IRBMANAGER – USER GUIDE

Los Angeles County Dept. of Public Health

Institutional Review Board

Table of Contents

You can navigate directly to a section by clicking on the links below (press Ctrl + Click link).

Revised: September 2024

Overview of IRBManager application process

Start new application → **Data Entry**

Application submitted → **PI signature**

- Changes can only be made to an application during the **Data Entry** stage

Co-PI signature⁺

DPH/DHS liaison signature⁺

⁺Not required for all projects

Division Director Signature

Screening for Completeness

IRB Review*

Approval

Project activities can begin

- During the **Screening for Completeness** stage, IRB staff check the application to make sure it is complete. If IRB staff identify any issues during this stage (e.g., missing documentation of RATE review, documents containing internal comments, expired training certifications, etc.), the application is returned to the **Data Entry** stage so that the submitter can make the necessary changes.

- Once the requested changes have been addressed and the application is re-submitted, it goes through the signature stages again until it returns to the **Screening for Completeness** stage where it is checked again. This process can happen multiple times before the application is ready to move to the Review stage.

*In the **IRB Review** stage, the project undergoes an ethical/regulatory review to ensure the project meets federal regulations and DPH IRB policies. If any aspects of the application require clarification and/or modification ("stipulations"), the application will be returned to the **Data Entry** stage so that stipulations can be addressed. The application must then be re-submitted through the IRBManager system for review and approval.

(Rev. July 1, 2024)

# Section 1: Accessing IRBManager

> Please click on the link below to access the IRBManager login page.

**IRBManager login link***: https://lacdph.my.irbmanager.com/

New Users: If this is your first time trying to log into IRBmanager and you are an LA County employee, please try logging into IRBManager using your County email address and password. If you are not an LA County employee and/or a contact has not yet been created for you, you will need to register for a user name and password before you can access the system. Click on the link that says *Click here to register* (as indicated in the image below) and on the subsequent screens enter the required information to complete the registration process.
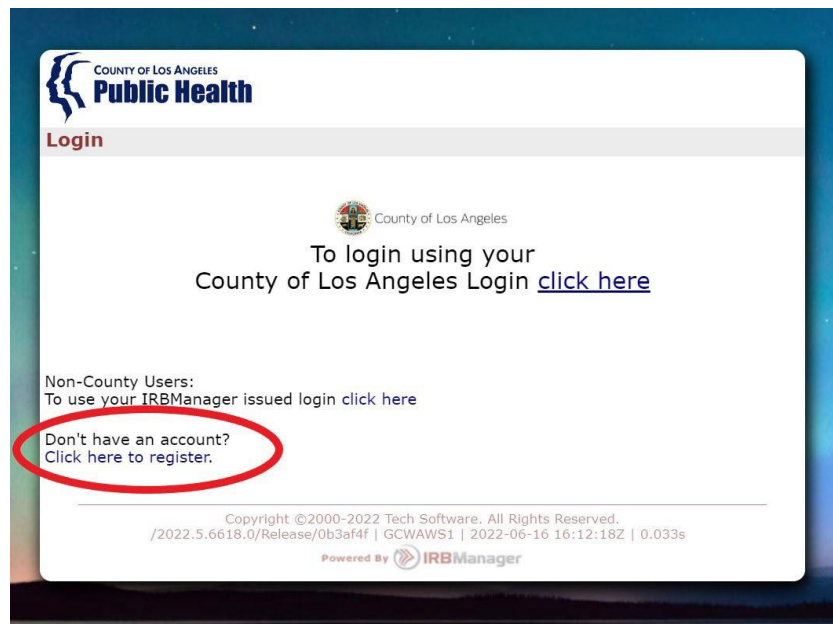
> If a contact was created for you (either by IRB staff or by someone working on an application), you do not need to complete the new user registration process again. You will receive an email notification when someone has created a contact for you. Proceed to the login page and use your email address as your username; make sure the email address matches the address that was used to create your contact. You will be prompted to enter a password.

