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# CUNY IRBMANAGER MANUAL

Researcher's Guide to IRBManager

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Originated by Keisha Peterson, Director, Office of Research Compliance & Outreach at Baruch College

# 1. Logging into IRBManager (New/Existing Users)

- i. Go to: <https://cuny.my.irbmanager.com> and click on the **BLUE** “click here” link.



- ii. Enter your CUNYfirst username/password



## CUNY Login

Log in with your [CUNY Login credentials](#)

If you do not have a CUNYfirst account, see the [FAQs](#).

### PROTECT YOUR PERSONAL INFORMATION AND PRIVACY

ONLY enter your CUNY Login password on CUNY Login websites (ssologin.cuny.edu and login.cuny.edu). NEVER share it with others or enter your CUNY Login password elsewhere without the approval of your campus IT department. More information on CUNY's policies regarding user accounts and credentials can be found in the [Acceptable Use of Computer Resources Policy](#).

Note: Please do not bookmark this page.

- iii. Once logged in you should be on your Dashboard (home page) (see section 4).
- iv. Profiles for New Users will be automatically created once they've logged into IRBManager with their CUNYfirst credentials.
- v. Contact your [HRPP Coordinator](#) if you have questions.

## 2. Linking CITI Certifications to IRBManager

When linked properly, CITI certification expiration dates will appear in IRBManager. See [Ensuring CITI Training is Up-to-Date](#) for information on viewing expiration dates.

**\*\*\*All study personnel are required by [CUNY policy](#) to have unexpired CITI training in the protection of human subjects before a submission can be approved\*\*\***

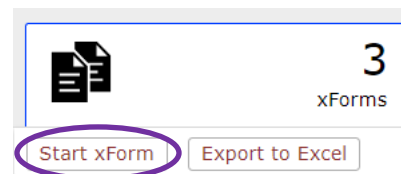
### Step 1: Adding CUNY college email to CITI User Profile

- i. Log into the [CITIProgram](#) website ([www.citiprogram.org](http://www.citiprogram.org))
- ii. In the upper right-hand corner, under your name and ID, click on the down arrow
- iii. On the drop-down menu, select “Profiles”
- iv. Under “Member Profiles”, click “Edit Profile”
- v. In the “Profiles” page, scroll down until you see “Your preferred email address.”
- vi. CUNY Researchers are required by [CUNY policy](#) to use their CUNY email addresses when registering for online services for CUNY research-related purposes.
- vii. Confirm that “Your preferred email address” is your current CUNY college email address, or revise if needed (do NOT use your CUNYfirst credentials ending in @login.cuny.edu)
- viii. Do not forget to confirm or revise your CUNY email address in the “Please verify your preferred email address” section as well
- ix. If you prefer, your personal email address can be entered as Your Secondary Email Address
- x. Click on the **BLUE** “Update” button at the bottom of the page

### Step 2: Adding CUNY college email address to IRBManager Profile

Once you’ve completed Step 1, please follow these instructions:

- xi. Log into [IRBManager](#) using your CUNYfirst credentials
- xii. Under the Dashboard tabs in the upper right, click on “Start xForm”
- xiii. Click on the “Update My Email Address” Form



Action	Form (Click to start)	Description
	Protocol Form	Use this form for your initial IRB submission. You will copy this form for any amendment.
	Update My Email Address	Use this form to update/change where you receive emails.

- xiv. Type your CUNY college email address under “New Email Address”, then click “Submit”  
**Use the same CUNY email address previously added as your “Preferred Email Address” in the CITIProgram website (see Step 1 above).**

### Step 3: Confirming CITI Expiration Linkage

- xv. Log into the [IRBManager](#), where you will see your Dashboard screen. Click on the “Settings” icon (appears as the person icon at the top-right corner of the screen)
- xvi. In the “Settings” page, click on the “My Expirations” tab
- xvii. Your CITI HSR expiration date should appear under the “Expirations” page **within 1-2 business days.**
- xviii. Contact your [HRPP Coordinator](#) if you do not see your CITI HSR expiration information in the “Expirations” page

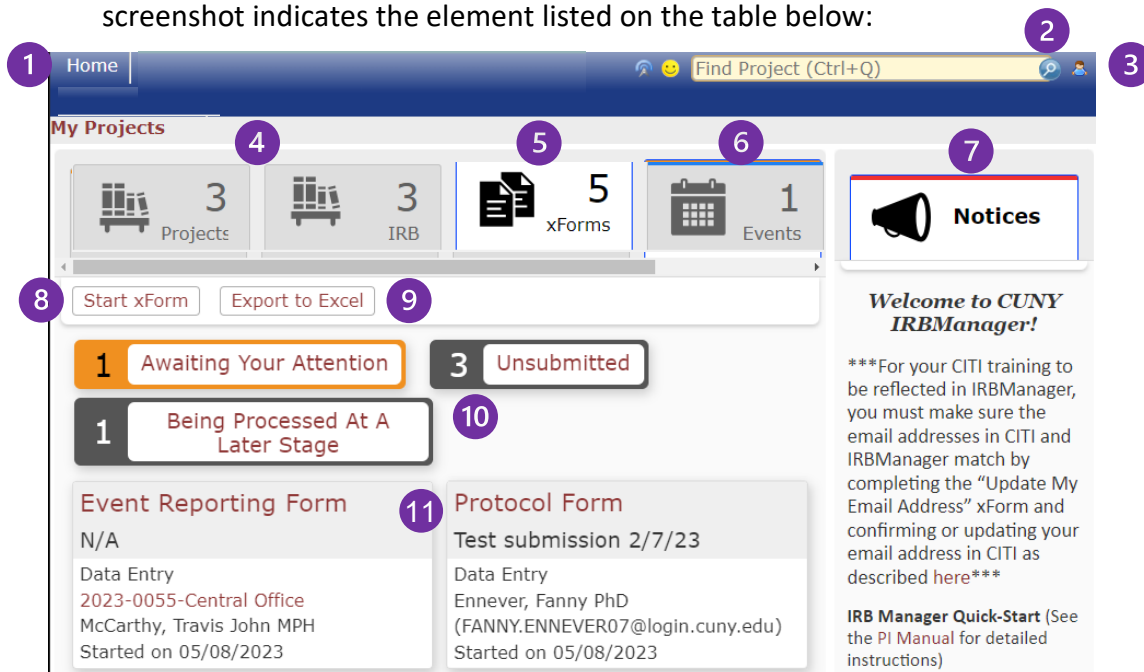


### 3. IRBManager Selected Terms




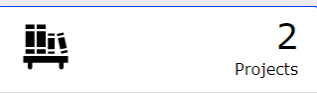


- i. **Project, protocol, study:** These terms all refer to a research project
- ii. **xForm:** xForms are the method for communicating between you and the IRB.
  - **Protocol xForm:** used for *initial submissions* prior to IRB approval (see section [6](#)), and for *amendments* to approved studies (see section [9](#)).
  - **Update My Email Address xForm:** used to enter your college email so your CITI training shows up in IRB Manager (see section [2](#)).
  - **Annual Check-In, Continuing Review, Event Reporting, and Final Report xForms:** these xForms are associated with an approved study and are started from the study page, not the dashboard (see section [10](#)).
  - **Stage:** the progress of an xForm.
    - **Data Entry:** Able to be edited by the study team – an xForm starts in Data Entry, and may be returned to Data Entry if revisions are requested by the IRB, the PI, or the Faculty Advisor.
    - **PI Signature / Faculty Advisor Signature:** Awaiting action by the PI or Faculty Advisor to review and either request revisions or submit (see section [5 viii](#)).
    - **Other:** various stages of review by the IRB
- iii. **Step:** the progress of IRB review for an event. Typical steps are:
  - Receive Submission
  - HRPP Administrative Pre-review
  - Request Modifications
  - Receive Modifications
  - Receive Member Review
  - Notify Researcher of Outcome
- iv. **Event:** A submission to the IRB: Initial Submission, Amendment, Continuing Review, Event Reporting, or Final Report.
- v. **Dashboard:** The home page on IRBManager, providing a listing of all of the projects, forms, and events you are associated with (see section [4](#))
- vi. **Card:** The box with information about a project, form, or event that appears on the Dashboard
- vii. **Project page:** The home page for an individual approved project, allowing you to see information and to initiate an amendment, annual check-in, continuing review, event report, or final report form for the project
- viii. **Event page:** A subpage of a project page, allowing you to see detailed information about an event, such as associated xForms, attachments, review steps, etc.

