OneAegis Site Guide

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Utilize these buttons to return to the top

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.
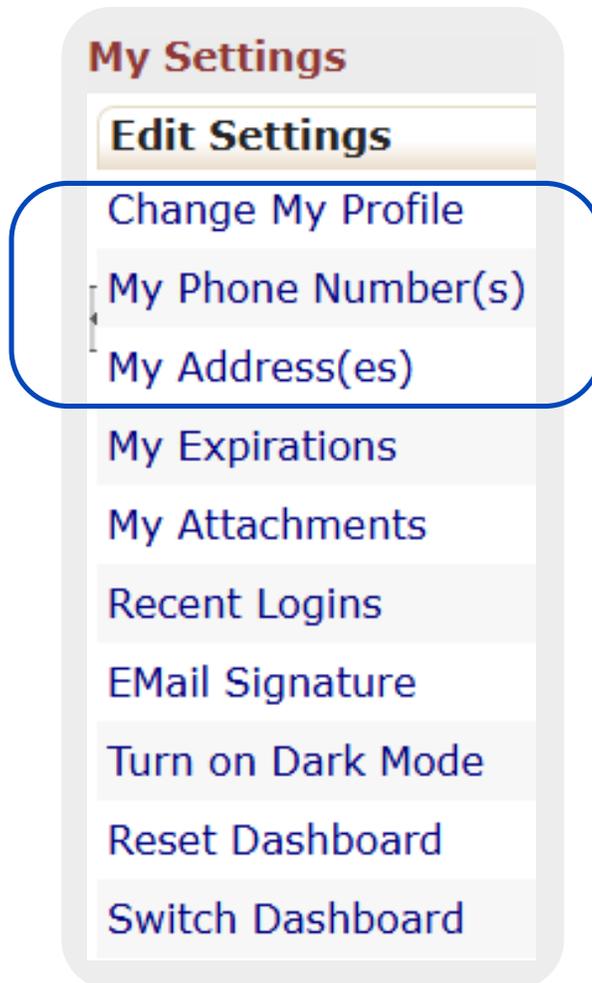
User Settings

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

Find Project (Ctrl+Q)

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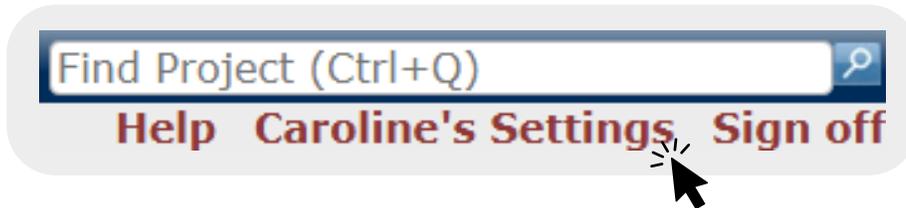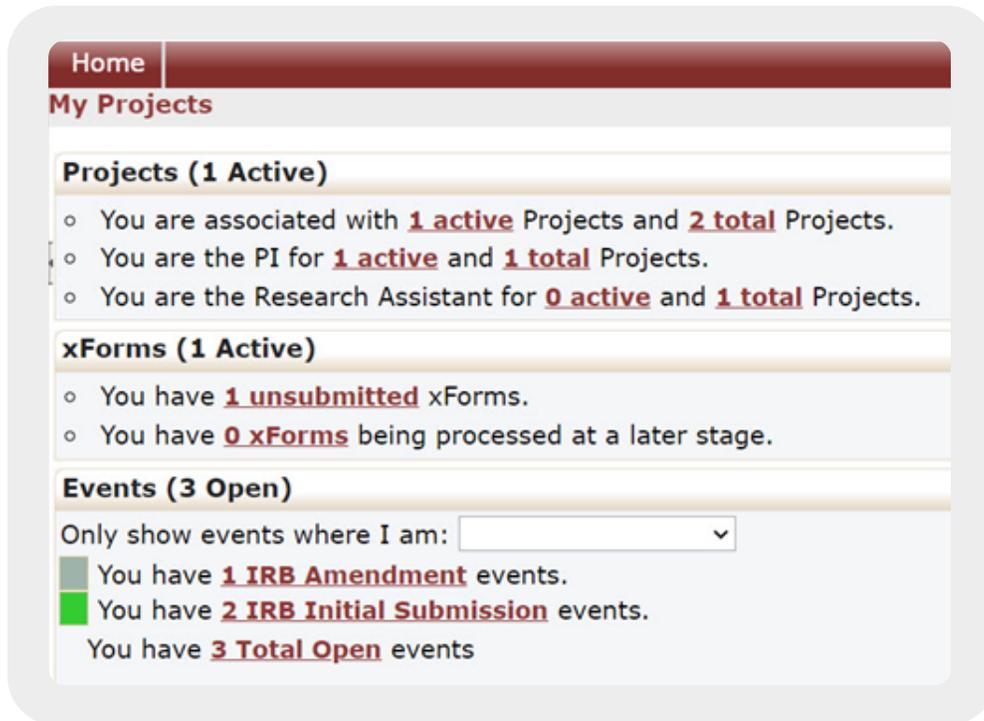
Select Change My Profile to update your name, prefix, suffix, and degree information. Please update My Phone Number(s) and My Address(es) to provide your contact information.

