CUNY IRBMANAGER MANUAL	
Researcher's Guide to IRBManager	

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

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



ii. Enter your CUNYFirst username/password



- 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.
- CUNY-affiliated research staff who do not have a CUNYFirst account will need to v. follow a different process to get access to IRB Manager. CUNY CIS has developed a process to create non-authoritative CUNYFirst accounts for these individuals, and it will require that an authority at each college or school provides a list of such vetted individuals to CUNY CIS so they can get access to IRBManager. The exact information needed from each user is as follows:
  - 1. First and Last Name
  - 2. EMPLID
  - 3. DOB (This does not have to be your actual date of birth).
  - 4. PIN (You can make something up).
  - 5. CUNY email address
  - 6. Sponsor EMPLID
- vi. Contact your HRPP Coordinator if you have questions.

#### 2. **Linking CITI Certifications to IRBManager Profile**

When linked properly, CITI certification expiration dates will appear in Researchers' IRBManager user profile. CITI certificates will no longer need to be uploaded to IRB applications.

\*\*\*As a reminder, CUNY Researchers are required by <u>CUNY policy</u> to use their CUNY email addresses when registering for online services for CUNY research-related purposes.\*\*\*

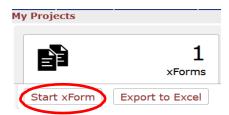
### **Step 1: Adding CUNY email to CITI User Profile**

- i. Log into the <u>CITIProgram</u> website (<u>www.citiprogram.org</u>)
- **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. Confirm that this is your current CUNY email address, or revise if needed
- **vii.** Do not forget to confirm or revise your CUNY email address in the "Please verify your preferred email address" section as well
- **viii.** If you prefer, your personal email address can be entered as Your Secondary Email Address
- ix. Click on the **BLUE** "Update" button at the bottom of the page

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

Once you've completed the process above, please follow these instructions:

- x. Log into IRBManager using your CUNYFirst login
- xi. Under "My Projects" screen (Dashboard tabs), click on the "Start xForm"



### button

- xii. Click on the "Update My Email Address" xForm
- **xiii.** Type your CUNY 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 Certificate Expiration is linked to IRBManager Account

**xiv.** Log into the IRBManager, where you will see your *Dashboard* screen



**xv.** 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 <u>HRPP Coordinator</u> if you do not see your CITI HSR expiration information in the "Expirations" page

## 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. Elements of Dashboard

<u>Home</u>	Returning user to Dashboard
<b>2</b>	Allows users to search for protocols they are associated with, based upon protocol number, principal investigator, and/or collaborators
	Menu icon that allows users to personalize their IRBManager settings
Start xForm	Allows the user to start an initial xForm or update their email address.
Export to Excel	Downloads an Excel document with information on all xForms, including when they were started and their current stage.
Notices	Updates and notices from CUNY's Research Compliance Office, when available, will be posted here
O xForms	Allows the user to view their current and past xForms
Projects	Allows the user to see all research protocols they are currently involved with
IRB 3	Allows the user to see all protocols they are involved with, within a specific committee (IRB)



Displays the number of events (submissions) the user has open (i.e. ones that have not been approved or otherwise finalized)

### iii. 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



## 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.





Being Processed At A Later Stage



**Events (Open Events)** 

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



## 4. Printing Initial Submission xForm

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

Start xForm

Then click on print icon to the left on form name. This will allow you to ii. 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".
- Once xForm has been completed please click on next and click on "I Agree" iv. checkbox and digitally sign application on Signature Page. Then click on next button.
- 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. Pl'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.

#### **Creating Initial Proxy Submissions in IRBManager** 6.

- i. On Homepage click on xForms Tab then Start XForm.
- ii. Click on Protocol Form.
- Then click "Start a New Application". iii.

- 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.
- Proxy submissions will be sent to the person listed as PI for approval prior to vii. 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. **Giving Research Team Members Edit Access to IRBManager xForms**

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

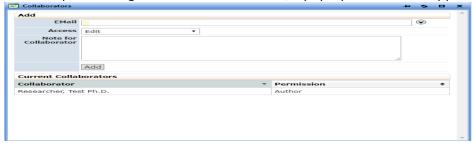




### **View xForm - Protocol Form**

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; adding a collaborator to your study does not automatically give them access to the **form** itself.

**ii.** Upon clicking the "Collaborators" link, a pop-up window will appear.



- **iii.** Enter the email address of the user you would like to grant access to the form (Note that the email address added should be a CUNYFirst email address <u>john.doenumber@login.cuny.edu</u>). The user must already have a Contact established within IRBManager to be added as a Collaborator.
- iv. Select the access rights you wish to grant
  - 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.