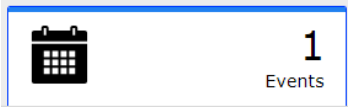
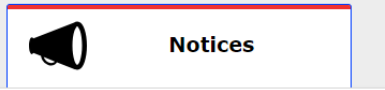

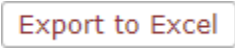
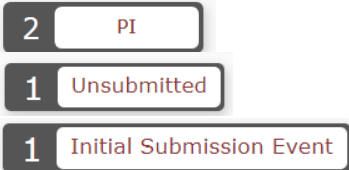
## 4. IRBManager Dashboard (Home Page)

- i. The Dashboard appears when you log into IRBManager. The dashboard is the hub of IRBManager. Projects, xForms, and Events that you are associated with can be located here. The number on the following screenshot indicates the element listed on the table below:



### ii. Elements of the Dashboard

	<p>1. Home: Returns user to Dashboard</p>
	<p>2. Search: Allows users to search for projects they are associated with, based upon the protocol number, principal investigator, and/or collaborators</p>
	<p>3. Profile: Menu icon that allows users to personalize their IRBManager settings</p>
	<p>4. Projects and IRB tabs: These tabs give the same view; both allow the user to see cards of all active research protocols they are currently involved with</p>
	
	<p>5. xForms tab: Allows the user to view cards for their current and past xForms</p>

	<p>6. Events tab: Displays cards for the events (submissions) that the user has open (i.e., ones that have not been approved or otherwise finalized)</p>
	<p>7. Notices: Updates and notices from CUNY's Research Compliance Office, when available, are posted here</p>
	<p>8. Start xForm: Allows the user to start an initial xForm or update their email address.</p>
	<p>9. Export to Excel: Downloads an Excel document with information on all xForms, including when they were started and their current stage.</p>
	<p>10. Filter: Allows you to see a subset of cards; different filters appear for projects, forms, and events</p>
<p>Project Card: 2023-0407-Central Office New From PI Ennever, Fanny PhD</p> <p>Form Card: Protocol Form Test submission 2/7/23 Data Entry</p> <p>Event Card: Initial Submission Event 2023-0407-Central Office 07/10/2023</p>	<p>11. Card: A box with information about the project, form, or event. The card has a clickable link in <b>dark red</b> font – the protocol number for projects, the form name for forms, and the event name for events</p>

### iii. Areas of the Dashboard

#### Projects or IRB tab – Active Projects



- The active studies you are associated with, as PI, Faculty Advisor, Co- PI, or Research Staff.
- You may use the filter buttons in this section to see only the studies where you have the specified role.



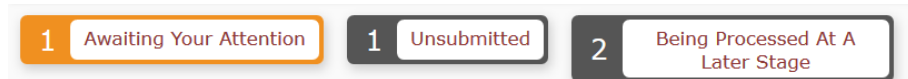
- If you have studies with an upcoming expiration date, the Expiring Soon! Filter will appear.



#### xForms tab – Active xForms



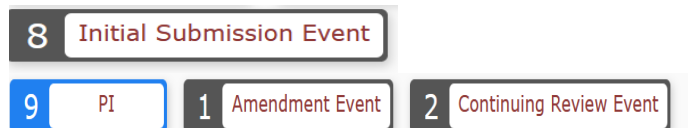
- Your xForms currently in process – Protocol Forms (both initial submissions and amendments) that have not yet been approved, and active Annual Check-In, Event Reporting, Continuing Review, and Final Report Forms for studies you are associated with.
- You may use the filter buttons in this section to see only the xForms that require action (review or signature), are not yet submitted, or are under review by the IRB (being processed at a later stage).



#### Events tab – Open Events



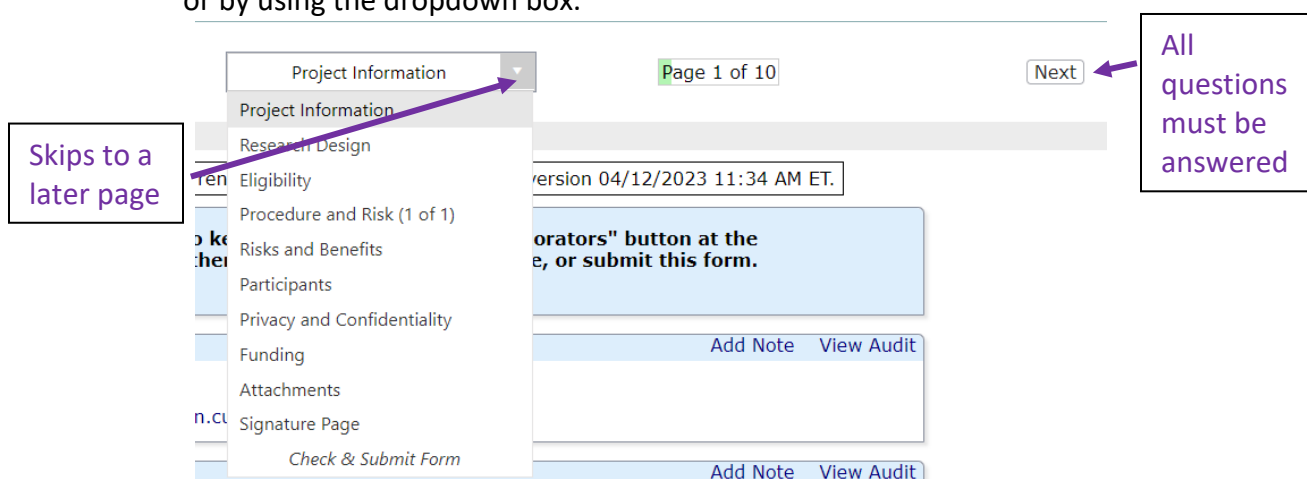
- The number of events in progress (not yet completed)
- You may use the filter buttons in this section to see the events by your role or by the type of event: Initial Submission, Amendment, Continuing Review, or Event Report





## 5. General Reminders for xForms

- i. Please read all questions carefully and answer completely.
- ii. Contact your [HRPP Coordinator](#) if you have questions.
- iii. Useful links:
  - [CITI Certificate Help](#)
  - [CUNY Human Research Protection Program \(HRPP\)](#)
  - [CUNY HRPP Policies and Procedures](#)
  - [CUNY Criteria for IRB Approval](#)
  - [Using IRB Manager at CUNY](#)
- iv. Every xForm has several pages of questions (the exact number of pages depends on which xForm it is and what is involved in the study). Your progress is shown at the top of the page (below, “Page 1 of 10”). You can open later pages either by answering all required questions and clicking the Next button, or by using the dropdown box.



- v. To add a person (e.g., in the PI, Faculty Advisor, or Key Personnel question), type at least two letters of the person’s name and select from the dropdown. If you cannot find a person’s name, have them log into IRBManager with their CUNYfirst credentials. This will add their name to the system. If a person’s name is very short, try typing their email address to see more than the first 20 matches.

The screenshot shows a form field labeled 'Faculty Advisor (Required)'. Below the label is a search input field with the placeholder text 'Type Name Here'. The input field contains the text 'tate, t'. A dropdown menu is open below the input field, showing search results. The first result is highlighted in blue and reads: 'Tate, Twyla (twyla.tate@brooklyn.cuny.edu) twyla.tate47@login.cuny.edu'. Below the dropdown, there is a 'Contact\*' label.

- vi. To answer the “Campus” question, PI’s should indicate the college where they have their primary affiliation. Student PI’s should indicate the college where their faculty advisor has their primary affiliation.

The screenshot shows a form field labeled 'Campus (Required)'. Below the label is a dropdown menu. Below the dropdown, there are two lines of text: 'STUDENT PI: select the primary campus of your Faculty Advisor.' and 'Non-Student PI: select your own primary CUNY campus.'