My Settings

Edit Settings

Change My Profile

My Phone Number(s)

My Address(es)

My Expirations

My Attachments

Recent Logins

EMail Signature

Turn on Dark Mode

Reset Dashboard

Switch Dashboard

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.

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.
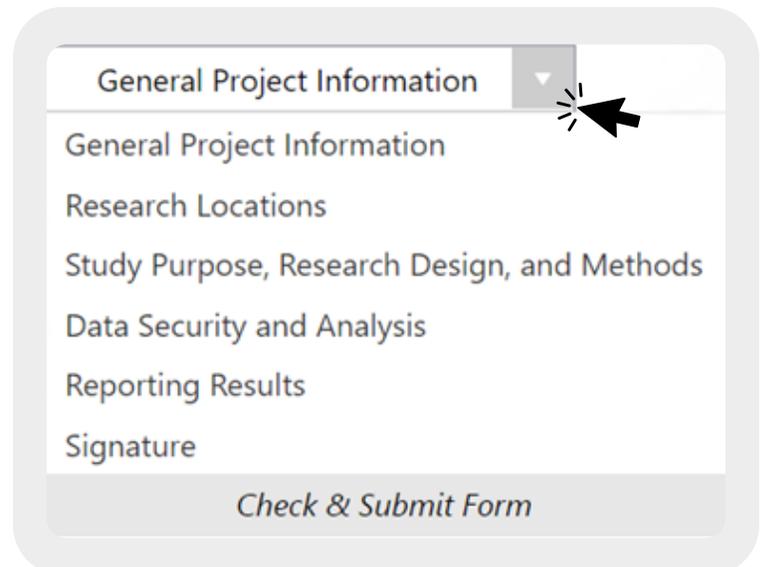
Saving Your Work

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.

Be sure to click SAVE after adding each research personnel

Who *	Role *	Subject Interaction *	Training	Action
				Save

Save

Co-Investigators *

Role *
Co-Investigator

Qualification
☐ PhD in field of research
☐ Publications in this area of research with this method
☐ Prior research project with approval using this methodology at BYU

Subject Interaction *
○ Yes
○ No

Training

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.