4

Logging in for LA County users

> ➢ Log in using your County credentials (email address and password).
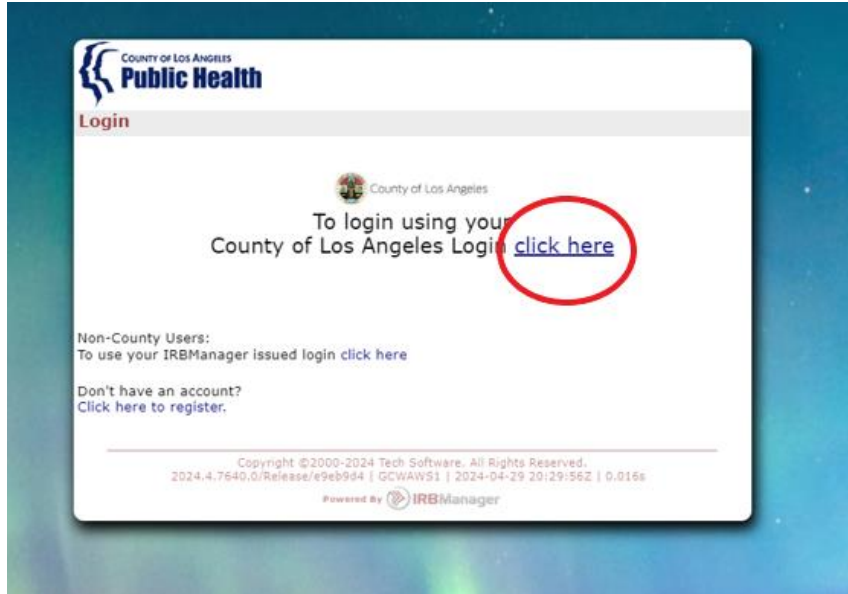
> ➢ Please follow the security prompts to successfully login.

Revised: September 2024
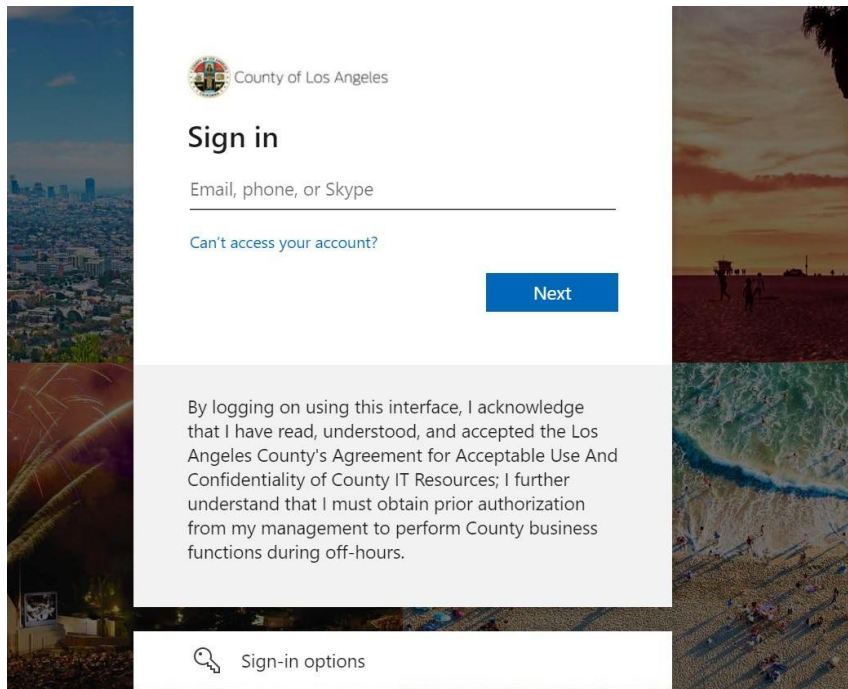
Logging in for Non-LA County users

