OneAegis Site Guide

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What is OneAegis?

OneAegis (OA) is a web-based IRB management system for submitting, tracking, and storing research protocols and compliance documents. It will replace the current iRIS system. All new studies must use OA.

How Do I Access OneAegis?

Login with your BYU Net ID and password at https://byu.oneaegis.com.

Logging in for the First Time

External users log in with their OneAegis-issued credentials (not BYU NetID/SSO) using the link: https://byu.oneaegis.com. “Externally-affiliated users: To use your OneAegis issued login, click here.”

On first login, they must change their password. Requirements:

- At least 15 characters
- Must include characters from 3 of 4 groups: uppercase, lowercase, numbers, special characters (!,@,#, etc.)

To update password:

1. Enter current password.
2. Enter and confirm new password.
3. Click Update.

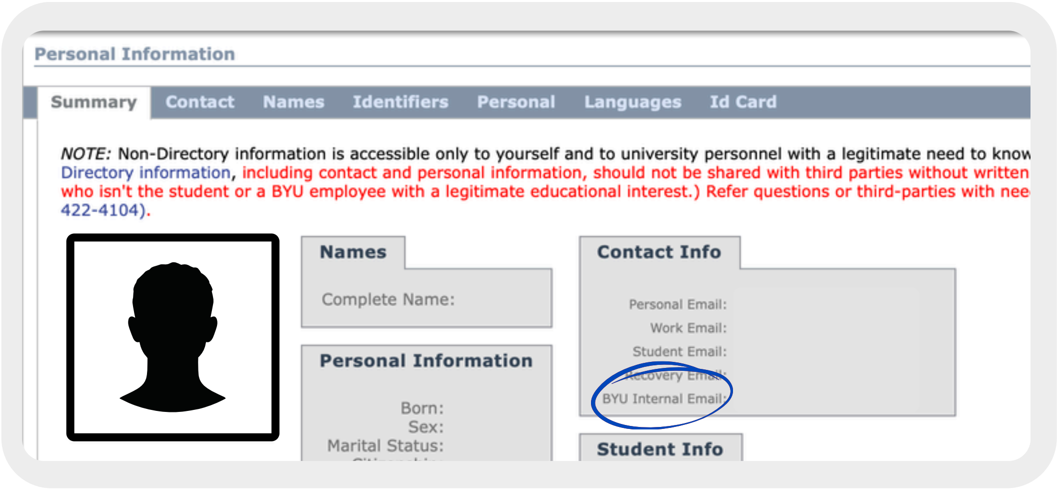
Password and Account Security

- Three failed login attempts will lock the account.
- To reset, click Forgot Password and follow the instructions.
- Once logged in, PIs can sign xForms electronically by entering their password.

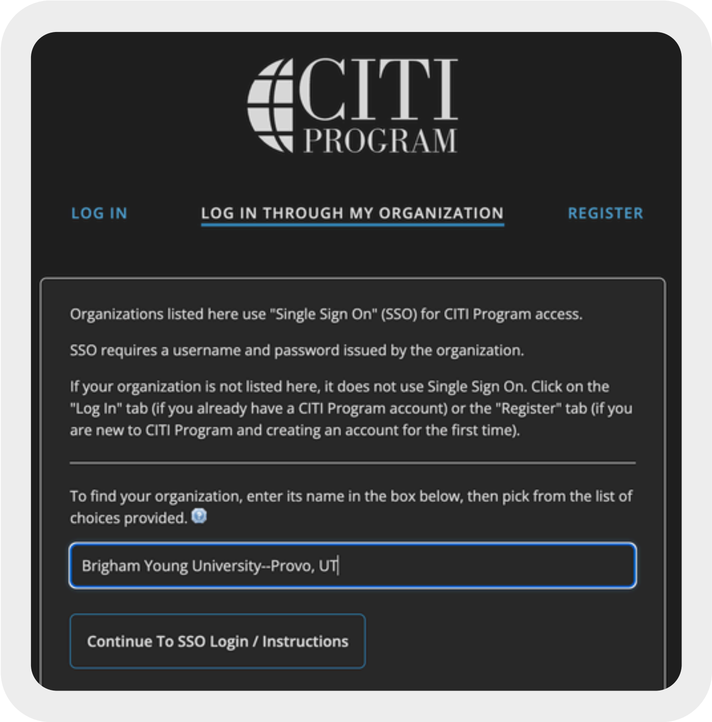
Connecting Your OneAegis and CITI Accounts

In order for your CITI training to appear as complete in your OneAegis account, the emails used for your accounts will need to match exactly. Specifically, your BYU **internal email** must match the **institutional email** listed in CITI. If you have completed the training, but it does not appear in your OneAegis account, take the following steps.

Step 1: Navigate to the [BYU Personal Information page](), and log in using your BYU credentials. On the summary page, copy the email listed as the **BYU Internal Email.**

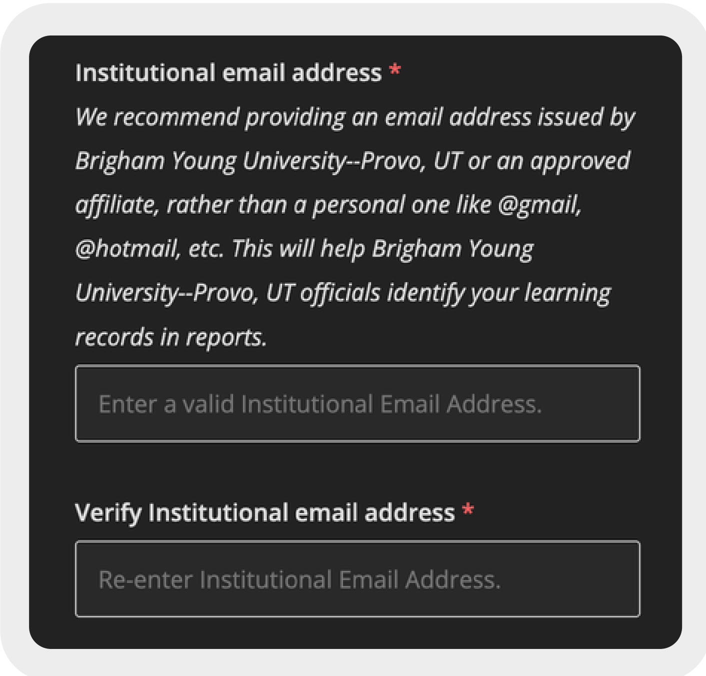


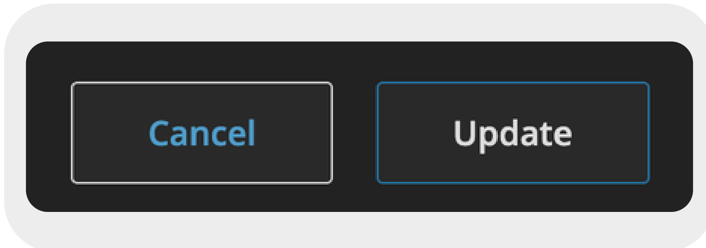
Step 2: Navigate to the [CITI training page](), and select **Log In Through My Organization**. Then select BYU Provo and continue to SSO Login.



Connecting Your OneAegis and CITI Accounts (cont.)

Step 3: CITI will automatically invite you to update your profile information when you log in. Copy your **BYU Internal Email** and paste it into the **Institutional Email** section. Then, scroll to the bottom, and click update.

