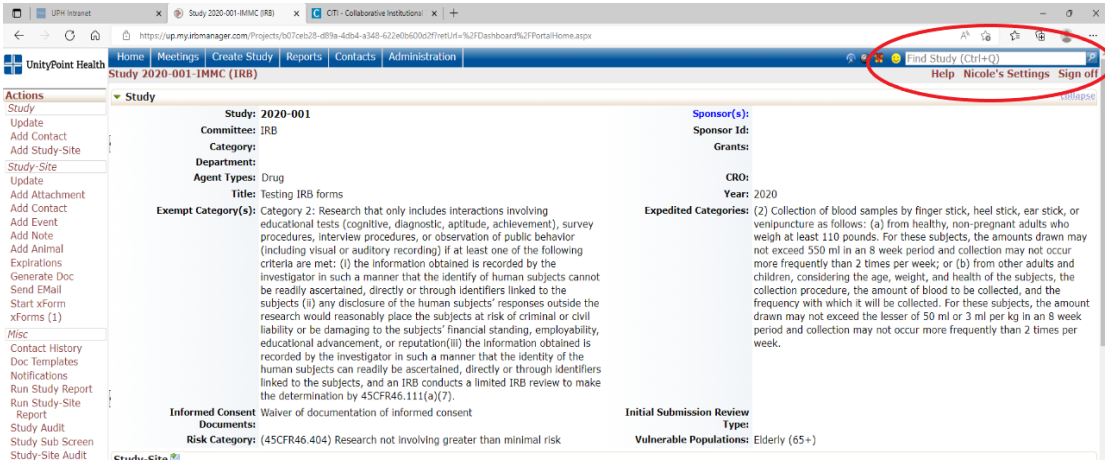
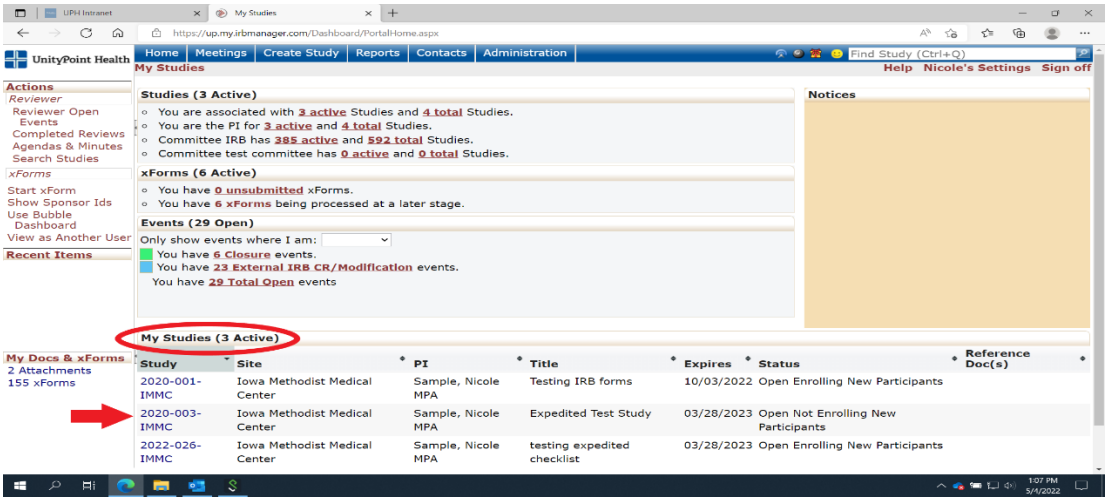


2) OR from your dashboard, go the "My Studies" located at the bottom of your screen and select the study you would like to begin the xform on:



