
IRBMANAGER – USER GUIDE



Los Angeles County Dept. of Public Health
Institutional Review Board



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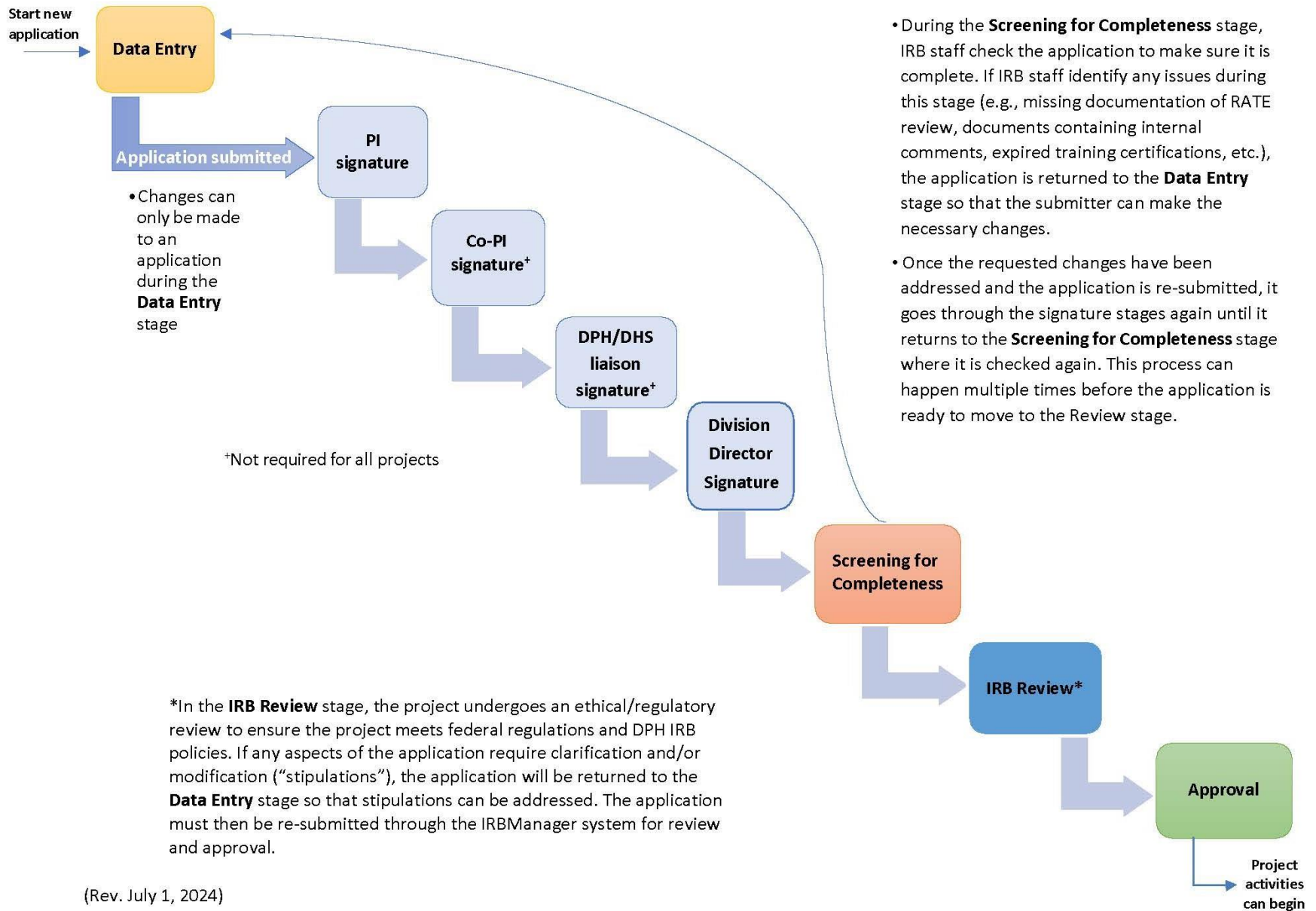
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Overview of IRBManager application process



