Albert Einstein College of Medicine | Montefiore | Office of Human Research Affairs

# OneAegis Training Guide – Research Teams

## Table of Contents

# SECTION I: GENERAL OVERVIEW

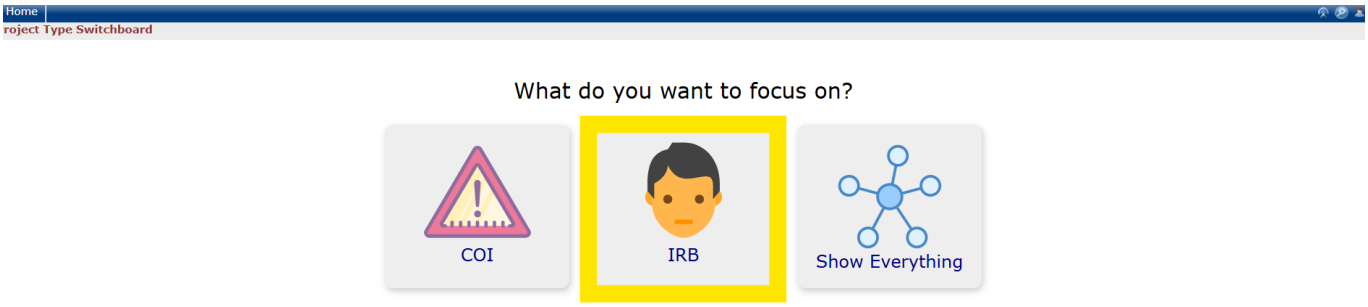
This guide provides step-by-step instructions for creating and submitting **IRB applications** in **OneAegis.** The first section describes the login process and the home screen dashboard you will encounter. Subsequent sections address the submission of initial IRB applications, including the institutional information and IRB stages of the application form; COI and CITI training requirements; responses to revision requests; and submission of post-approval forms (i.e., amendments, continuing reviews).

## *A. Logging In*

Login at https://einsteinmed.oneaegis.com by selecting "Click here to login with your enterprise login."

You will be taken through the prompts of SSO (single sign on) using your Montefiore Einstein credentials.

Once you are logged into OneAegis, click the IRB button to view your IRB dashboard.

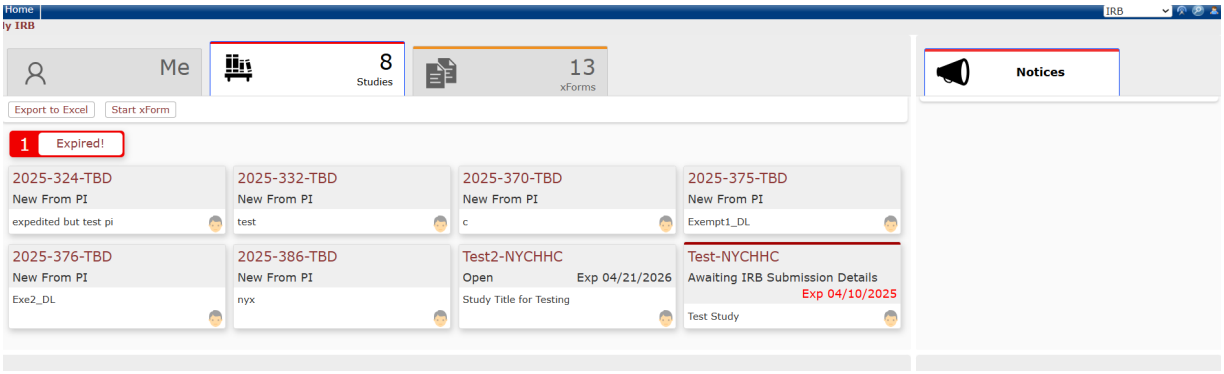



## *B. Understanding your Dashboard*

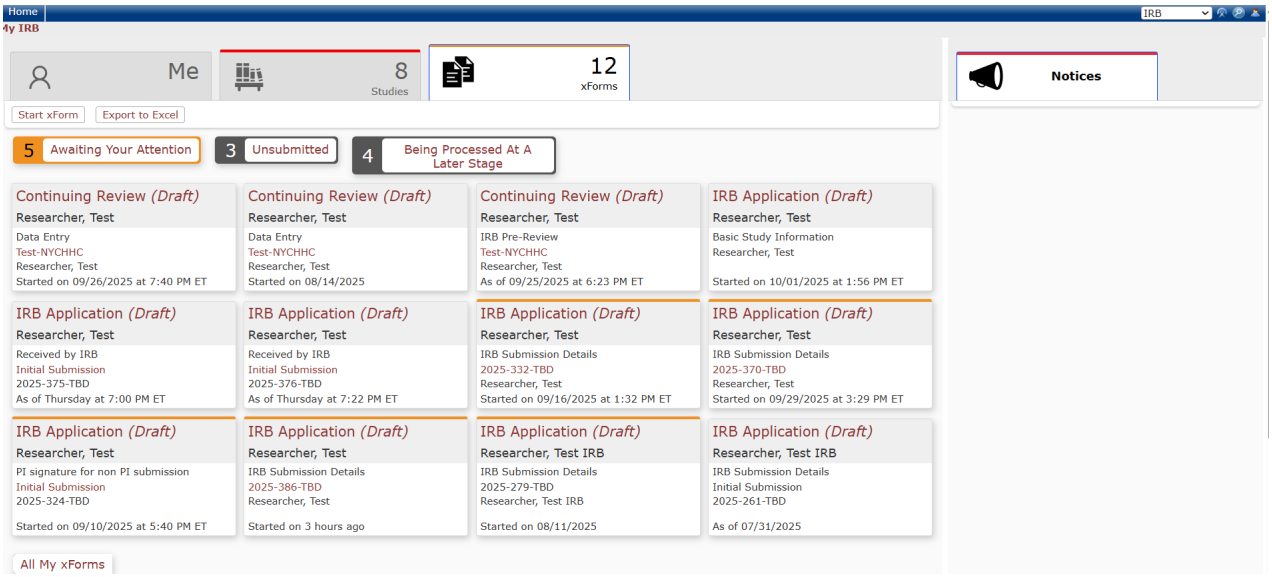
Your **Dashboard** is your homepage in OneAegis and shows both your active studies and any submissions in progress.

**To view the status of a study or submission:**

1. From the top navigation, click the **Studies** tab. This tab displays all **active studies,** that is, studies that are currently open and not yet closed or terminated.




2. Click the **xForms** tab to view all your **pending submissions** (forms you are currently working on before approval).



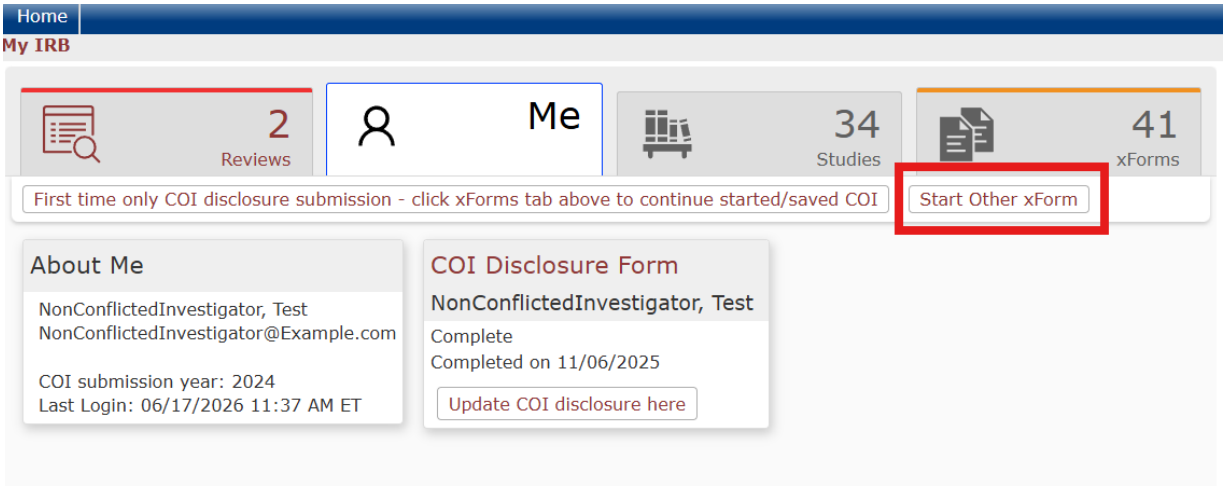

## i. Dashboard Filters

Use the dashboard tiles to quickly monitor the progress of all your studies and submissions:

- **Awaiting Your Attention**: Displays submissions that require an action from you (e.g., signatures, revisions, or additional information).
- **Being Processed at a Later Stage**: Displays submissions you have already submitted that are now with someone else in the review process (for example, a form waiting on departmental or divisional sign-off).
- **Unsubmitted**: Displays draft forms that have been started but not yet submitted.

# SECTION II: SUBMITTING AN INITIAL IRB APPLICATION

Click "Start other xForm" from your Dashboard.




Next, click **IRB application**.


## *A. Completing the IRB Application*

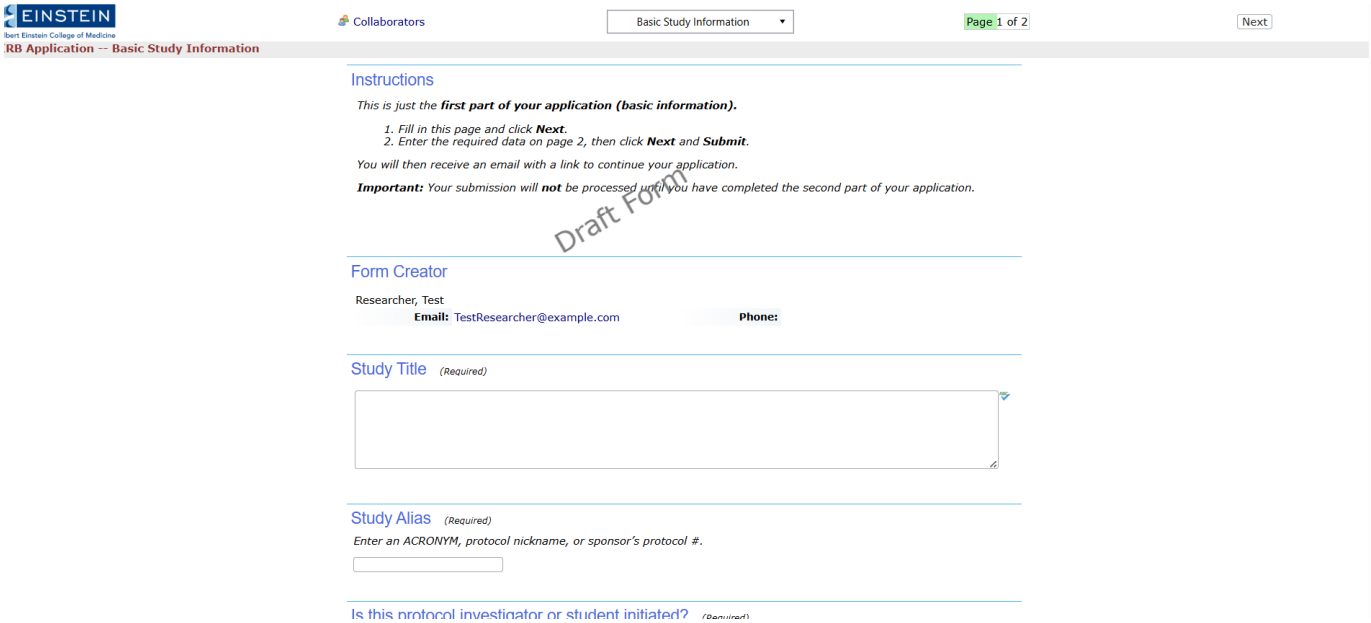
The IRB application in OneAegis is divided into **2 stages**:

- **The first stage** contains *institutional questions* (e.g., departmental details, signatories). Questions in this stage define routing requirements for various signatories (such as department or division chairs).
- **The second stage** contains *IRB-specific questions*.