- vii. **A submission cannot be approved unless ALL research personnel show unexpired up-to-date CITI training** (see section 2).
- viii. If the xForm is submitted by someone other than the PI or is submitted by a student PI, an email with a link to the xForm will be sent to the PI or the Faculty Advisor. The PI or Faculty Advisor must review the xForm, make Notes if appropriate (see section 15), determine whether the form is ready for submission, and proceed to the Signature page.
  - **Form is ready for submission:**

Is the information accurate and ready for submission? (Required) Add Note View Audit

Yes  
 No

By signing below I certify that the statements herein are true, complete and accurate to the best of my knowledge. (Required) Add Note View Audit

Sign...

- **Form requires changes:**

Is the information accurate and ready for submission? (Required) Add Note View Audit

Yes  
 No

Revision needed. (Required)

- ix. Signing and submitting are two separate consecutive steps.

- *Step 1: click on Sign... and enter your CUNYfirst credentials in the popup*

I certify that the statements herein are true, complete and accurate to the best of my knowledge. (Required) Add Note

I agree

**Signature** (Required)

Sign... Previous Next

**CUNY**

**Web Applications Login**

If you are logging into a University cloud service offering, such as Dropbox or Microsoft Office 365 for Education, you agree to abide by the terms in the [CUNY Acceptable Use of University Data in the Cloud policy](#).

Log in with your [CUNY Login credentials](#):

Username

Password

- *Step 2: Click on “Submit” on the first Form Complete page. You will then see a second page saying “Your form has been submitted. You may close this window.” If you do not click on Submit, your xForm will not proceed to the next step (IRB, PI, or Faculty Advisor review).*
  - *First Form Complete page*

**Form Complete**

**Form Completed**

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

- *Second Form Complete page (no action is required, this page appears to provide confirmation that the xForm was submitted)*

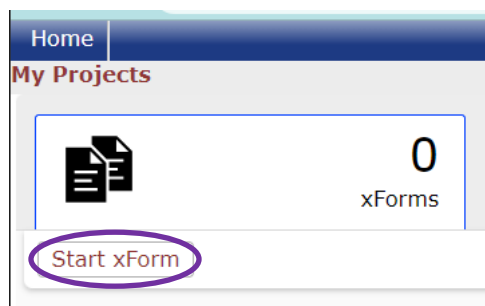
**Form Complete**

**Form Submitted**

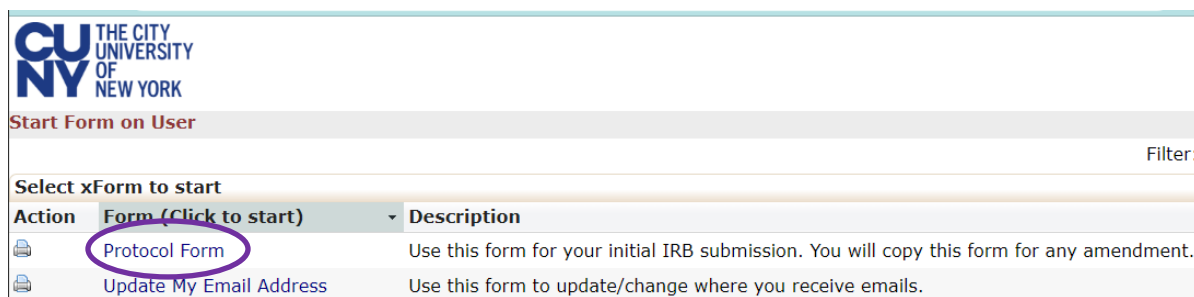
Your form has been submitted. You may close this window.

## 6. Creating Initial Submission xForms

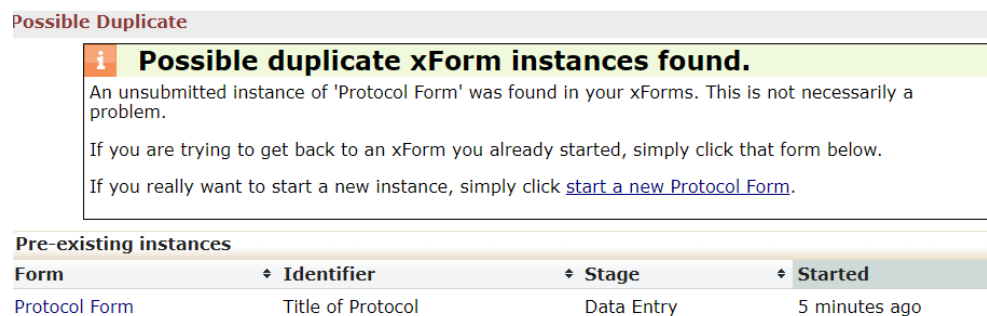
- i. On the Dashboard, click on the Start xForm button.



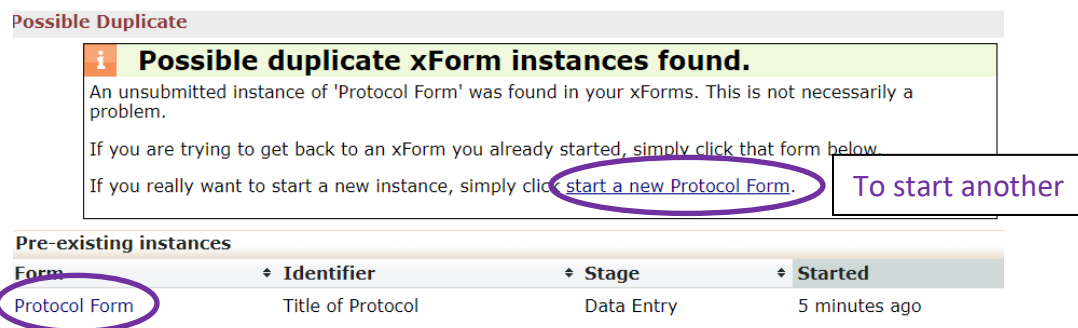
- ii. On the Start Form on User page, click on Protocol Form.



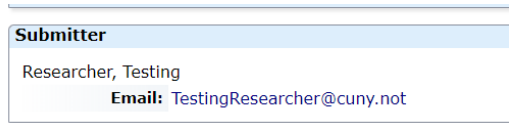
- iii. If you would like to print a copy of the full Protocol Form, click on the Print icon to the left on the form name. This will allow you to print the entire application.
- iv. If you have any other unsubmitted Protocol Forms, you will see the following screen:



- v. Either click on the existing "Protocol Form" to continue working on it, or click on "start a new Protocol Form" to begin a separate submission with a blank protocol form.

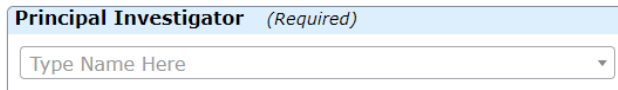


- vi. On the protocol form, your name will automatically appear as the “Submitter”



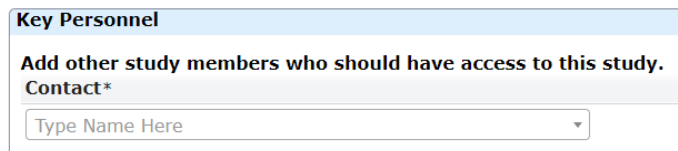
**Submitter**  
Researcher, Testing  
Email: [TestingResearcher@cuny.net](mailto:TestingResearcher@cuny.net)

- vii. In the “Principal Investigator” question on the first page, enter your own name if you are the PI, or the PI’s name if you are not.