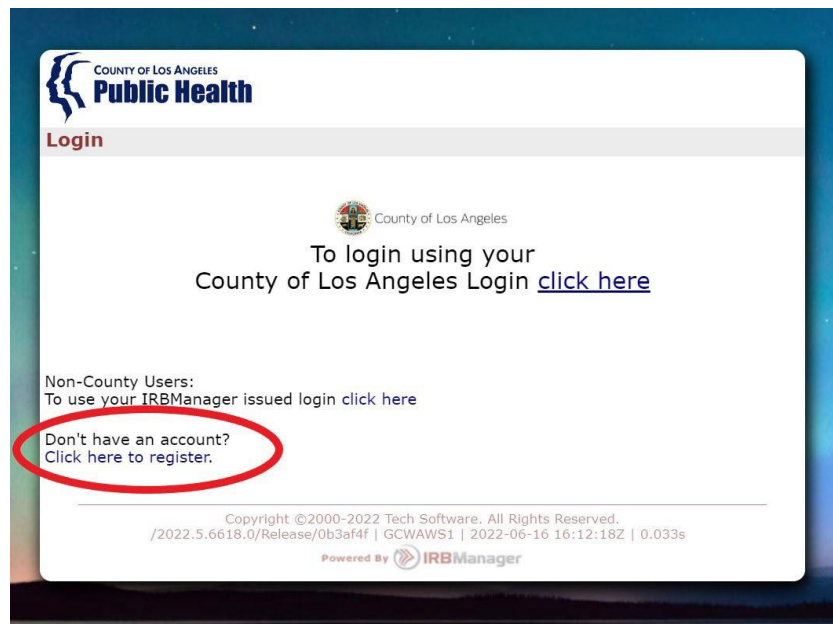
Section 1: Accessing IRBManager

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

IRBManager login link: <https://lacdph.my.irbmanager.com/>



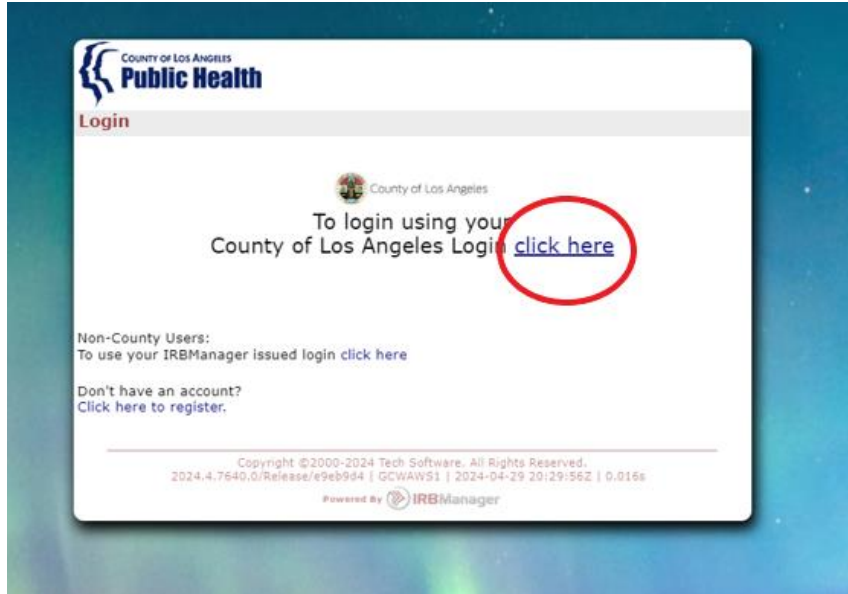
New Users: If this is your first time trying to log into IRBmanager and you are an LA County employee, please try logging into IRBManager using your County email address and password. If you are not an LA County employee and/or a contact has not yet been created for you, you will need to register for 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.



