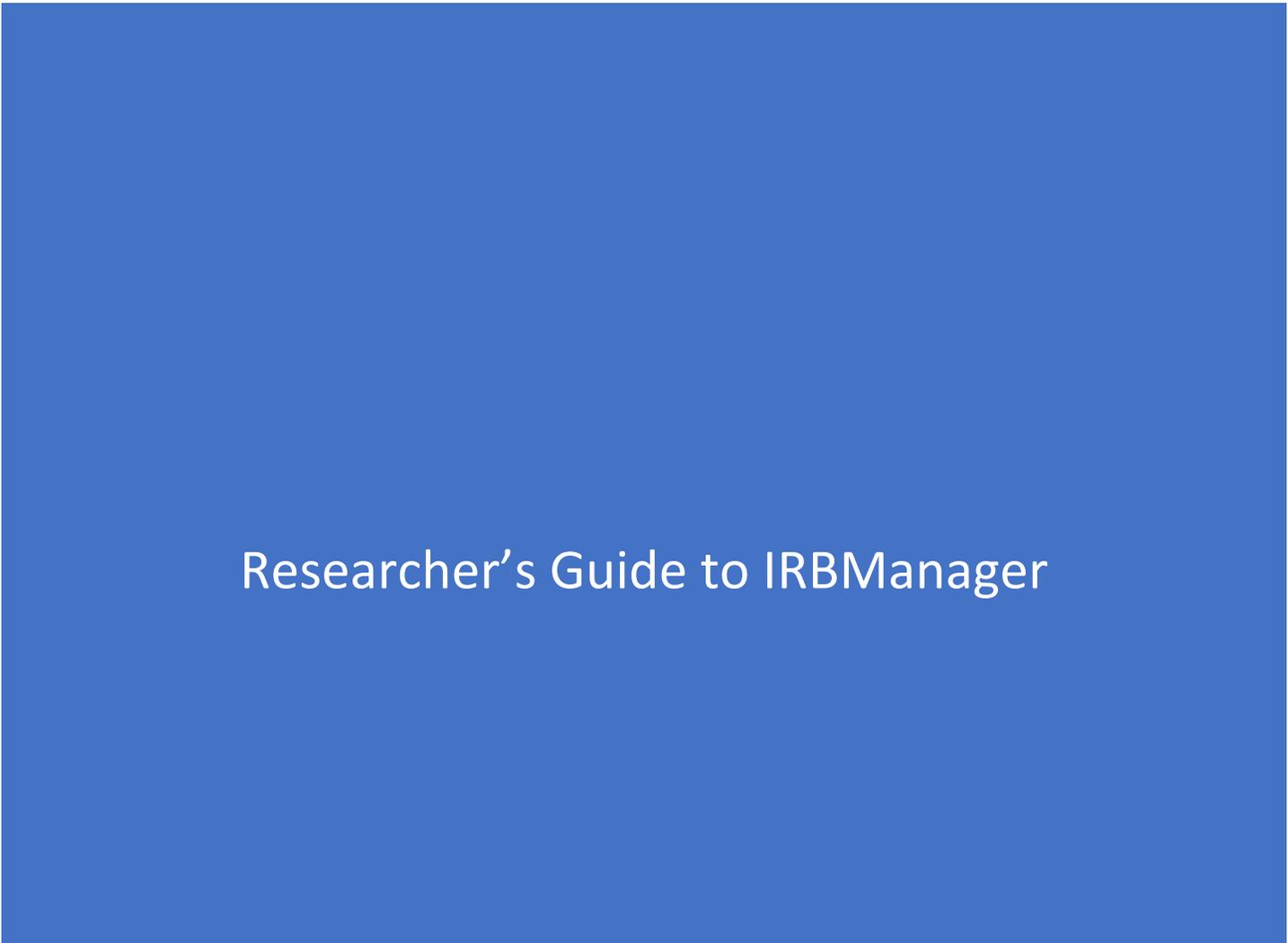




CUNY IRBMANAGER MANUAL



Researcher's Guide to IRBManager

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1. Logging into IRBManager (New/Existing Users)

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



- ii. Enter your CUNYFirst username/password



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](#):

Login to IRBManager

Username

Password

Login

[> Forgot Password](#) [> New User](#)
[> Forgot Username](#) [> Manage your Account](#)

Production environment

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](#).