**Principal Investigator** *(Required)*  
Type Name Here

- viii. If you are NOT the PI, make sure to add the PI as a Collaborator (see section 8) and enter **your own name** in the Key Personnel question

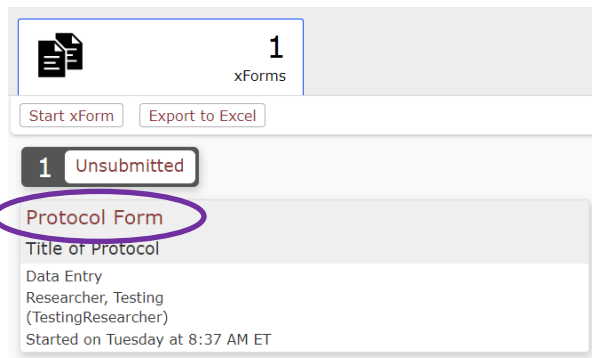


**Key Personnel**  
Add other study members who should have access to this study.  
Contact\*  
Type Name Here

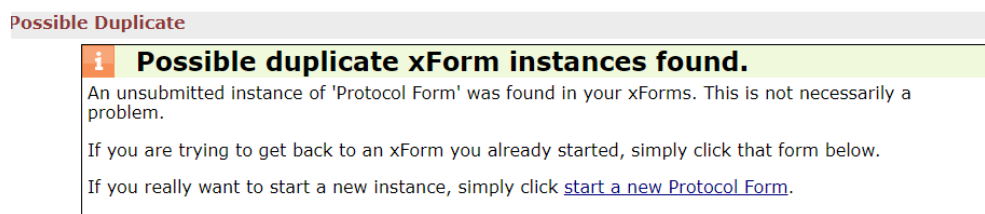
- ix. If you are not the PI, the PI will receive an email telling them to review and submit the application to the college HRPP office.
- x. See [xForm Reminders](#)

## 7. Continuing to Work on an Unsubmitted xForm

- i. On the dashboard, click on the name of the form (in red) in the card showing your unsubmitted form



- ii. If you instead clicked on Start xForm, click on the name of the form in the table of Pre-existing instances:

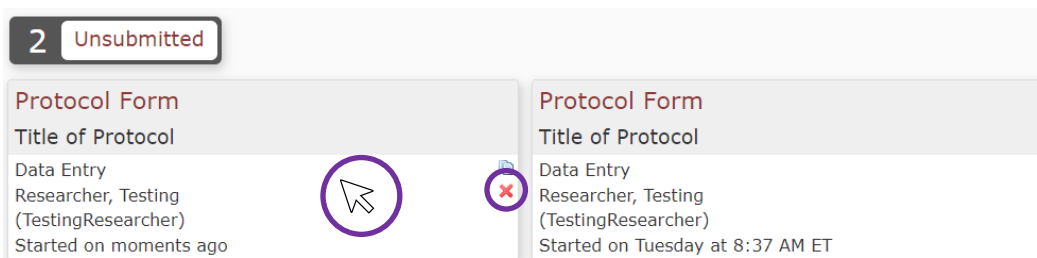


### Pre-existing instances

Form	Identifier	Stage	Started
Protocol Form	Title of Protocol	Data Entry	5 minutes ago

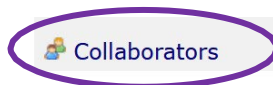
Continue working

- iii. If you instead mistakenly clicked on the copy icon within the card, which immediately creates a duplicate, delete the duplicate by positioning the cursor within the card and clicking on the red X that appears, then click on the form name in the original card to continue working on it.



## 8. Giving Research Team Members Access to xForms

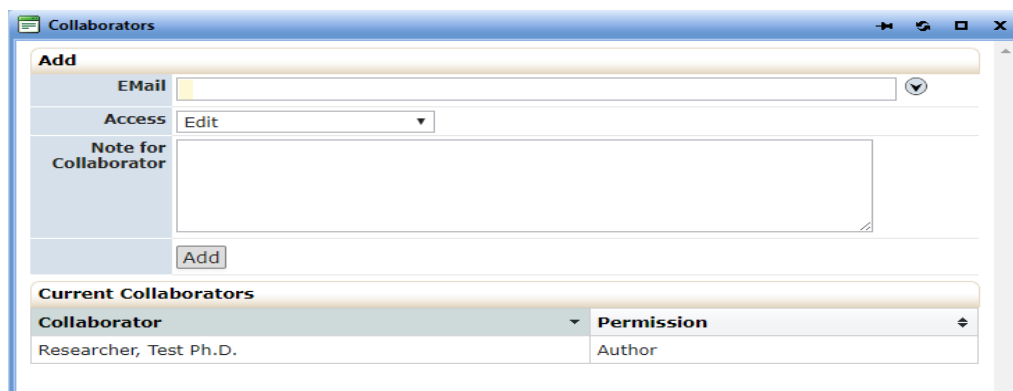
- i. The person originally creating an initial IRB xForm is initially the only individual who will have access to the xForm. To allow others access to the xForm prior to approval, these other users must be added via the “Collaborators” function located in the upper left of the xForm.



**View xForm - Protocol Form**

*Note that collaborators on a **study** (e.g., co-Investigators, Project Coordinators, Research Assistants, etc.) are added by responding to the study personnel questions in the application xForm; they will have access to the project after the study is approved. Adding a collaborator to your initial or amended Protocol Form does not give them access to the **xForm** itself.*

- ii. Upon clicking the “Collaborators” link, a pop-up window will appear.

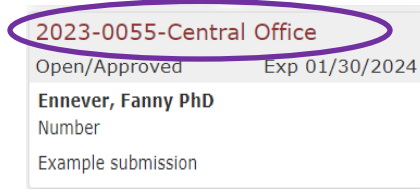


- iii. Type the first few letters of the name of the user you would like to grant access to the form and select their name and email address. The user must already have a Contact established within IRBManager to be added as a Collaborator.
- iv. Select the Access the collaborator will have:
  - “View only” will give the user view only access.
  - “Edit” will allow the user to make edits only.
  - “Edit and manage” will allow the user to make edits and add other collaborators.
  - “Edit, manage and submit” will allow the user to make edits, add other collaborators, and submit.
- v. Add a note for the collaborator (optional). Text entered in this box will be included in the email sent to the collaborator.
- vi. Click Add. This will automatically send an email to the collaborator with instructions to access the form.
- vii. If you would like to delete a collaborator you have added, simply click the red X that will appear next to their name after adding.

***Students should add their faculty advisors as collaborators to their submissions which will allow advisors to view, access, and edit submissions during data entry stage.***

## 9. Creating Amendments

- i. On the Dashboard click on the Projects Tab, then click on the protocol number of the project (in red) in the Protocol card.



- ii. Locate **Reference xForms** in the middle of the Project page.

**Project: 2023-0055**  
**Committee:**  
**Category:**  
**Department:**  
**Last Review:** Full Board  
**Agent Types:**  
**Title:** This is a test title for a test project.  
**Non-CUNY IRB of Record:**  
**Comments:** Testing draft form

**Funding Source(s):**  
**Funding ID:**  
**Grants:**  
**Next Review:** Full Board  
**CRO:**  
**Year:** 2023  
**Grant/Contract Number and Title:**  
**Expedited Determination:**  
**Exempt Determination:**  
**Ideate Link:**

**Project-Site**  
**Site(s):** Central Office - CUNY Central Office  
**Status:** Open/Approved  
**Approval:** January 31, 2023 for 12 months  
**Initial Approval:** January 31, 2023  
**Approved Enrollment Number:** 50  
**Risk Determination:**  
**Tags:** Amendment In Process

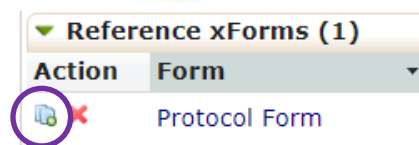
**PI:** McCarthy, Travis John MPH  
**Additional:** N  
**Expiration:** January 30, 2024  
**Other Expirations:**  
**HRPP Coordinator:** Travis McCarthy at 646-664-8906 or travis.mccarthy@uny.edu

Name	Role	Expirations
Ennever, Fanny PhD	Co-Investigator	CITI HSR Training - 02/21/2026
Test, Researcher	Co-Investigator	

Action	Form	Identifier	Stage	As Of	Ref Active	Inactivated
	Protocol Form	N/A	Complete	01/31/2023	01/31/2023	

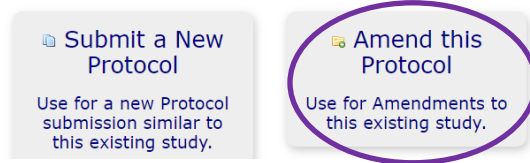
Event	Att	Instance/UDF	Start	Complete
Initial Submission Event	4	McCarthy, Travis John MPH	01/31/2023	05/26/2023

- iii. Click on the two sheets under Reference xForms next to Protocol Form.