Next   Save for Later   More ▶

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.
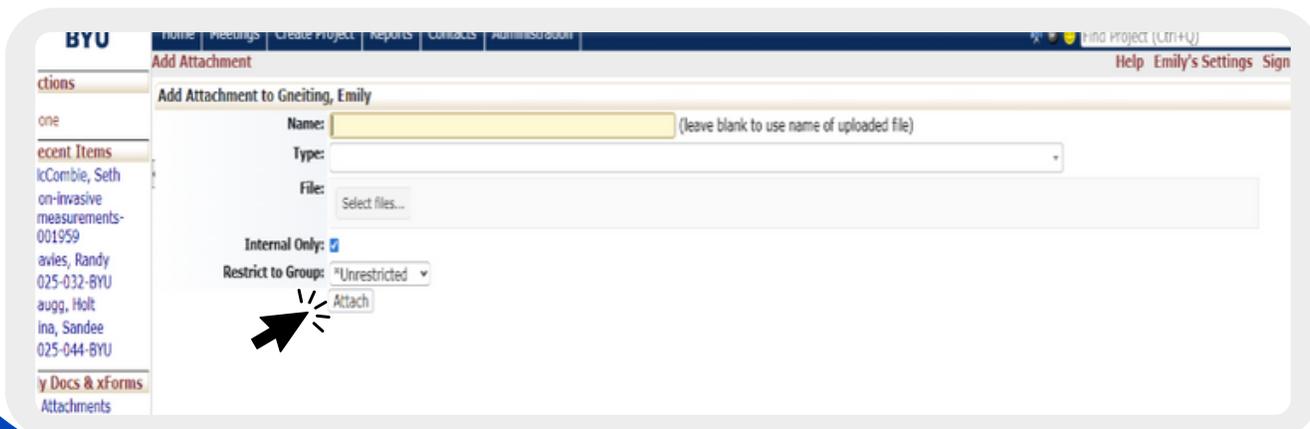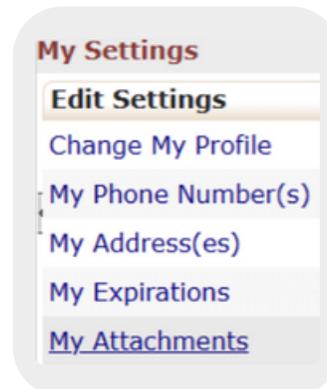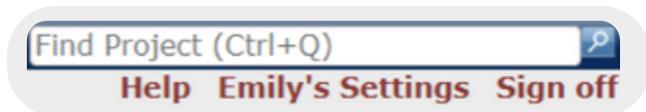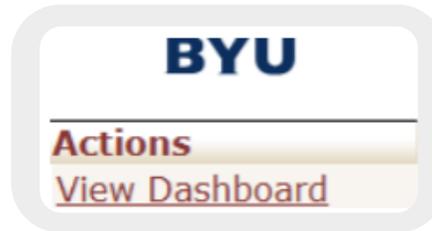
Adding Collaborators

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.

 Collaborators

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.

Be sure to click SAVE after adding each research personnel

Who *	Role *	Subject Interaction *	Training	Action
				Save
	Project Manager			
	Research Assistant (Read only)			
	Research Assistant (write)			
	Research Development Officer			

Are there any external investi...   Add Note View Audit

○ Yes
● No

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 Officer, 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 ammendments).

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.

What do you want to focus on?

IACUC   IBC   IRB   Show Everything
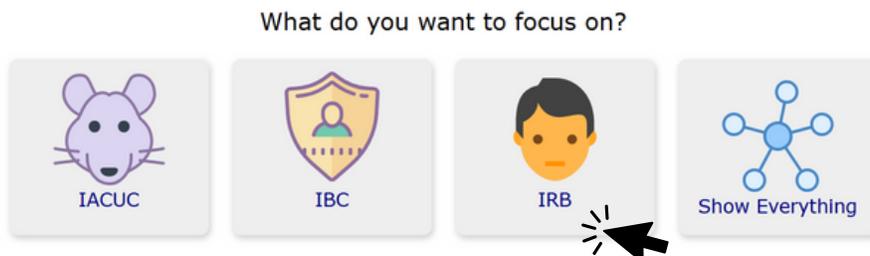
There are two dashboard types. You can start your xForm from either view.

Bubble Dashboard View

Select the xForms tab.

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

0
xForms

New IRB Application   Start Other xForm

Power Dashboard View

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

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

Actions
Start xForm

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.

Attach your recruitment materials
Click here for guidance about recruiting materials.

Name the document using the following format: "Type of recruitment"_"group"_"version date", i.e., Email_Control group_10.20.2021, Flyer_10.20.2021

