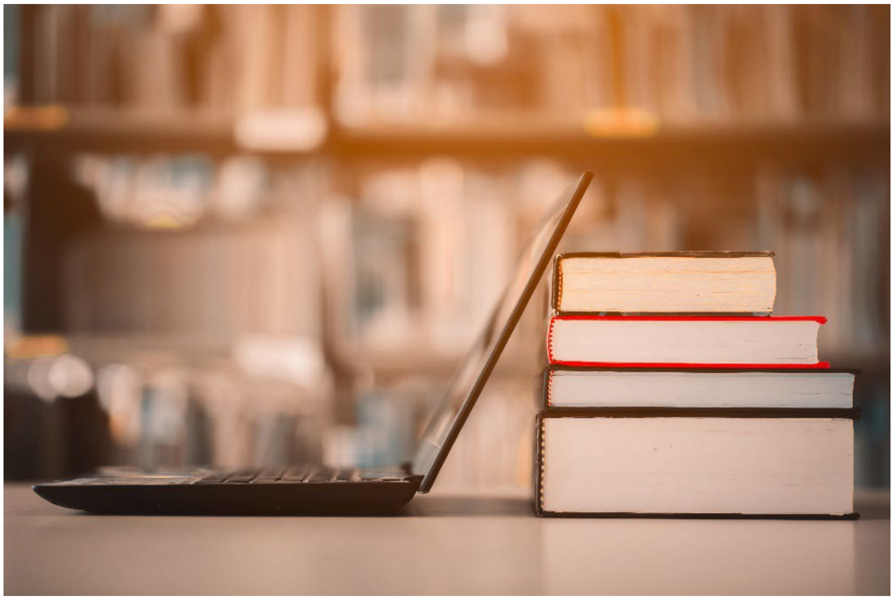
IRBManager – User Manual

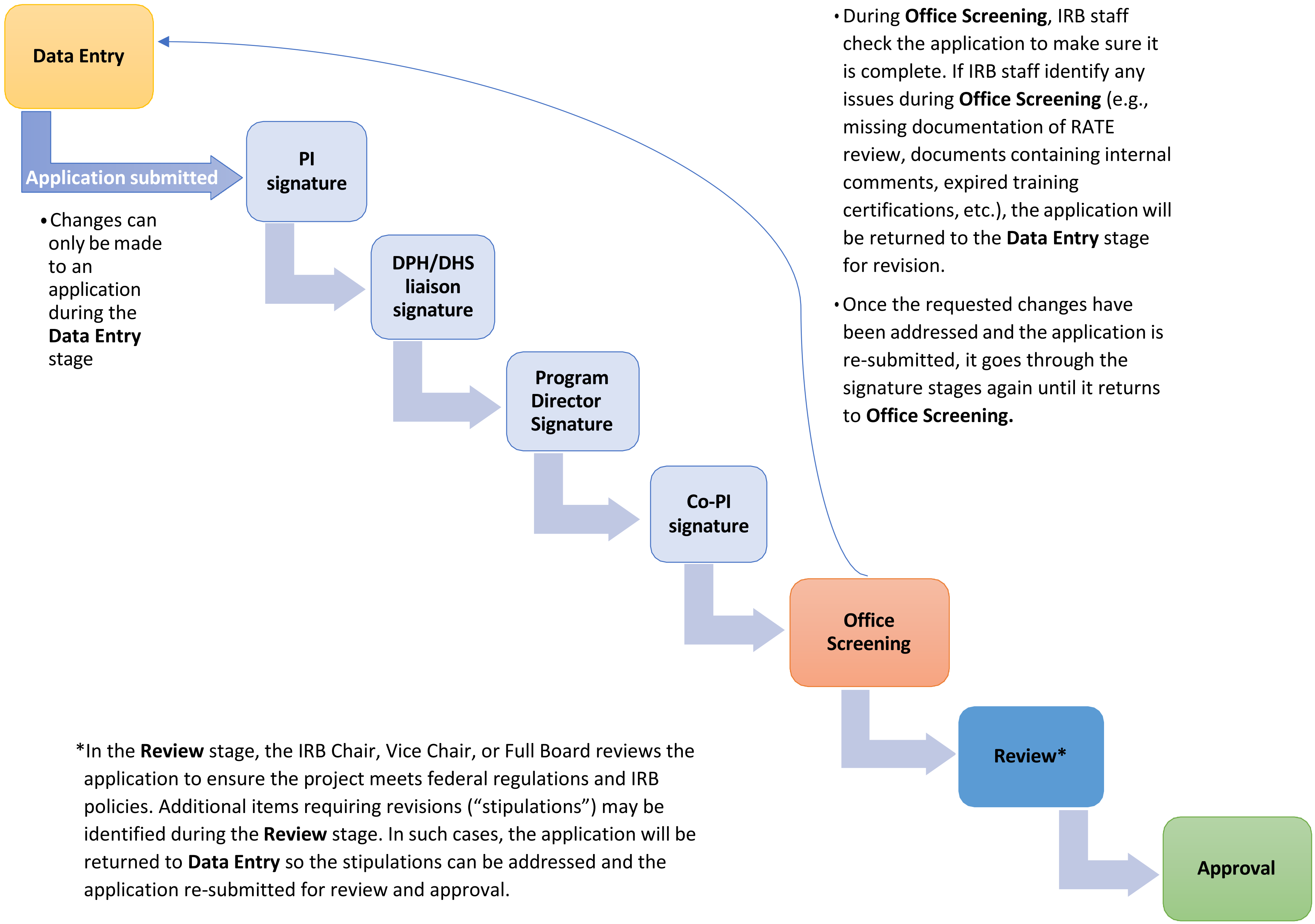


Los Angeles County Dept. of Public Health

Institutional Review Board

Table of Contents

Overview of the IRBManager application process



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

- During **Office Screening**, IRB staff check the application to make sure it is complete. If IRB staff identify any issues during **Office Screening** (e.g., missing documentation of RATE review, documents containing internal comments, expired training certifications, etc.), the application will be returned to the **Data Entry** stage for revision.
- Once the requested changes have been addressed and the application is re-submitted, it goes through the signature stages again until it returns to **Office Screening.**

*In the **Review** stage, the IRB Chair, Vice Chair, or Full Board reviews the application to ensure the project meets federal regulations and IRB policies. Additional items requiring revisions ("stipulations") may be identified during the **Review** stage. In such cases, the application will be returned to **Data Entry** so the stipulations can be addressed and the application re-submitted for review and approval.