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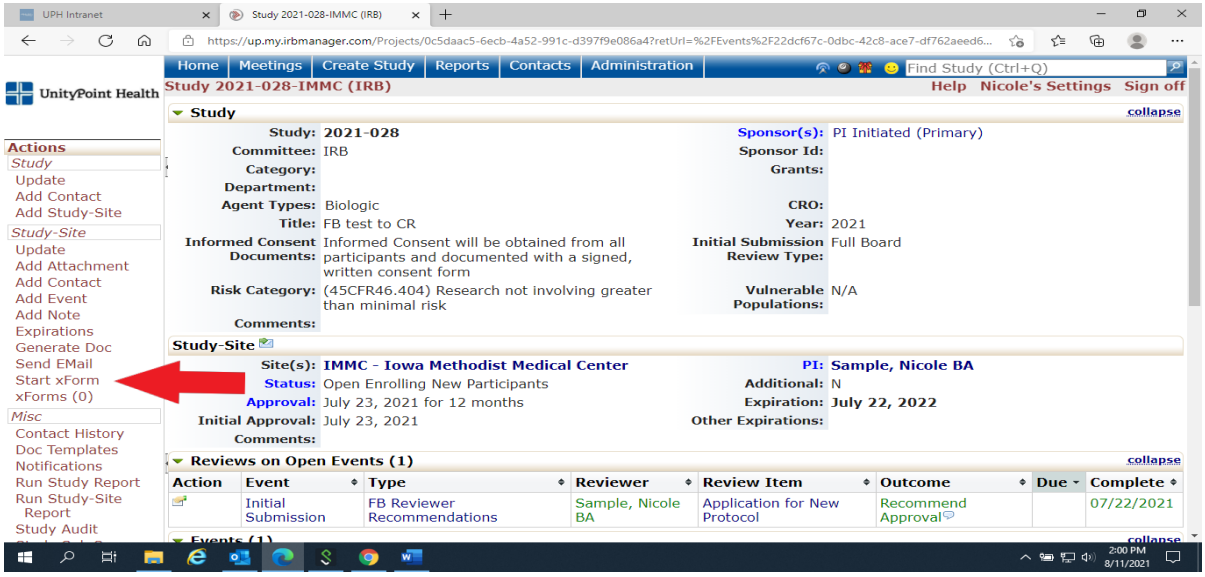
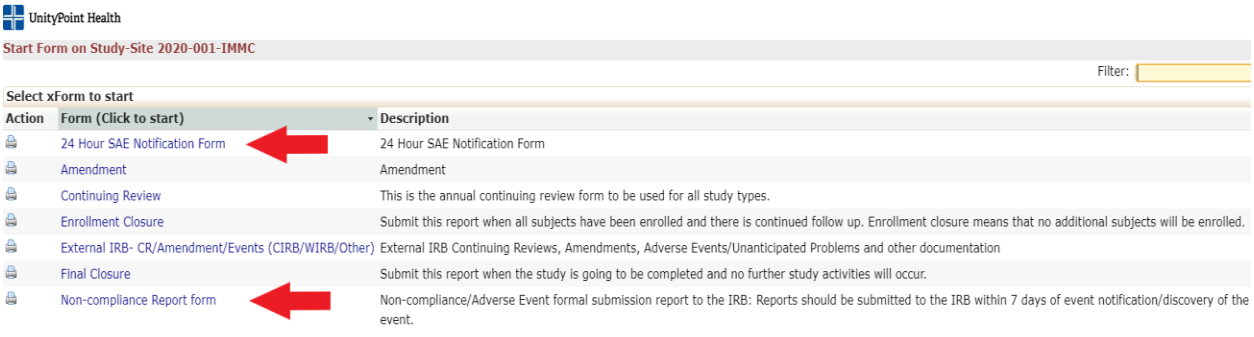
Once you are in the study, navigate to the “Actions” panel on the left of the screen and select “Start xForm”.



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).

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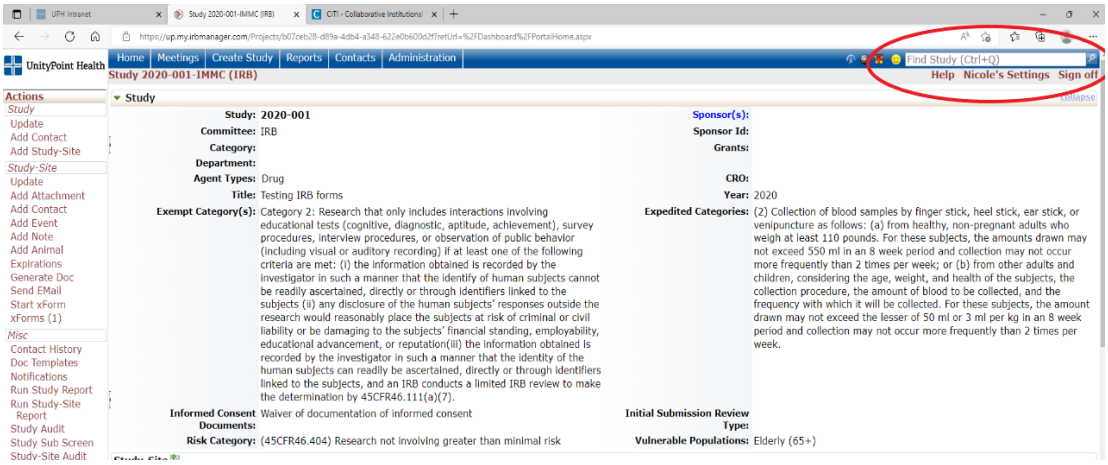
Event Pages