- *For visual recruiting materials (i.e., flyers, social media, etc.) attach the final wording and graphics to be used*
- *For verbal recruiting materials (i.e., personal contact, phone call, etc.) attach the script outlining what you will say*
- *For emails, please include the subject line*
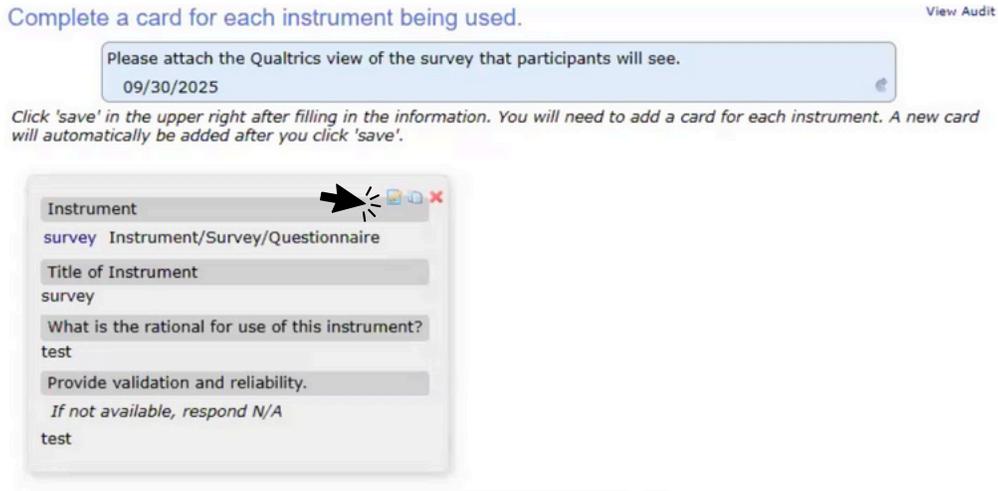
Add Attachment

✖ ♻ updated email recruitment 10.6.25   Recruitment Materials

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 <u>Adding Attachments</u> for naming guidelines and other tips.**
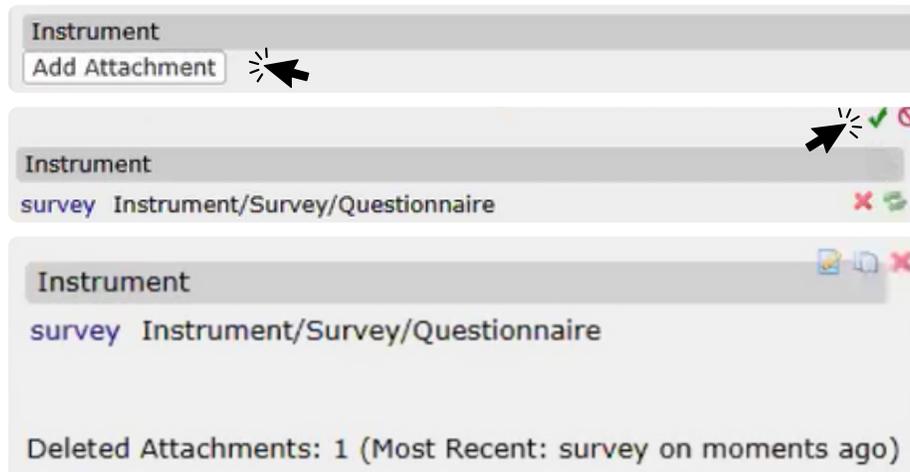
Step 1: You will need to remove the previous document and add a new one. Click the edit button on the survey card.

Complete a card for each instrument being used.   View Audit

Please attach the Qualtrics view of the survey that participants will see.
09/30/2025

Click 'save' in the upper right after filling in the information. You will need to add a card for each instrument. A new card will automatically be added after you click 'save'.

Instrument
survey Instrument/Survey/Questionnaire
Title of Instrument
survey
What is the rational for use of this instrument?
test
Provide validation and reliability.
  If not available, respond N/A
test

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

Instrument
survey Instrument/Survey/Questionnaire
Title of Instrument
survey

byu.oneaegis.com says
Are you sure you want to delete ?
OK   Cancel

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.

Instrument
Add Attachment

Instrument
survey Instrument/Survey/Questionnaire

Instrument
survey Instrument/Survey/Questionnaire

Deleted Attachments: 1 (Most Recent: survey on moments ago)

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!

By entering my OneAegis password below, I attest that the information contained in this application is accurate and complete. (Required)   Add Note   View Audit

Note: You will need to click "Next" and "Submit" to submit the application for processing after entering your password.

To sign, enter password for

[ ]

Previous   Next   Save for Later   More ▸

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

Form Completed

You've completed the form. You can now either save the form for later revision, or submit it.