➢ Non-County users (i.e, users who are not County staff) will need to click on the link in the bottom left of the screen in order to log in (as indicated in the image below).
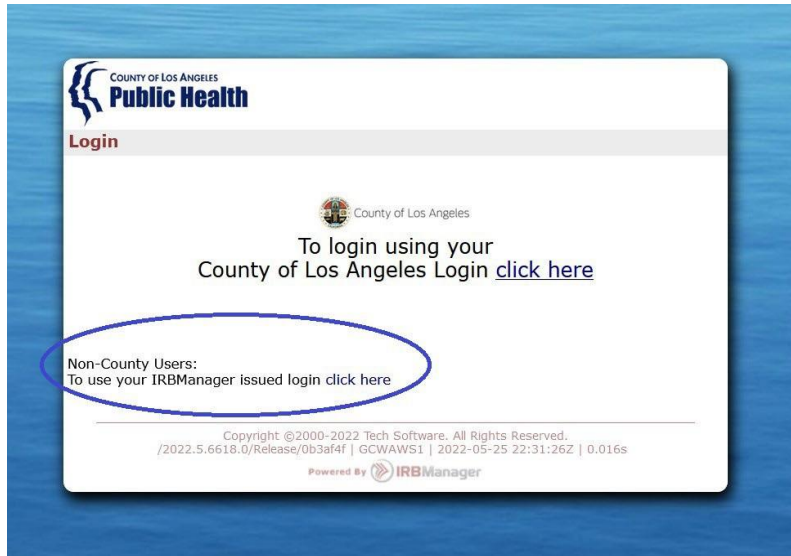
➢ On the next screen, you will need to enter your **User Name** and **Password**. If you need to reset your password, click on *Forgot Password?* and follow the steps to change your password.

6
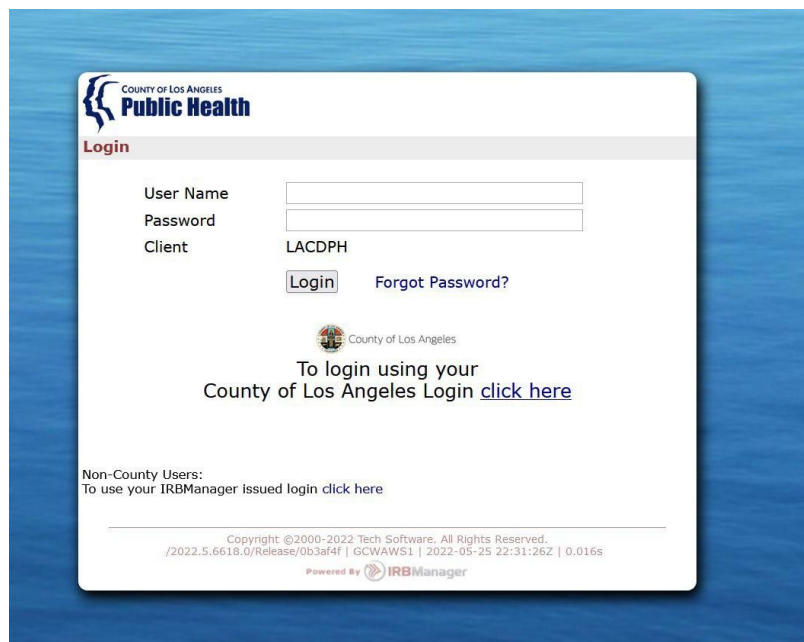
Please contact IRB@ph.lacounty.gov if you encounter any trouble logging into IRB Manager. If possible, please include screenshots of any error messages to help IRB staff troubleshoot the issue.

Section 2: Navigating Your Dashboard

➢ Once you have successfully logged in you will be automatically taken to your dashboard. Your dashboard may appear slightly different than the image below, but the basic functions noted throughout this guide will be available.

➢ From the dashboard, you can access any IRB projects you are associated with (i.e., listed as PI, Co-PI, Division Chief/Program Manager, DPH/DHS liaison, program coordinator, point of contact, and/or key personnel). You can also start a new IRB application (see Section 3), start an amendment application for requesting changes to approved projects, and/or submit reports such as continuing review requests, annual progress reports, final reports, and adverse event reports (see Section 6 for assistance with submitting amendment applications and reports).
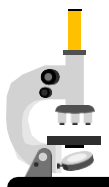
Let's take a closer look at the features available on your Dashboard.

➢ From the **IRB** tab (see the image below) you can view your approved projects (both active and inactive/closed projects). Click on the IRB # for a particular project to open the project details page.