**IMPORANT:** After **submitting the first stage**, you must **proceed to the second stage** of the application to continue the submission. Once the first stage is submitted, you will receive an **email from OneAegis** containing a link to complete the IRB portion of the application form. Your application will **not reach the IRB office** until both stages have been fully completed and submitted. You may complete the two stages at different times if needed.

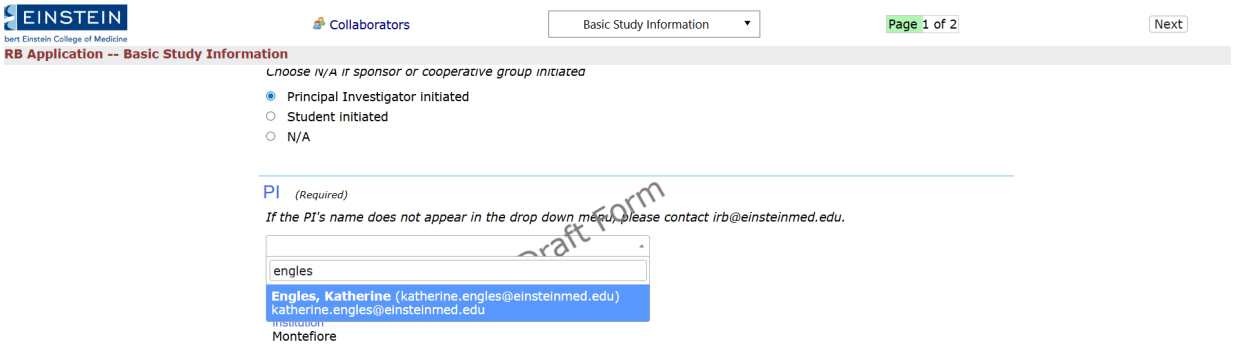
## i. The First Stage

Begin filling out **the first stage** of the application. **The first stage** consists of two pages.




When entering names for the **PI** or **key personnel**, you will search the OneAegis contact directory.

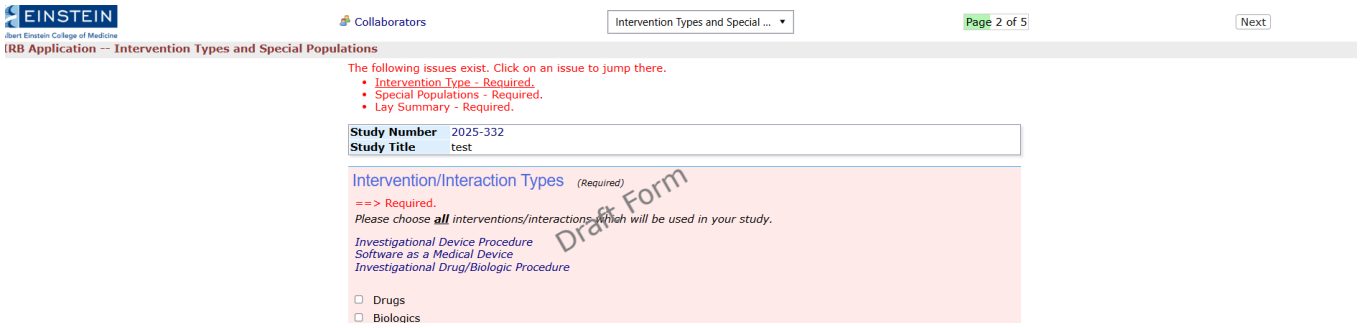
- Type **<u>only</u> the first name OR last name** in the search box.
- For example, typing *"John Doe"* will not yield a result; instead, type *"John"* or *"Doe."*




Notes on completing the application form:

- Click **Next** at the bottom of each page to move forward.

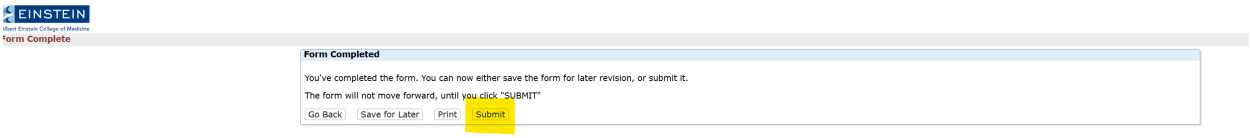
- The form includes questions designated as **required**. You cannot advance until **all** required questions are completed.
- If you attempt to move forward with missing information, a **red error message** will appear at the top of the page.
- These red messages are **clickable links** that take you directly to the question that must be completed.




At the end of this stage, you will be prompted to identify the required **Department Chair** and/or **Division Chief signatories**, as applicable.

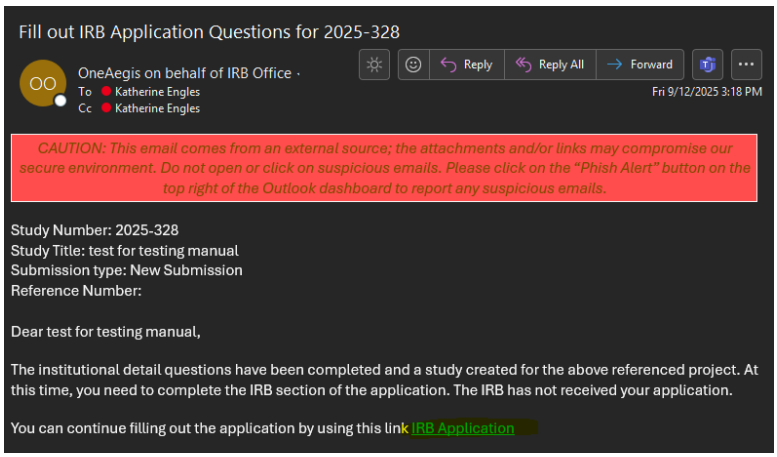
- Please note, the Division Chief field will only appear if Division Chief signoff is required for your department. Division Chief signoff is generally required for Department of Medicine studies.
- Refer to the current list of signatories here: https://einsteinmed.edu/administration/human-research-affairs/policies-procedures/administrative-approvals/

When you reach the “Form Completed” page, click **Submit** to finish the first stage.




## ii. The Second Stage

**IMPORANT:** The form creator and the PI will receive an **email from OneAegis** with a link labeled **“IRB Application.”** Click this link to continue your submission and begin the second stage.

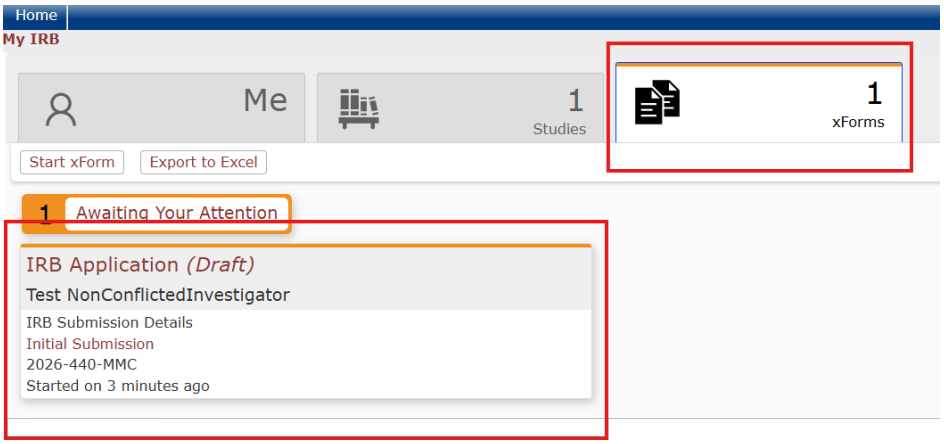



You can also proceed to the stage 2 application directly from your IRB Dashboard under the “xForms” tab.

- Once the Stage 1 application has been submitted, the status in the study card on your dashboard will change from “basic study information” to “IRB submission details.” It will also be marked “awaiting your attention.”

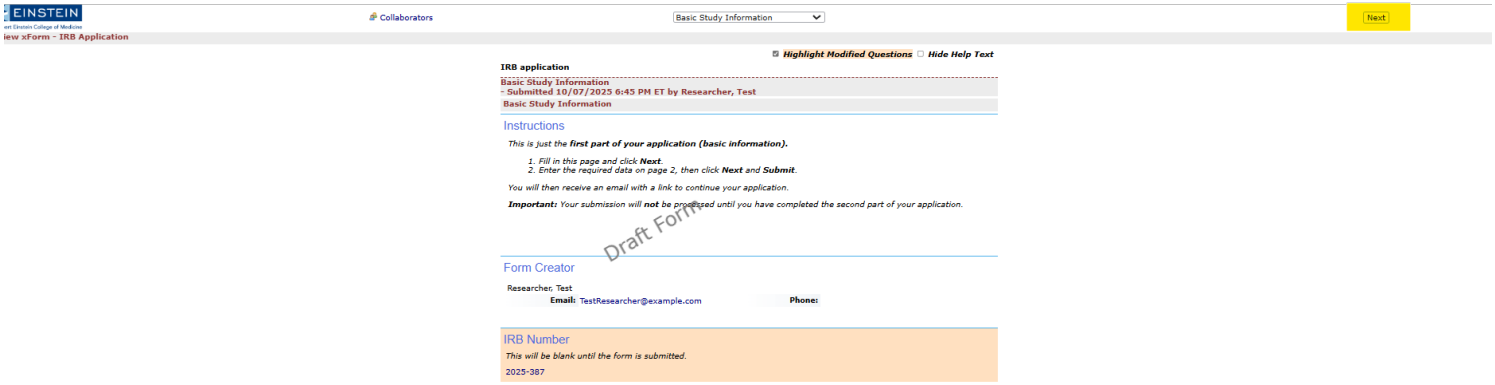
- Please note, there may be a few minutes delay after clicking “submit” from the Stage 1 application before the link to the Stage 2 application is available on your dashboard.