Go Back   Save for Later   Print   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.
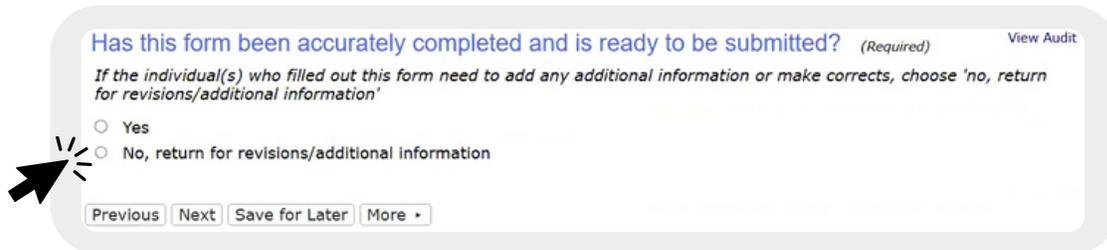
> Has this form been accurately completed and is ready to be submitted? *(Required)*   View Audit
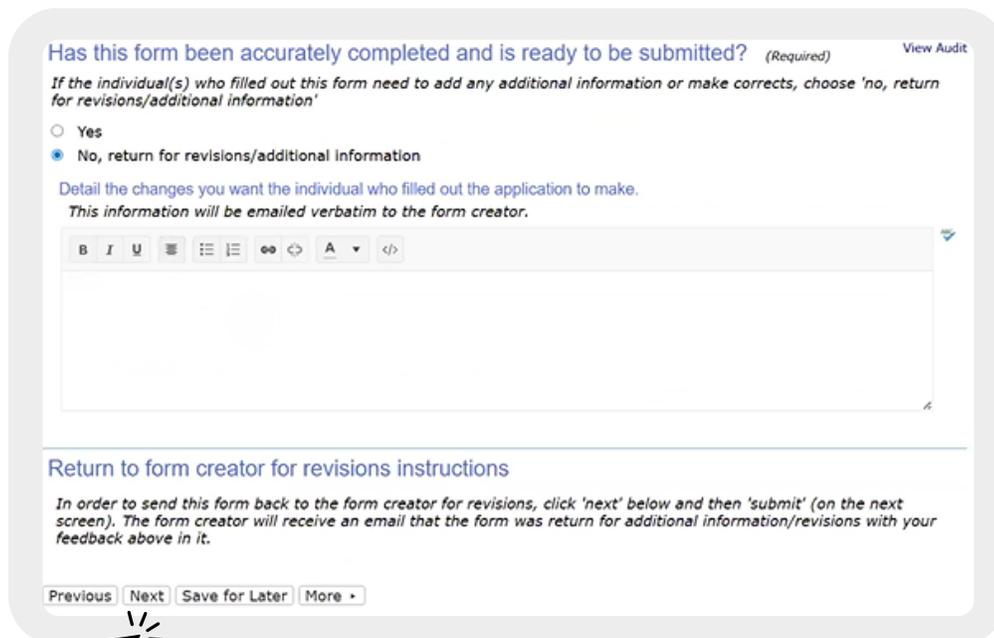>
> *If the individual(s) who filled out this form need to add any additional information or make corrects, choose 'no, return for revisions/additional information'*
>
> ○ Yes
>
> ○ No, return for revisions/additional information
>
> Previous | Next | Save for Later | More ›

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.

> Has this form been accurately completed and is ready to be submitted? *(Required)*   View Audit
>
> *If the individual(s) who filled out this form need to add any additional information or make corrects, choose 'no, return for revisions/additional information'*
>
> ○ Yes
>
> ⦿ No, return for revisions/additional information
>
> Detail the changes you want the individual who filled out the application to make.
> *This information will be emailed verbatim to the form creator.*
>
> B I U ≡ ≔ ≔ ∞ <> A ▾ </>
>
> [comment box]
>
> **Return to form creator for revisions instructions**
>
> *In order to send this form back to the form creator for revisions, click 'next' below and then 'submit' (on the next screen). The form creator will receive an email that the form was return for additional information/revisions with your feedback above in it.*
>
> Previous | Next | Save for Later | More ›

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.