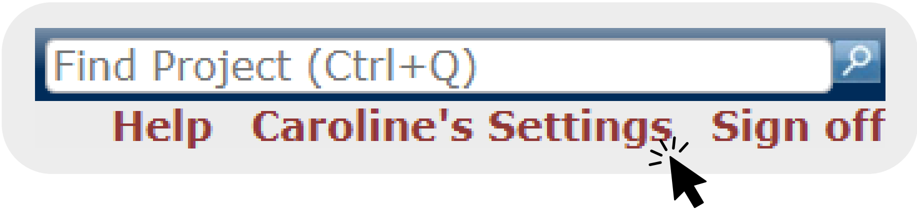




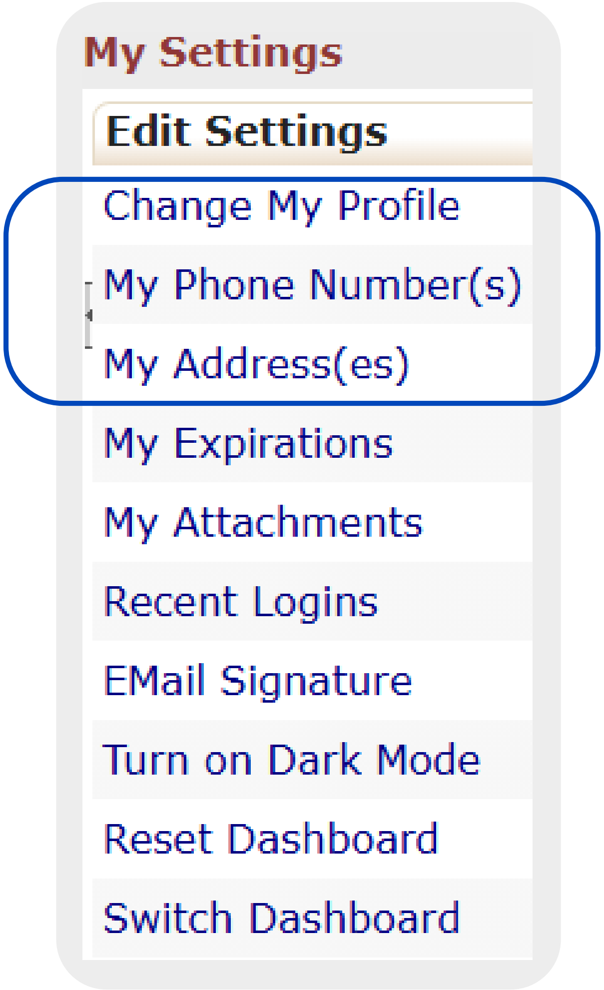
Step 4: Once logged in to CITI, verify that your training modules are up to date. Please note that it will take about 24 hours for CITI to transfer the training to OneAegis after you have updated your email. If you have questions, contact IRB@byu.edu.

User Settings

The first time you log into OneAegis, please complete your user information. In the upper right corner, select your name.

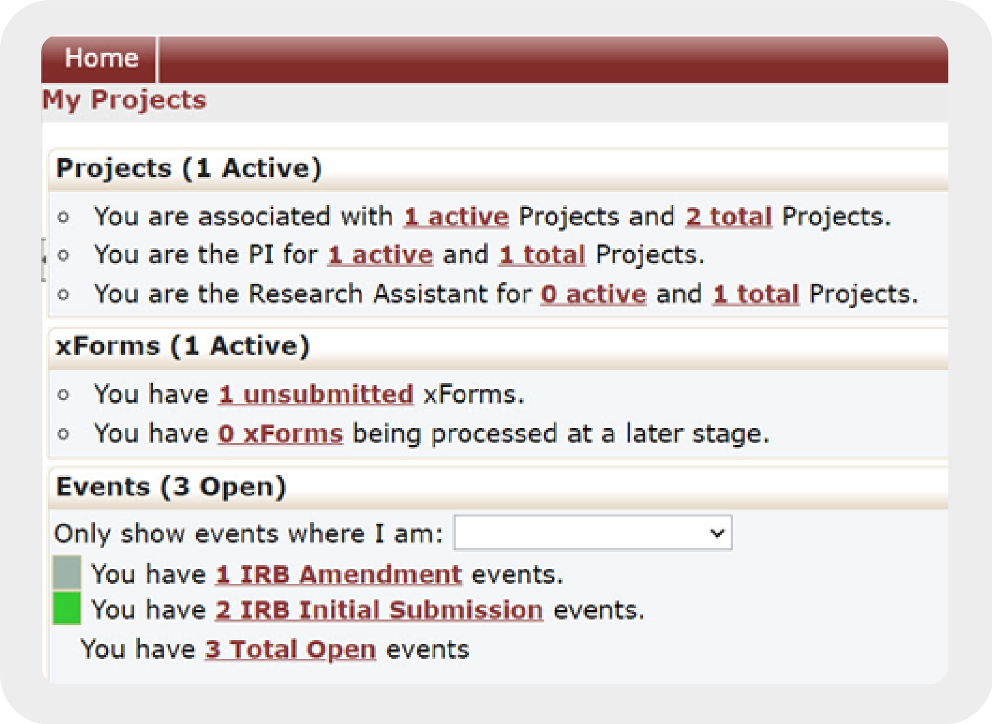


Select Change My Profile to update your name, prefix, suffix, and degree information. Please update My Phone Number(s) and My Address(es) to provide your contact information.

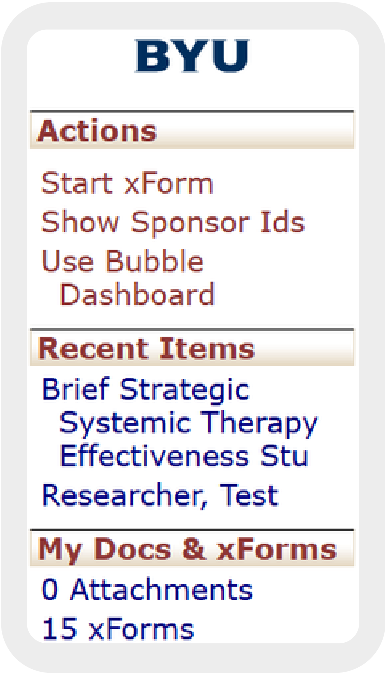


Site Navigation

Once logged in, you will be directed to your Dashboard. This will show you all of your **Projects**, **xForms**, or **Events**.

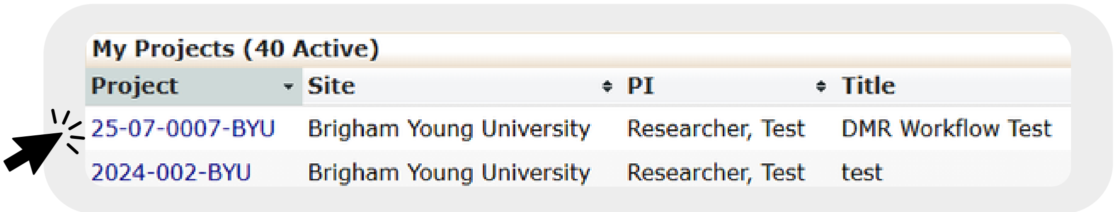


On the left of your screen, you will see: **Actions**, **Recent Items**, and **My Docs** & **xForms**.



Site Navigation (continued)

In the Power Dashboard, under **My Projects** (lower half of your screen), you can view any study with which you are associated. You can go directly to the study by clicking on the project number. The project number is assigned after submission.