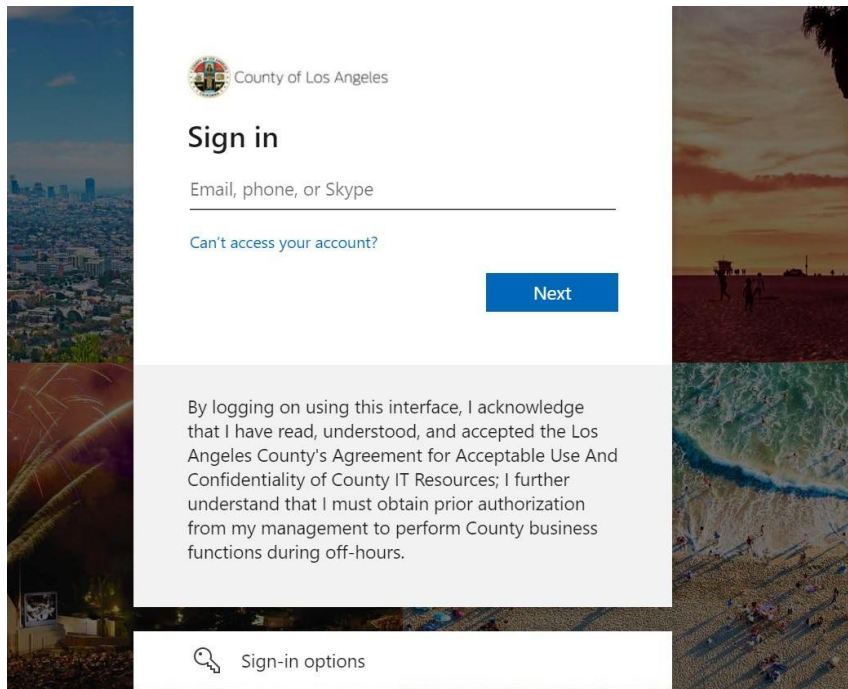
- If a contact was created for you (either by IRB staff or by someone working on an application), you do not need to complete the new user registration process again. You will receive an email notification when someone has created a contact for you. Proceed to the login page and use your email address 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.

Logging in for LA County users

- Log in using your County credentials (email address and password).

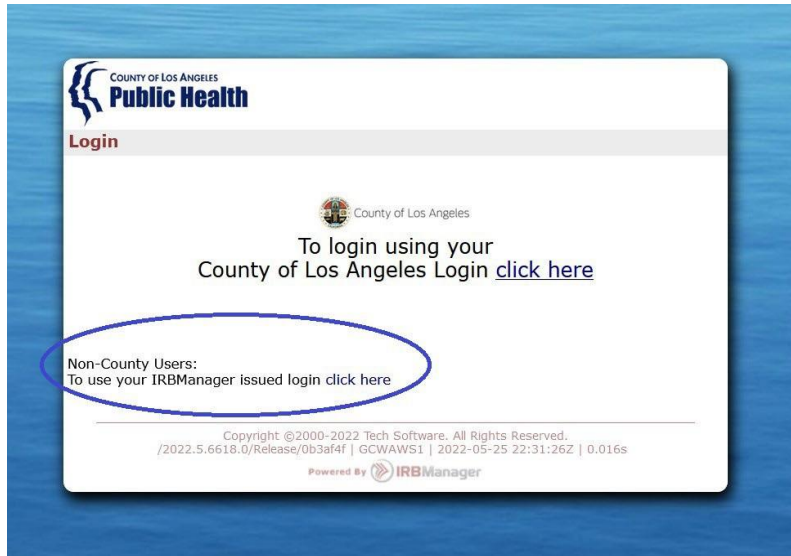


- Please follow the security prompts to successfully login.

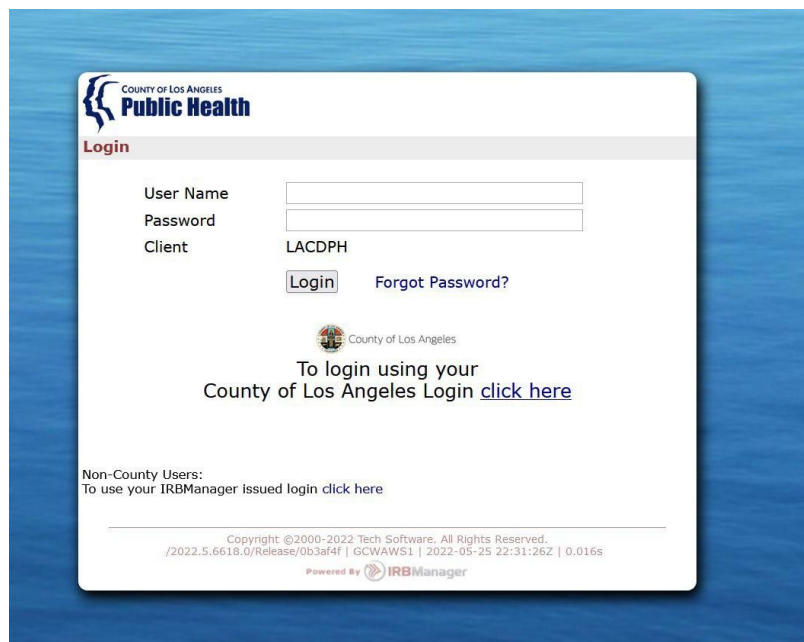


Logging in for Non-LA County users

- 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.