> **Form Completed**
> You've completed the form. You can now either save the form for later revision, or submit it.
>
> Go Back | Save for Later | Print | Submit

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.
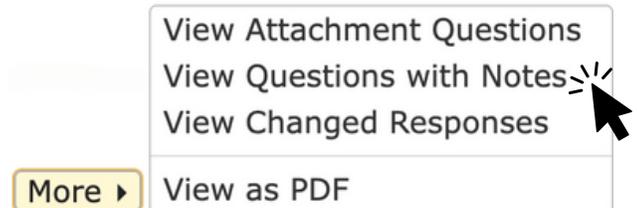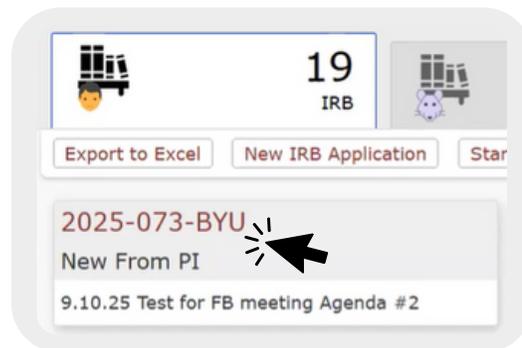
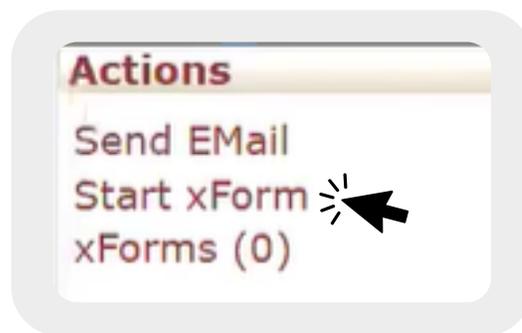Note: Some changes may shorten or lengthen the application.

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.

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.
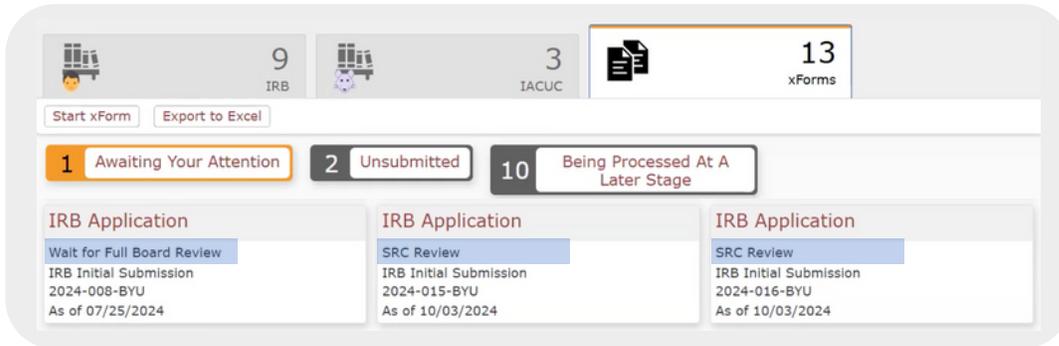