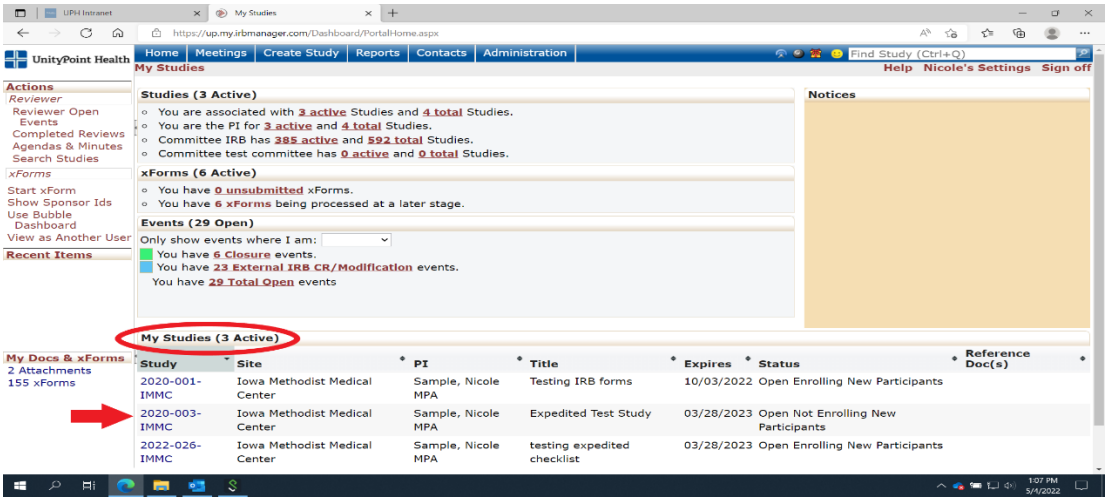
Any time you submit an xform to the IRB (new application, continuing review, amendment, etc.) it creates an event for that submission. It is within the event page(s) that you can obtain more detail for each submission such as attachments to the xform/event, viewing the approved xform, approval letters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



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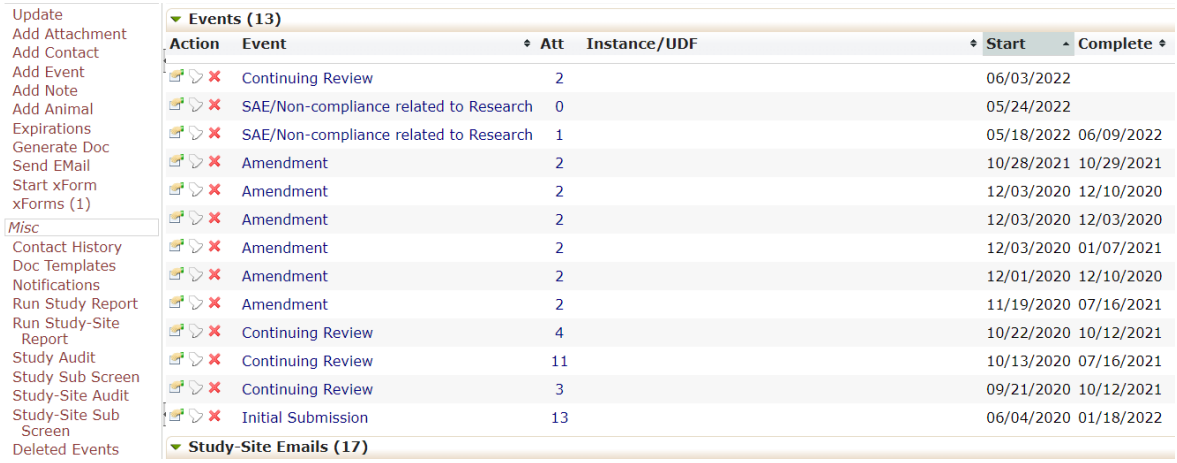
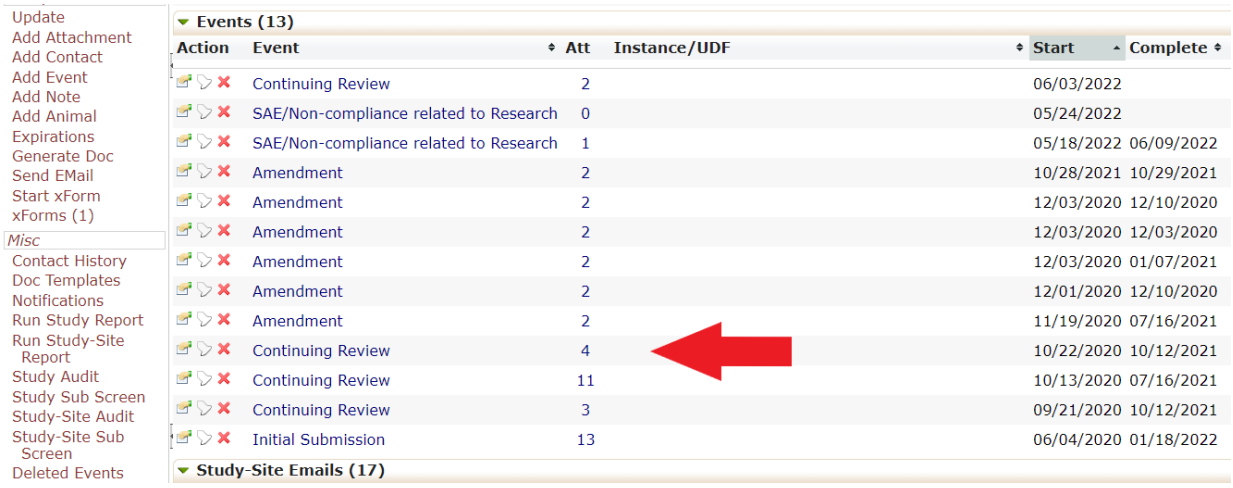
Once you are in the study, scroll to the bottom of the page to “Events”:



From here, you can select the event you want:



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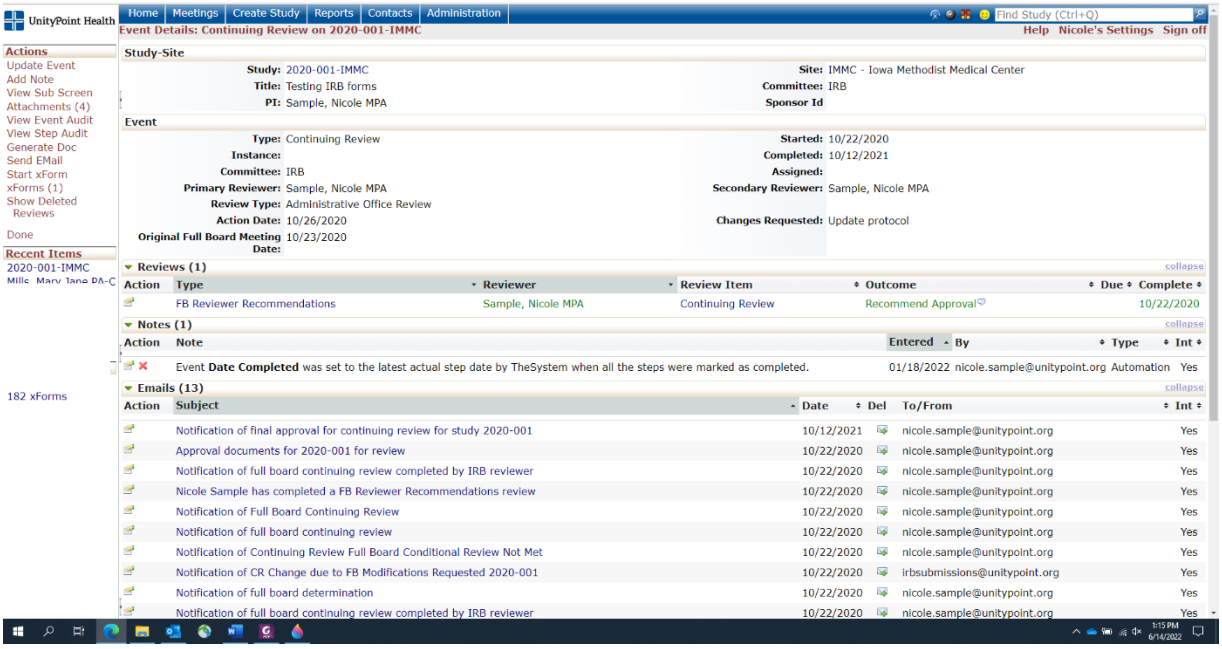
Once you have clicked on the event, it will open the event details page:



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

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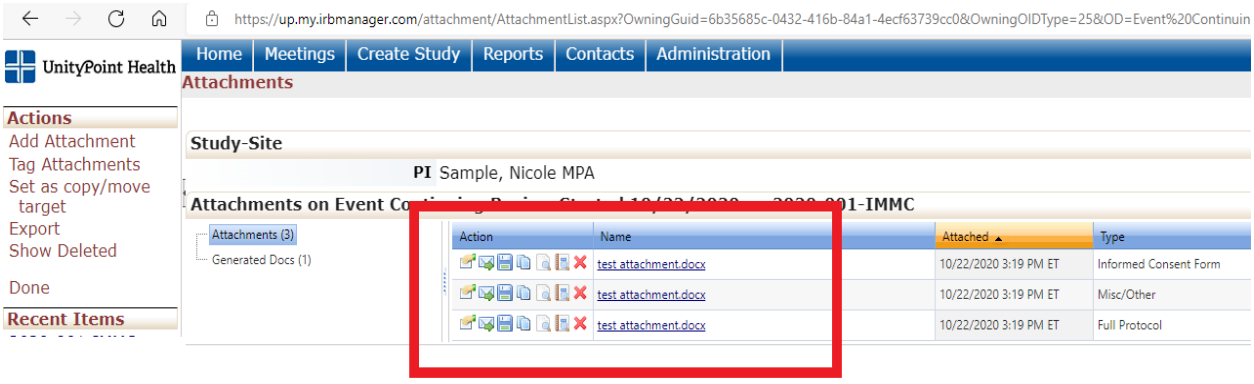
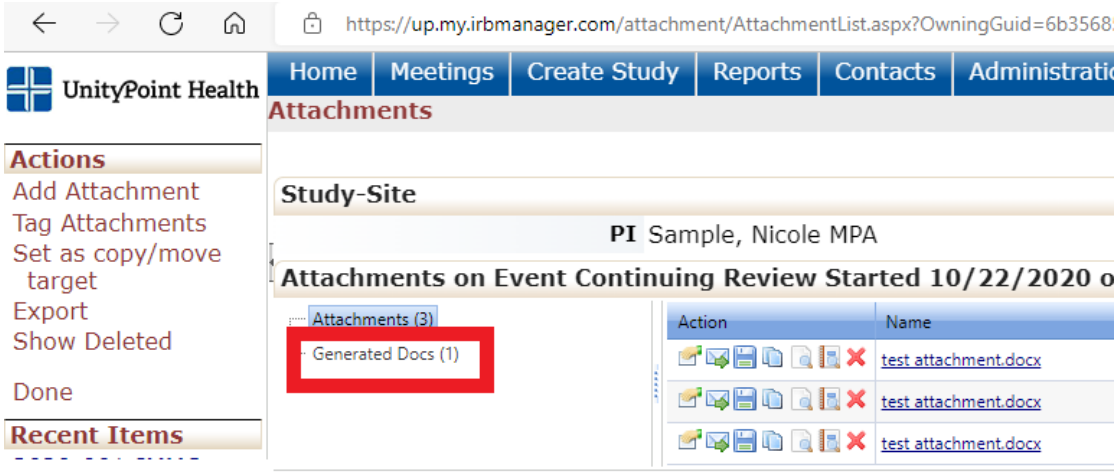
To access attachments for the event, select “Attachments” under Actions on the left side of the page:

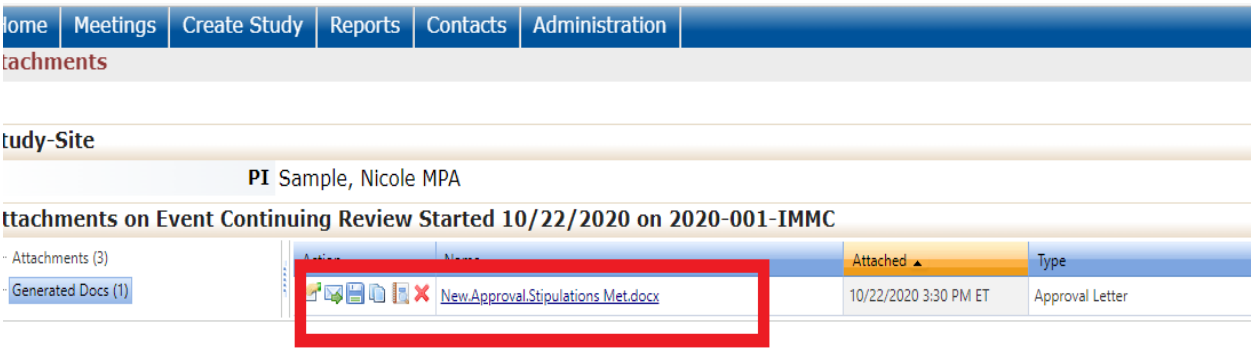
The attachments page will open, from here you can select, open, and download attachments.



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.