- You can then click the “IRB Application (Draft)” header corresponding to the application you initiated to proceed with the Stage 2 application.

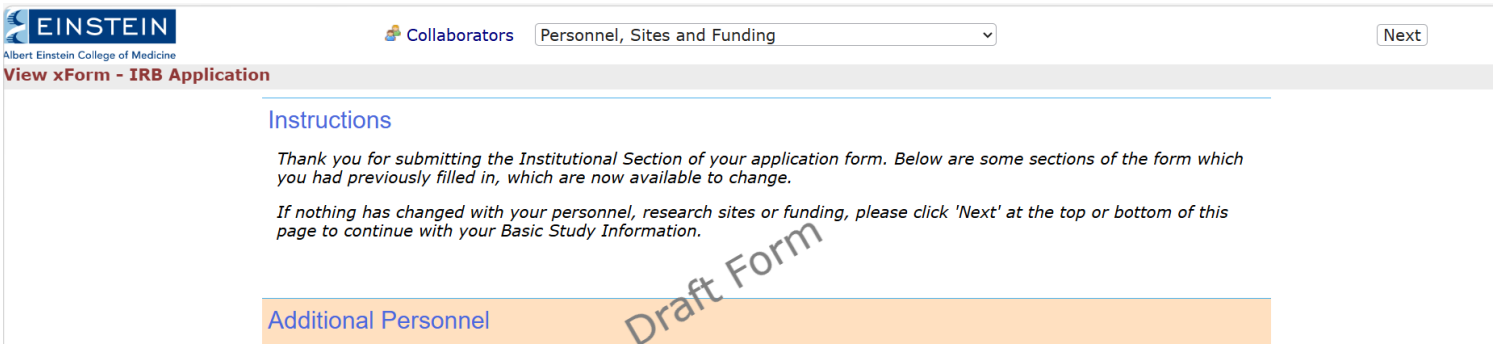



Clicking the email link or “IRB Application (Draft)” link from the Dashboard will reopen the pages of the first stage which was completed.

Review your responses by scrolling through the pages. Click **Next** after reviewing.




The first page of **the second stage** will allow you to review and edit certain information from the first stage. Make any necessary updates and click **Next**. Continue filling out the application until you reach the **Signature** page.



- **Required Fields:** As in the first stage, certain fields are **required**. If you attempt to move forward without completing a required field, **red text** will appear identifying which question(s) must be completed or corrected before you can continue.

- **Dropdown Navigation:** You can navigate between sections at any time by clicking the **dropdown menu** at the top of the page, which displays all sections of the application. Clicking a section title will take you directly to that part of the form.

- **Dynamic Forms:** Keep in mind that the form is **dynamic**. This means that the questions you see will depend on how you answer earlier questions. For example, if you indicate that your study involves children as participants, additional questions related to research with children will automatically appear. If you indicate that children are not included, those questions will remain hidden.

### iii. FAQs: Application Stages

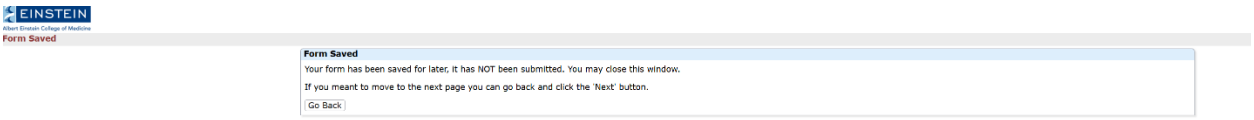
**Can I submit the first stage and complete the second later?**
Yes. The first and second stage can be completed at different times. Submitting the first stage initiates institutional processes and/or approvals that may apply to the submission. You will receive an email with a link to continue to the second stage when ready.

**Can I upload new versions of documents after submitting the first stage?**
Yes. You can upload updated versions of any documents—such as the protocol, consent forms, or other attachments—once you reach the second stage. The application is designed to accommodate revised and evolving document versions as your submission progresses. When prompted, enter the **version number and version date** for each updated study document to maintain accurate version control and ensure proper tracking within the study record.

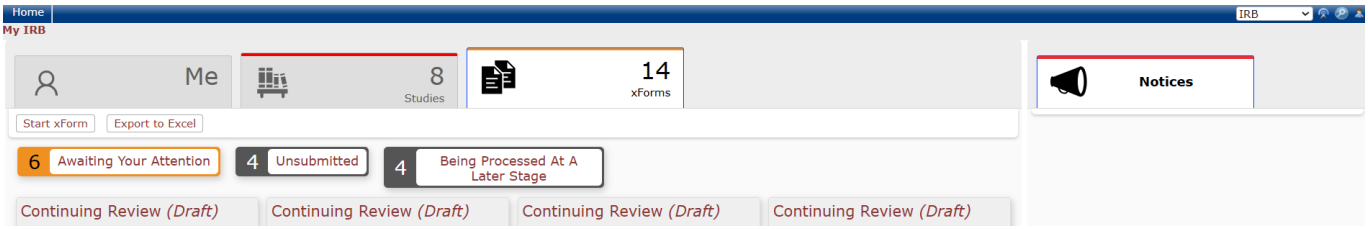
### iv. Saving an In-Progress Application

If you wish to save your progress on an application and resume at a later point in time, click “save for later” at any point.

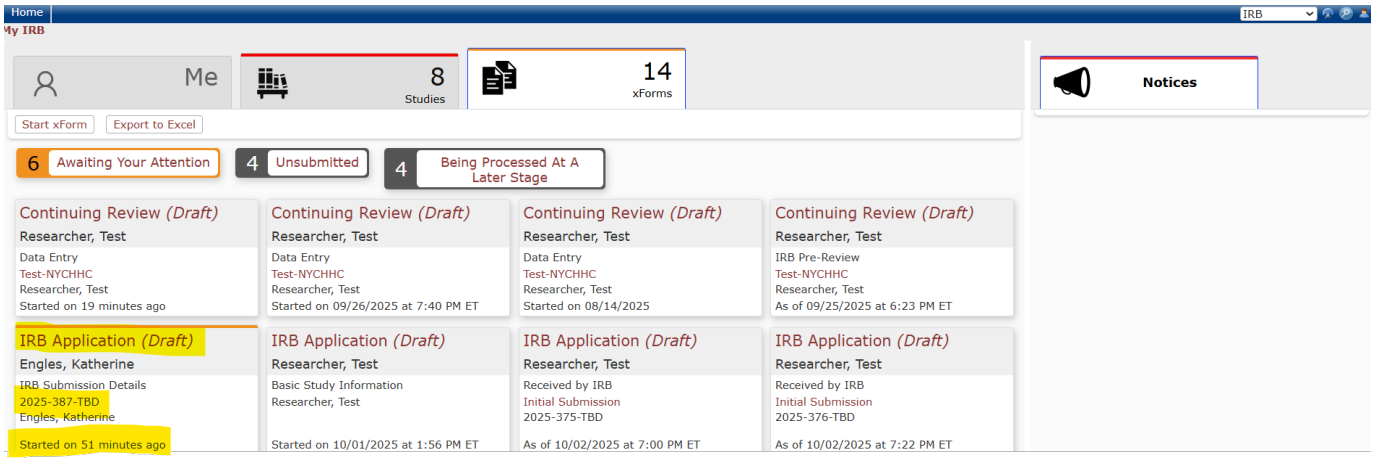

Once you click “save for later” the following screen will pop up, and you can close out of the window.




To find and resume an in-progress application, you will need to log in to OneAegis and click “Home” at the top left of the browser page at any time to view your dashboard.




The xForms tab is where you can find any in progress applications that you have “saved for later” or that are in progress. Find the appropriate application box based on the IRB# and time stamp details.




The window will then open to the part of the application where you clicked “save for later.” You may have to click “Next” or use the drop-down navigation bar to reach the exact section where you left off.

## v. Attaching Required Documents

You will be prompted to upload required study documents at several points throughout the IRB application. These may include, for example, the study protocol, consent and assent forms, recruitment materials, investigator brochures, or other supporting documents.

Each section that requires an upload will display an **“Add Attachment”** button. Click this button to browse and upload the appropriate file. The field label will specify the type of document expected (e.g., “Protocol,” “Consent Form,” “Supporting Documentation”).

Be sure to upload the most current and finalized versions of all required documents before submitting your application. If an attachment is missing, the system will alert you with an error message when you attempt to proceed.

For cancer-related studies, please note that you will be required to attach the PRMC approved protocol once PRMC has reviewed and approved a submission. You will receive an email notification with a link to upload the PRMC-approved protocol document:

Dear Test Researcher,

PRMC has approved this submission. You are now required to provide the final approved protocol. Use this link to upload the protocol: IRB Application

After you click on the link, you will need to click "next" at the bottom of the top of the page to advance to where you can upload the protocol.

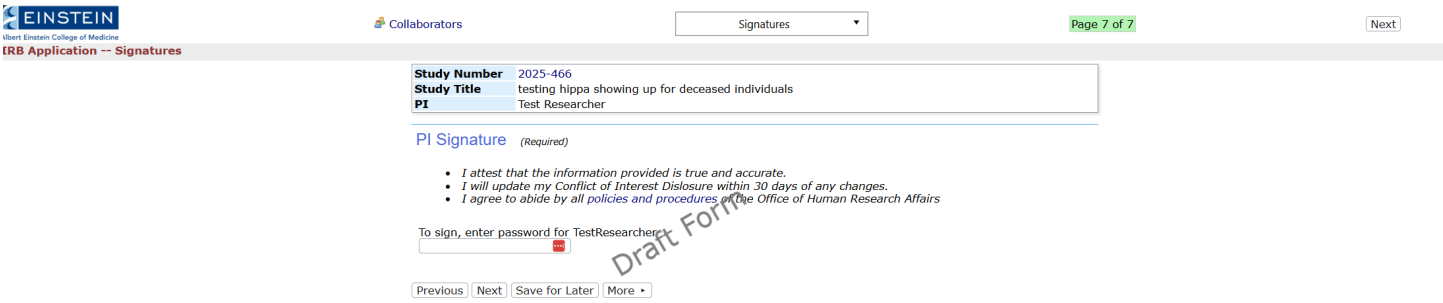
Once you've opened the form, click 'next' to proceed to the page the upload the approved protocol.

You will need to submit this form after uploading your protocol.