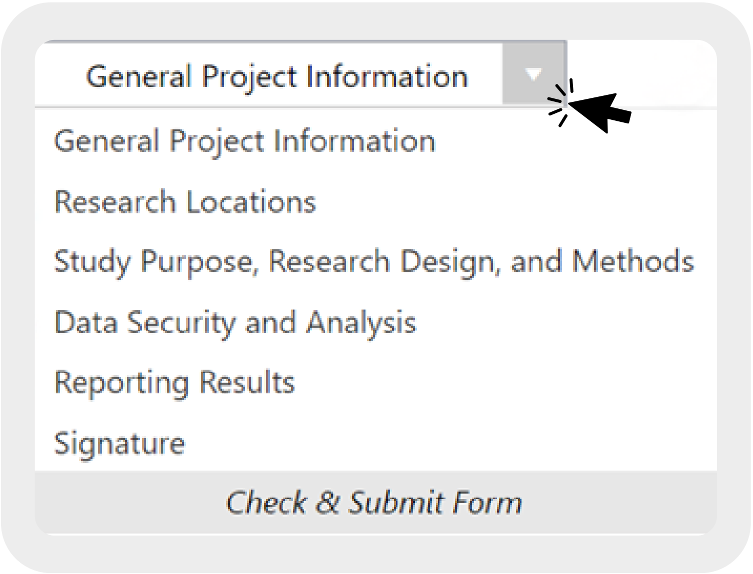


My Projects (40 Active)

Project	Site	PI	Title
25-07-0007-BYU	Brigham Young University	Researcher, Test	DMR Workflow Test
2024-002-BYU	Brigham Young University	Researcher, Test	test

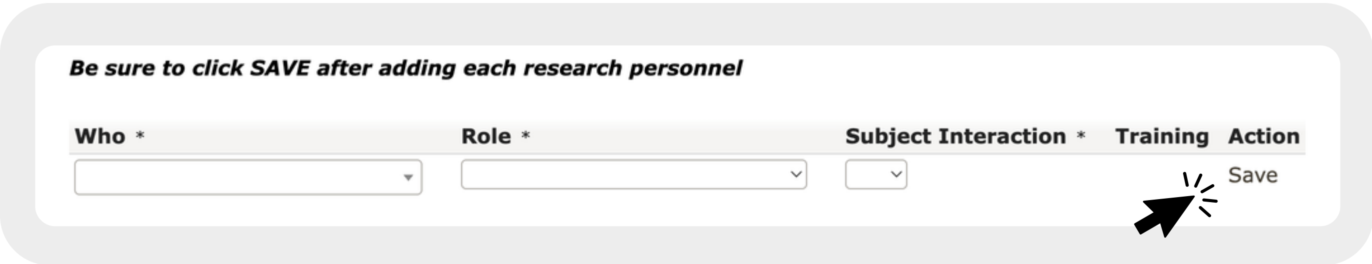
When you are working on an application, you must answer all “required” questions before advancing to the next page using the **Next** button at the bottom of the page.

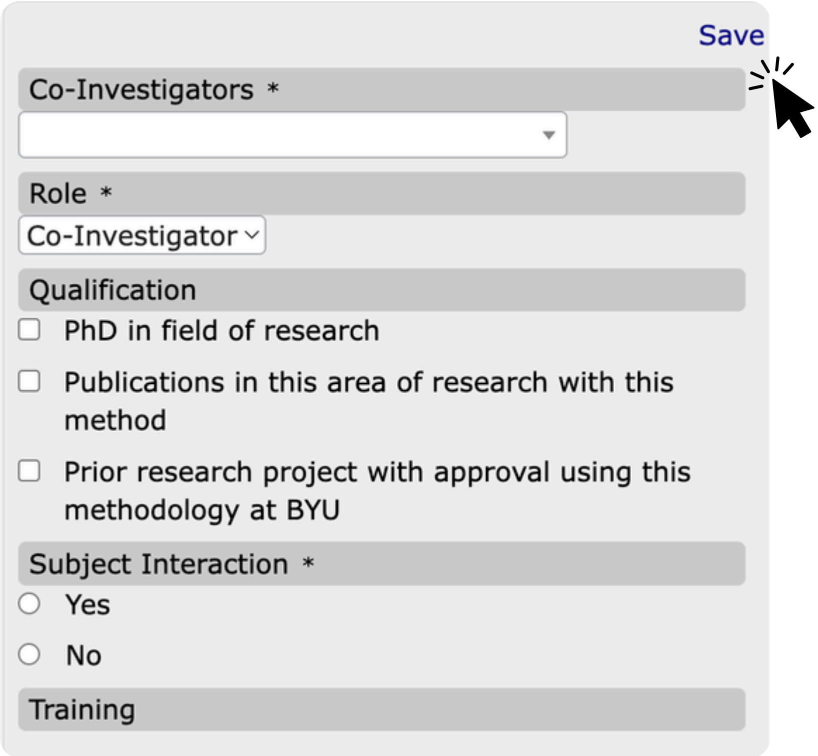
However, if there are questions that you do not want to answer immediately, but you would like to move on to the next section, you can navigate to other sections using the dropdown menu at the top of the page.



Saving Your Work

The program does save automatically when you click **Next** to navigate between pages, but there are certain cases when it is best to click save as you move through the application.





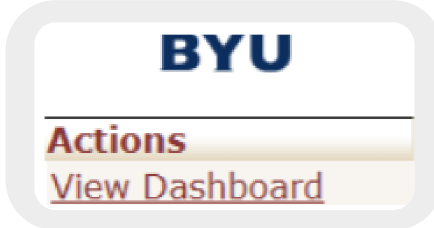
Only one blank row or card will appear at a time. After completing an entry, click **Save** to generate a new blank row.

Be sure to click Save after your final entry.

If you want to complete your application later, click **Save for Later** at the bottom of the page, then you may exit the program. If you do not do this, the part of the application that you were working on may not be saved.

Upload Your CV

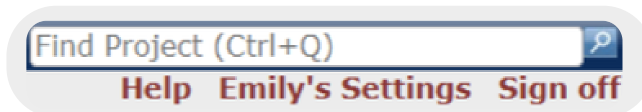
Step 1: Login to OA. From your homepage, click **View Dashboard**.

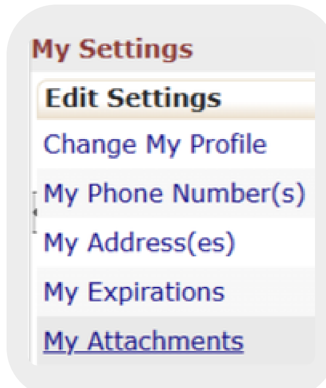


Step 2: From here, click the **Attachments** link under My Docs & xForms.

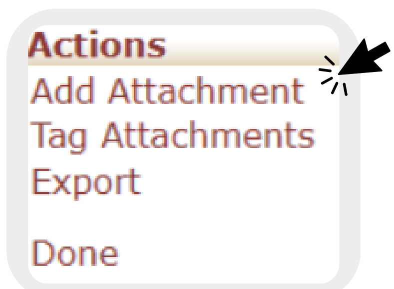
- If there is a number in front of it, that means you already have uploaded document(s) previously.

You can also get to the attachments page by clicking on your Settings in the top right corner, then selecting **My Attachments**.