- iii. Once logged in you should be on your *Home* page.

- iv. Profiles for New Users will be automatically created once they've logged into IRBManager with their CUNYFirst credentials.

- v. If you are a CUNY researcher/research personnel who **DOES NOT** have CUNYFirst credentials request an IRBManager account by emailing irbmanager@cuny.edu and including the following information in your email:
 - First and Last Name
 - EMPLID
 - DOB (Does not need be your actual DOB)
 - PIN (You can make something up)
 - CUNY email address

*You will be notified within 1-2 business days with your credentials to log into IRBManager.

2. Linking CITI Certifications to IRBManager Profile

i. If you have completed CITI training as a CUNY researcher, information related to your CITI training will be linked automatically to your IRBManager profile and will be available to HRPP and IRB reviewers; **however**, you **MUST** log into CITI and confirm that **your preferred email address in CITI is your CUNY email address. Your secondary email address should be a personal email address. Please follow these instructions to ensure that your CITI Certifications are linked to your IRBManager Profile:**

- a. Log in to CITI at <https://www.citiprogram.org>
- b. In the upper right under your name and ID, click the down arrow.
- c. Select "Profiles".
- d. Under "Member Profiles", click "Edit Profile".
- e. Scroll down to Your preferred email address.
- f. Confirm that this is your current CUNY email address, or revise if needed.

ii. If you have not completed the process above then you **MUST** upload your current CITI Certification to your profile in IRBManager. Please follow these instructions:

- a. Log in to IRBManager at <https://cuny.my.irbmanager.com>
- b. In the upper right click on Settings.

- c. Select “My Attachments”.
- d. Select “Add Attachment”.
- e. In dropdown box choose “Education – CUNY CITI completion certificate”
- f. Then click “Select Files...” select the CITI Certificate saved to your computer then click Open.
- g. Lastly, click on Attach button to attach CITI Certification to profile.

3. IRBManager Dashboard

- i. **Once you’ve logged into IRBManager you will be forwarded to your Dashboard.** The dashboard is the hub of the xForms (applications) and the landing page when logging in to IRBManager. Projects and Events that individuals are associated with can be located here. Clicking on the buttons under each tab allows you to view and sort the projects, events, or xForms.

- ii. **Areas of the Dashboard**



Projects (Active Projects)

- The studies you are associated with (i.e., PI, Faculty Advisor, Co-PI, or Research Staff)
- *Note: Clicking the buttons in this section shows the xforms (IRB applications) that meet the criteria selected.*



- Studies expiring soon



4

xForms

xForms (Active xForms)

- The number of unsubmitted xForms – the IRB applications that you have initiated (as the submitter)
- The number being processed at a later stage (after application data entry)
- You may start a new application by click on the Start xForm Button.

Start xForm

- xForms awaiting your attention (e.g., review and sign, etc.)
- *Note: Clicking the buttons in this section shows the xforms (IRB applications) that meet the criteria selected.*

1 Awaiting Your Attention

1 Unsubmitted

2 Being Processed At A Later Stage



2

Events

Events (Open Events)

- The number of events you have open (i.e., that have not been approved or otherwise finalized)
- *Note: Clicking on the buttons allows you to sort the events by role or event type.*

8 Initial Submission Event

9 PI

1 Amendment Event

2 Continuing Review Event

4. Printing Initial Submission xForm

- i. On Dashboard, please click on Start xForm Button:

A rectangular button with a thin border and the text "Start xForm" in a reddish-brown font.

- ii. Then click on print icon  to the left on form name. This will allow you to print the entire application.