➢ The **xForms** tab lets you view any applications/reports you are currently working on. You can view forms that have already been submitted (but not yet approved) as well as forms that have been started but not submitted.

➢ The **Events** tab lets you view any items that require your attention such as Annual Continuing Review due dates or expiration dates for studies whose approval period is coming to an end.

➢ The tiles indicated in the screenshot below are filters that allow you to view certain projects depending on the filter. Different filter tiles will be available depending on the tab that is selected. In the image below, the IRB tab is selected and the filter tiles let you filter your projects by your role (i.e., Co-Investigator, etc.).

Revised: September 2024

➢ The buttons indicated in the image below allow you to complete various tasks directly from the dashboard. However, if you would like to submit an application for an already approved project, you will not be able to do so using these buttons. You will need to open the project details page for that particular project and start an application from there (see Section 6).
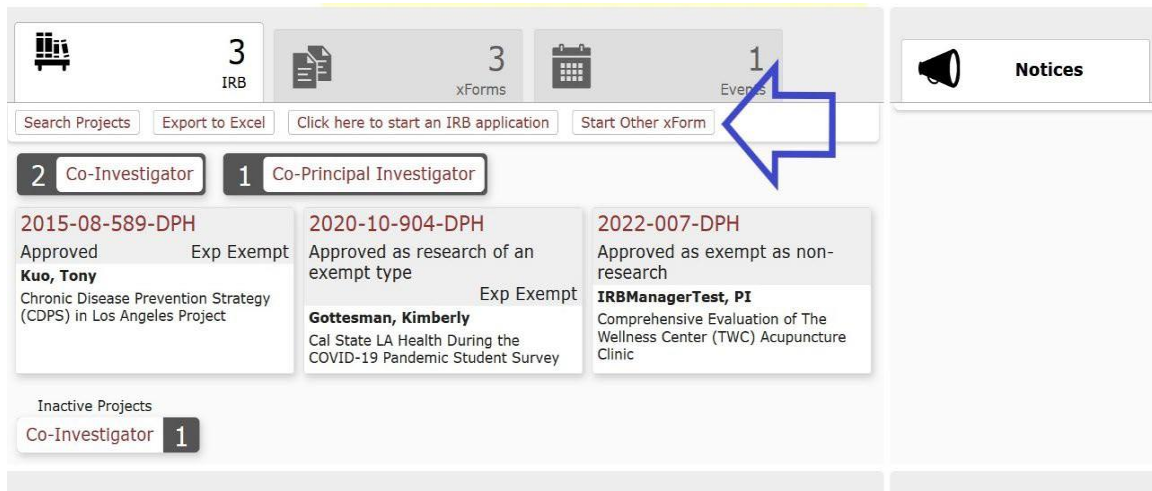
➢ The *Export to Excel* function will generate an Excel spreadsheet that displays your projects and their associated project details.