- iv. Choose “Amend this Protocol” under “Choose an Action”  
Choose an Action



- v. If you receive the following “Incompatible Tags” message:

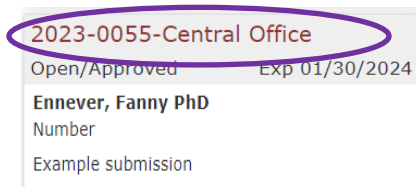
**Incompatible Tags**      **Help**   **Fanny's Settings**   **Sign off**  
**This Protocol Form xForm cannot be started/copied due to incompatible tags. Check with your admin for access to this xForm.**

- a. First check the xForms section of your dashboard (see section [4](#)) to see if you already have an amendment in progress)
  - b. If so, continue editing the existing amended xForm
  - c. If not, this likely means that you started an amendment in the past that was autodeleted after 90 days. Contact your [HRPP Coordinator](#) to request either that the Amendment in Progress tag be removed from your protocol so that you can create a new amendment or that the deleted draft amendment be reactivated for editing.
- vi. Edit the relevant sections of the xForm. Be sure to provide a description of all changes and attach all edited documents.
- vii. See [xForm Reminders](#)

## 10. Creating an xForm for an Annual Check-In, Continuing Review, Event Report, or Final Report for a Project

Note that normally you create an Annual Check-In or Continuing Review form by clicking on a link in an email reminder. This section describes how to create a form manually.

- i. On the Dashboard click on the Projects tab then click on the protocol number of the project (in red) in the project card



- ii. Locate and click on “Start xForm” from the menu to the left on the Protocol page

The screenshot shows the IRBManager interface for a specific project. On the left sidebar, under the 'Actions' section, the 'Start xForm' button is circled in red. The main content area displays project details for 'Project 2023-0055-Central Office (IRB)'. Key information includes:
 

- Project:** 2023-0055
- Committee:** (blank)
- Category:** (blank)
- Department:** (blank)
- Last Review:** Full Board
- Agent Types:** (blank)
- Title:** This is a test title for a test project.
- Non-CUNY IRB of Record:** (blank)
- Comments:** Testing draft form
- Funding Source(s):** (blank)
- Funding ID:** (blank)
- Grants:** (blank)
- Next Review:** Full Board
- CRO:** (blank)
- Year:** 2023
- Grant/Contract Number and Title:** (blank)
- Expedited Determination:** (blank)
- Exempt Determination:** (blank)
- Ideate Link:** (blank)

 Below this, the 'Project-Site' section shows:
 

- Site(s):** Central Office - CUNY Central Office
- Status:** Open/Approved
- Approval:** January 31, 2023 for 12 months
- Initial Approval:** January 31, 2023
- Approved Enrollment Number:** 50
- Risk Determination:** (blank)
- Tags:** Amendment In Process
- PI:** McCarthy, Travis John
- Additional:** N
- Expiration:** January 30, 2024
- Other Expirations:** (blank)
- HRPP Coordinator:** Travis McCarthy at 646-travis.mccarthy@uny.e

 Further down, there are sections for 'Project-Site Contacts (2)', 'Reference xForms (1)', and 'Events (1)'. The 'Reference xForms' table shows one entry:
 

Action	Form	Identifier	Stage	As Of	Ref Active
	Protocol Form	N/A	Complete	01/31/2023	01/31/2023

- iii. Click on the name of the applicable xForm

Start Form on Project-Site 2023-0055-Central Office

Filter:

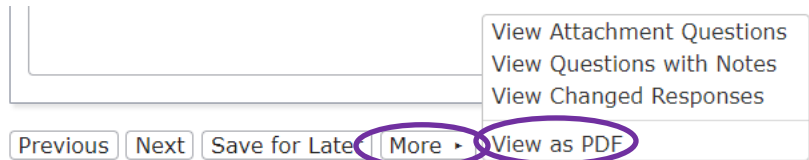
Select xForm to start

Action	Form (Click to start)	Description
	<a href="#">Annual Check-In</a>	Annual Check-In for Exempt/non-expiring protocols
	<a href="#">Children as Research Subjects Quiz</a>	Non-compliance quiz for the enrollment of children as research subjects
	<a href="#">Continuing Review Form</a>	Use this form to submit your continuing review application.
	<a href="#">Event Reporting Form</a>	Use this form for submitting any type of reportable event, including: protocol deviation, subject complaint, adverse event, unanticipated problem, etc.
	<a href="#">Exempt Review Quiz</a>	Non-compliance quiz for researchers on exempt protocols
	<a href="#">Expedited Review Quiz</a>	Non-compliance quiz for researchers on expedited protocols
	<a href="#">Faculty Advisor or Research Program Director Responsibility Quiz</a>	Non-compliance quiz for faculty advisor or program director responsibilities
	<a href="#">Final Report Form</a>	Use this form as your Final Report to close your study.

- iv. Complete and submit the xForm (see [xForm Reminders](#)).


## 11. Creating a PDF of a Completed xForm

- i. A PDF of any xForm is available for download at the bottom of the opened xForm.
- ii. The completed xForm may be saved as a PDF for ease of collaboration and record-keeping.



## 12. Copying existing Initial Application xForms for new submissions

*This option creates a duplicate of an existing project that then can be edited to create a new submission that is similar to an existing application. Do not use this option to respond to requests for changes during IRB review.*

- i. On Dashboard click on Projects Tab then select the protocol number of the project in red on the project card.
- ii. Click on the two sheets  under Reference xForms in middle of page.
- iii. Choose “Submit a New Protocol”.

Choose an Action



- iv. Complete and submit the xForm (see [xForm Reminders](#)).

## 13. Faculty Advisor Review and Approval

- i. Once the Student PI submits their xForm it will be forwarded to their advisor for review and approval. Faculty advisors are required to review their student’s project prior to submitting it to the HRPP Office.
- ii. The faculty advisor will receive an email from IRBManager informing them that their student has submitted an xForm.
- iii. Faculty advisors may click on the BLUE link within this email to access the xForm. If not logged into IRBManager, the faculty advisors will first see the page to log into IRBManager using their CUNYfirst credentials.
- iv. The entire application will appear on the page.
- v. The faculty advisor may use the Notes feature (see section [15](#)) if appropriate to communicate comments or suggested changes to the student PI. If the faculty advisor has been added as a Collaborator with edit rights (see section [8](#)), they may also edit the xForm.
- vi. When the faculty advisor has completed their review of the submission, they should click on Next button (on either the top or the bottom of the screen).
- vii. The question “Is this project is ready for submission?” appears. If the project is ready to be sent to the HRPP Office, the answer is “Yes”. If the project requires revisions, the answer is “No”, and a text box appears for the faculty advisor to communicate to the student what edits are needed (see section [5 viii](#)).
- viii. The faculty advisor should click on Next button on the top or bottom of the page and then on the Submit button to submit the project (to the HRPP Office if the project is ready for submission or back to the Student PI if revisions are needed).
- ix. See [xForm Reminders](#)

## 14. Information Requested by the IRB Office

- i. The xForm may be returned to you during the pre-review or IRB Review Process for additional information requested by the HRPP Office
- ii. An email will be sent to the submitter, PI, and Faculty Advisor informing them that the project is being sent back for revisions by the HRPP Office.
- iii. Click on the **BLUE** link provided in the email to be forwarded directly to the protocol. If you are not logged into IRBManager, you will first see the page to log into IRBManager with your CUNYfirst credentials.

The Protocol Form is being returned to you by the HRPP Coordinator Office for revisions.

### Message

**From:** no-reply@cuny.my.irbmanager.com

Requested revisions: Please update your application with the approved IAA form.

Please click the following link to go directly to the form [Protocol Form.](#)

- iv. In addition to the emails, items that require your attention will appear on your dashboard in the xForms tab – either look for an orange line at the top or click on the Awaiting your Attention filter.