Status	Definition
Data Entry	In this stage, the application is editable. IRB staff can view the application, but it is not in the processing queue.
Principal Investigator Review and Signature	The application is still with the PI. The IRB has not yet received it. If more edits are needed at this stage, 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.
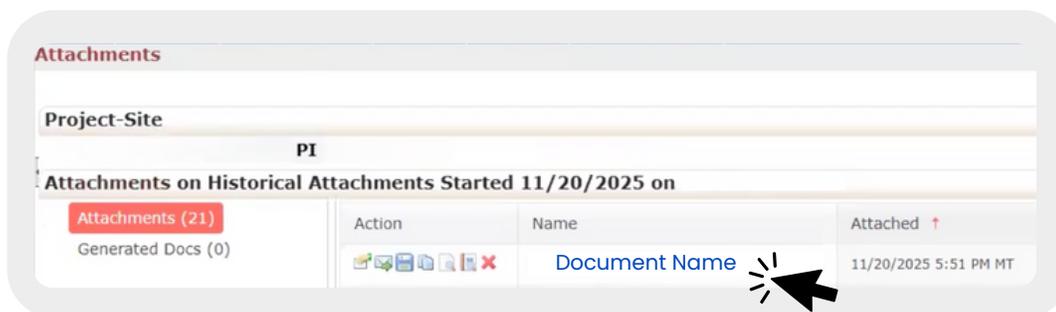
Step 1: From the **Projects** view, click on the name of the study you wish to modify.
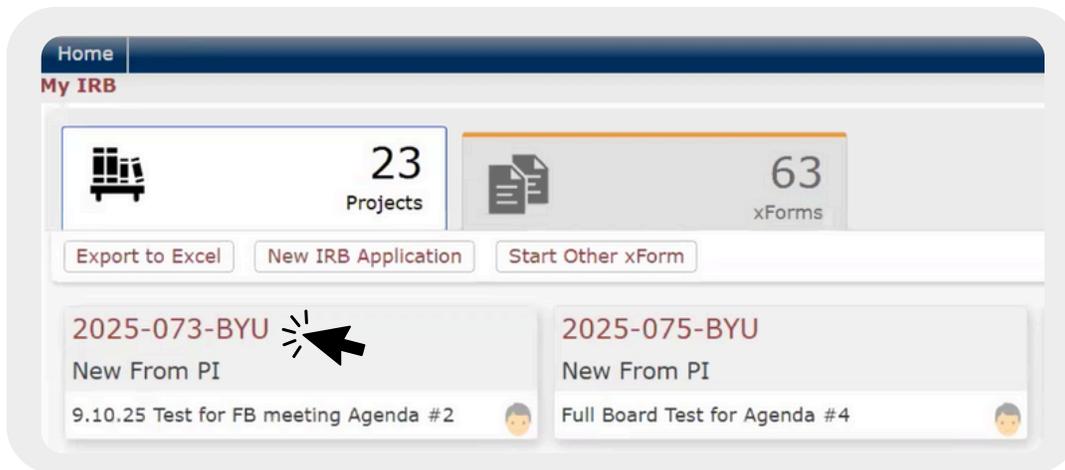
Step 2: Scroll down until you see the **Events** heading. Look for **Historical Attachments** and click the number under **Attachments**.
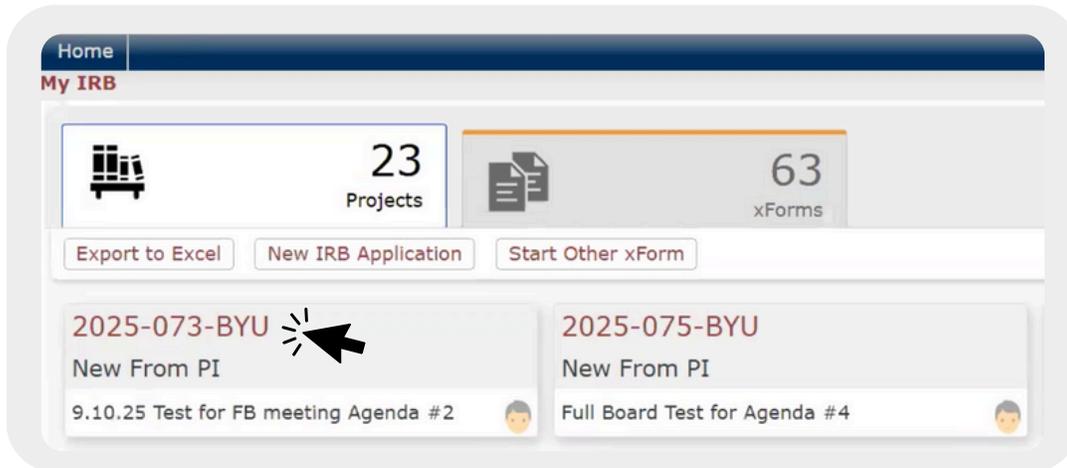

Step 3: Download an attachment by clicking on its name.

Submitting an Adverse Event, Continuing Review, Closure, or Personnel Change Form

Step 1:   From the **Projects** view, click on the name of the study you wish to submit a continuing review for.

Step 2:   In the top left corner, click on **xForms** under **Actions.**

Step 3:   Click on the form you want to start. Follow all instructions, submitting all necessary documentation, and submit for IRB review.