## *B. Completing the PI Signoff*

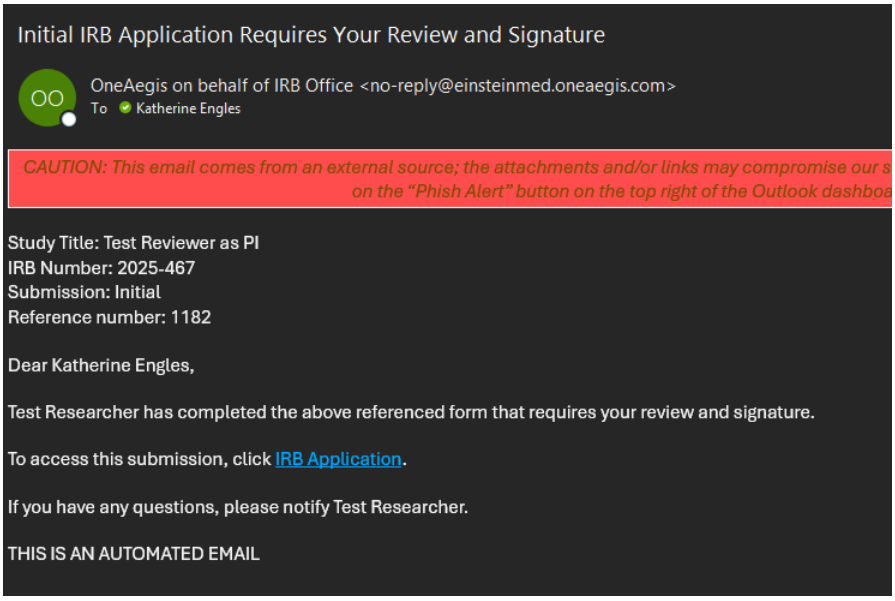
A PI signature is required on all submissions.

**If you are the PI filling out the form**, the final page will be your signature page where when you sign, click next, and submit your application.




**If you are not the PI and you are filling out the form,** you will submit the form after reaching the "Submit to PI for Signature Instructions" page.

The PI will receive an email with a link to the IRB Application xForm where they can review and click “Next” to log their signature.




When they click Next, the screen titled **“PI Signature for Initial Application”** will appear. Here, they must choose one of the following options:

- **Return for Changes**: Select this if they want to return the form to the data entry stage (for yourself or a coordinator) to make edits before submission.
- **Ready for Departmental Chair Signoff**: Select this if they are ready to approve and submit the application for the next stage of review.

Selecting “Ready for Departmental Chair Signoff” will allow them to sign and click “Next” and then “Submit” to complete and send the IRB application.

After the PI has signed off on the submission, it will be routed to any additional **institutional signatories or committees** indicated by your responses in the institutional section (for example, departmental chairs, division chiefs, Office of Clinical Research, or PRMC for cancer-related studies).

You can track the progress of your submission by returning to your **Dashboard**, selecting the **xForms** tab, and filtering by **“Processing at a Later Stage.”** This view will show applications that have been submitted and are currently under review by another office or approver.

# SECTION III: COI DISCLOSURE AND CITI TRAINING REQUIREMENTS

This section describes the CITI Training and Conflict of Interest (COI) disclosure requirements for personnel listed on IRB applications. OneAegis automatically checks the status of these 2 requirements at the time of submission. You will not be able to submit the application if any of the CITI training or COI disclosure requirements are not met.

## *A. Conflict of Interest (COI) Disclosure Requirements*

OneAegis automatically checks for required COI disclosures for the PI and all listed co-investigators. The Principal Investigator and all co-investigators must have an up-to-date (i.e., submitted in the current annual campaign cycle) COI disclosure on file before the application form can be submitted.

Please note that students/trainees, research coordinators, and research assistants do not need to complete and submit COI disclosures for IRB submissions.

If any investigators have an out of date or missing COI disclosure, the submission will not proceed until their COI disclosure form has been submitted. Once all listed investigators have current COI disclosures on file, the submission will automatically advance to be routed to approval signatories, committee signoffs as needed, before subsequently reaching the IRB queue.


For assistance updating or confirming your COI disclosure, contact the COI Office at **coi@einsteinmed.edu**.

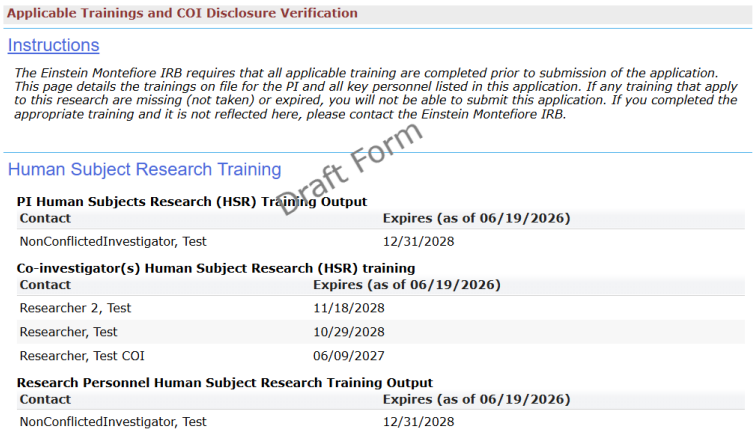
## *B. CITI Training Requirements*

OneAegis automatically checks required CITI training for the PI and all listed study personnel. You must meet these requirements to submit an initial application. If any listed personnel have missing or expired training, you will not be able to submit your initial application until all training is up to date.

On the **Applicable Trainings** page (the last page before the signature/submission step in your initial IRB application), you will see the following for each personnel:

  - The **PI Human Subjects Research (HSR) Training** expiration date.
  - **GCP Training** expiration date, if applicable.
  - A **Personnel Training** table showing each team member's status (e.g., current, *Missing*, or expired).

- If anyone is missing or out of date, clicking **Next** will display a red error banner summarizing what must be fixed, and you will not be able to proceed.




Once all training records are current and synced, you will be able to proceed to the signature and submission steps.

## *C. How to Resolve CITI Training Verification Issues*

There are several possible reasons for CITI training verification issues:

- **Training not yet completed:** One or more of your personnel have not yet taken the CITI exam or have incomplete required coursework. If this is true, follow the

instructions for the CITI course here: https://einsteinmed.edu/administration/human-research-affairs/training-education/citi-training-support/

- **Incorrect institutional affiliation:** One or more of your personnel are not affiliated with "*Albert Einstein College of Medicine"* in CITI.
- **Duplicate CITI accounts:** Personnel may have more than one CITI account. These must be merged by contacting CITI Support at support@citiprogram.org.
- **Recent completion or update to CITI website:** It has been less than 24 hours since CITI training was completed or updated. Updates will not appear until after the next scheduled sync.
- **Missing or mismatched email address:** The most common reason for failed CITI validation is an email mismatch between CITI and OneAegis. **Please note, you must use your institutional email address for CITI training to ensure that the sync occurs.**

### i. The Most Common Issue: Email Mismatch

For OneAegis to recognize CITI training, the **Preferred Email Address** in each person's CITI profile must exactly match their **OneAegis account email, which is the person's Montefiore/Einstein email address.**

**To update the Institutional Email Address in CITI:**

1. Log in to CITI Program.
2. In the top right corner, click your name and select **Profiles**.
3. Click "Edit Profile" under Member Profile.
4. Scroll to the **Preferred Email Address** field and update it to match your OneAegis email address (this should be your Einstein or Montefiore email address).
5. Click **Save Changes.**
6. Once the preferred email address matches, OneAegis will automatically update your training record after the next daily CITI sync.

Keep in mind that your OneAegis email address will be the email address that you use for Single Sign On (SSO) when you are logging in.

# SECTION IV: RESPONDING TO A REQUEST FOR REVISIONS

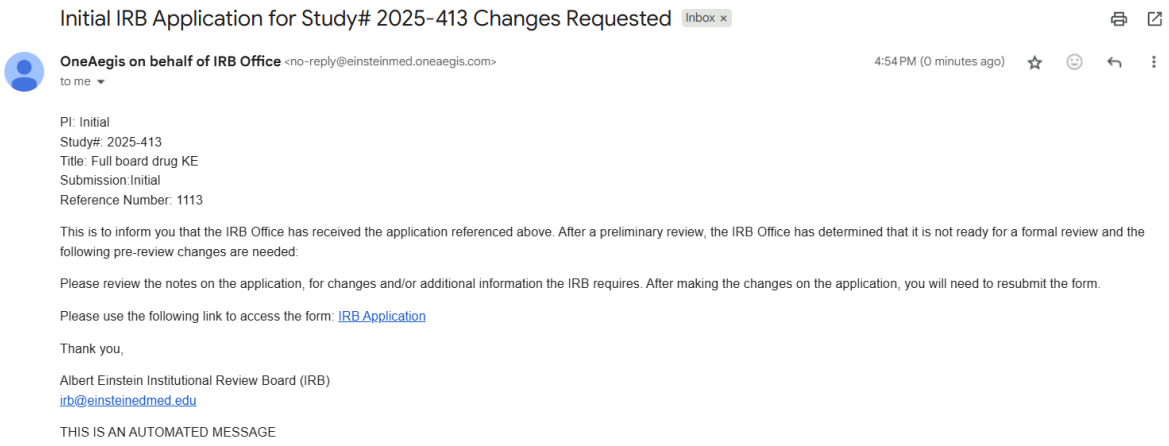
**Note on Terminology:** In OneAegis, what was previously referred to as *"stipulations"* in IRIS is now called **Request for Revisions**. Throughout this training guide, the term **Request for Revisions** will be used to align with OneAegis terminology.

## *A. Notification that Revisions are Required*

When your submission is returned with Request for Revisions or requested changes, the form creator and PI will receive an **automated email notification** from OneAegis.

### Request for Revisions Email Notification

- The email subject line will state that *changes are requested* (see example below).
- Click the **IRB Application** link in the email to return directly to your submission. *(screenshot of example email below)*



Initial IRB Application for Study# 2025-413 Changes Requested Inbox ×

**OneAegis on behalf of IRB Office** <no-reply@einsteinmed.oneaegis.com> 4:54 PM (0 minutes ago)
to me

PI: Initial
Study#: 2025-413
Title: Full board drug KE
Submission:Initial
Reference Number: 1113

This is to inform you that the IRB Office has received the application referenced above. After a preliminary review, the IRB Office has determined that it is not ready for a formal review and the following pre-review changes are needed:

Please review the notes on the application, for changes and/or additional information the IRB requires. After making the changes on the application, you will need to resubmit the form.