5. Creating Initial Submission XForms in IRBManager

- i. On Homepage click on Start xForms tab then Start xForm button.
- ii. Click on Protocol Form.
- iii. Then click "Start a New Application".
- iv. Once xForm has been completed please click on next and click on "I Agree" checkbox and digitally sign application on Signature Page. Then click on next button.
- v. Then click on the Submit button to submit the application to the campus HRPP Office.
- vi. **Reminders:**
 - a. You may complete application sections by using the dropdown box at the top of the xForm. This will allow researchers to navigate through the application without having to answer all questions on the form.
 - b. Please select campus where the application will be sent in "Campus" question. PI's should indicate the campus where they have their primary affiliation. Student PI's should indicate the campus where their faculty advisor has their primary affiliation
 - c. If you can not find Personnel's name in IRBManager, please have them log into IRBManager with their CUNYFirst credentials. This will add their name to the system.
 - d. Please make sure that ALL research personnel have either updated their email information in CITI or added their CITI Certificates to their IRBManager profiles. See instructions in "Linking CITI Certifications..." section for details.
 - e. Student PI submissions will be sent to their faculty advisor for approval prior to submission to the campus HRPP office.

6. Creating Initial Proxy Submissions in IRBManager

- i. On Homepage click on xForms Tab then Start XForm.
- ii. Click on Protocol Form.

- iii. Then click “Start a New Application”.
- iv. Enter name of person who will be serving as PI in “Principal Investigator” question in xForm.
- v. Once xForm has been completed please click on next and click on “I Agree” checkbox and digitally sign application on Signature Page. Then click on next button.
- vi. Then click on the Submit button to submit the application to the PI for review/submission to the campus HRPP Office.
- vii. Proxy submissions will be sent to the person listed as PI for approval prior to submission to the campus HRPP Office.
- viii. **Reminders:**
 - a. You may complete application sections by using the dropdown box at the top of the xForm. This will allow researchers to navigate through the application without having to answer all questions on the form.
 - b. Please select campus where the application will be sent in “Campus” question. PI/Submitter should indicate the campus where PI has their primary affiliation. Student PI/Submitters should indicate the campus where their faculty advisor has their primary affiliation.
 - c. If you cannot find Personnel’s name in IRBManager, please have them log into IRBManager with their CUNYFirst credentials. This will add their name to the system.
 - d. Please make sure that ALL research personnel have either updated their email information in CITI or added their CITI Certificates to their IRBManager profiles. See instructions in “Linking CITI Certifications...” section for details.
 - e. Student PI submissions will be sent to their faculty advisor for approval prior to submission to the campus HRPP office.

7. Creating Amendments in IRBManager

- i. On Homepage click on Projects Tab then select Protocol Number of Project.
- ii. Click on the two sheets  under Reference xForms in middle of page.
- iii. Choose “Copy for Amendment” then fill out Xform.
- iv. Once xform has been completed please click on next and click on “I Agree” checkbox and digitally sign application on Signature Page. Then click on next button.

- v. Then click on the Submit button to submit the application to the campus HRPP Office.
- vi. **Reminders:**
 - a. If you cannot find Personnel's name in IRBManager, please have them log into IRBManager with their CUNYFirst credentials. This will add their name to the system.
 - b. Please make sure that ALL research personnel have either updated their email information in CITI or added their CITI Certificates to their IRBManager profiles. See instructions in "Linking CITI Certifications..." section for details.
 - c. Student PI submissions will be sent to their faculty advisor for approval prior to submission to the campus HRPP office.

8. Creating Continuing Review XForms in IRBManager

- i. On Homepage click on Projects Tab then select Protocol Number of Project
- ii. Click on Start xForm under Actions
- iii. Choose "Continuing Review" then fill out xForm.
- iv. Once xForm has been completed please click on next and click on "I Agree" checkbox and digitally sign application on Signature Page. Then click on next button.
- v. Then click on the Submit button to submit the application to the campus HRPP Office.
- vi. Student PI submissions will be sent to their faculty advisor for approval prior to submission to the campus HRPP office.