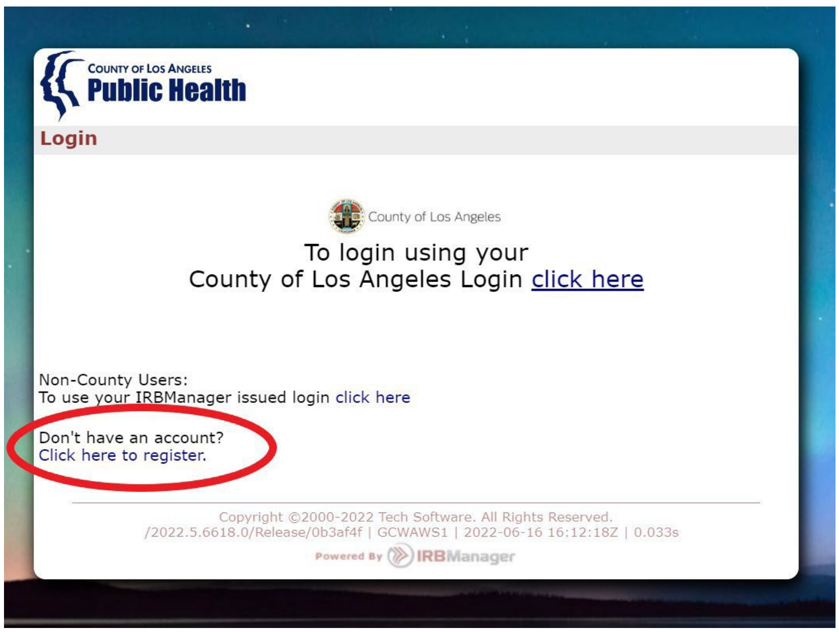
(June 30, 2023)

Section 1: Accessing the System

- Please click on the link below to access the IRB Manager login page.

  IRB Manager URL: https://lacdph.my.irbmanager.com/

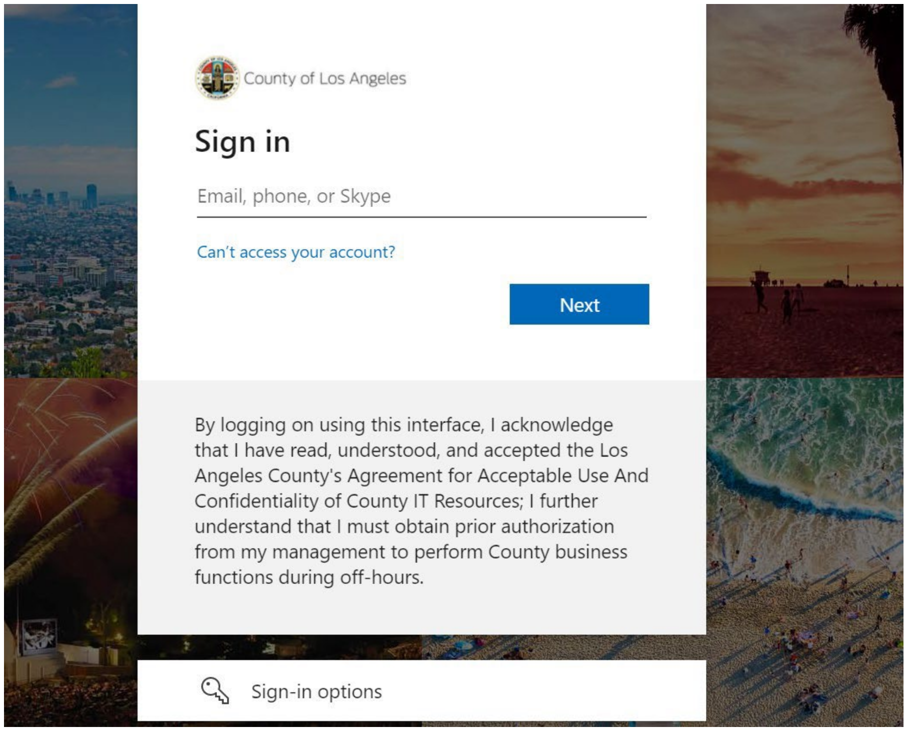
New Users: If this is your first time accessing the system and a contact has not already been created for you, you will need to register for a user name and password before you can access the system. Click on the link that says *Click here to register* (as indicated in the image below) and on the subsequent screens enter the required information to complete the registration process.



- If a contact was created for you (either by IRB staff or by someone submitting an application), you do not need to complete the new user registration process again. Proceed to the login instructions and use your email address as your username; you may need to confirm the email address that was entered with whomever created your contact.