**My Projects**

2 Projects    2 IRB    7 xForms

Start xForm    Export to Excel

1 Awaiting Your Attention    6 Unsubmitted

**Protocol Form**  
Test Submission.  
Data Entry

- v. **Notes** will be provided within the xForm alongside the question(s) they pertain to with detailed information about the requests. Initially the background for the notes will be in a **brighter blue**; they may be marked “Resolved” in which case the background will be a **lighter blue**. To view all the questions that have notes, click on the More button at the bottom of an opened xForm and select View Questions with Notes.

View Attachment Questions  
View Questions with Notes  
View Changed Responses  
View as PDF

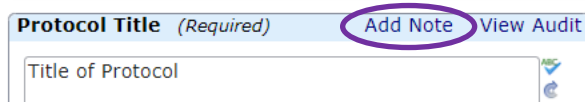
Previous    Next    Save for Later    More ▾

- vi. Once revisions are completed, sign the xForm and submit the form back to the HRPP Office for review.
- vii. See [xForm Reminders](#)

## 15. Notes Feature

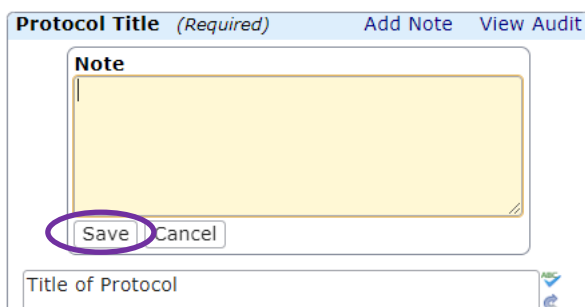
- i. Notes may be added in the xForm. Notes are essentially electronic sticky-notes; using this feature allows easy communication between researchers and IRB Staff (or any others working on the xForm). Notes can be added and removed as needed; notes removed by the research team prior to submission will not be available to IRB Staff. Notes can be added to each question in the xForm.

- ii. Click on Add Note to start a note





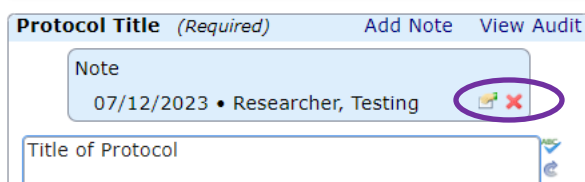
The screenshot shows the top of the xForm interface. At the top, there is a header bar with 'Protocol Title (Required)' on the left, 'Add Note' in the center, and 'View Audit' on the right. Below the header is a text input field labeled 'Title of Protocol'. The 'Add Note' button is circled in purple.

- iii. Click Save to save the note



The screenshot shows the 'Add Note' dialog box. It has a yellow background and a large text area for writing the note. Below the text area are two buttons: 'Save' and 'Cancel'. The 'Save' button is circled in purple. The 'Title of Protocol' input field is visible at the bottom of the dialog.

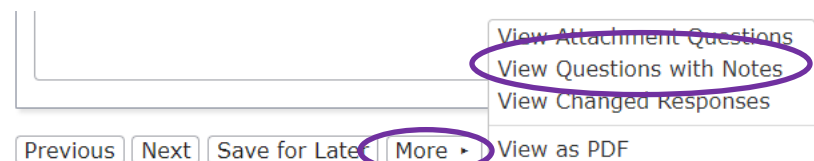
- iv. The note can be edited by clicking on the hand-paper icon  or deleted by clicking on the red X icon  in the bottom right corner of the note box.



The screenshot shows a note box with a light blue background. The note text is '07/12/2023 • Researcher, Testing'. In the bottom right corner of the note box, there are two icons: a hand-paper icon and a red X icon. Both icons are circled in purple. The 'Title of Protocol' input field is visible below the note box.

- v. Notes are NOT retained when an IRB Application xForm is copied for amendment. **Therefore, notes do not replace complete responses to questions or within application fields. Any information pertinent to the IRB Application must be incorporated into relevant application fields.**

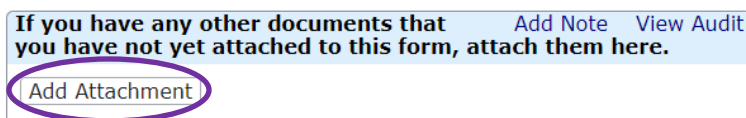
- vi. At the bottom of the xForm page, there is an option under “More” to view all questions that have notes, which is helpful when collaborating during data entry, or when the HRPP Office returns the xForm to the submitter for additional information.



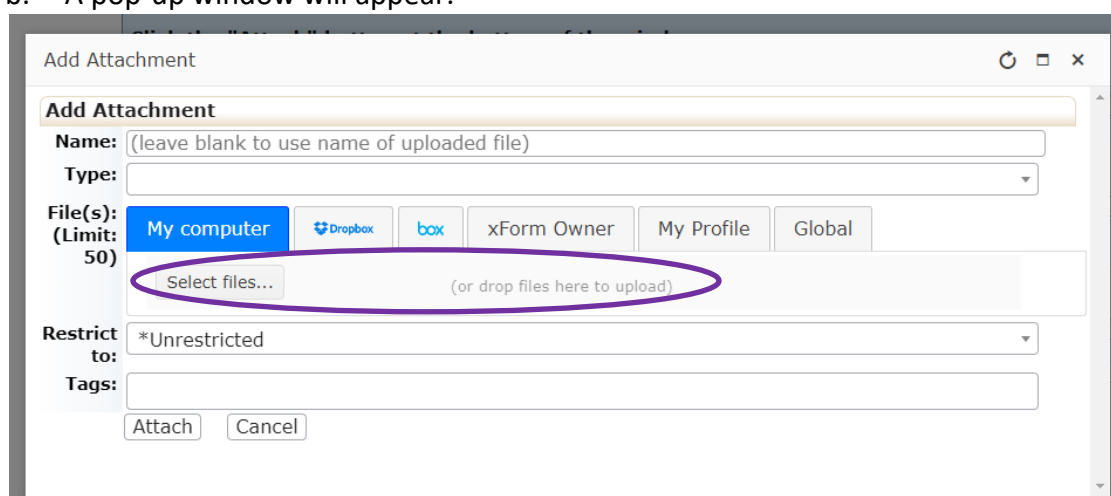
The screenshot shows the bottom navigation bar of the xForm. It includes buttons for 'Previous', 'Next', 'Save for Later', and 'More'. The 'More' button is circled in purple and has a dropdown menu open. The dropdown menu contains three options: 'View Attachment Questions', 'View Questions with Notes', and 'View Changed Responses'. The 'View Questions with Notes' option is circled in purple.

## 16. Uploading Documents as Attachments

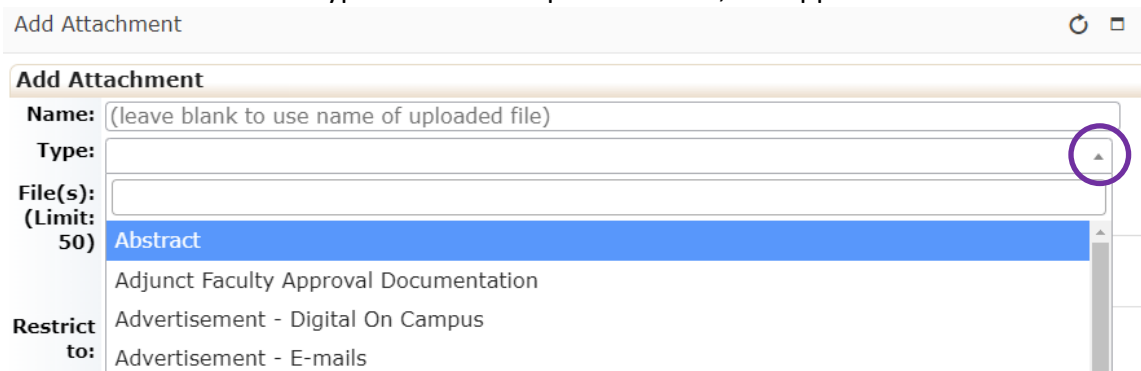
- i. Each attachment question should only contain the indicated document type (e.g., recruitment letter, informed consent document, survey questions, etc.).
- ii. Documents of the same attachment type should be uploaded as separate files (e.g., consent forms and also parent permission forms; survey questions for different subject groups).
- iii. The Attachments section is located at the end of initial submission xForm. Please follow these instructions for attaching documents in xForms:
  - a. Click the "Add Attachment" button to open a pop-up window on screen.