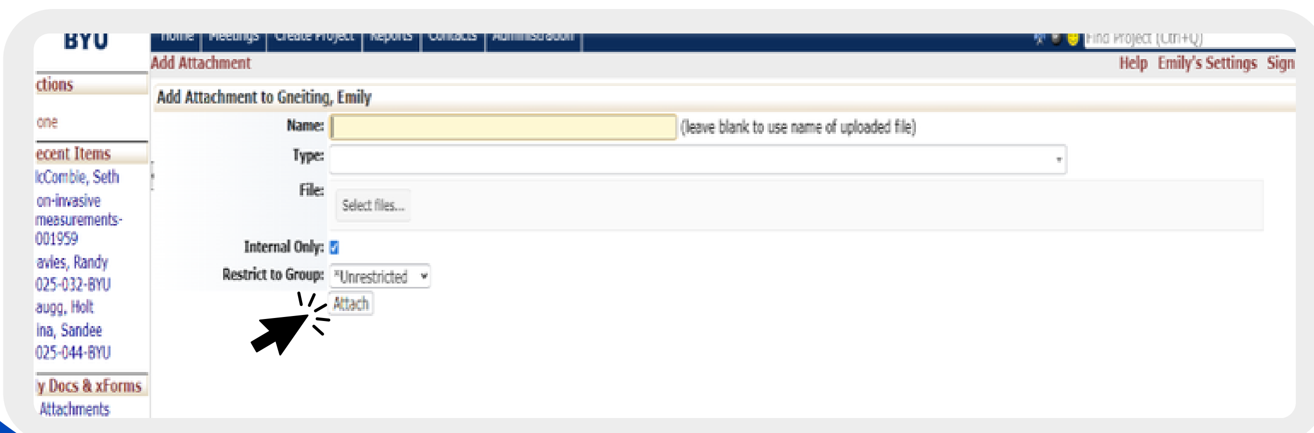




Step 3: Once you are on the attachments page, click **Add Attachment** under Actions.



Step 4: You can then add your CV. Make sure to attach and save the document.



Adding Collaborators

While in draft, before the study is submitted to the IRB, only the form creator will initially have access to the form. All collaborators must be added individually.

Step 1: Open your xForm and click **Collaborators** on the top left of the page.

Step 2: Type in and select the name or email of the collaborator. If you cannot find their name, instruct them to login to OA so they are recognized in the system. If you still can't find them, contact OAHelp@byu.edu.

Step 3: Select the access level you would like them to receive.

Step 4: Clicking the **Add** button at the bottom will finalize the process and send your collaborator an email. Select the box that says **CC Me** if you wish to be copied on this email.

Step 5: Repeat for each collaborator.

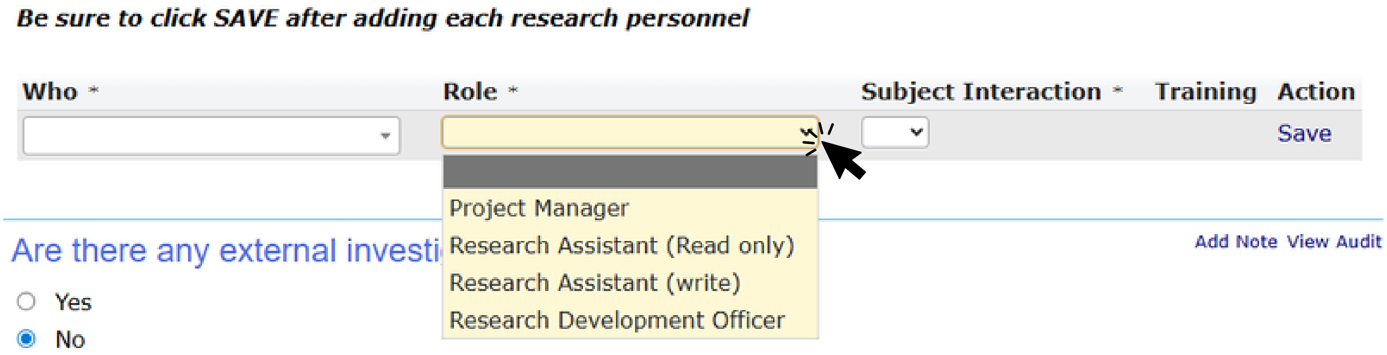
Note: Your collaborator can access the form by clicking the link in their email or by logging in to OA. You can edit access level at any time.

Access Levels

View Only	Can see content but cannot make any changes.
Edit	Can see and answer questions.
Edit and Manage	Can see and answer questions and add collaborators
Edit, Manage, and Submit	Full access: can see and answer questions, add collaborators, and submit final content for PI signature.

Adding Collaborators (continued)

Those listed as as a co-investigator or BYU research personnel in the application may automatically receive collaborator access after the form has been submitted to the IRB.



Access Levels After Initial Submission

Principal Investigator	Has full access to manage the form. Is the only person who can sign the form, which submits it for IRB approval.
Research Assistant (Read Only)	Can see form in OneAegis but cannot make any changes.
All other roles: Co-Investigator, Project Manager, Research Development Rep, Research Assistant (Write)	Can edit the form, see and answer questions, and submit form for PI signature. They can also start additional forms (such as modifications or amendments).

Note: Once the form has been submitted for IRB approval by the PI, those with edit access will be unable to make changes to the form until the form is returned or approved by the IRB.

Adding External Investigators

For security reasons, external (non-BYU) investigators have limited access to OneAegis. By default, they cannot log in or edit applications. However, if they are engaged in the research, they must be listed on the IRB application.

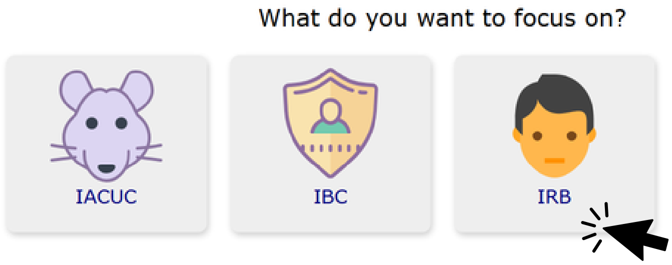
How to List External Investigators

There are two ways to include non-BYU investigators:

1. List without access
    - In the Study Information section, type the investigator’s name and role.
    - Answer “Yes” to the question: “Are there any external investigators?”
2. Grant limited editing access (case-by-case)
    - In some cases, external investigators may be given login access to a specific study/xForm.
    - To request this access, contact OAhelp@byu.edu.
    - The HRPP Administrator will:
        - Review the request and verify the investigator’s affiliation.
        - Confirm whether a reliance/IRB agreement is in place (if applicable).
        - Provision an account if appropriate.
    - Once approved, the investigator will receive login instructions by email.

Begin a New Application

Login to [OneAegis](#) using your BYU username and password. [Additional Resources.](#) When you log in, you will be directed to the Project Switchboard. Select IRB.



There are two dashboard types. You can start your xForm from either view.

Bubble Dashboard View

Select the xForms tab.

Click **Start xForm** or **New IRB Application** in the top left corner.

Power Dashboard View

Click **Start xForm** in the top left corner under Actions.

If you prefer, click **Use Bubble Dashboard** and follow those instructions.

Adding Attachments

The application will prompt you to enter several documents. Keep the following in mind when adding attachments.

Naming: Please enter a descriptive title in the format described in the application. This will typically include the type of document, the group it is for, and the version date.

Multiple Documents: You may add multiple documents in some sections. Please attach each instrument and/or document that is mentioned in the appliaction or the IRB will require you to add them in revisions. Documents such as verbal consent and email communication templates are often overlooked but need to be included.