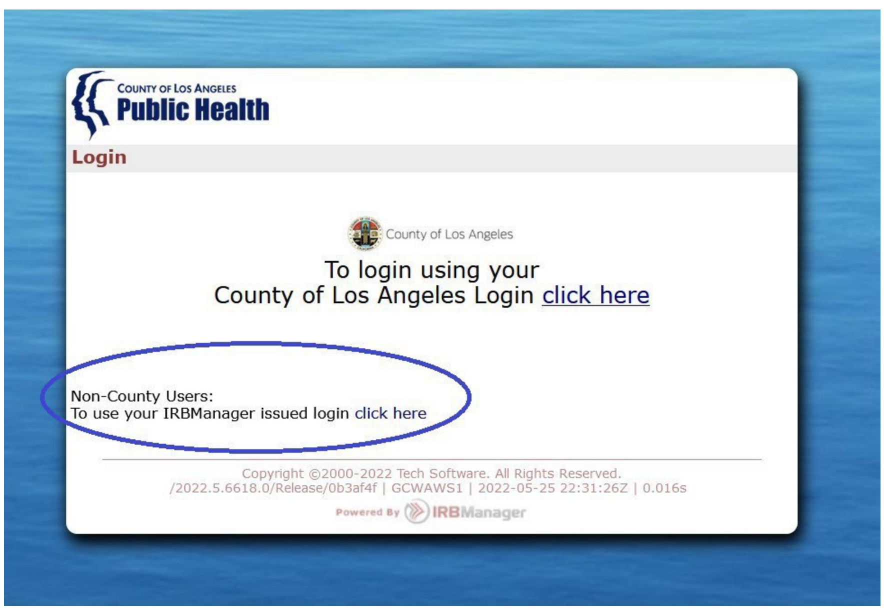
For LA County users

- Log in using your County SSO credentials (email address and password). Please follow the security prompts to successfully login. If you need to reset your password, click on *Can't access your account?* and follow the steps to change your password.

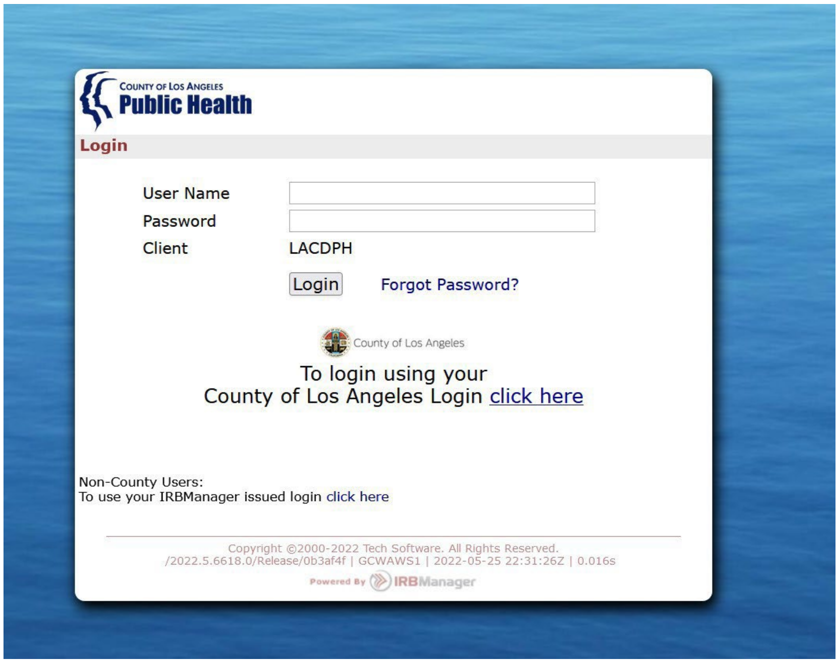


For Non-LA County users

- 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).



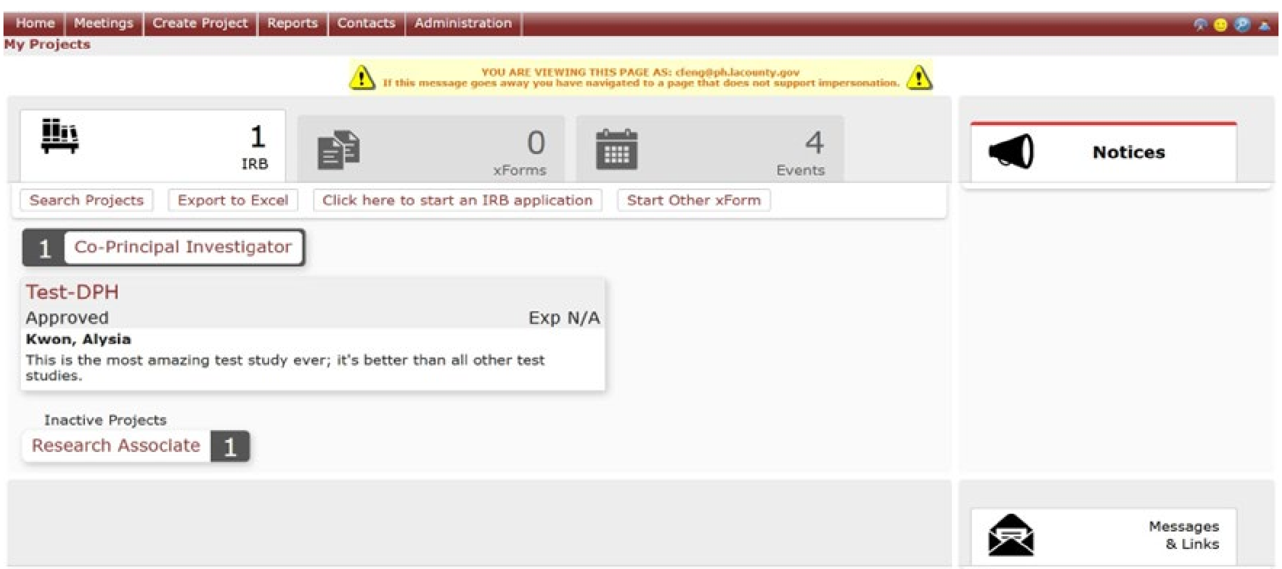
- On the next screen, you will need to enter your **User Name** and **Password**. If you need to reset your password, click on *Forgot Password?* and follow the steps to change your password.