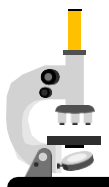


Please contact IRB@ph.lacounty.gov if you encounter any trouble logging into IRB Manager. If possible, please include screenshots of any error messages to help IRB staff troubleshoot the issue.

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 screenshot shows a dashboard with three main tabs: IRB (3), xForms (2), and Events (12). Below these are buttons for 'Search Projects', 'Export to Excel', 'Click here to start an IRB application', and 'Start Other xForm'. A row of filters shows '1 PI', '2 Point of Contact', and '1 Program Director'. The main area displays three project cards. The first card is for '2022-04-995-DPH' (Approved as exempt as non-research, Exp Exempt) by Kwon, Alysia. The second card is for '2023-06-009-DPH' (Pending) by Kwon, Alysia. The third card, '2023-10-004-DPH', is circled in blue and has a red arrow pointing to it from a 'Notice' box on the right. This card is 'Approved as exempt as non-research, Exp Exempt' by Camarena, Paul. Below the projects are filters for 'Inactive Projects' with '2 PI', '2 Co-Principal Investigator', and '1 Research Associate'.

- 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 screenshot shows the 'My Projects' dashboard with the 'xForms' tab selected, showing 4 items. There are also 0 Reviews and 4 IRB items. Below the tabs are buttons for 'Start xForm' and 'Export to Excel'. A row of filters shows '1 Unsubmitted' and '3 Being Processed At A Later Stage'. The main area displays three project cards. The first card is 'Amendment application (Draft)' by Camarena, Paul, with 'Data Entry' and '2024-01-008-DPH'. The second card is 'IRB Application' by Camarena, Paul, with 'Vice Chair review' and 'Initial Submission' on '2024-05-003-DPH'. The third card is 'IRB Application' by Kwon, Alysia, with 'Office screening' and 'Camarena, Paul'.

- 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.

IRB	xForms	Events
4	4	12

PI	2 Amendment	1 Annual Progress Report	1 Continuing Review
NHSR Submission	1 Reportable Events		

Initial Submission 2024-03-003-DPH 03/13/2024 Romo, Tiffany	Reportable Events 2022-04-995-DPH 10/27/2023 Kwon, Alysia	Initial Submission 2023-05-011-DPH 05/25/2023 Moore, Kim
NHSR Submission 2023-04-004-DPH 04/10/2023	Initial Submission 2022-12-006-DHS 12/29/2022	Initial Submission 2022-05-998-DPH 10/20/2022

- 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.).