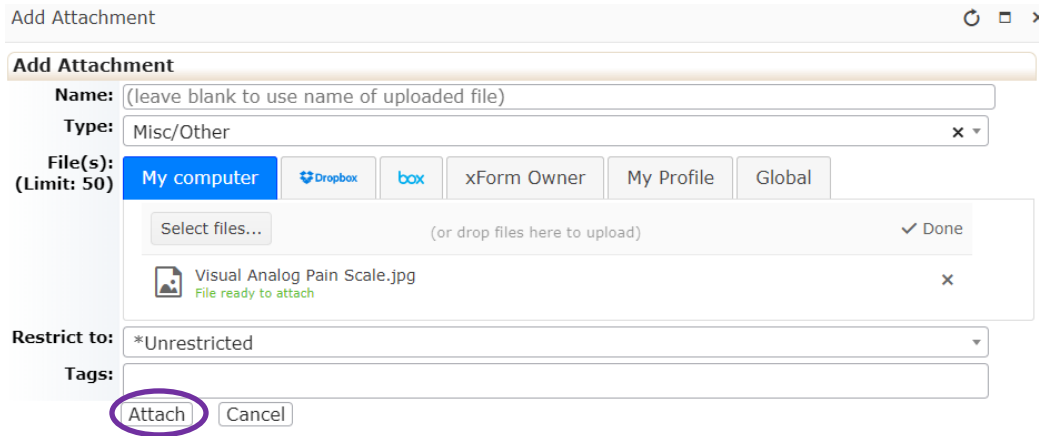
- b. A pop-up window will appear.



- c. Click "Select files..." to browse for the document(s) you wish to attach, or drag and drop files at the message "(or drop files here to upload)".
  - d. Choose the document type from the dropdown menu, if it appears.



- e. Click the "Attach" button at the bottom of the window.



- f. The pop-up window will auto-close and attach the document to your application.

## 17. Document Naming Conventions

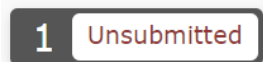
- i. Be intentional with document naming.
- ii. Use consistent naming conventions for document.
- iii. Use *descriptive* file names (e.g., Group\_1\_Informed\_Consent). Descriptive file names are VERY helpful for reviewers.
- iv. Use *distinctive* file names (e.g., Control Consent, Condition 1 Consent, Condition 2 Consent, instead of three items all named "Consent"). Unique names allow researchers to quickly find the right item when updating materials and enable IRB reviewers to easily communicate about specific documents. Uploading items one at a time will automatically capture the document's distinctive file name.
- v. Using the same filename for a document when replacing the previous version is helpful to the reviewer so that it is clear what was replaced. The document name may include version number or dates but maintaining the descriptive part of the name (e.g., child\_assent\_letter.doc, parental\_consent\_letter.doc, etc.) is requested.



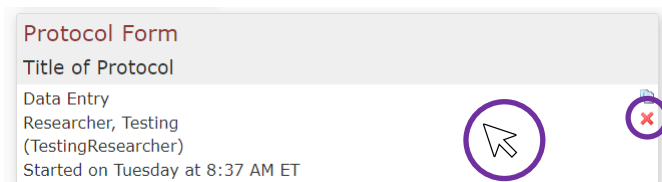
## 18. Deleting xForms and Withdrawing xForms

- i. xForms can only be DELETED when they are in Data Entry stage (i.e., prior to being submitted for review). You may delete xForms by following these instructions:

- a. Click on the xForms tab then on the unsubmitted forms filter.



- b. Position the cursor within the card for an unsubmitted xForm and click on the red X that appears to delete the unsubmitted xForm.

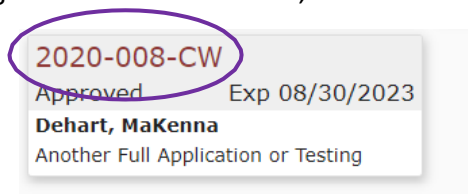


- ii. If you need to withdraw xForms that have been submitted for review, contact your [HRPP Coordinator](#) to request withdrawal, providing the following information:
  - o PI's name (if different than Submitter)
  - o Protocol Number
  - o Protocol Title
  - o Form Type (i.e., Protocol, Amended Protocol, Event Report, Annual Check-In, Continuing Review)

## 19. Locating Approved xForms

All study information and files are stored within IRBManager. xForms in progress appear on the Dashboard in the xForms tab. Completed xForms can be accessed within the relevant event for a study.

1. Starting at the user dashboard, click on the study ID in red on the projects card

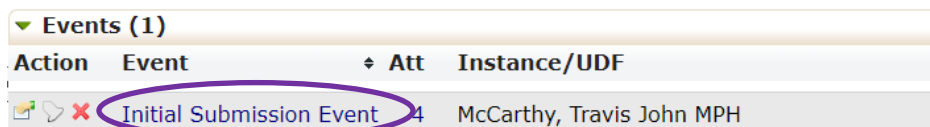


2. Locate the Events section on the Protocol page

The screenshot shows the IRBManager interface for project 2023-0055. The 'Events (1)' section is circled in red. It contains a table with the following data:

Action	Event	Att	Instance/UDF	Start	Complete
	Initial Submission Event	4	McCarthy, Travis John MPH	01/31/2023	05/26/2023

3. Click on the event name in the Event column



4. Click on xForms in the menu to the right under Actions on the Event page

**CU NY THE CITY UNIVERSITY OF NEW YORK**

Home Find Project (Ctrl+Q)

**Event Details: Initial Submission Event on 2023-0055-Central Office** Help Researcher's Settings Sign off

**Project-Site**

**Project:** 2023-0055-Central Office **Site:** Central Office - CUNY Central Office

**Title:** This is a test title for a test project. **Committee:**

**PI:** McCarthy, Travis John MPH **Funding ID:**

**Event**

**Type:** Initial Submission Event **Started:** 01/31/2023

**Instance:** McCarthy, Travis John MPH **Completed:** 05/26/2023

**Committee:** IRB 1

**Review Type:** Full Board

**Review Date:** 02/09/2023

**Steps (11)**  Hide Skipped

Step	Planned	Actual	Complete
Receive Submission		01/31/2023	Yes
HRPP Administrative Pre-review	02/06/2023	01/31/2023	Yes
IRB Administrator Review		01/31/2023	Yes
Receive Member Review	02/13/2023	01/31/2023	Yes
Notify Researcher of Outcome		01/31/2023	Yes

**Actions**

- Attachments (4)
- Send Email
- xForms (1)**
- Done

**Recent Items**

- 2023-0055-Central Office
- TEST 227-Baruch

**Messages**

Welcome to IRBManager at CUNY

**Useful Links**

- CITI Certificate Help
- CUNY Human Research Protection Program (HRPP)
- CUNY Consent

5. Click on the name in the Form column to view the form

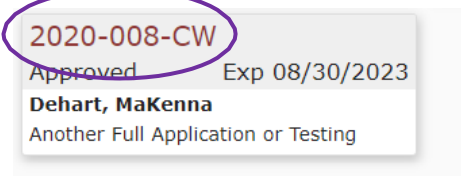
**Forms on Event Details: Initial Submission Event on 2023-0055-Central Office**

Action	Form	Identifier	Stage/Status	Started	Submitted
	<b>Protocol Form</b> (Reference xForm)	N/A	Complete	01/31/2023	01/31/2023

## 20. Locating Approved Attachments

All study information and files are stored within IRBManager. Attachments can be accessed within the relevant event for a study.