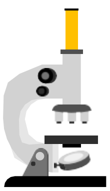
Please contact IRB@ph.lacounty.gov if you encounter any trouble logging in to IRB Manager. If possible, please include screenshots of error messages, etc., to help IRB staff better troubleshoot the issue.

Section 2: Navigating Your Dashboard

- Once you have successfully logged in you will be automatically taken to your IRB Manager dashboard. Your dashboard may appear slightly different than the images below, but the basic functions noted throughout this manual will be present.

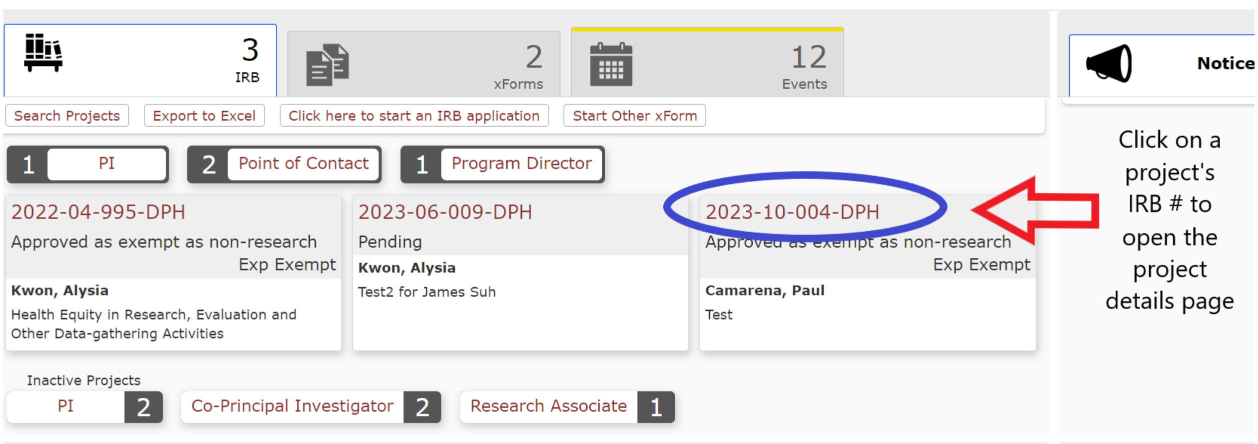


- From the dashboard, you can access all IRB projects you are associated with (i.e., listed as PI, Co-PI, Division Chief/Program Manager, DPH/DHS liaison, program coordinator, point of contact, and/or key personnel). If you have submitted any pYou can also submit IRB applications for new projects, submit amendment requests for approved projects, and upload reports (continuing review/annual and study closeout).



Let's take a closer look at the features available on your Dashboard.

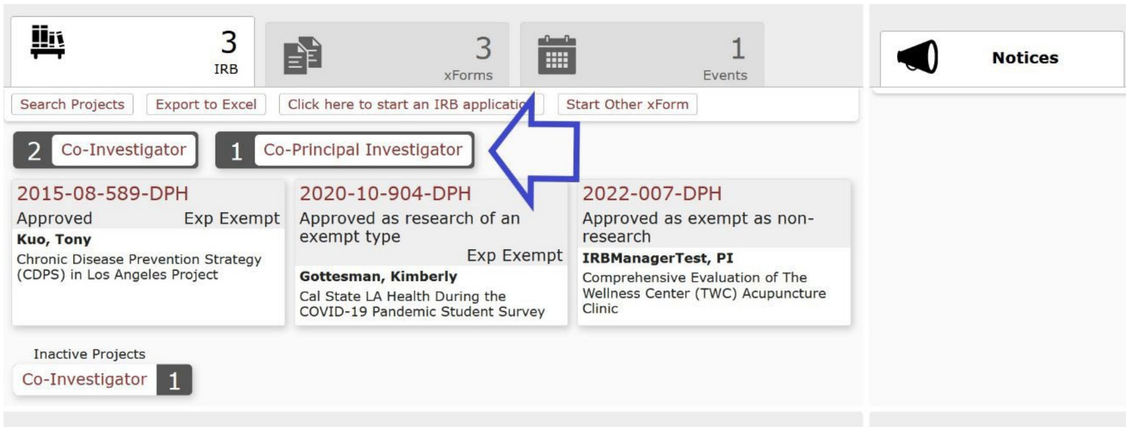
- From the **IRB** tab (see the image below) you can view your projects (both active and inactive/closed projects). Click on the IRB # for a particular project to open the project details page.



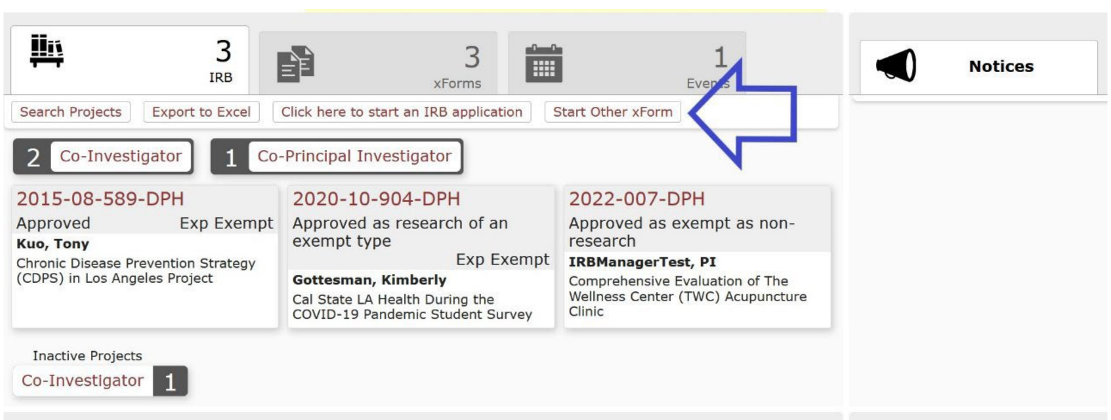
- The **xForms** tab lets you view any applications you have initiated in the system such as *IRB Applications* and *Create new contact* forms. You can view forms that have already been submitted as well as forms that are still in progress.