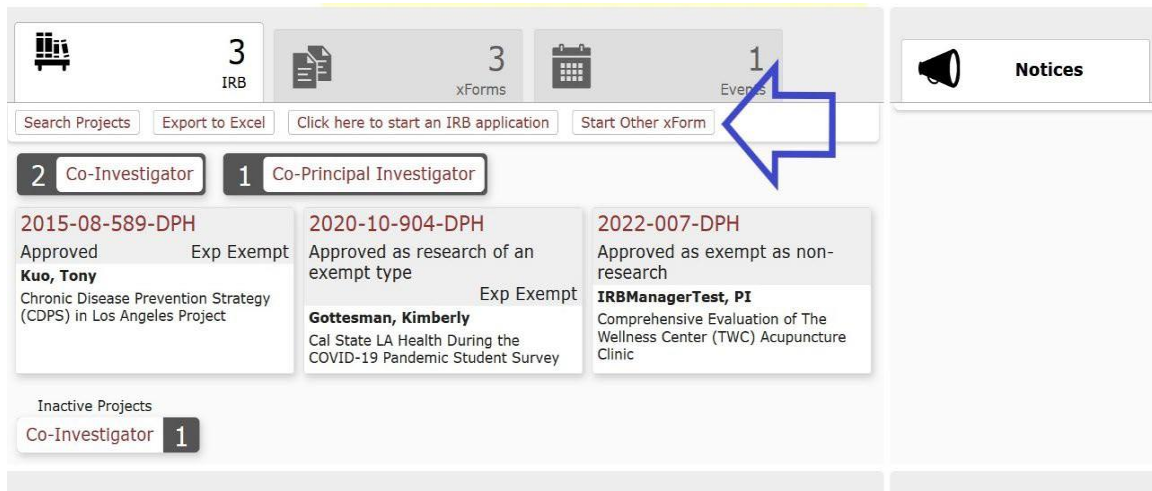
IRB	xForms	Events
3	3	1

2 Co-Investigator	1 Co-Principal Investigator
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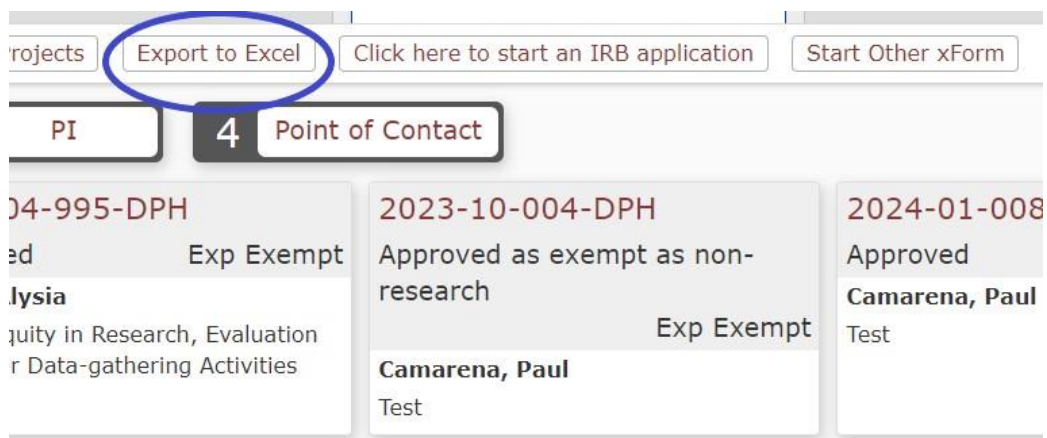
2015-08-589-DPH Approved Exp Exempt Kuo, Tony Chronic Disease Prevention Strategy (CDPS) in Los Angeles Project	2020-10-904-DPH Approved as research of an exempt type Exp Exempt Gottesman, Kimberly Cal State LA Health During the COVID-19 Pandemic Student Survey	2022-007-DPH Approved as exempt as non-research IRBManagerTest, PI Comprehensive Evaluation of The Wellness Center (TWC) Acupuncture Clinic
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Inactive Projects	Co-Investigator 1
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- 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.



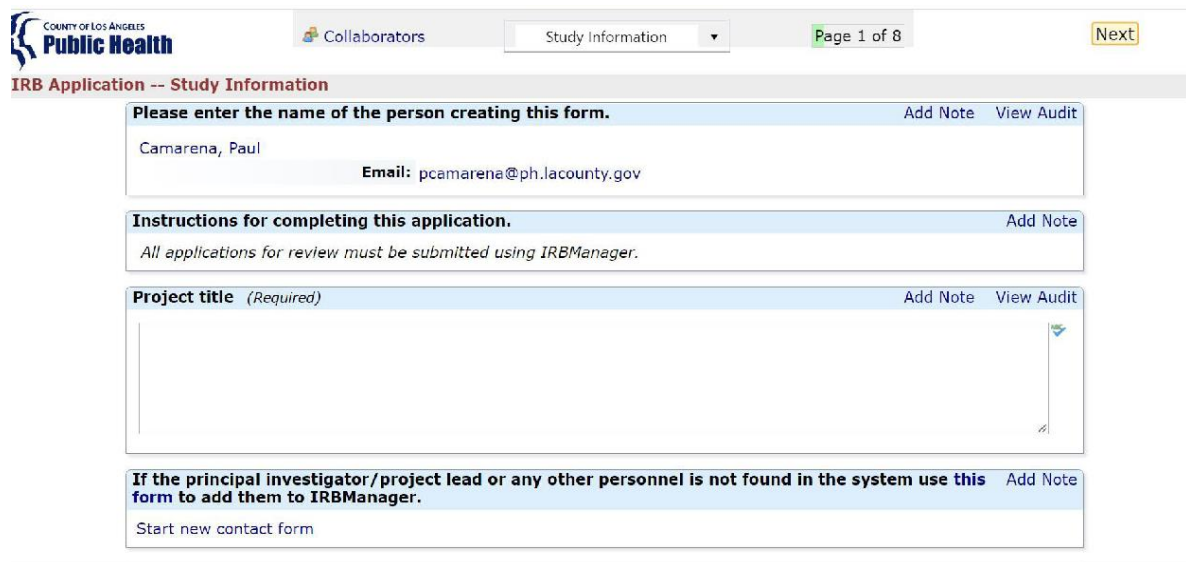
SECTION 3. SUBMITTING A NEW IRB APPLICATION

- 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).