Please use the following link to access the form: IRB Application

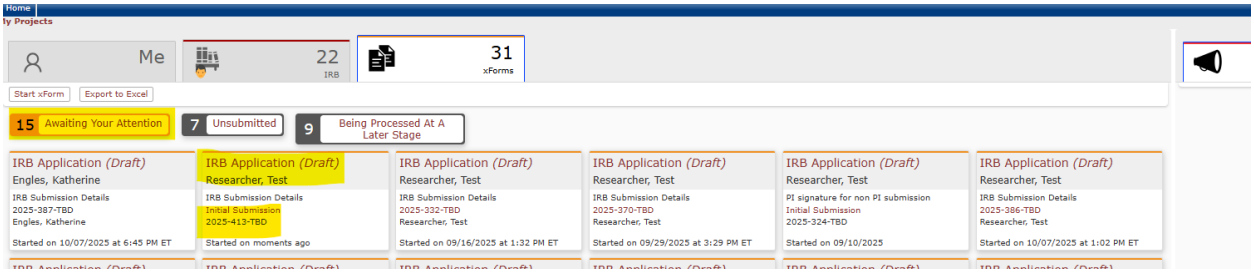
Thank you,

Albert Einstein Institutional Review Board (IRB)
irb@einsteinedmed.edu

THIS IS AN AUTOMATED MESSAGE

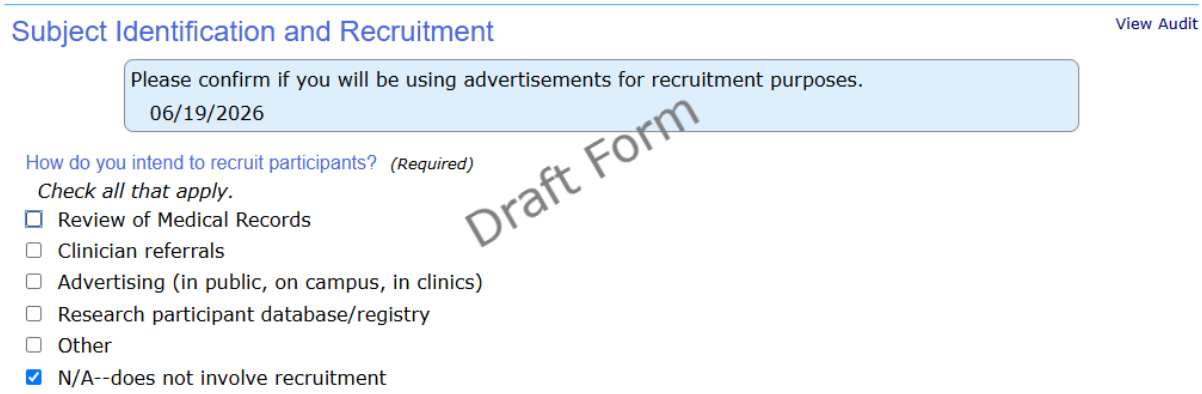
### Accessing the Requested Revisions via the Dashboard

- You can also locate the submission from your **Dashboard**.
- Go to the **xForms** tab and click the **"Awaiting Your Attention"** filter.
- The returned study will appear here, labeled with the study number (e.g., *2025-413*).

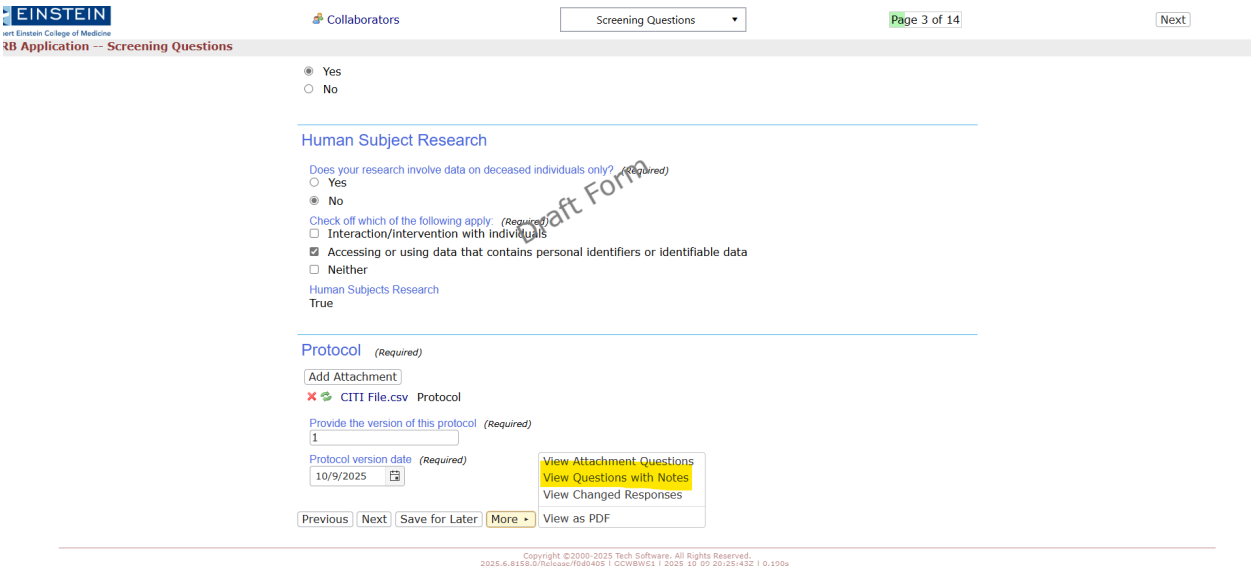



## *B. Locating the Request for Revisions in the Application Form*

- Open the IRB Application from the email notification or your dashboard.
- The first page that appears is a **summary of the first stage of the application** (institutional section).
- Click **Next** to move into **the second stage**, where you can view the **Requests for Revisions** entered by the IRB analyst. As you move through the application, **Request for Revisions will appear in blue boxes** attached to the relevant question(s).




- At any time, you can view all Requests for Revisions by scrolling to the bottom of the form, clicking **More**, then selecting **"View Questions with Notes."**




## *C. Making the Required Changes*

Review the blue note boxes throughout your application that contain Request for Revisions from the IRB analyst.

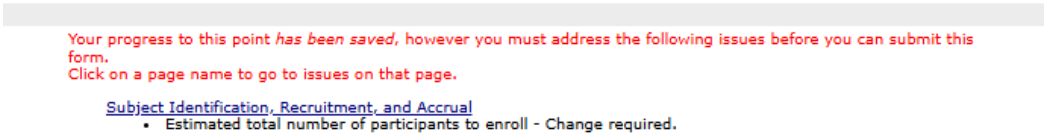
- Edit your responses directly in the application where the note appears.
- Changes are **not saved** until you click **Next** at the bottom of the page after making your edits.
- Continue clicking **Next** to ensure all pages have been reviewed and required changes are completed. No changes to a form page will be saved unless you click next on that page (or if you click save for later from that page).
- When finished, proceed to the final page, **Sign**, and click **Submit** to resubmit your application to the IRB Office for further review.

### i. If a Requested Revision Is Not Addressed

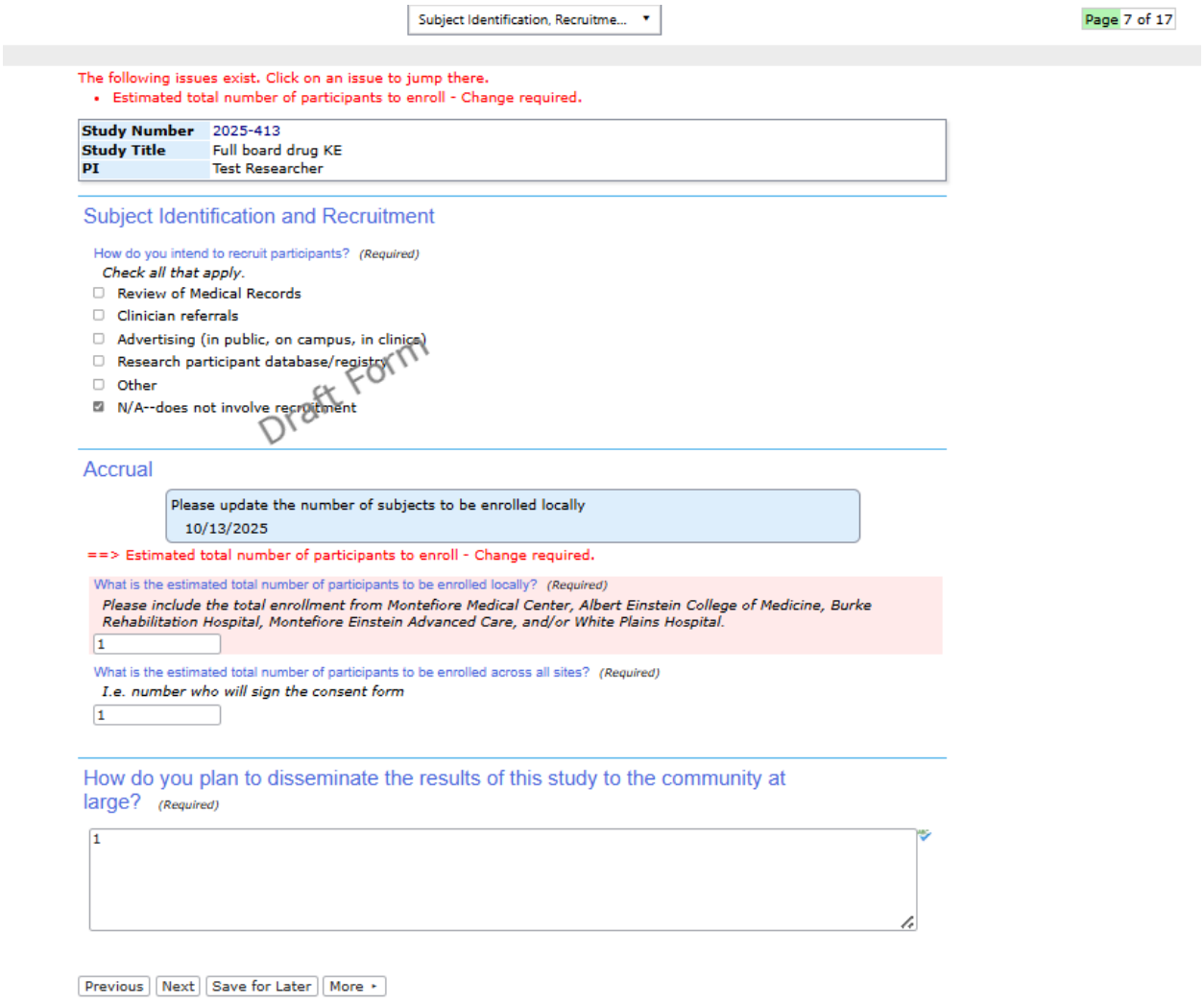
If any requested revisions have not been addressed, you will not be able to resubmit the form.

- You will see a **red error message** indicating which question still requires updates.

- Click the blue **page name link** in the error message to return directly to the page that needs correction.




Clicking the link in the error will lead you back to the page and question that you have to edit as shown below.

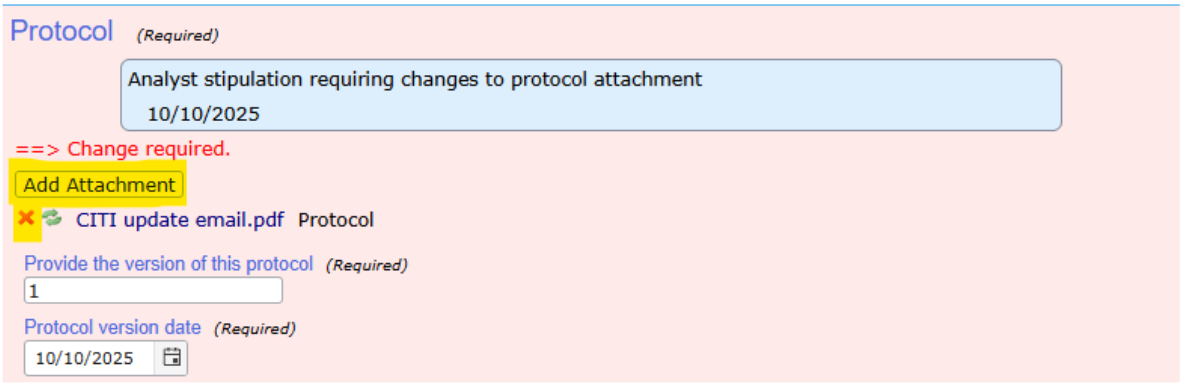


## ii. Attachment Revisions

Occasionally, the IRB analyst may request changes to a document you have uploaded as an attachment. These requests will appear as blue stipulation notes in the relevant section of your application (e.g., *Protocol*, *Consent Form*, *Recruitment Materials*).