- The **Events** tab lets you view any events you have open (i.e., 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 image below are filters that allow you to filter the projects that are displayed. Different filter tiles will be available depending on the tab that is selected. In the image below, the IRB tab is selected so the buttons let you filter your projects by your role (i.e., Co- Investigator or Co-Principal Investigator).



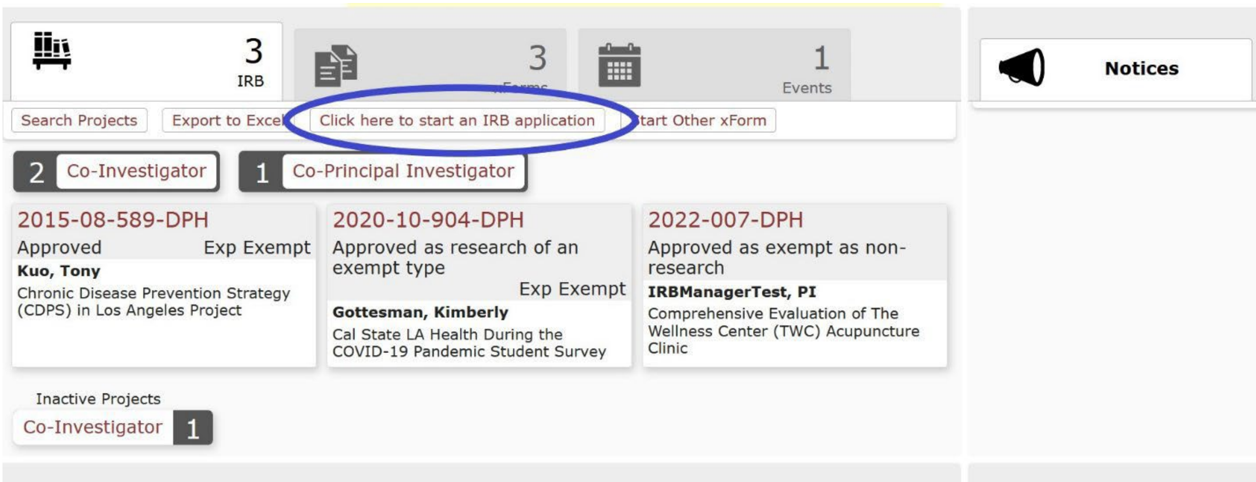
- The buttons indicated in the image below allow you to complete various tasks directly from the dashboard. However, if you would like to submit an application for an already approved project, you will not be able to do so using these buttons. You will need to open the project details page for that particular project and start an application from there (explained in later sections of this manual).



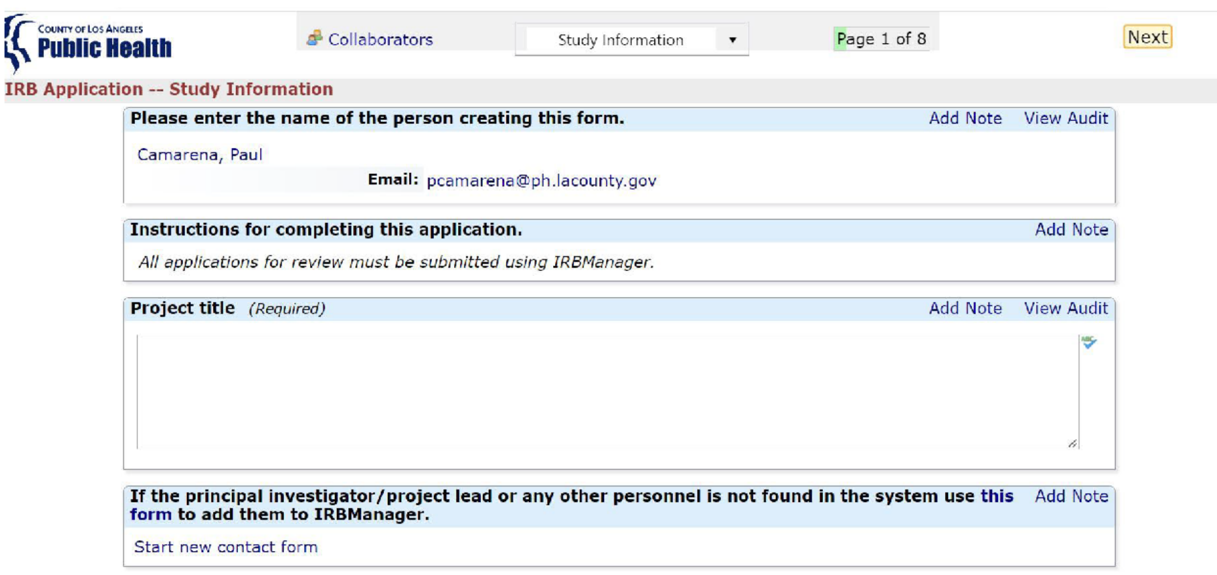
- The *Export to Excel* function will generate an Excel spreadsheet that displays your projects and their associated project details.

Section 3. Submitting a new IRB Application

- If you would like to start a new **IRB Application**, please click on the *Click here to start an IRB application* button (circled in the image below).