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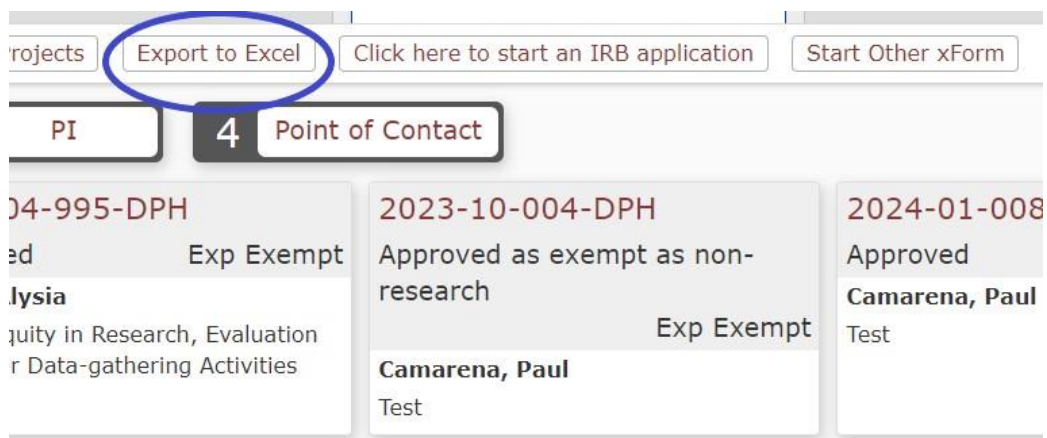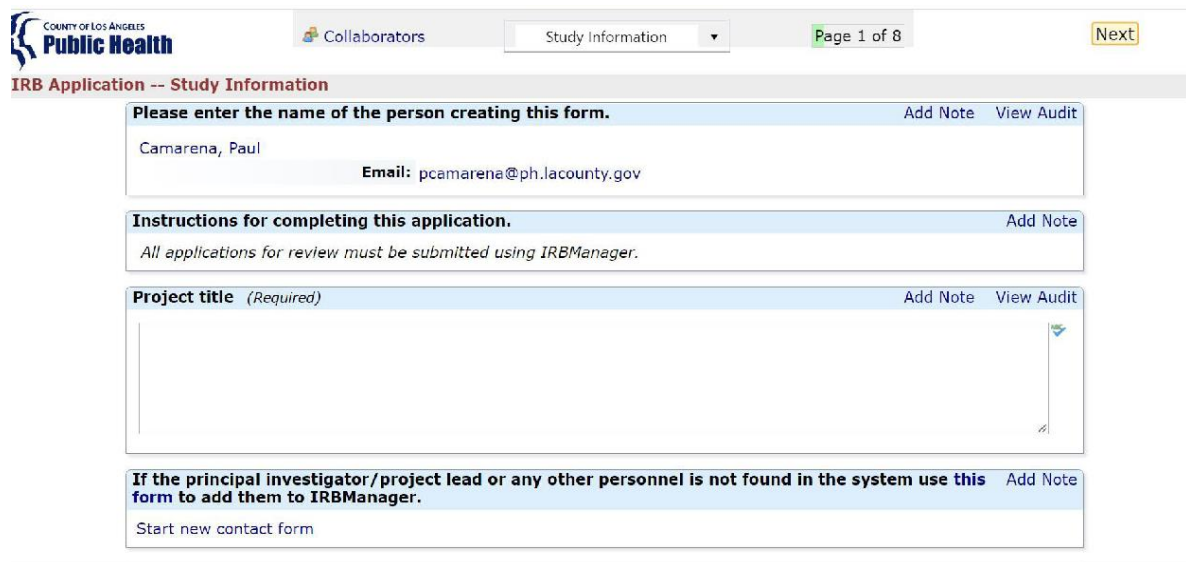
SECTION 3. SUBMITTING A NEW IRB APPLICATION

➢ If you would like to start a new **IRB Application**, make sure the IRB tab is selected on your dashboard and click on the button that says *Click here to start an IRB application* (see the image below).

➢ A new page will open with a blank IRB application. Please enter the required information and upload supporting documents in the spaces provided.

➢ Please ensure that supporting files are labeled in a way that makes them easily identifiable and that they are uploaded in the appropriate sections of the application.