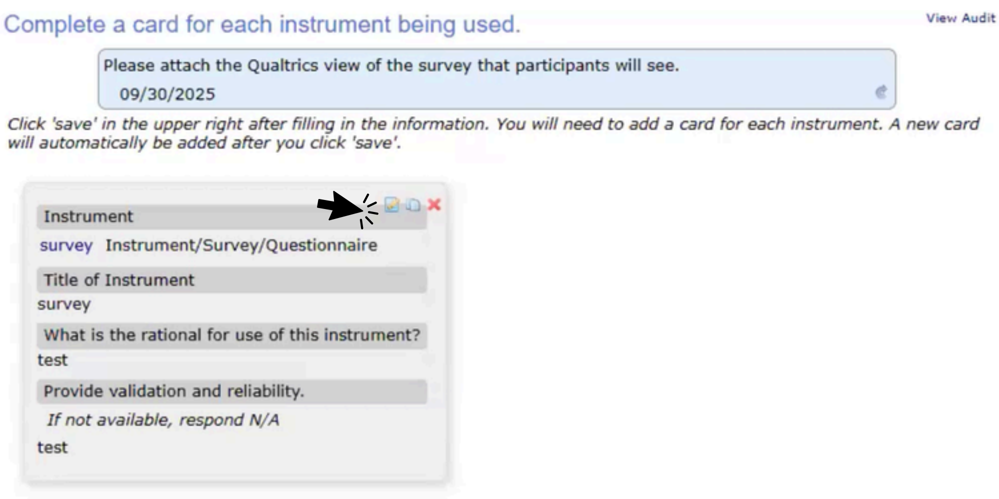
Guidelines: All forms must meet all IRB and federal guidelines. For example, HRPP contact information must be listed on consent forms. For sample documents and tips, click here.

Replace Attachments: Use the green arrows to replace attachments. Make sure to click attach when you are finished or the document will not update correctly.

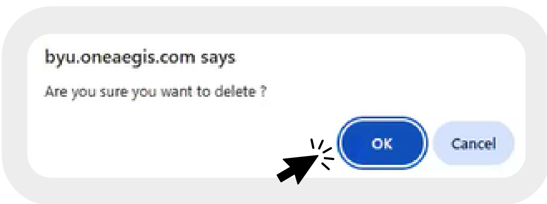
Editing Attachments

If the IRB requests that you edit a document or add a new one to the application, the PI should take the following steps. Other collaborators with editing permissions may perform these tasks as well. **Please see Adding Attachments for naming guidelines and other tips.**

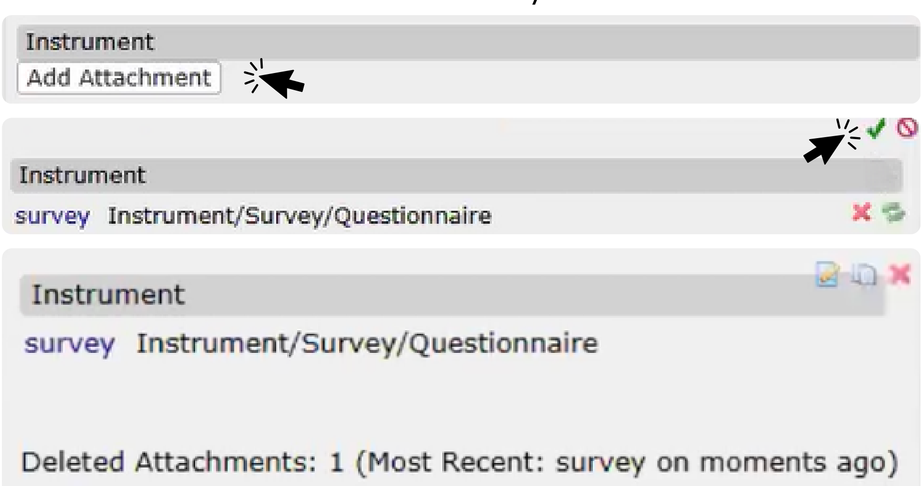
Step 1: You will need to remove the previous document and add a new one. Click the edit button on the survey card.



Step 2: Click the **red X** under Instrument to remove the previous document. Then click the blue **OK** button.



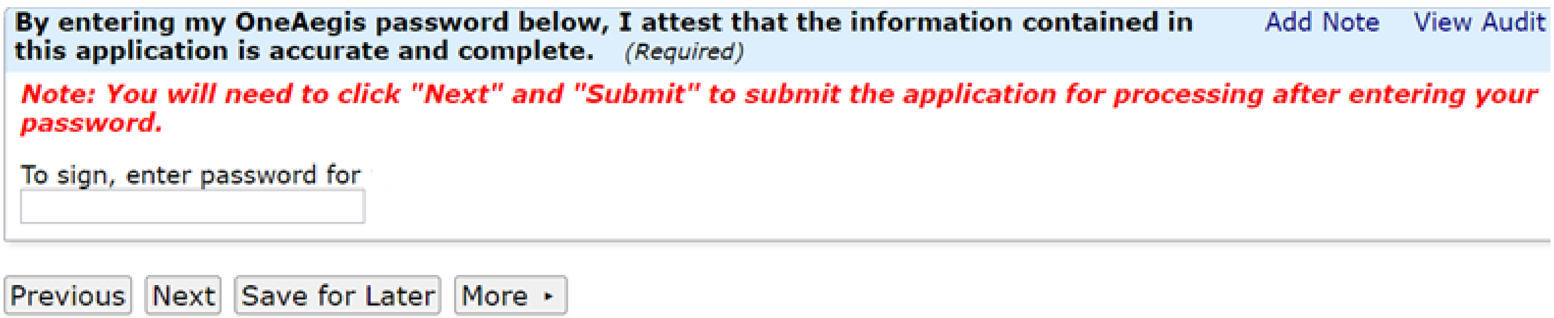
Step 3: Click **Add Attachment** and select the file you would like to add. Then click the **green checkmark** to save the attachment when you are done.



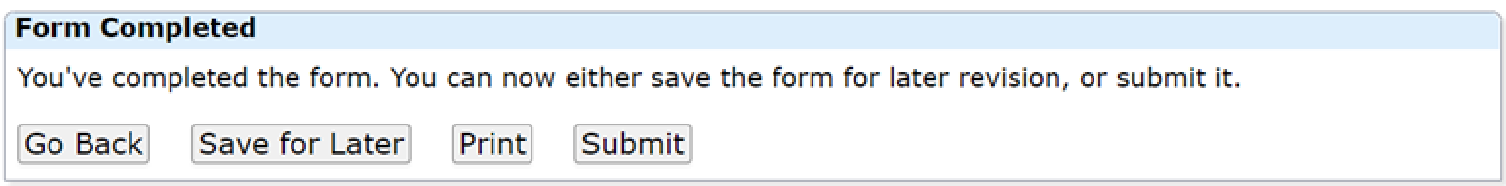
Step 4: When finished adding the new document, please double check the "note" and ensure that all requirements have been met before moving on.

Submitting Your Application

After entering your protocol information, the PI needs to sign the submission by entering their password and clicking Next.
THIS DOES NOT SUBMIT YOUR PROJECT!



You will then see Form Completed, and you will need to click **Submit**.

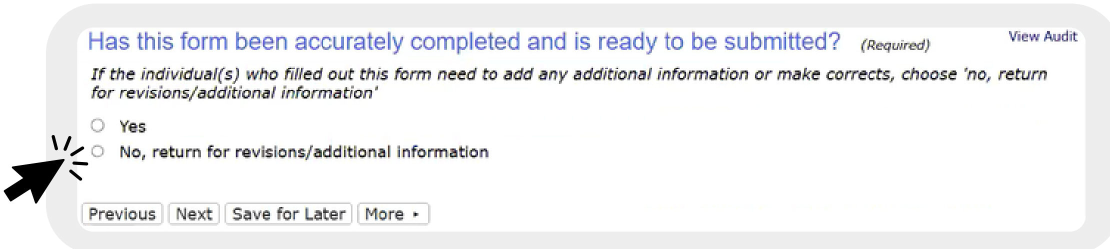


If you are not the PI, submitting the application will send the PI an email requesting their signature. The PI must sign and submit the form to receive IRB review.