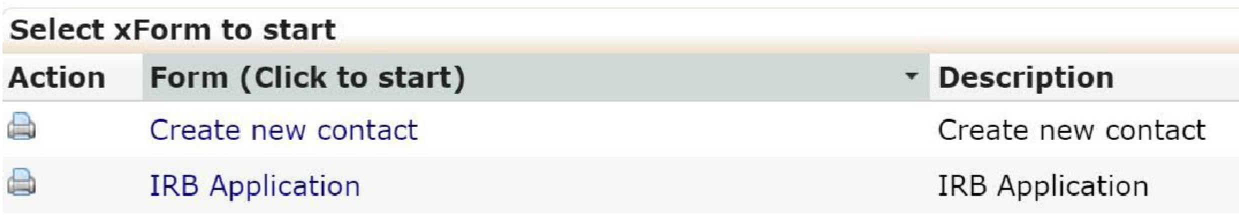


- A new page will open with a blank IRB application (see image below). Please enter the required study information and follow the prompts to submit your application for IRB review.

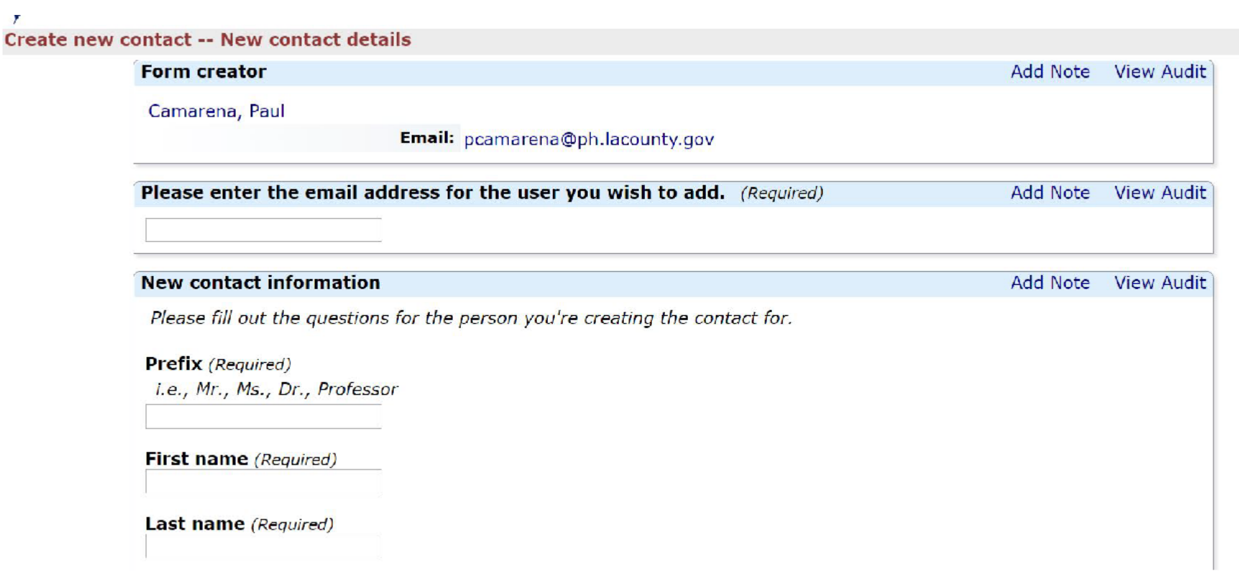


Section 4. Creating a New Contact

- 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 enter the new contact details page.

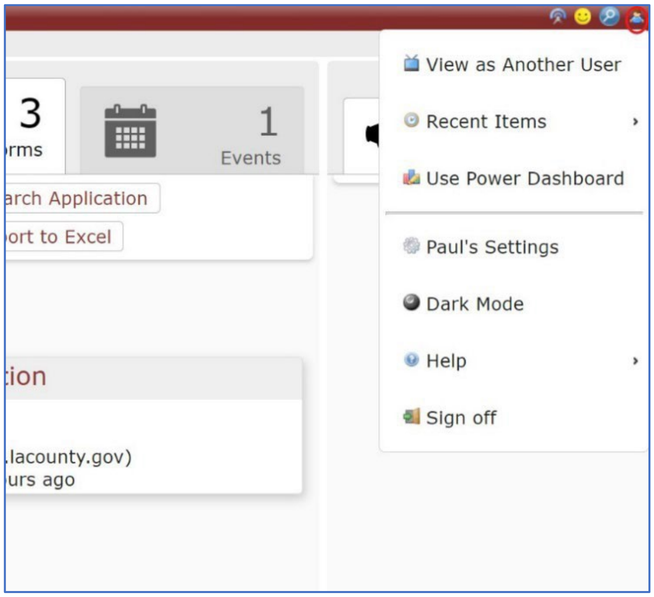


- Enter the required new contact information and click Next at the bottom of the xform to submit the new contact request.



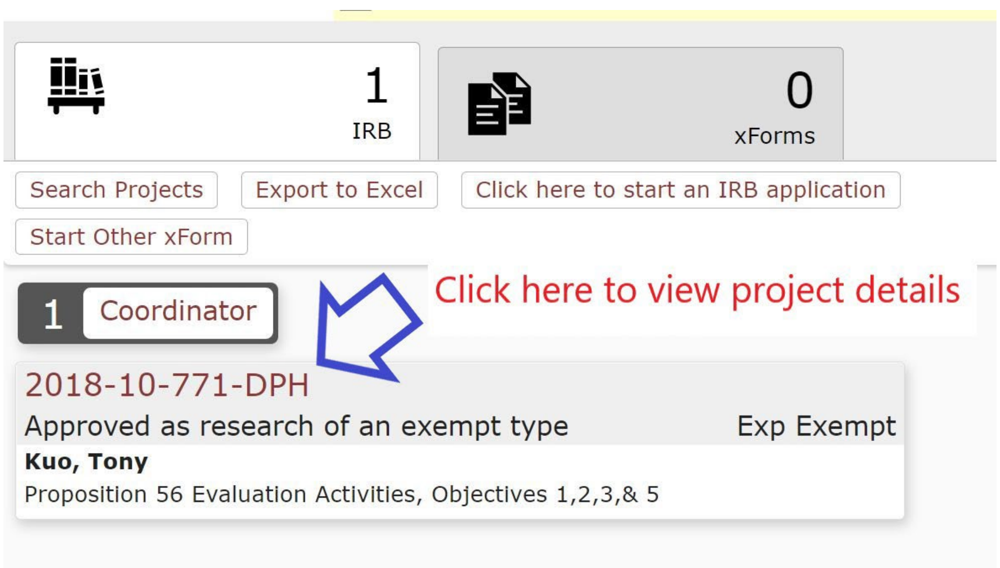
Section 5. Changing Settings and Logging Off

- 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.