9. Creating Final Report XForms in IRBManager

- i. On Homepage click on Projects Tab then select Protocol Number of Project.
- ii. Click on Start xForm under Actions.
- iii. Choose "Final Report" then fill out xForm.
- iv. Once xform has been completed please click on next and click on "I Agree" checkbox and digitally sign application on Signature Page. Then click on next button.

- v. Then click on the Submit button to submit the application to the campus HRPP Office.
- vi. Student PI submissions will be sent to their faculty advisor for approval prior to submission to the campus HRPP office.

10. Creating Event Reporting XForms in IRBManager

- i. On Homepage click on Projects Tab then select Protocol Number.
- ii. Click on Start xForm under Actions
- iii. Choose “Event Reporting Form” then fill out xForm.
- iv. Once xForm has been completed please click on next and click on “I Agree” checkbox and digitally sign application on Signature Page. Then click on next button.
- v. Then click on the Submit button to send the application to the campus HRPP Office.
- vi. Student PI submissions will be sent to their faculty advisor for approval prior to submission to the campus HRPP Office.
- vii. Proxy submissions will be sent to the PI for review/approval prior to submission to the campus HRPP Office.

11. Copying existing Initial Application xForms for new submissions:

- i. On Homepage click on Projects Tab then select Protocol Number of Project.
- ii. Click on the two sheets  under Reference xForms in middle of page.
- iii. Choose “Copy for use for a New Protocol” then fill out xForm.
- iv. Once xForm has been completed please click on next and click on “I Agree” checkbox and digitally sign application on Signature Page. Then click on next button.
- v. Then click on the Submit button to submit the application to the campus HRPP Office.
- vi. **Reminders:**
 - a. Make sure that you’ve revised application to meet the criteria of new project. All documents should be revised to be consistent with new submission.
 - b. You may complete application sections by using the dropdown box at the top of the xForm. This will allow researchers to navigate

through the application without having to answer all questions on the form.

- c. If you cannot find Personnel's name in IRBManager, please have them log into IRBManager with their CUNYFirst credentials. This will add their name to the system.
- d. Please make sure that ALL research personnel have either updated their email information in CITI or added their CITI Certificates to their IRBManager profiles. See instructions in "Linking CITI Certifications..." section for details.
- e. Student PI submissions will be sent to their faculty advisor for approval prior to submission to the campus HRPP office.

12. Creating HRPP IRB of Record XForms in IRBManager

- i. Please consult with your campus HRPP Coordinator to inquire as to whether or not an IRB Authorization Agreement can be entered into prior to submitting this xForm.
- ii. On Homepage click on xForms tab then Start xForm button.
- iii. Click on HRPP IRB of Record Form.
- iv. Then click "Start a New Application".
- v. Once xForm has been completed please click on next button then click on the submit button to send application to campus HRPP Office.
- vi. Student PI submissions will be sent to their faculty advisor for approval prior to submission to the campus HRPP office.

13. Transferring IDEATE protocols into IRBManager

- i. PI/SUBMITTER Transfer Instructions:

This process should **ONLY** be used if there are no changes being made to the approved IDEATE protocol. **Any changes (i.e. addition of new research personnel, change in research design/procedures, changes to research instruments, etc.) requires HRPP/IRB review and approval prior to implementation.**

1. PI/SUBMITTER may transfer their IDEATE protocols by going to their homepage click on Projects Tab then select Protocol Number.