1. Starting at the dashboard, click on the study ID in red in the project card



2. Locate the Events section on the Protocol page

A screenshot of the IRBManager Protocol page for project 2023-0055-Central Office (IRB). The page shows various details including Project, Committee, Category, Department, Last Review, Agent Types, Title, Non-CUNY IRB of Record, Funding Source(s), Funding ID, Grants, Next Review, CRO, Year, Grant/Contract Number and Title, Expedited Determination, Exempt Determination, and Ideate Link. The 'Project-Site' section includes Site(s), Status, Approval, Initial Approval, Approved Enrollment Number, Risk Determination, and Tags. The 'Project-Site Contacts (2)' section lists contacts like Ennever, Fanny PhD and Test, Researcher. The 'Reference xForms (1)' section shows a Protocol Form. The 'Events (1)' section is circled in red and contains one event: 'Initial Submission Event' with 4 attachments, Instance/UDF 'McCarthy, Travis John MPH', Start date '01/31/2023', and Complete date '05/26/2023'.

3. Choose A or B below.




### A. Path #1: (one step)

- Click on the number under the Att column

A close-up screenshot of the 'Events (1)' section. The table has columns for Action, Event, Att, Instance/UDF, Start, and Complete. The row for 'Initial Submission Event' has the number '4' under the 'Att' column, which is circled in red.

B. Path #2: (two steps)

- Click on the name in the Event column

▼ Events (1)			
Action	Event	Att	Instance/UDF
  	Initial Submission Event	4	McCarthy, Travis John MPH

- Click on Attachments in the menu to the right under Actions on the Event page



**Event Details: Initial Submission Event on 2023-0055-Central Office**

**Project-Site**

Project: 2023-0055-Central Office      Site: Central Office - CUNY  
 Title: This is a test title for a test project.      Committee:  
 PI: McCarthy, Travis John MPH      Funding ID

**Event**

Type: Initial Submission Event      Started: 01/31/2023  
 Instance: McCarthy, Travis John MPH      Completed: 05/26/2023  
 Committee: IRB 1  
 Review Type: Full Board  
 Review Date: 02/09/2023

**Steps (11)**

Step	Planned	Actual
Receive Submission		01/31/2023
HRPP Administrative Pre-review	02/06/2023	01/31/2023
IRB Administrator Review		01/31/2023
Receive Member Review	02/13/2023	01/31/2023
Notifv Researcher of Outcome		01/31/2023

4. The following screen will appear after either 3.A. or 3.B. To view/download documents that the study team uploaded, click on “Attachments” at the left, then click on the blue link under “Name”.

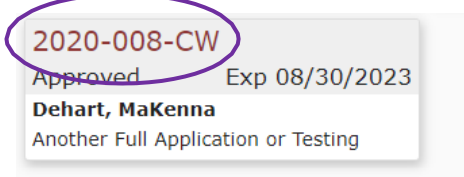
**Attachments on Event IRB Initial Submission - Manual Started 08/31/2020 on 2020-008-CW**

Attachments (2)			
Name	Attached	Type	
<a href="#">Oral History Project Form 4-7-16.doc</a>	8/31/2020 2:48 PM	Misc/Other	
<a href="#">Oral History Project Form 4-7-16.doc</a>	8/31/2020 2:48 PM	Medical History Form	

## 21. Locating an Approval Letter for an Event

Approval letters are considered attachments in IRBManager. Letters are associated with an event.

- Starting at the user dashboard, click on the study ID in red in the projects card.



- Locate the Events section on the Protocol page

**Project:** 2023-0055  
**Committee:**  
**Category:**  
**Department:**  
**Last Review:** Full Board  
**Agent Types:**  
**Title:** This is a test title for a test project.  
**Non-CUNY IRB of Record:**  
**Comments:** Testing draft form

**Funding Source(s):**  
**Funding ID:**  
**Grants:**  
**Next Review:** Full Board  
**CRO:**  
**Year:** 2023  
**Grant/Contract Number and Title:**  
**Expedited Determination:**  
**Exempt Determination:**  
**Ideate Link:**

**Project-Site**  
**Site(s):** Central Office - CUNY Central Office  
**Status:** Open/Approved  
**Approval:** January 31, 2023 for 12 months  
**Initial Approval:** January 31, 2023  
**Approved Enrollment Number:** 50  
**Risk Determination:**  
**Tags:** Amendment In Process  
**PI:** McCarthy, Travis John MPH  
**Additional:** N  
**Expiration:** January 30, 2024  
**Other Expirations:**  
**HRPP Coordinator:** Travis McCarthy at 646-664-8906 or travis.mccarthy@cuny.edu

Name	Role	Expirations
Ennever, Fanny PhD	Co-Investigator	CITI HSR Training - 02/21/2026
Test, Researcher	Co-Investigator	

Action	Form	Identifier	Stage	As Of	Ref Active	Inactivated
	Protocol Form	N/A	Complete	01/31/2023	01/31/2023	

Event	Att	Instance/UDF	Start	Complete
Initial Submission Event	4	McCarthy, Travis John MPH	01/31/2023	05/26/2023

- Choose A or B below.

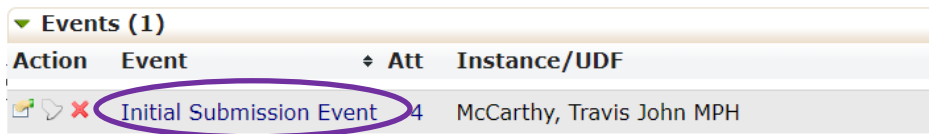
A. Path #1: (one step)




- Click on the number under the Att column

Action	Event	Att	Instance/UDF
	Initial Submission Event	4	McCarthy, Travis John MPH


B. Path #2: (two steps)

- Click on the name in the Event column



Action	Event	Att	Instance/UDF
  	<a href="#">Initial Submission Event</a>	4	McCarthy, Travis John MPH

- Click on Attachments in the menu to the right under Actions on the Event page



**CUNY THE CITY UNIVERSITY OF NEW YORK**

Home Find Project

**Event Details: Initial Submission Event on 2023-0055-Central Office** Help Re

**Project-Site**

**Project:** 2023-0055-Central Office **Site:** Central Office - CUNY

**Title:** This is a test title for a test project. **Committee:**

**PI:** McCarthy, Travis John MPH **Funding ID:**

**Event**

**Type:** Initial Submission Event **Started:** 01/31/2023

**Instance:** McCarthy, Travis John MPH **Completed:** 05/26/2023

**Committee:** IRB 1

**Review Type:** Full Board

**Review Date:** 02/09/2023

**Steps (11)**

Step	Planned	Actual
Receive Submission		01/31/2023
HRPP Administrative Pre-review	02/06/2023	01/31/2023
IRB Administrator Review		01/31/2023
Receive Member Review	02/13/2023	01/31/2023
Notifv Researcher of Outcome		01/31/2023

**Actions**

[Attachments \(4\)](#)

[Send Email](#)

[xForms \(1\)](#)

Done

**Recent Items**

2023-0055-Central Office

TEST 227-Baruch

**Messages**

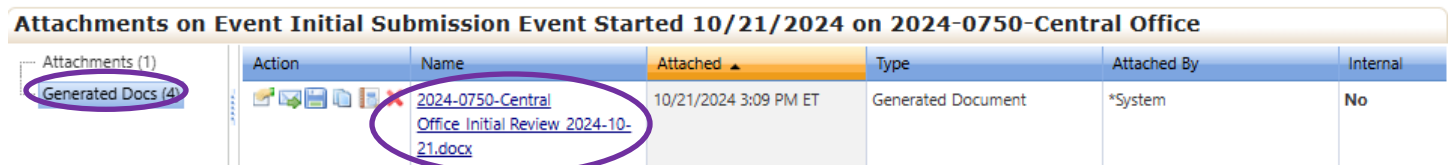
Welcome to IRBManager at CUNY

**Useful Links**




1. CITI Certificate Help

2. CUNY Human Research Protection Program (HRPP)

4. The following screen will appear after either 3.A. or 3.B. To view/download IRB **Approval Letters**, click on “Generated Docs” at the left, then click on the blue link under “Name” to download the letter.



**Attachments on Event Initial Submission Event Started 10/21/2024 on 2024-0750-Central Office**

Action	Name	Attached	Type	Attached By	Internal
  	<a href="#">2024-0750-Central Office Initial Review 2024-10-21.docx</a>	10/21/2024 3:09 PM ET	Generated Document	*System	No