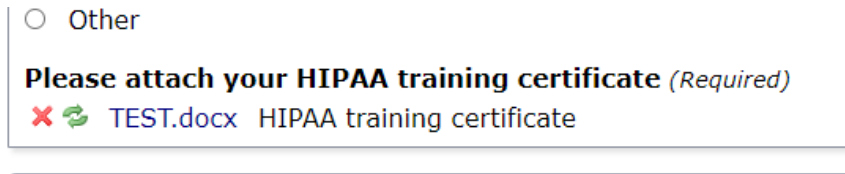
The screenshot shows a dashboard with several navigation options and project cards. At the top, there are three main tabs: IRB (with a count of 3), Forms (with a count of 3), and Events (with a count of 1). Below these tabs, there are four buttons: 'Search Projects', 'Export to Excel', 'Click here to start an IRB application' (which is circled in blue), and 'Start Other xForm'. Below the buttons, there are two more tabs: '2 Co-Investigator' and '1 Co-Principal Investigator'. The main area contains three project cards. The first card is for '2015-08-589-DPH', approved by 'Kuo, Tony' for a 'Chronic Disease Prevention Strategy (CDPS) in Los Angeles Project'. The second card is for '2020-10-904-DPH', approved by 'Gottesman, Kimberly' for a 'Cal State LA Health During the COVID-19 Pandemic Student Survey'. The third card is for '2022-007-DPH', approved by 'IRBManagerTest, PI' for a 'Comprehensive Evaluation of The Wellness Center (TWC) Acupuncture Clinic'. At the bottom left, there is a section for 'Inactive Projects' with a '1 Co-Investigator' button.

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

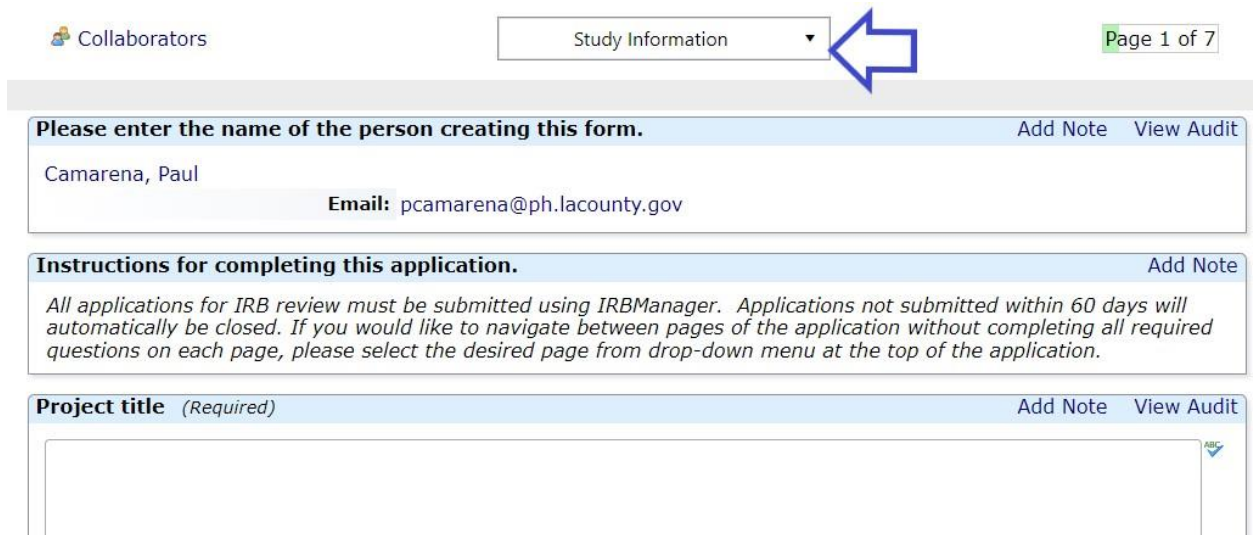


The screenshot shows the 'IRB Application -- Study Information' form. At the top left is the 'COUNTY OF LOS ANGELES Public Health' logo. To the right of the logo are 'Collaborators', 'Study Information' (with a dropdown arrow), 'Page 1 of 8', and a 'Next' button. The form has a title bar 'IRB Application -- Study Information'. Below the title bar are four sections, each with a title and an 'Add Note' or 'View Audit' link. The first section is 'Please enter the name of the person creating this form.' with 'Camarena, Paul' and 'Email: pcamarena@ph.lacounty.gov'. The second section is 'Instructions for completing this application.' with the text 'All applications for review must be submitted using IRBManager.'. The third section is 'Project title (Required)' with a large text input area. The fourth section is 'If the principal investigator/project lead or any other personnel is not found in the system use this form to add them to IRBManager.' with the text 'Start new contact form'.