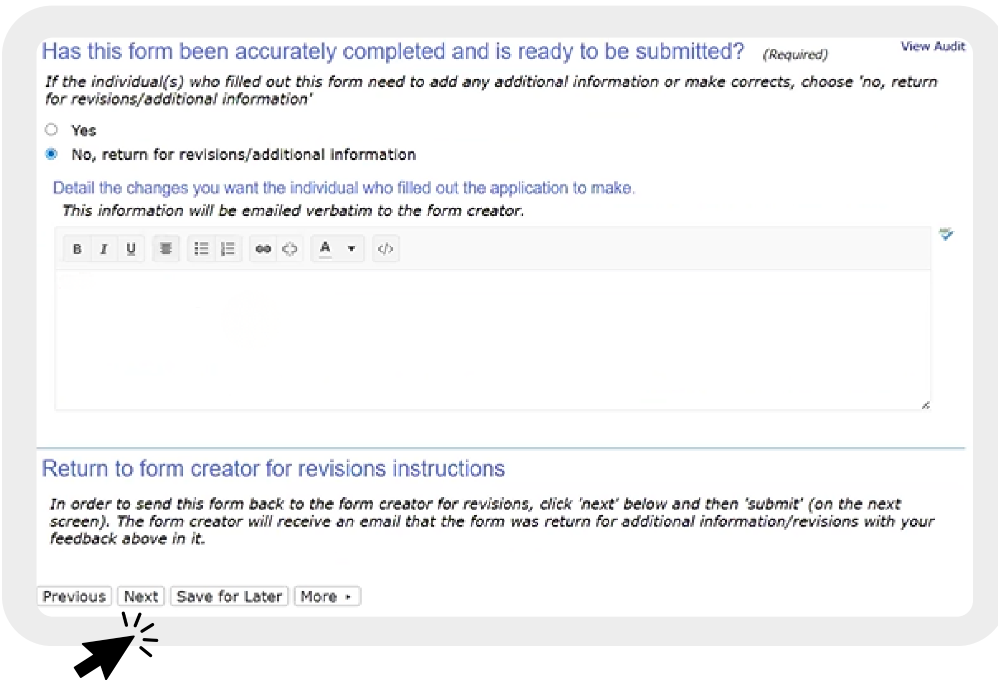
Returning a Form for Revisions

Once a form has been sent for PI signature, the PI needs to take the following steps if they wish to edit the form before it is submitted to the IRB.

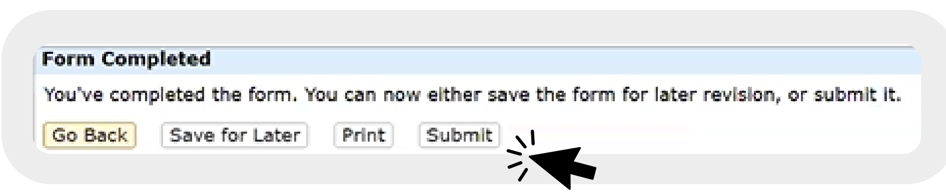
Step 1: Open the form using the link from the email alerting you that the form is ready for PI signature, or from your OA dashboard.



Step 2: Click **Next** until you reach the screen below. If you determine the form needs more edits, select **No, return for revisions/additional information**. Doing so will open an optional comment box.



Step 3: Once you are finished, click **Next** at the bottom of the page. Then, click **Submit** on the next page. The form has now been sent back to the Data Entry stage and is accessible from your OA dashboard. It has not been submitted to the IRB.

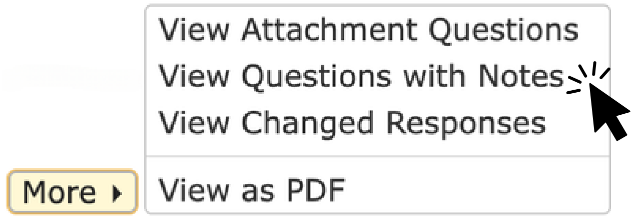


Responding to Notes

Notes are comments or changes from the IRB that require attention. If your submission requires changes after initial screening, the PI will receive an email containing a link to revise the application. In OA, the PI should take the following steps.

Step 1: Scroll to the bottom of the application and click **More** >> **View Questions with Notes**. This will open a second tab and give you a list of all IRB notes. Notes will appear in light blue boxes.

Step 2: To edit, right click the section title and select **Open link in new tab** to be directed to the correct part of the application.



Step 3: Update the application with the appropriate changes.

Step 4: Move to the next section. If there is an error, it will be shown at the top of the page.

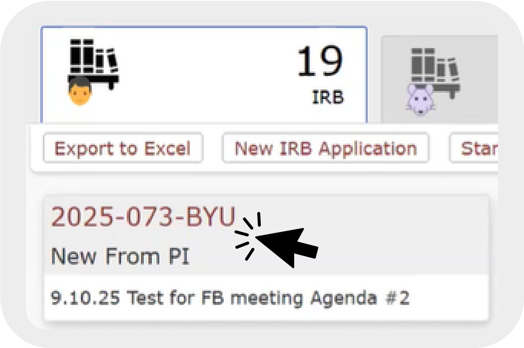
Step 5: Repeat the process for all notes and resubmit to the IRB. If the IRB requires change to a section and no change is made, you will be redirected to that portion of the application and must make changes before it may be submitted again.

Note: Some changes may shorten or lengthen the application.

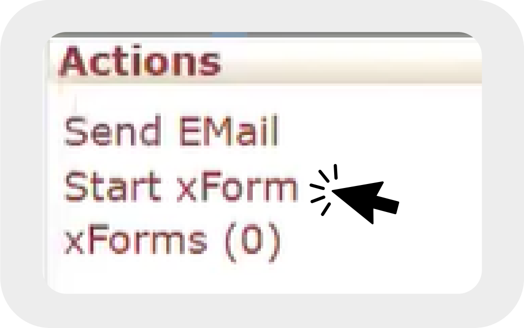
Modifications

Anyone with edit/mange/submit access will be able to submit modification forms in OneAegis.

Step 1: From the IRB tab in OneAegis, click on the study you wish to modify.



Step 2: Next, click on **Start xForm** in the top left under Actions.



Step 3: Select the form you would like to create, and fill it out.

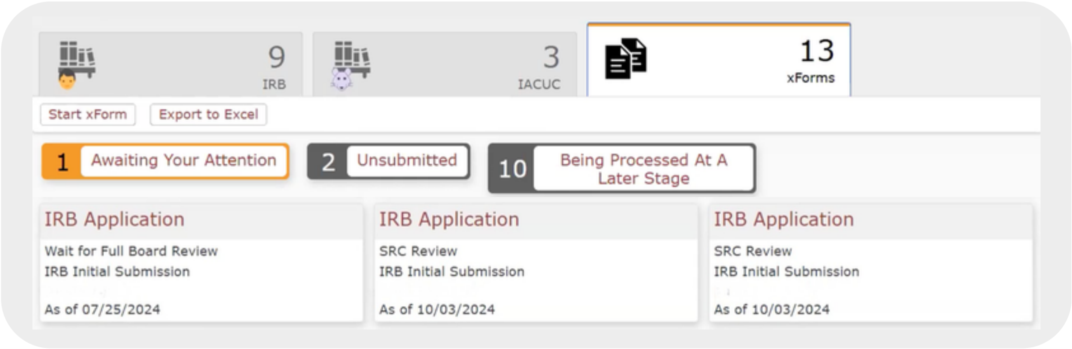
Select xForm to start

Action	Form (Click to start)	Description
	IRB Adverse Event Form (Draft)	IRB Adverse Event
	IRB Closure Form	IRB Closure Form
	IRB Continuing Review Form	IRB Continuing Review Form
	IRB Personnel Change Form	Personnel Change Submission Form to add and/or remove personnel from an existing IRB project.