➢ Please delete any files that are no longer needed. You can delete existing attachments by clicking on the red "X" next to the attachment.
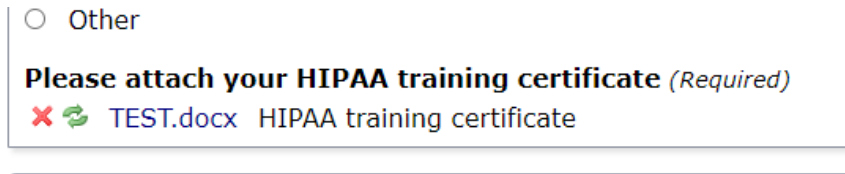
➢ Some questions require a response and you will not be able to navigate to the next page using the Next button (bottom of the page) without providing an answer to those questions. If you would like to navigate between the different pages of the application without answering all required questions on a page, you can use the dropdown menu at the top of the page (as indicated in the image below).
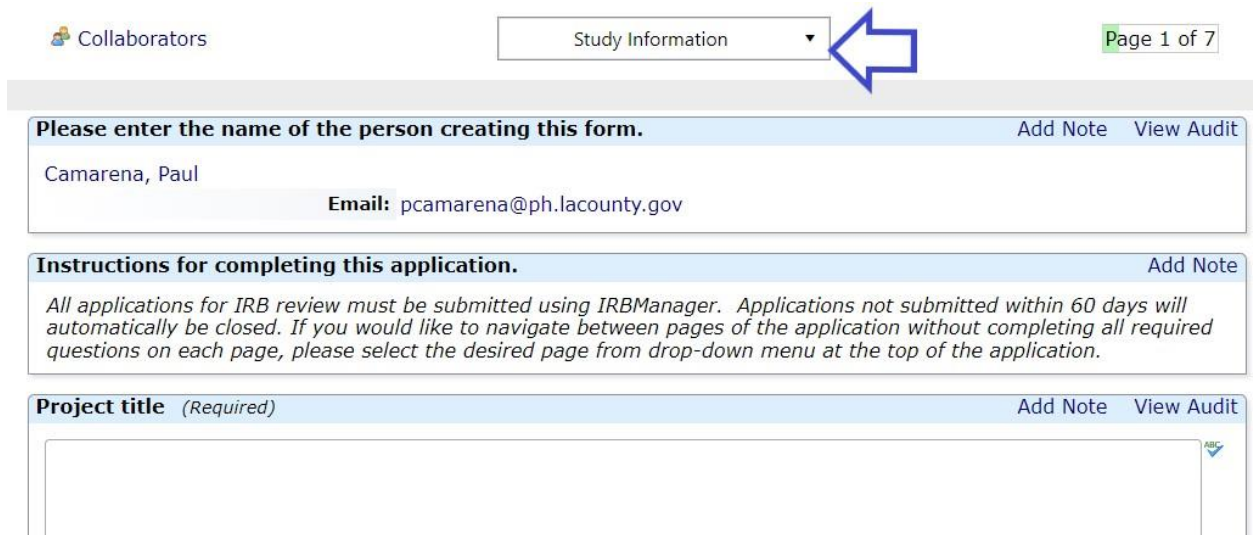
➢ Clicking on the dropdown menu will allow you to select the specific page of the application you would like to open. Any information you have entered on the application will be saved when navigating between the pages using the dropdown menu.

➢ If you would like to save the application and continue working on it at a later time, click on the "Save for Later" button at the bottom of the page.

➢ If you would like to download your application as a PDF, click on the "More" button at the bottom of the page and select "View as PDF" – a PDF file will begin to download.

13

SECTION 4. CREATING A NEW CONTACT

➢ Each person who will be added to an application must have a contact in the IRBManager system. You can create a contact in two ways: from your dashboard when you first log in, or by clicking on the "Start new contact form" button directly from an open application.

➢ To create a contact from your dashboard, click on "Start xform" (make sure the *xforms* tab is selected) and you will be taken to the screen shown below. Click on "Create new contact" to open the *new contact details* page.

Select xForm to start		
Action	**Form (Click to start)** ▾	**Description**
🖨	Create new contact	Create new contact
🖨	IRB Application	IRB Application

➢ Enter the required information and click "Next" at the bottom of the xform to submit the new contact request.

Create new contact -- New contact details

Form creator		Add Note	View Audit
Camarena, Paul			
Email: pcamarena@ph.lacounty.gov			

Please enter the email address for the user you wish to add. *(Required)*   Add Note   View Audit

New contact information   Add Note   View Audit

Please fill out the questions for the person you're creating the contact for.

Prefix *(Required)*
i.e., Mr., Ms., Dr., Professor

First name *(Required)*

Last name *(Required)*

➤ To create a contact from an open application, you can click on the "Start new contact form" button which is found just before the section where you are asked to name the Principal Investigator (PI)/project lead for the project. You can click this button multiple times if you need to create multiple contacts.


➤ Clicking on "Start new contact form" will open the *new contact details* page. Enter the required information and click "Next" at the bottom of the xform to submit the new contact request.

SECTION 5. CHANGING SETTINGS AND LOGGING OFF

➤ If you would like to change settings or sign off from IRB Manger, click on the person icon in the upper right-hand corner of the dashboard. Your menu may look slightly different than the image but the *settings* and *sign off* functions will be present.