<u>Section 6. Creating Amendments, Annual Status Reports, and Annual Continuing Review Requests</u>

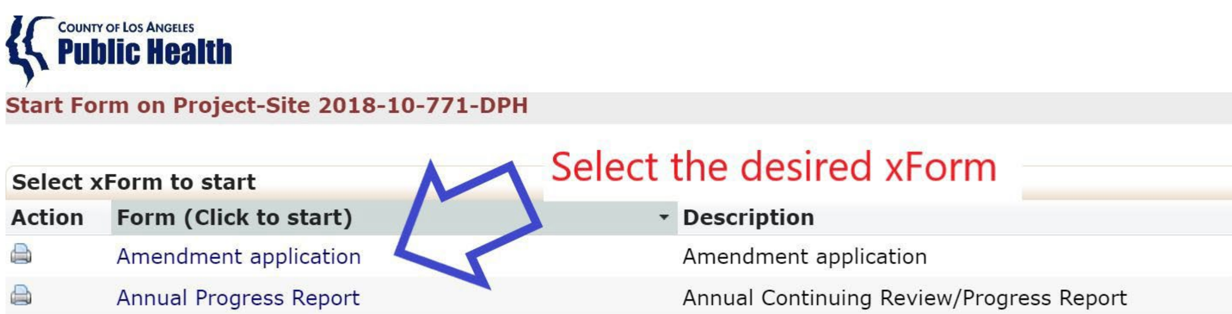
- On your Dashboard, select the project for which you are submitting an amendment.



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 **Actions** menu on the left-hand side to proceed.

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



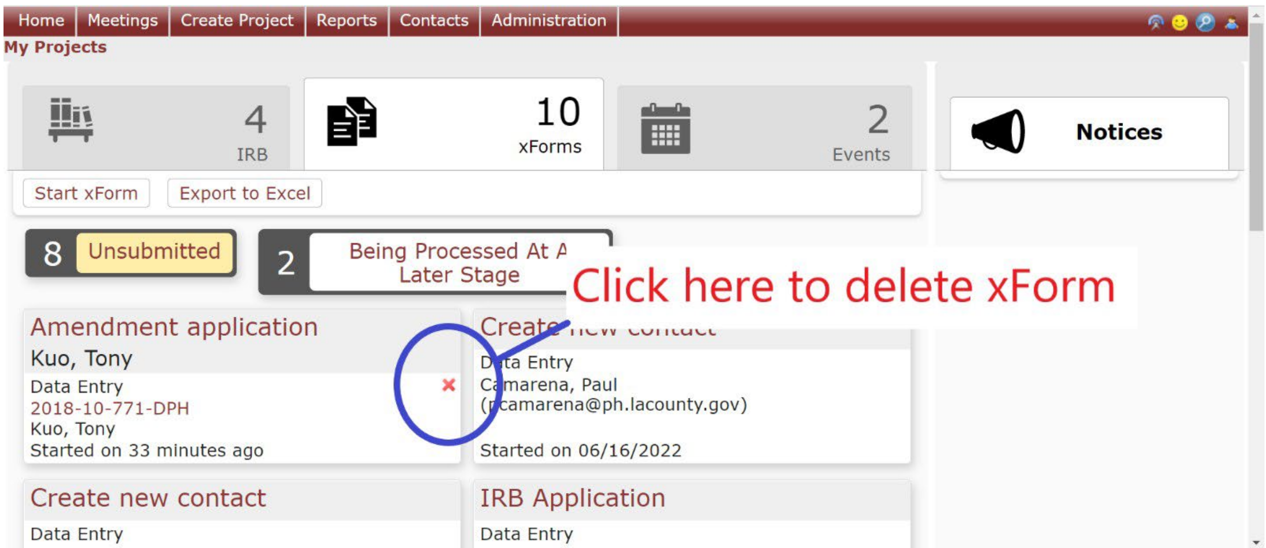
➢ Complete the desired xForm by responding to all questions and then click "Submit" to send the xForm to the IRB for review.

Section 7. Deleting xForms

➢ xForms can only be deleted during 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.



<u>Section 8. Uploading Documents as Attachments</u>

➢ 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:

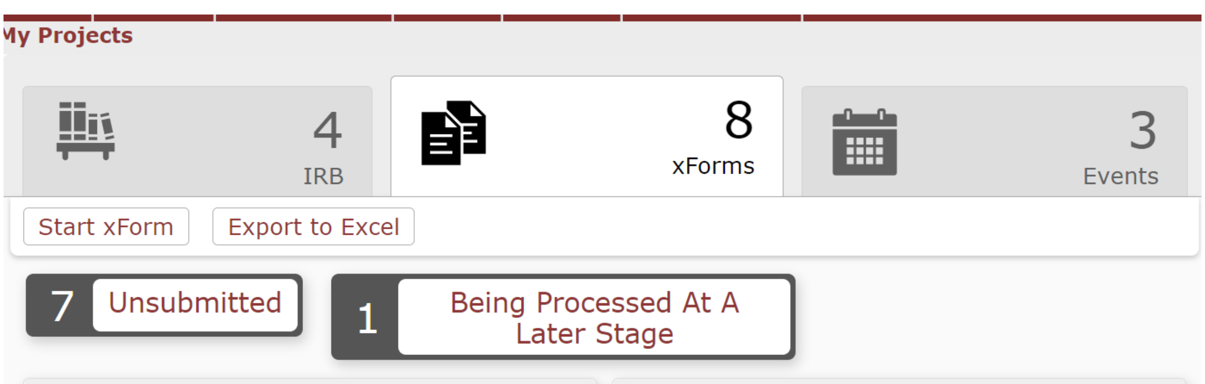
  - Click the Add Attachment button to open a pop-up window on screen
  - Click Select files to browse for the document you wish to attach
  - Click the Attach button - the window will auto-close and attach the document to your application