Step 4: Once you are finished, you may submit the form for PI signature. The PI must sign all forms in order for them to be sent to the IRB.

Checking Project Status

The following are status definitions that may be listed on your **xForms** page. Please note that unless added as a collaborator before submission to the IRB, research personnel will not be able to see the xForm until it is approved. Once approved, an application will be listed in the **Project** section.

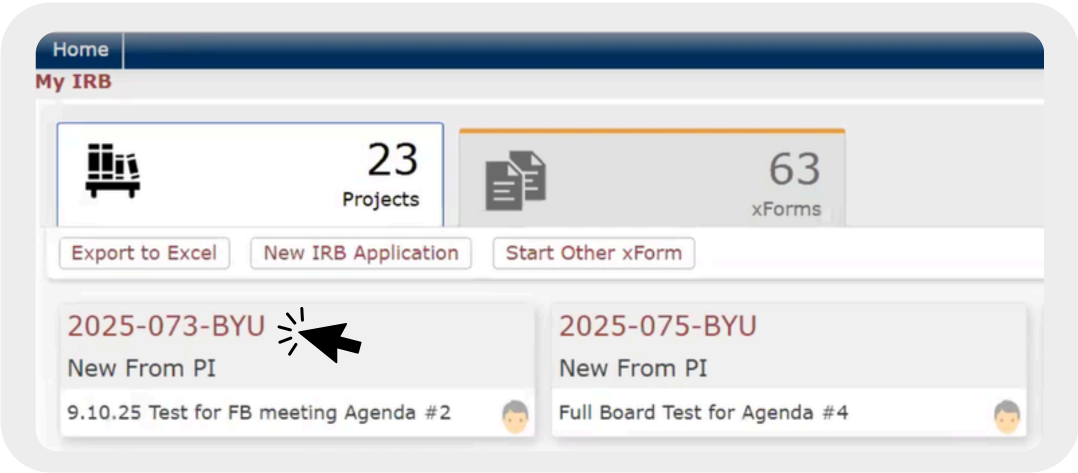


Status	**Definition**
Data Entry	In this stage, the application is editable. IRB staff can view the application, but it is not in the processing queue.
Principal Investigator Review and Signature	The application is still with the PI. The IRB has not yet received it. If more edits are needed at this stage, the PI may disapprove it and send it back to the Data Entry stage.
SRC Review	The application is awaiting approval from the Scientific Review Committee.
IRB Pre-review	The IRB has received the application.
Under Review	No additional action is needed from the researcher at this stage. The application is most likely with an IRB committee member, and is still being reviewed.
Committee Review Processing	No additional action is needed from the researcher at this stage. The application is being processed by the IRB Committee.
Wait for Full Board Review	The application will be discussed at an IRB Committee Meeting. These take place on the first Thursday of each month.

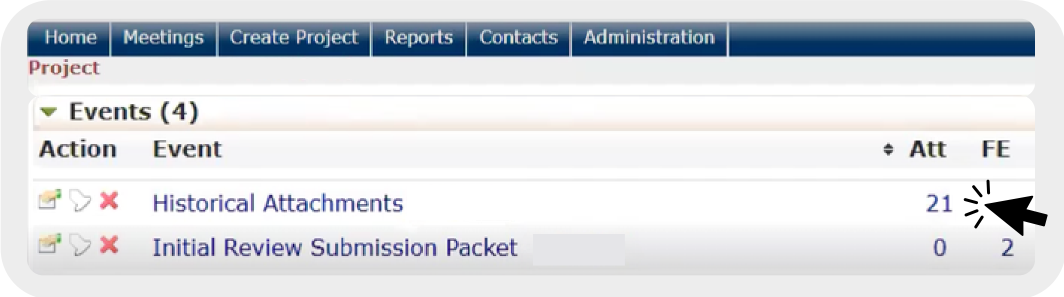
Locating Attachments of Approved Studies from iRIS

If you submitted a request for the IRB to manually transfer your study from the iRIS pdf to the OA platform, you will need to download your approved study documents and attach them to the form the IRB sends you.

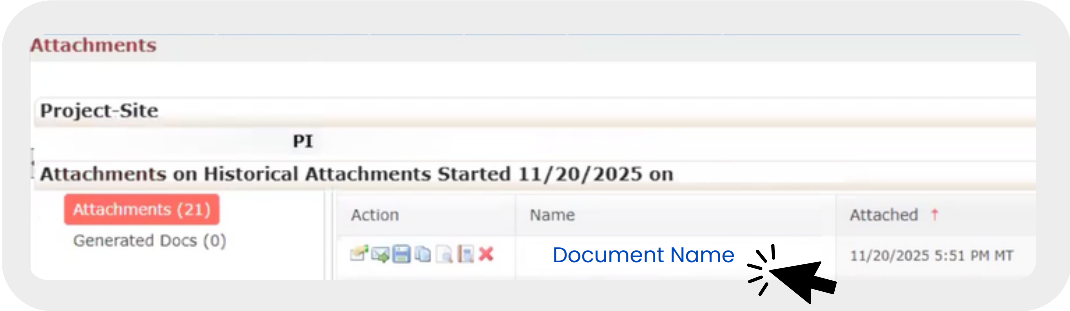
Step 1: From the **Projects** view, click on the name of the study you wish to modify.



Step 2: Scroll down until you see the **Events** heading. Look for **Historical Attachments** and click the number under **Attachments**.



Step 3: Download an attachment by clicking on its name.



Amendments

Anyone with edit/mange/submit access will be able to create amendment forms in OneAegis.

There are two kinds of amendments in OneAegis.

1) Legacy Amendments - for minor changes to studies approved in iRIS that have not been transferred to OneAegis. Please contact IRB staff at byu.hrpp@byu.edu if you think your study may qualify.

2) Traditional Amendments - These apply in two cases:

- Studies originally submitted in OneAegis
- Studies transferred from iRIS

Legacy Amendments - If your study has the option to begin a legacy amendment, it will appear as an xForm option. Please see the **Modifications** section of this site guide and follow the instructions.

Traditional Amendments - If your study was originally approved in OneAegis, you may skip to the tutorial on the next page. If your study was originally approved in iRIS, it will need to be transferred to OneAegis before modifications can be made. The IRB is currently accepting transfer requests via the link on the homepage. Once the IRB staff transfers your study, you will be sent further instructions on how to proceed. Please be aware of the following:

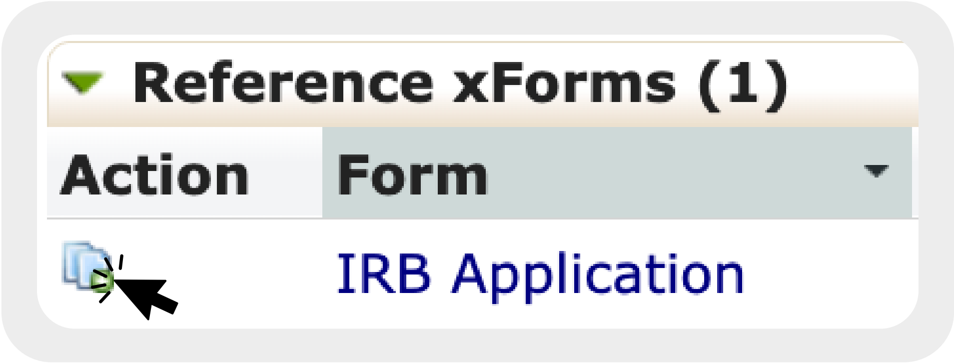
- For EXEMPT studies, the transfer will be submitted to the IRB and reviewed in the same manner as a new exempt study. Modifications to the original protocol can be made to the transfer application. If regulations have changed since the study's original approval, updates to the protocol may be required.
- For EXPEDITED studies, IRB staff will open a form linked to the original project's OneAegis folder. The study must be submitted exactly as initially approved, then an amendment may be initiated. If regulations have changed since the study's original approval, updates to the protocol may be required.