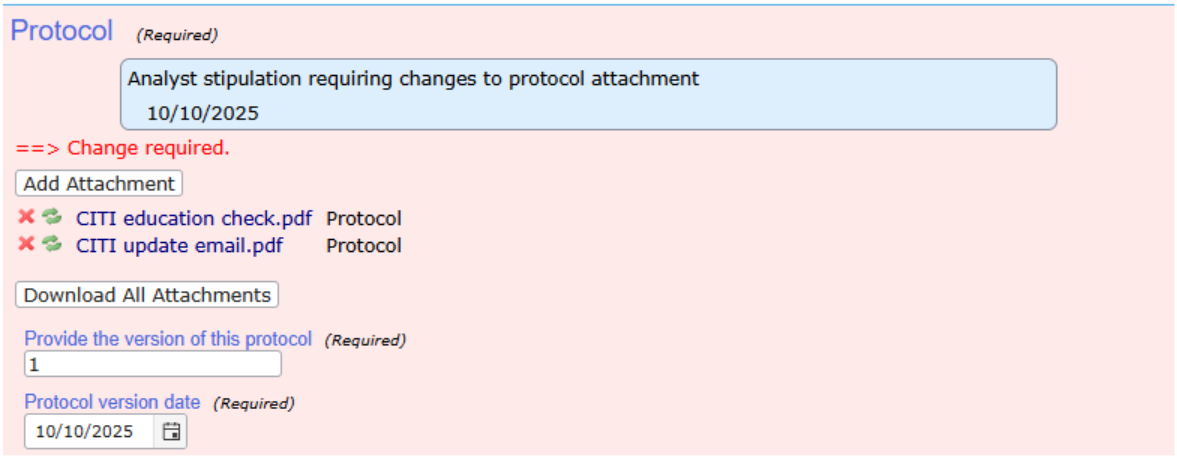
**If you are asked to modify an existing attachment:**

- Click the **icon of the 2 green arrows next to the current file name to** replace the existing document.
- Then click **Add Attachment** to upload the revised document.



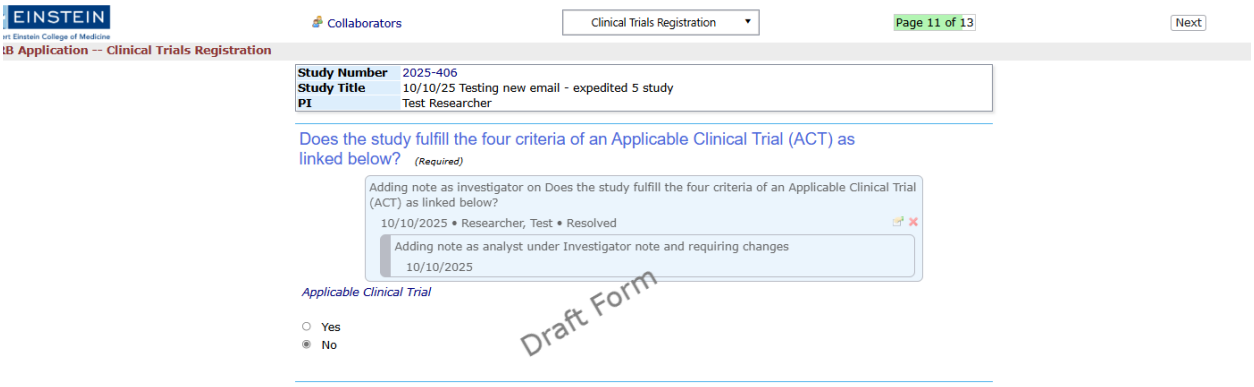

**If you are asked to add an additional attachment:**

- Click **Add Attachment** and upload the new file requested by the IRB.



### iii. Understanding Resolved vs. Active Notes

- When you move through your form after multiple rounds of Request for Revisions, you may see some **grayed-out blue notes**.
    - These indicate that IRB staff have marked the note as **resolved**, and **no further action** is required for that item.
- Any **blue notes that are not grayed out** remain **active** and must still be addressed before resubmitting your form.




## *D. Tips for Responding to Request for Revisions*

- **Save frequently:** Always click **Next** or **Save for Later** to ensure your edits are recorded.
- **Use clear file names:** When uploading revised attachments, label them clearly (e.g., Protocol_v2_10.2025.pdf) so IRB staff can easily identify updated versions.
- **Check for remaining notes:** Before submitting, scan for any remaining blue note boxes. Only *gray* notes are resolved.
- **View all Request for Revisions at once:** Use **More → View Questions with Notes** to generate a single PDF summary of all IRB comments.
- **Reopen from Dashboard:** If you close your form before resubmitting, you can always return to it under **xForms → Awaiting Your Attention.**
- **Watch for confirmation:** A "Form Submitted" message means your response has successfully been sent back to the IRB.

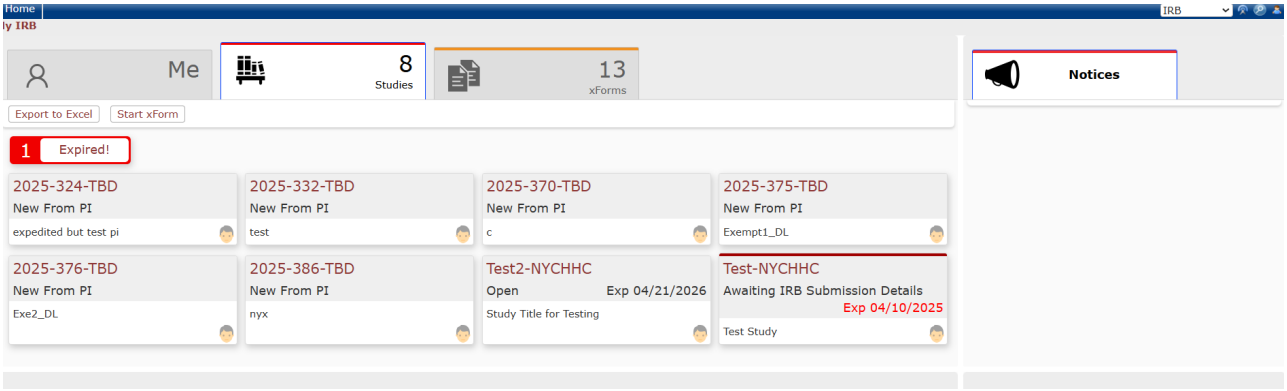
# SECTION V: POST-APPROVAL SUBMISSION FORMS

This section covers the submission of post-approval forms, such as amendments, continuing reviews, and reportable events.

## *A. Starting a Post-Approval Submission Form*

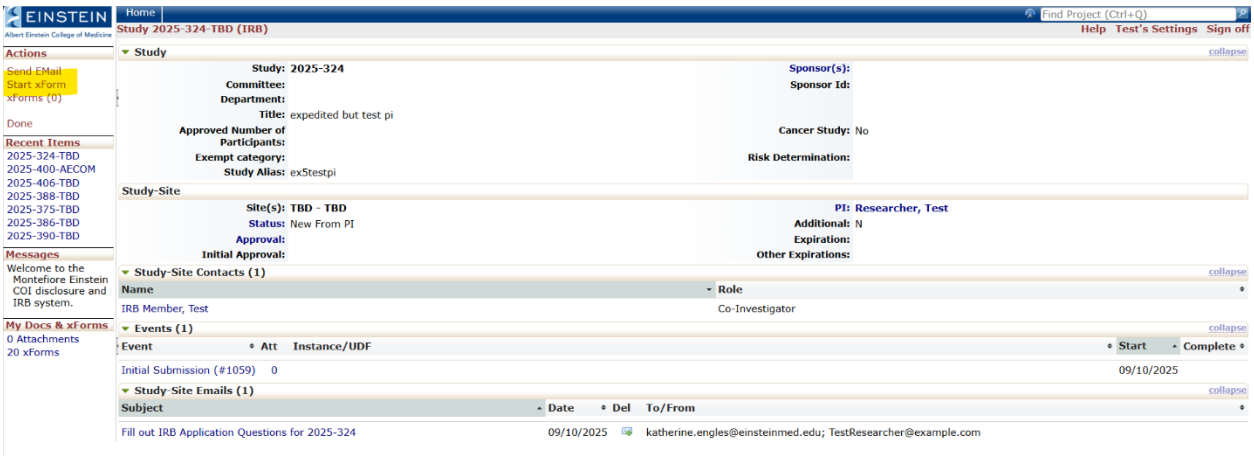
To submit a post-approval submission form, you will first need to open the study from your Dashboard.

**From your Dashboard**, click the **Studies** tab. This tab displays all *active studies* — meaning studies that are currently open and not yet closed or terminated.

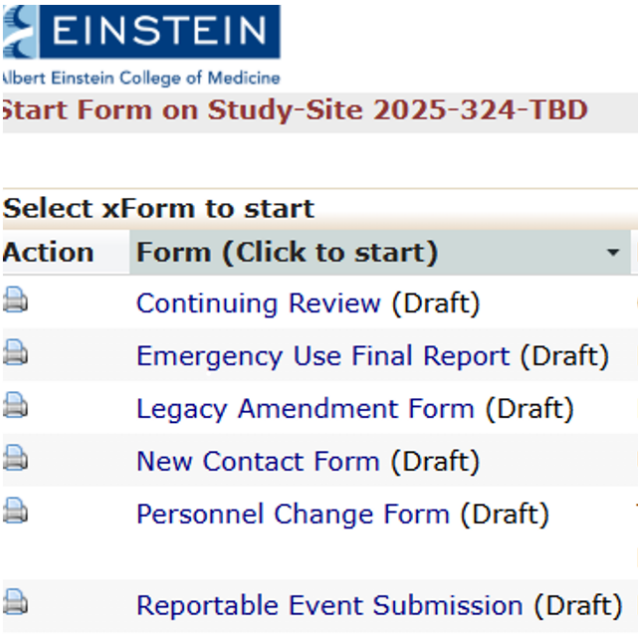



**Click the study title** for the project in which you wish to create a new submission. This will open the study's homepage (also called the **Study Landing Page**).

On the Study Landing Page left-hand sidebar under **Actions**, click **Start xForm**.