Section 9. Information Requested by the IRB

- Your application (xForm) 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.
  - 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.
  - Items that require attention can be viewed by selecting the xForms tab and then clicking on the Awaiting your Attention button.
  - Notes may sometimes be provided in the xForm alongside the question(s) to which they pertain. To view questions with notes, please click on the More button at the bottom of the xForm and then select View Questions with Notes. IRB Manager will generate a pdf of the application questions that have notes associated with them.
- Once revisions are completed, please sign and submit the xForm to send it back to the IRB for review.

Section 10. Checking the status of your application

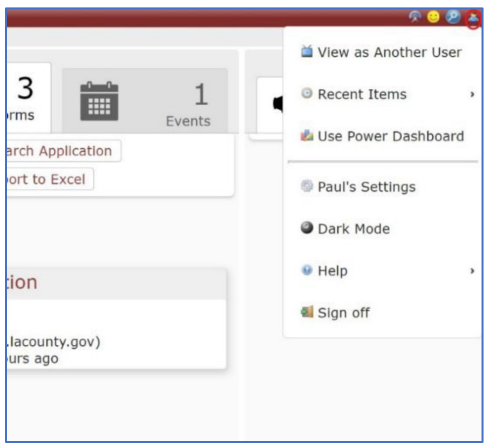
- To view the status of an application, navigate to your dashboard. On your dashboard page, click on the xForms tab.



- 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.

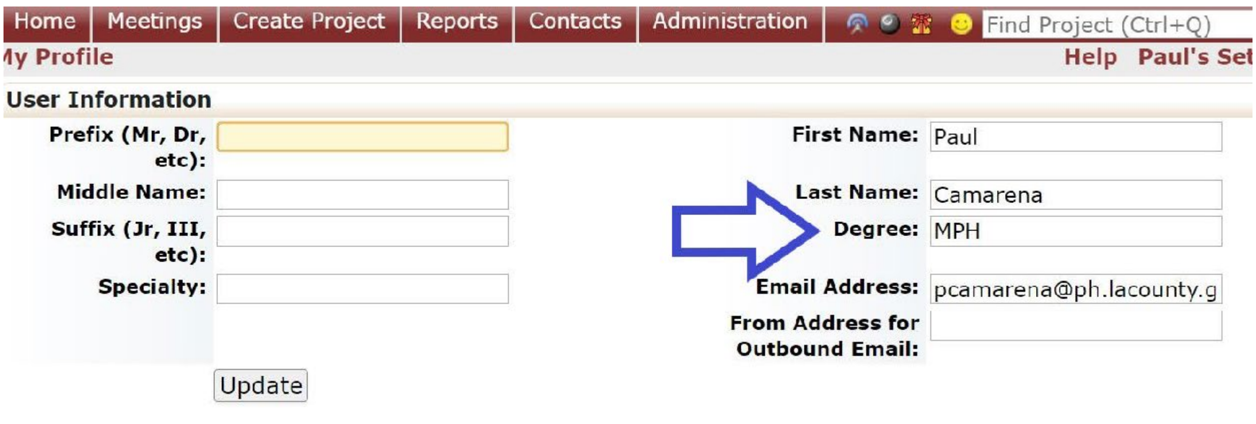
Section 11. Updating your Profile Information

- 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.



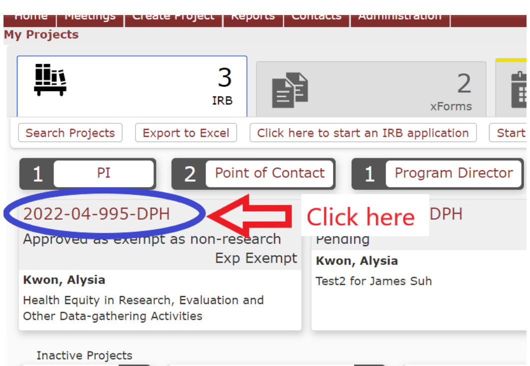
- On the "Settings" page, select "Change My Profile" (see image below)

- 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.

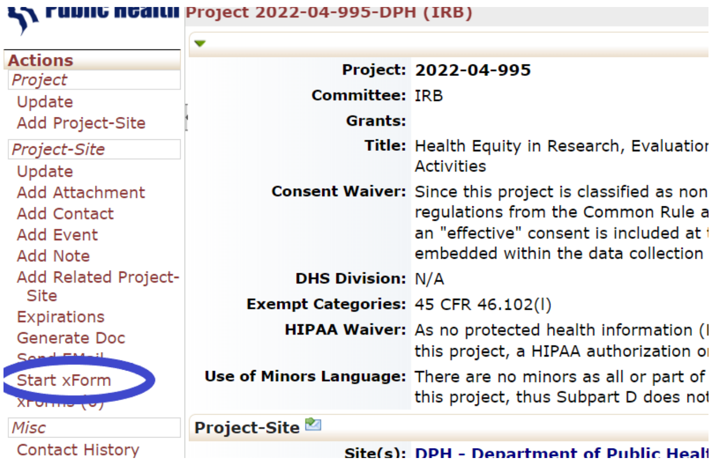


Section 12. Reporting an Unanticipated/Adverse Event

- 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.



- 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.