Amendments (cont.)

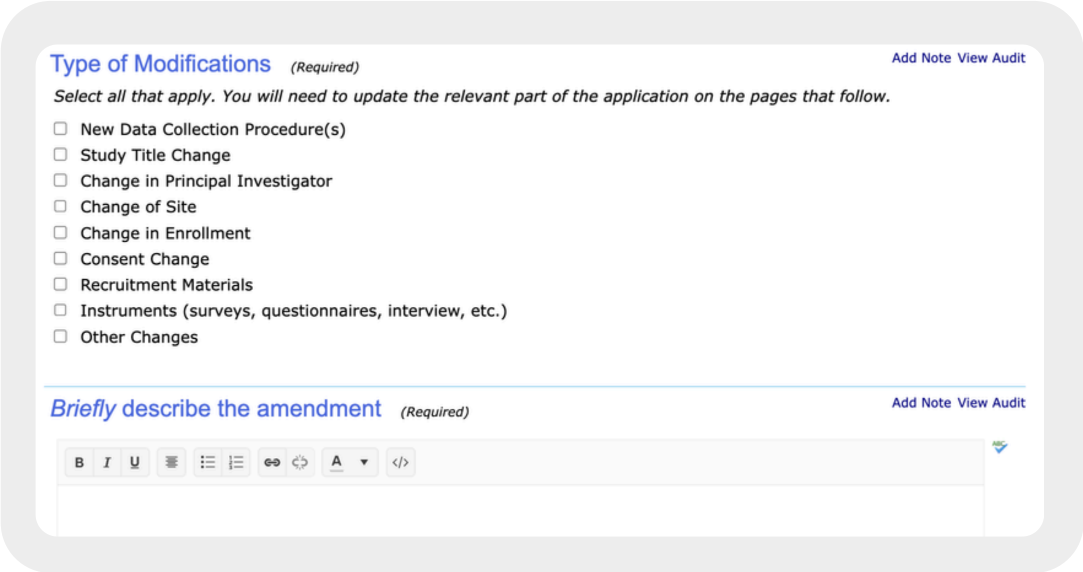
Traditional Amendment Instructions

Step 1: Open the study's project page by searching for the study number, or selecting it from your dashboard.

Step 2: Under the **Reference xForms** section, click on the **blue pages** next to the IRB application. This will open the amendment form.



Step 3: Select all modifications you would like to make, update the protocol to reflect those changes, and submit the amendment form.



Amendments (cont.)

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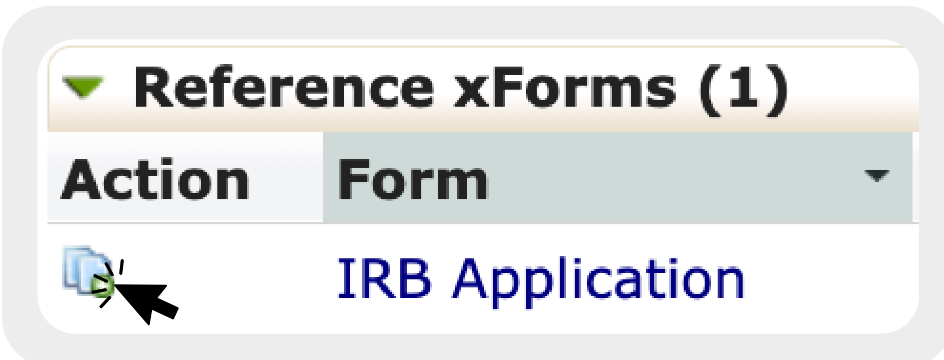
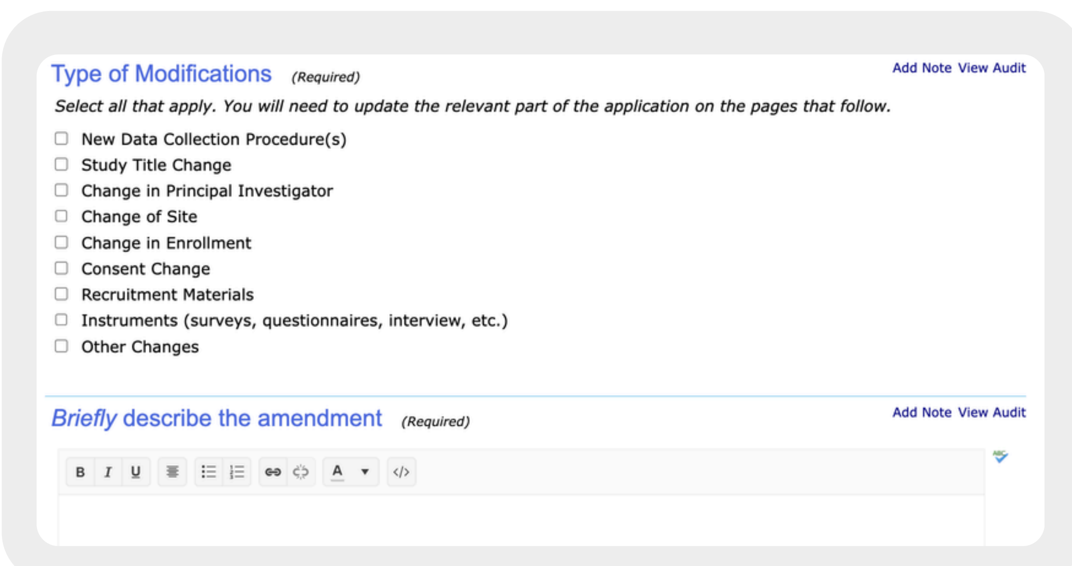
Step 2: Under the **Reference xForms** section, click on the **blue pages** next to the IRB application. This will open the amendment form.



Step 3: Select all modifications you would like to make, update the protocol to reflect those changes, and submit the amendment form.

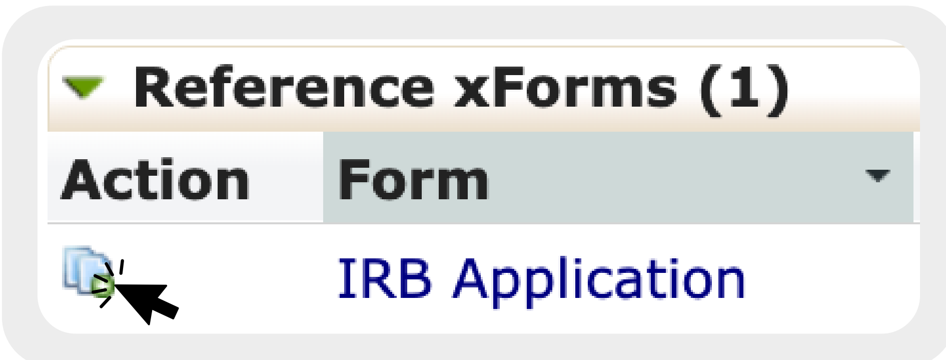


Amendments (cont.)

Traditional Amendment Instructions

Step 1: Open the study's project page by searching for the study number, or selecting it from your dashboard.

Step 2: Under the **Reference xForms** section, click on the **blue pages** next to the IRB application. This will open the amendment form.



Step 3: Select all modifications you would like to make, update the protocol to reflect those changes, and submit the amendment form.