2. You can access a link to a read-only version of the IDEATE Application in “IDEATE Legacy Link” towards the top of Protocol Site page.
3. Click on the two sheets  under Reference xForms in middle of page.
4. Choose “Copy for Amendment” then fill out XForm and add all currently approved documents (i.e., recruitment, consent, research materials, etc.)
5. PI/SUBMITTER should indicate yes to “Are you ONLY creating this submission in order to populate your currently approved protocol information?”.
6. Once PI/SUBMITTER has completed application, they must enter their password on Signature Page. Then click on the Next button at the top/bottom of screen.
7. Lastly, PI/SUBMITTER must click on Submit button which will automatically upload completed form onto IRBManager
8. **Reminders:**
 - a. Please select campus where the application will be sent in “Campus” question. PI’s should indicate the campus where they have their primary affiliation. Student PI’s should indicate the campus where their faculty advisor has their primary affiliation.
 - b. If you cannot find Personnel’s name in IRBManager, please have them log into IRBManager with their CUNYFirst credentials. This will add their name to the system.
 - c. Please make sure that ALL research personnel have either updated their email information in CITI or added their CITI Certificates to their IRBManager profiles. See instructions in “Linking CITI Certifications...” section for details.
 - d. Student PI submissions will be sent to their faculty advisor for approval prior to submission to the campus HRPP office.

- e. Please be reminded to attach all approved attachments in IRB Manager. See FAQs section at the end of this guide.
9. Researchers may also obtain assistance from staff at CUNY Central. Please coordinate this process with your campus HRPP Office.

14. Faculty Advisor Approval Instructions

- i. Once the Student PI submits their xForm it will be forwarded to their advisor for review/approval. Faculty advisors are required to review their student's projects 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 onto IRBManager advisors must log into IRBManager using their CUNYFirst credentials to access the application.
- iv. The entire application will appear on the page. Once Faculty Advisor has completed their review of the submission please click on Next button on either top/bottom of screen.
- v. Then answer "yes" to is this project is ready for submission if the project is ready to be sent to the HRPP Coordinator Office. If the project requires revisions, please answer "no" to this question and provide information to student as to information is required.
- vi. Then click on Next button on top/bottom of page to either submit the project to the HRPP Coordinator Office (if project is ready for submission) or back to the Student PI for revisions.
- vii. **Reminders:**
 - a. Please make sure that student has selected campus where faculty advisor has their primary affiliation in "Campus" question on xForm (i.e., Initial Submissions and Amendments).
 - b. Please ensure that all CUNY/Non-Affiliated Personnel have been added to the submission. If you cannot find CUNY Personnel's name in IRBManager, please have them log into IRBManager with their CUNYFirst credentials. This will add their name to the system.

- c. Please make sure that ALL research personnel have either updated their email information in CITI or added their CITI Certificates to their IRBManager profiles. See instructions in “Linking CITI Certifications...” section for details.
- d. Faculty Advisors will be copied on all correspondence sent to Student PI’s.
- e. Faculty Advisors may also view items that require their attention by selecting xForms tab then clicking on Awaiting your Attention button.

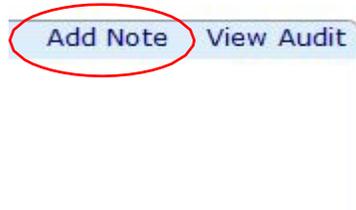
15. Information Requested by the IRB Office

- i. The xForm may be returned during the pre-review or IRB Review Process for additional information requested by the HRPP Coordinator Office
- ii. An email will be sent to the submitter, PI, and Faculty Advisor informing them that protocol is being sent back for revisions by the HRPP Coordinator Office.
- iii. Please click on the **BLUE** link provided in the email to be forwarded directly to the protocol. If you are not logged into IRBManager PI/Submitter will have to log into IDEATE with their IDEATE credentials.
- iv. Submitter, PI, and Faculty Advisor may also view items that require their attention by selecting xForms tab then clicking on Awaiting your Attention button.
- v. Notes will be provided within the xForm alongside the question(s) they pertain to with detailed information about the requests. To view questions with notes please click on More button at the bottom of opened xForm and select View Questions with Notes. IRB Manager will generate a pdf of application questions that have notes on them.
- vi. Once revisions are completed, please sign the xForm and submit the form back to the HRPP Coordinator Office for review.
- vii. Student PI submissions will be sent first to the faculty advisor for review/approval prior to submission to the HRPP Coordinator Office.
- viii. If projects are submitted on behalf of PI, PI will be required

to review/sign off on projects prior to submission to the HRPP Coordinator Office.