## 8. 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.

## 9. Creating Continuing Review XForms in IRBManager

 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.
- Once xForm has been completed please click on next and click on "I iv. Agree" checkbox and digitally sign application on Signature Page. Then click on next button.
- Then click on the Submit button to submit the application to the campus HRPP Office.
- Student PI submissions will be sent to their faculty advisor for vi. approval prior to submission to the campus HRPP office.

#### 10. **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.
- Then click on the Submit button to submit the application to the campus HRPP Office.
- Student PI submissions will be sent to their faculty advisor for vi. approval prior to submission to the campus HRPP office.

#### 11. 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.

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

- On Homepage click on Projects Tab then select Protocol Number of Project.
- Click on the two sheets under Reference xForms in middle of page. ii.
- 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.
- Then click on the Submit button to submit the application to the campus ٧. HRPP Office.

#### **Reminders:** vi.

- 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.

#### **13.** Creating HRPP IRB of Record XForms in IRBManager

- i. Please consult with your campus HRPP Coordinator to inquire as to whether 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.

#### 14. 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. Pl'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.
- 9. Researchers may also obtain assistance from staff at CUNY Central. Please coordinate this process with your campus HRPP Office.

#### **15. 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 (i.e. approval/signature) by selecting xForms tab then clicking on Awaiting your Attention button on their dashboard.

#### **16.** Information Requested by the IRB Office

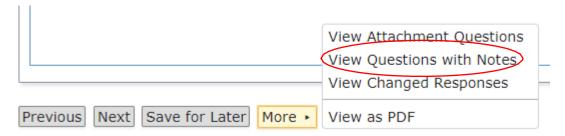
- The xForm may be returned during the pre-review or IRB Review Process for additional information requested by the **HRPP** Coordinator Office
- ii. An email will be sent to the submitter, PI, and Faculty Advisor informing them that protocol is being sent back for revisions by the HRPP Coordinator Office.
- 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.
- ٧. 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

### 17. 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.

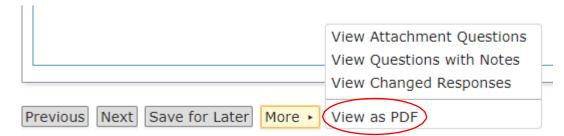


- ii. Notes are not retained when an IRB Application xForm is copied for amendment. Therefore, notes do not replace complete responses to questions or within application fields. Any information pertinent to the IRB Application must be incorporated into relevant application fields.
  - **iii.** An option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



## 18. Creating PDF of Completed IRB Application

- 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.



## 19. Uploading Documents as Attachments

- i. Each attachment should only contain <u>one</u> 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.

## 20. 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.

## 21. Deleting xForms

- i. xForms can only 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.

## 22. 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:
  - PI's name (if different than Submitter)
  - Protocol Number
  - o Protocol Title
  - Event Type (i.e., Initial Submission, Amendment, Continuing Review, etc.)

## 23. Locating Approved Information and Materials

All study information and files are stored within IRBManager. When a user clicks on the study ID from the dashboard, they will be routed to the study page, which contains all basic study information (title, sponsor, status, approval date, expiration date, collaborators, etc.). Attachments and xForms for each study can be accessed within the relevant event (i.e. initial submission, modification, historical attachments, continuing review, etc.).

Researchers can locate their xForm and attachments for their individual studies via the following series of steps:

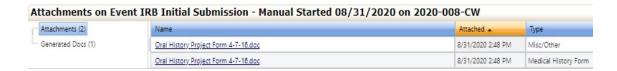
1. Starting at the user dashboard, click on the study ID



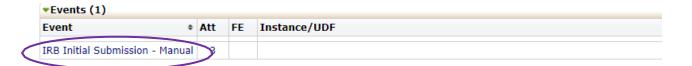
2. Navigate to the Events section on Protocol Front Page



- 3. To quickly see any uploaded attachments that are part of the study, click the number under the "Att" column
- 4. The following screen will appear. To view an attachment, simply click on the title/name of file.
- 5. IRB Approval Letters are in "Generated Docs" sub-tab.



- 6. To view/download documents click on the blue link under "Name".
- 7. To see any xForms, or for an alternative way to view attachments, click on the title of the event.



8. In the Actions menu located on the left side of the Event page, select either xForms (to view any xForms associated with the protocol event) or Attachments (to view any attachments that were uploaded).