- 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.

https://www.surveymonkey.com/r/ZMWZKWN

Are any members of the research team non-DPH badged, include the PI, co-PI, outside contractors, volunteers,

Yes
 No

Next | **Save for Later** | More ▾

Copyright ©2000-2024 Tech
2024.4.7640.0/Release/e9eb9d4 | GCW
Powered By

- 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.



I, outside contractors, volunteers, students

View Attachment Questions
View Questions with Notes
View Changed Responses

More ▾ | **View as PDF**

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.

Project title *(Required)*

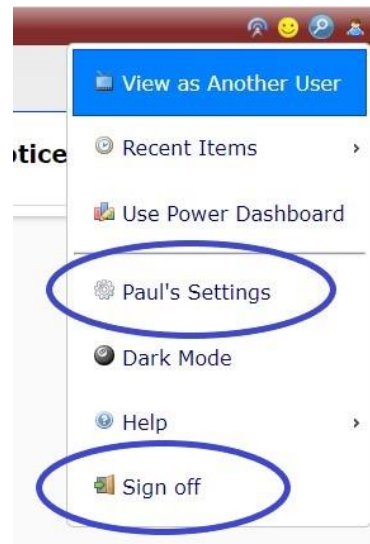
If the principal investigator/project lead or any other personnel is not found in the system, click the link below to create a contact for them.

[Start new contact form](#)

- 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.



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.

The dashboard shows 1 IRB and 0 xForms. Below are buttons for 'Search Projects', 'Export to Excel', 'Click here to start an IRB application', and 'Start Other xForm'. A project card for '2018-10-771-DPH' is highlighted, showing it is 'Approved as research of an exempt type' by 'Kuo, Tony'. A blue arrow points to the project ID with the text 'Click here to view project details'.



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.

The screenshot shows the project details for 'Project 2018-10-771-DPH (IRB)'. The left-hand menu has 'Start xForm' circled in red with a blue arrow and the text 'Click here'. The main content area shows project details such as Department, Title, Consent Waiver, Review, Program, Use of Minors, Language, Agent Types, Year, Continuing review justification, Exempt, Categories, HIPAA Waiver, Purpose of the study, and Vulnerable populations.

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



Start Form on Project-Site 2018-10-771-DPH

Select xForm to start

Select the desired xForm

Action	Form (Click to start)	Description
	Amendment application	Amendment application
	Annual Progress Report	Annual Continuing Review/Progress Report

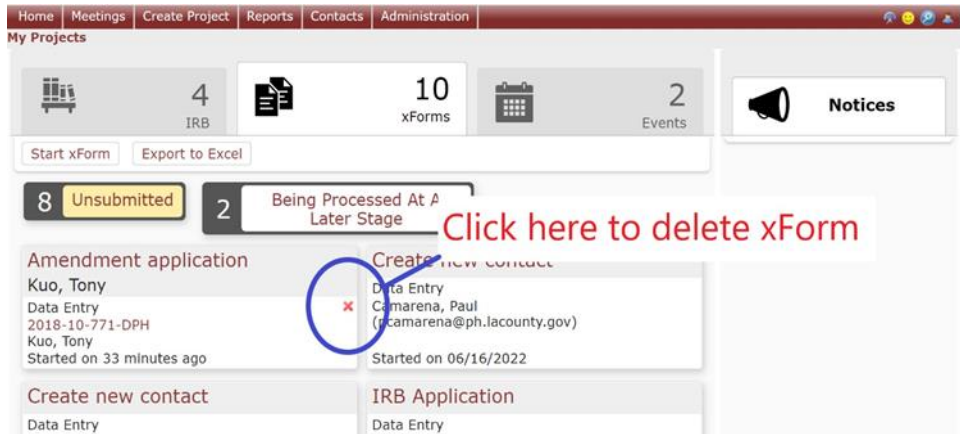
- Complete the desired application by responding to all questions and uploading all required documents. When you reach the end of the application, click “Submit” to move the xForm to the next stage.