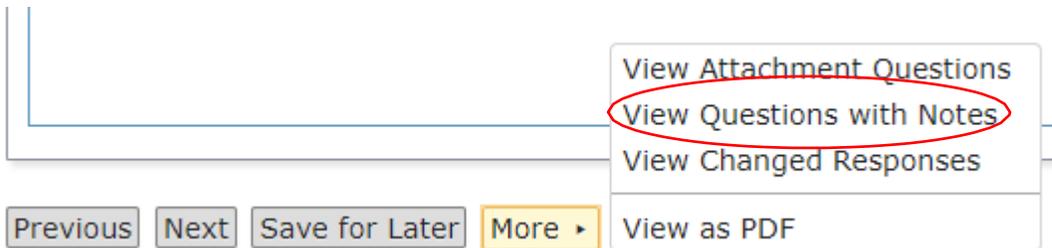
16. Notes Feature

- 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.



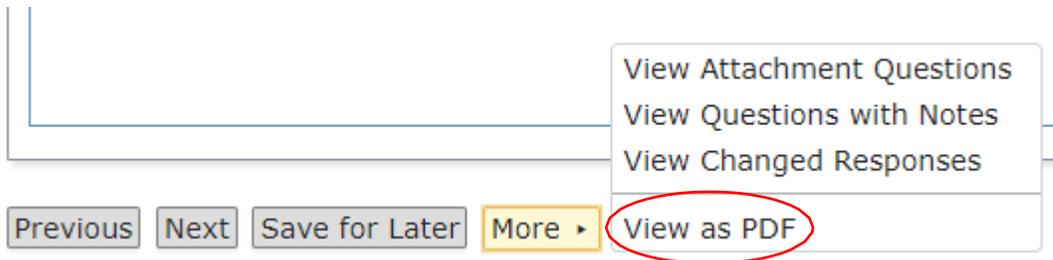
- ii. Notes are not retained when an IRB Application xForm is copied for amendment. **Therefore, notes do not replace complete responses to questions or within application fields. Any information pertinent to the IRB Application must be incorporated into relevant application fields.**

- iii. An option to view a summary of the notes on the form is available, which is helpful when collaborating on the Application Data Entry stage of the form, or when the IRB returns the xForm to the submitter for additional information.



17. Creating PDF of Completed IRB Application

- 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.



18. Uploading Documents as Attachments

- i. Each attachment should only contain one document type (e.g., recruitment letter, informed consent document, survey questions, etc.). For instance, when uploading data collection materials, do not include or attach consent or recruitment documents.
- ii. If more than one type of data collection materials will be used (e.g., survey questions, interview questions, etc.), upload them separately.
- 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. Click "Select files..." to browse for the document(s) you wish to attach.
 - c. Click the "Attach" button at the bottom of the window.
 - d. The window will auto-close and attach the document to your application.

19. 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.

20. Deleting xForms

- i. xForms can only be deleted during data entry stage (i.e., prior to being submitted for review). You may delete xForms by following these instructions:
 - a. Click on xForms tab then unsubmitted forms filter.
 - b. Scroll mouse on xForms that appear in this section and click on the red X to delete them.
- ii. If you need to withdraw xForms that have been submitted for review, please see our Withdrawal Instructions below.

21. Withdrawing xForms

- i. If PI/Submitters wish to withdraw applications that were submitted for review they must contact their HRPP Coordinator to request withdrawal providing the following information:
 - o PI’s name (if different than Submitter)

- Protocol Number
- Protocol Title
- Event Type (i.e., Initial Submission, Amendment, Continuing Review, etc.)