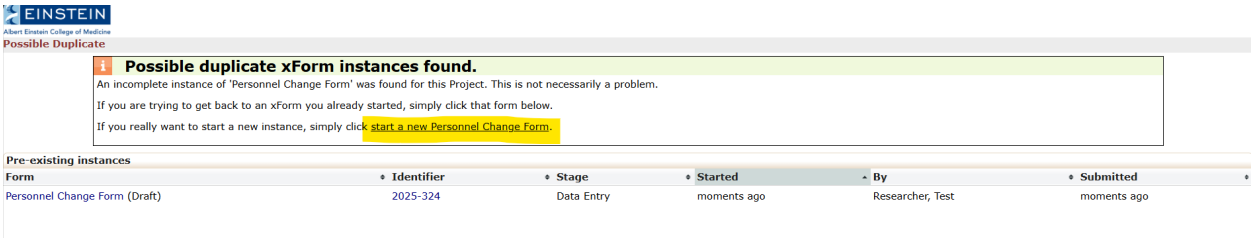
A list of available form types will appear. Click the hyperlinked **post-approval submission form** you wish to complete.




If other forms of the same type are already in progress under this study, a pop-up window will appear. You can choose to either:

- Click one of the **Pre-existing Instances** to continue a saved draft, **or**
- Click **Start a New [form name]** (e.g., *Start a New Personnel Change Form*, as highlighted below) to begin a new form.

Each **Pre-existing Instance** is listed with a **Started** date and a **By** column showing who began that form. Use these details to identify the correct draft if multiple versions exist.




Complete the form, clicking **Next** at the bottom of each page to move forward. When you reach the **Form Completed** page, click **Submit** to finalize your submission.

## *B. Amendment Form Overview*

The amendment submission process has changed in the OneAegis system. In OneAegis, there are several modification forms for different purposes:

- **Legacy Amendment Form:** The Legacy Amendment form is used to modify studies initially created in iRIS. This form can only be used for studies transferred from iRIS.

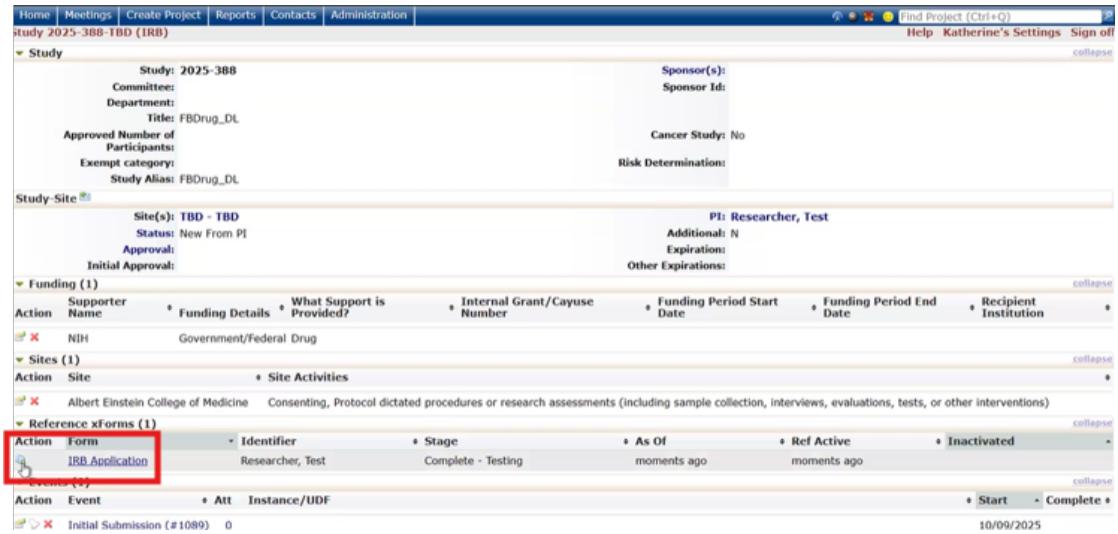
- **Personnel Change Form:** The Personnel Change form should be used to make add or remove non-investigator study staff. This form can be used for all studies in OneAegis, regardless of whether they are transferred studies or new studies created in OneAegis. Changes to the PI or co-investigators should use the main Copy-for-Amend Amendment process.

- **Amendment Form (Copy for Amend):** The regular amendment process is used to modify studies that were initially approved in OneAegis. This form can only be used for studies that were initially approved in OneAegis.

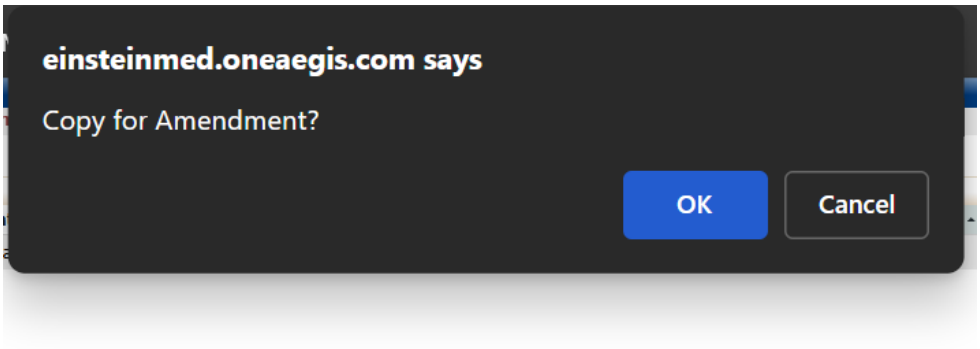
    - The **"Copy for Amend"** function generates an editable version of your existing approved application so that you can make the necessary revisions while preserving the prior version for recordkeeping.

### i. The Amendment Form (Copy for Amend) Process

1. Navigate to your **Study Landing Page** by clicking an IRB number link from the "IRB" tab on your dashboard.
2. Locate the **IRB Application** under the **Reference xForms** section.
3. Click the two-page icon with the plus sign ( ) to initiate the Copy for Amend Process.

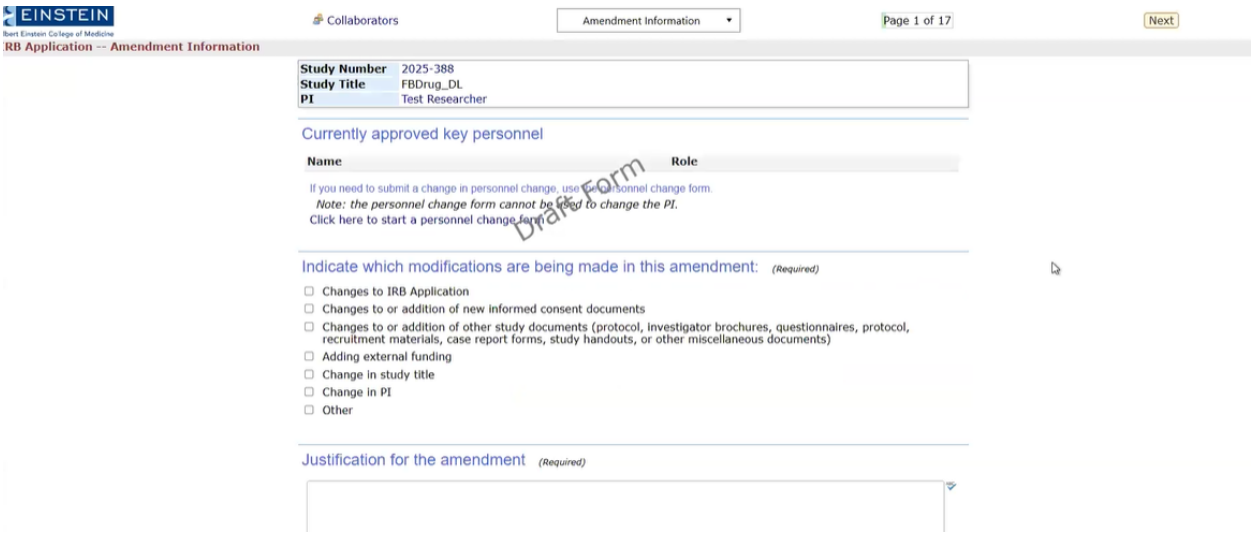



Click “OK” when a pop-up message asks if you would like to “Copy for Amendment?”




This action activates the **Copy for Amend** function for the initial application form. Your original application will open in editable mode, allowing you to make the necessary revisions as part of your amendment submission.

After initiating the Copy for Amend process, your original initial submission xForm will be opened. You can scroll to review. Click “Next” to proceed to the Amendment Information section.




Once you complete the form click “Next” and **Submit**.

# SECTION VI: UNDERSTANDING THE STUDY LANDING PAGE

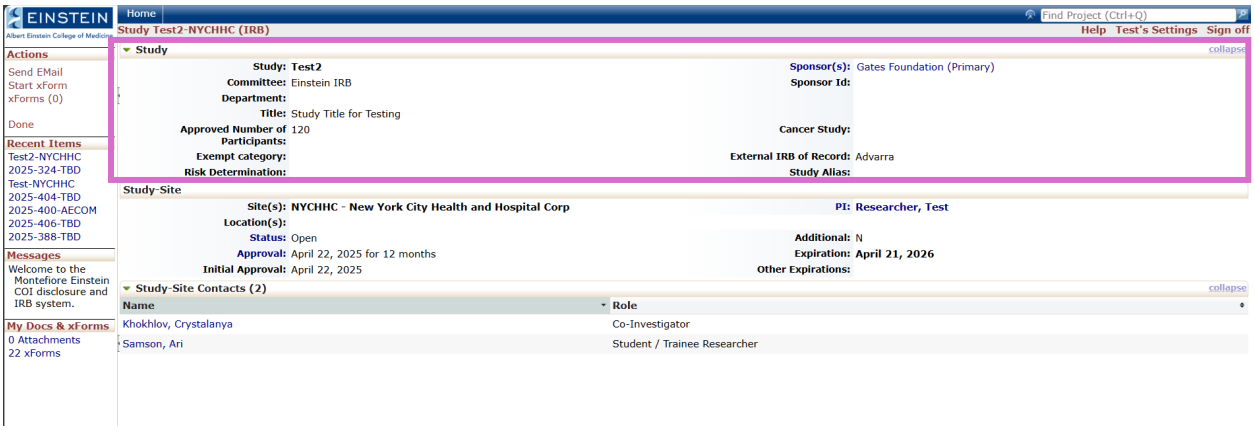
There are two key *Landing Page* views in OneAegis that are important to understand:

1. **Study Landing Page View**
    - This is the homepage for an IRB study.
    - It contains all forms, events, and an overview of the study record.
2. **Event Details Landing Page View**
    - This is the homepage for each individual *event* within a study.
    - Each submission (for example, an Initial Application, Continuing Review, or Amendment) is considered an *event* within the overall study.

## *A. Study Landing Page*

From your Dashboard, click the study title for the project to view the **Study Landing Page**.