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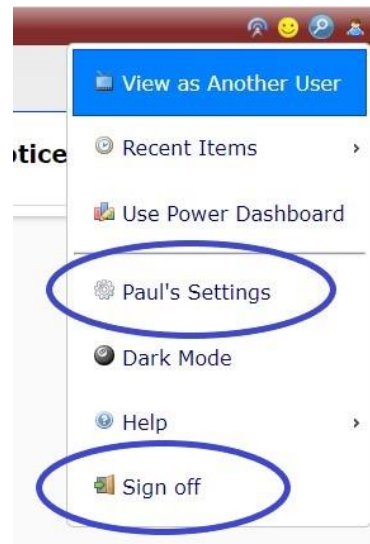
Section 6. Creating Amendments, Annual Status Reports, and Annual Continuing Review Requests

➤ From your Dashboard, select the project for which you are submitting an amendment.

Please note: If the project for which you would like to submit an amendment, annual status report, or annual continuing review request is not in the system, please contact the IRB.

➤ On the *project details* page, click on "Start xForm" from the left- hand side.

Revised: September 2024

- On the next page, select either "Amendment application" or "Annual Progress Report" to begin the desired xForm.


- Complete the desired application by responding to all questions and uploading all required documents. When you reach the end of the application, click "Submit" to move the xForm to the next stage.

FINAL REPORTS: to submit a final report, start by opening the annual progress report xForm. When asked to indicate the current study status, select the "Study completed, attach final report" option. Proceed to answer the remaining questions. You will be prompted to upload a final report near the end of the application.

SECTION 7. DELETING XFORMS

- xForms can only be deleted during the *Data Entry* stage (i.e., prior to being submitted for review). To delete an xForm, click on the xForms tab and then select the "unsubmitted forms" filter.

- Scroll your mouse on the xForm you would like to delete and click on the red "X" to complete the deletion (shown below).
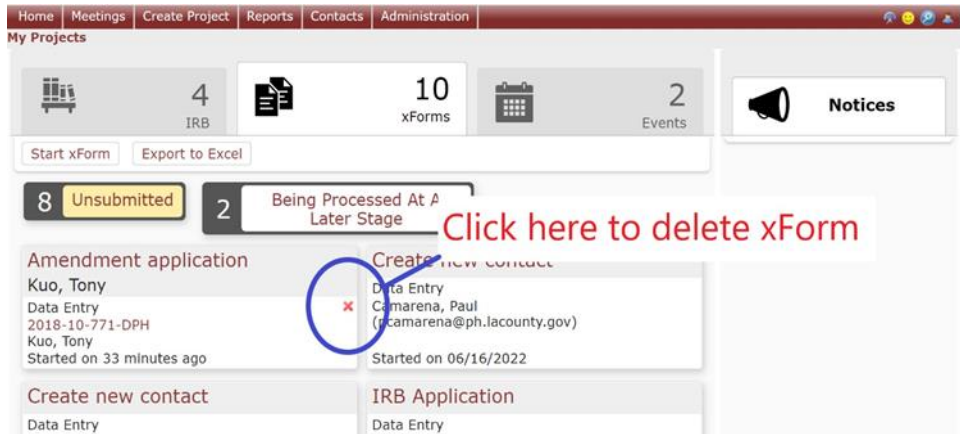
SECTION 8. UPLOADING DOCUMENTS AS ATTACHMENTS

➢ Each attachment should only contain one document type (e.g., recruitment letter, informed consent document, survey, etc.) For instance, when uploading data collection materials, do not include or attach consent or recruitment documents.

➢ If more than one type of data collection materials will be used (e.g., a survey, an interview script, etc.), upload each document separately.

➢ Please follow these instructions for attaching documents in xForms:

  o Click the Add Attachment button to open a pop-up window on screen
  o Click Select files to browse for the document you wish to attach
  o Click the Attach button - the window will auto-close and attach the document to your application

SECTION 9. INFORMATION REQUESTED BY THE IRB

➢ Your application may be returned to you during the pre-review or IRB review process with a request for additional information and/or revisions.

➢ An email will be sent to the xForm creator and study PI/project lead informing them that their application is being sent back for additional information and/or revisions.

18

- o Please click on the BLUE link provided in the email to navigate directly to your application. If you are not logged in to IRB Manager, you will be prompted to do so.
- o Items that require attention can be viewed by selecting the xForms tab and then clicking on the "Awaiting your Attention" filter.

➢ Once revisions are completed, please sign and submit the application to move it on to the next stage

SECTION 10. CHECKING THE STATUS OF YOUR APPLICATION

➢ To view the status of an application, navigate to your dashboard. On your dashboard, click on the *xForms* tab.
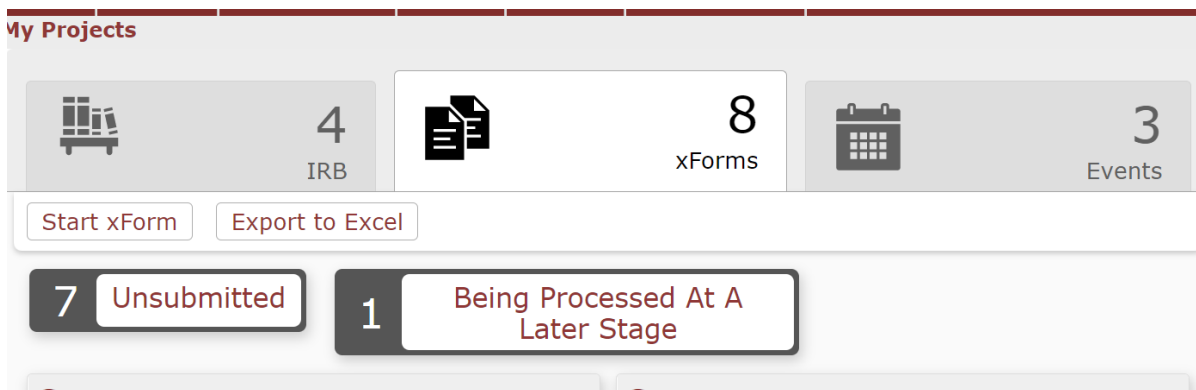
➢ Next, select the "Being Processed At A Later Stage" filter tile (see the image above). This will filter your existing xForms to display projects that are in a stage of review by the IRB and do not require your immediate attention.

➢ Clicking on the "Unsubmitted" filter tile will filter your existing xForms to display forms that have not yet been submitted to the IRB.

Revised: September 2024

SECTION 11. UPDATING YOUR PROFILE INFORMATION

➢ All users should make sure their profile information, including name and degree(s), is correct. To update your profile information, click on the person icon in the top right corner of your dashboard (see image below) and select "Settings" to go to the next page.

➢ On the *Settings* page, select "Change My Profile" (see image below).

➢ On the *Change My Profile* page (see image below), please make sure your name, degree, and email address are correct. If you need to make corrections, update your information on this page and then click the "Update" button at the bottom of the page.

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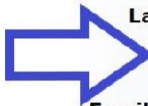
Section 12. Reporting an Unanticipated/Adverse Event

➢ From your dashboard, click on the IRB # of the study that pertains to the unanticipated/adverse event. Clicking on the IRB # hyperlink will open the study details page.

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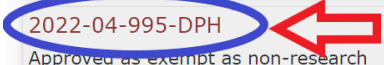
➢ On the study details page, click on "start xForm" from the menu on the left-hand side of the page.

➢ On the following screen you will be presented with a list of forms. Please select the "Unanticipated/Adverse Events Form" by clicking on the hyperlink to open the form.

➢ Respond to the questions in the form and click "Submit" at the bottom of the page.

Section 13. Viewing Attachments from Past Applications

Revised: September 2024

➢ If you would like to view any supporting documents from past applications, first open the project details page by clicking on the desired project from your dashboard (screenshot below).

➢ On the project details page (screenshot below), scroll down to the "Events" section. Here you can find a list of all events (i.e., applications that have been approved) for this project.

➢ From the list of events, find the application for which you would like to download the attachments. Click on the number next to the name of the application to view the attachments that were included with the application (screenshot below).

➢ On the next page, you can download an attachment by clicking on the file name. Files will be downloaded to your local computer by default.

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