### i. Study Section



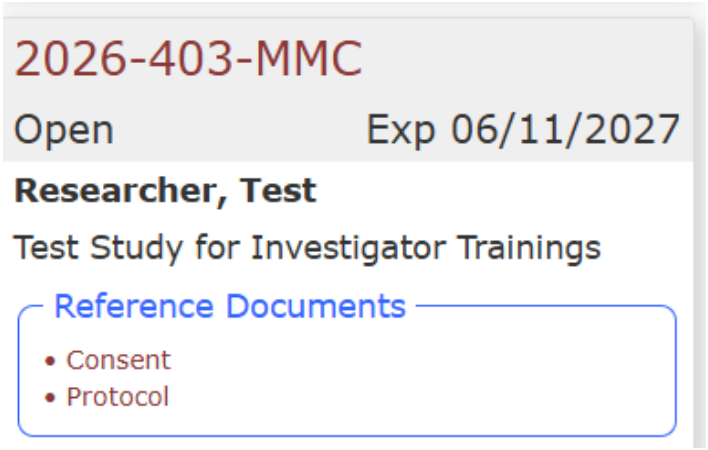

This section provides basic information about the protocol, such as:

- **Study:** IRB number
- **Sponsor(s):** Funding Organization (if applicable)
- **Review Type:** Full board, expedited, exempt, etc
- **Risk Determination:** Minimal Risk or Greater than Minimal Risk

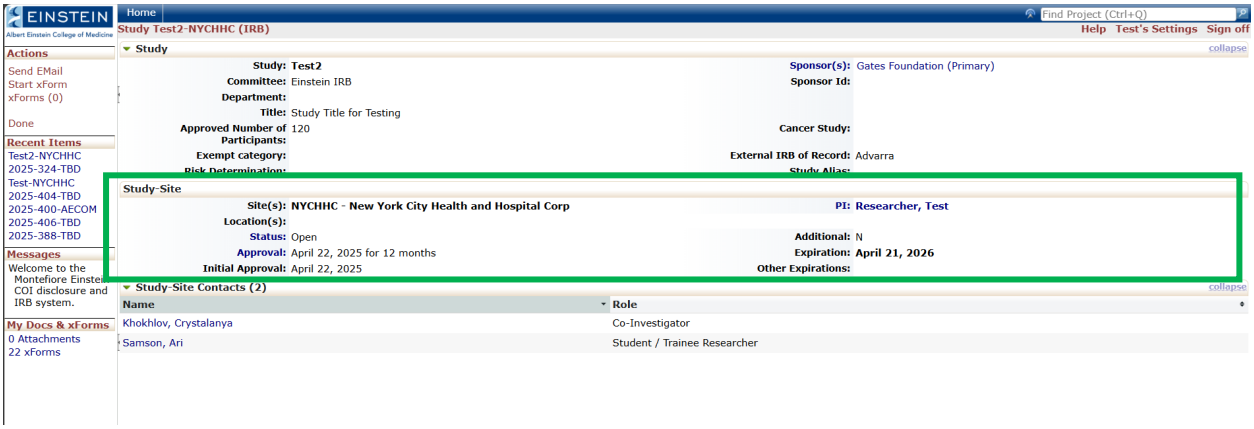
## ii. Reference Documents

This section lists the currently approved versions of the protocol and consent documents.


The reference documents are also accessible from the study card located on your Dashboard.




## iii. Study Site

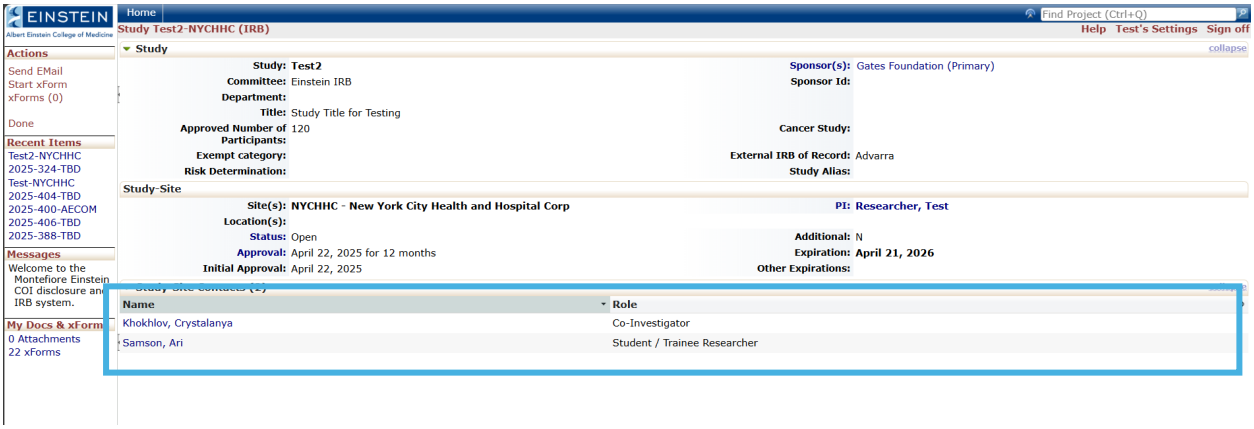



This section includes information about the study site and its status, such as:

- **Site(s):** The location of the study.
- **Status:** Active, Closed, New from PI, Withdrawn
- **Approval:** Current approval date
- **Initial Approval:** Initial approval date

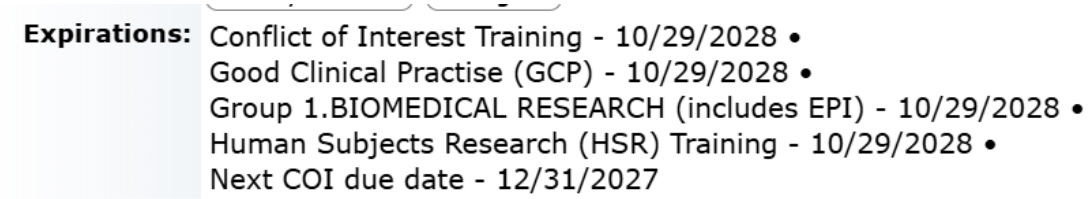
- **PI:** Name of Principal Investigator
- **Expiration:** Date IRB approval expires (if applicable)
- **Other Expirations:** Date institutional approval expires (if applicable)

## iv. Contacts

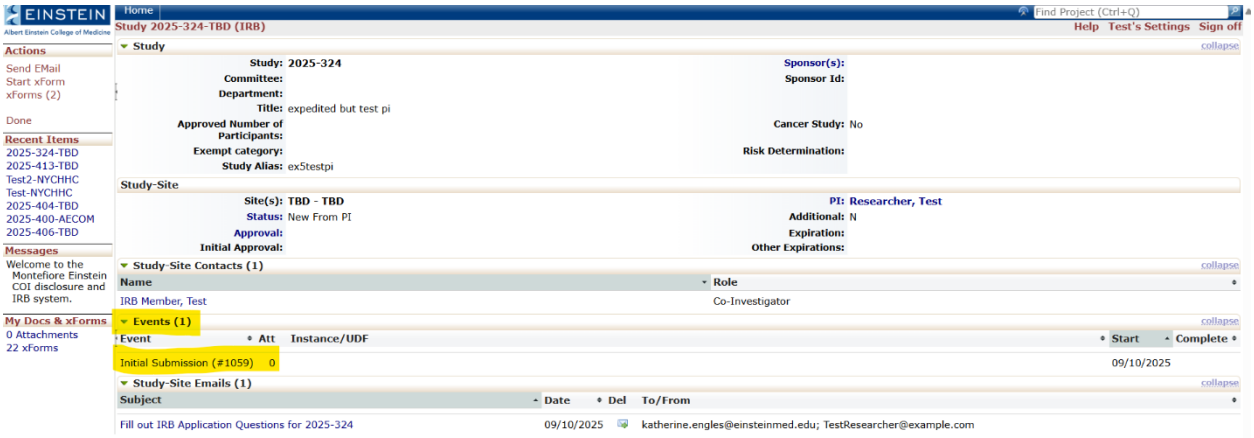



This section lists all contacts associated with the study.

- All approved study personnel and collaborators are listed here.
- Investigators and staff will only be able to view the study in OneAegis **if they are listed as a contact**.
- You can review CITI training records and COI expiration dates for everyone on the project by clicking the **name** of the individual whose training record you wish to view.
    - A pop-up box will appear. The person's **CITI training status and expiration date** will be listed in the **"Expirations"** section of the pop-up.



### v. Events

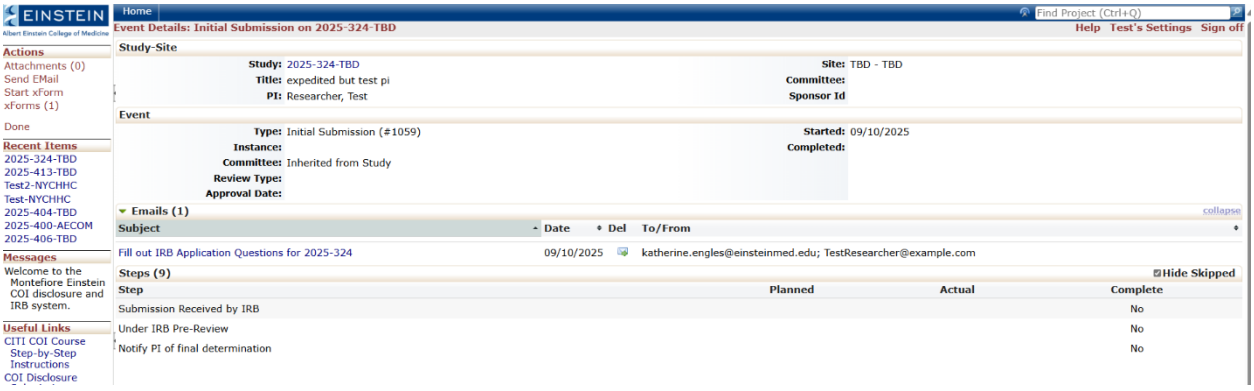



OneAegis uses the term **"Event"** to refer to a specific submission. This section displays all IRB **events** (submissions) that have been completed or are in progress for the protocol.

- Each blue hyperlink in this section represents a specific event.
- Clicking on the blue link will open the **Event Details Landing Page**, which contains detailed information about that specific submission.

## *B. Event Details Landing Page*

The Event Details Landing Page provides detailed information about the submission currently being viewed.



- **Emails**: Displays all automated emails sent by the system to the research team for that event.
- **Steps:** Shows the submission workflow steps and corresponding dates, including:
    - Planned dates
    - Actual completion dates
    - When the event is scheduled for Full Board review or notification

## i. Actions Sidebar on Event Details Landing Page

The sidebar on the right-hand side of the Event Details page contains key links and tools:

- **Attachments**: Lists all attachments related to the event (e.g., consent forms, questionnaires, scripts, etc., depending on the submission type).
    - **Generated Docs:** Once "Attachments" has been selected, this link provides access to IRB approval documents associated with the study.

**xForms**: Provides access to the form used to submit the event.