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:
 - 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

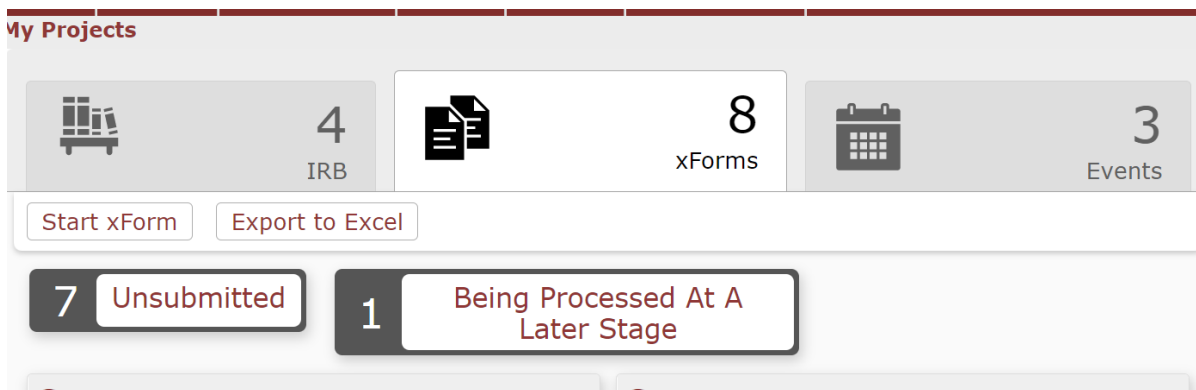
SECTION 9. INFORMATION REQUESTED BY THE IRB

- Your application 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” 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.

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.

Home Meetings Create Project Reports Contacts Administration Find Project (Ctrl+Q)

My Profile Help Paul's Set

User Information

Prefix (Mr, Dr, etc):

Middle Name:

Suffix (Jr, III, etc):

Specialty:

Update

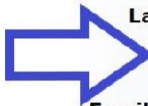
First Name:

Last Name:

Degree:

Email Address:

From Address for Outbound Email:



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.

Home Meetings Create Project Reports Contacts Administration

My Projects

3 IRB 2 xForms

Search Projects Export to Excel Click here to start an IRB application Start

1 PI 2 Point of Contact 1 Program Director

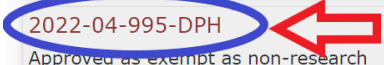
2022-04-995-DPH [Click here](#) DPH

Approved as exempt as non-research Exp Exempt Pending

Kwon, Alysia
Health Equity in Research, Evaluation and Other Data-gathering Activities

Kwon, Alysia
Test2 for James Suh

Inactive Projects



- 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.

Action	Form (Click to start)
	Amendment application
	Annual Continuing Review
	Annual Progress Report
	Unanticipated/Adverse Events Form

- Respond to the questions in the form and click “Submit” at the bottom of the page.

Section 13. Viewing Attachments from Past Applications

- 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).

The screenshot shows a dashboard with several project cards. The card for project 2023-10-004-DPH is highlighted with a blue circle. A red arrow points from a text box on the right to this card. The text box contains the instruction: "Click on a project's IRB # to open the project details page".

- 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.

The screenshot shows the project details page for project 2022-04-995-DPH (IRB). The page is divided into several sections:

- Project:** 2022-04-995
- Committee:** IRB
- Grants:** Title: Health Equity in Research, Evaluation and Other Data-gathering Activities
- Consent Waiver:** An alteration or waiver of documentation of informed consent has been approved per 45 CFR 46.116(f)(3) as the research involves no more than minimal to the subjects; the research could not practicably be carried out without the requested waiver or alteration; if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; the waiver of consent will not adversely affect the rights and welfare of the subjects; and, whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.
- DHS Division:** N/A
- Exempt Categories:** 45 CFR 46.102(l)
- HIPAA Waivers:** As no protected health information (PHI) will be accessed in this project, a HIPAA authorization or waiver is not needed.
- Use of Minors Language:** There are no minors as all or part of the target population in this project, thus Subpart D does not apply.
- Funding source(s):** Agency: DPH, Agent Types: Year: 2022
- Continuing review justification:**
- DPH Bureau:** Chief Science Office
- Full Board Review:** No
- Program:** IRB
- Vulnerable populations:** None foreseeably known
- Project-Site:** Site(s): DPH – Department of Public Health, Status: Approved, Approval: April 18, 2022, Initial Approval: April 18, 2022, Determination Date: 04/18/2022
- PI:** Kwon, Alysia
- Additional:** N
- Expiration:** Exempt
- Other Expirations:** Annual Progress Report Du
- Project-Site Contacts (2):** Name, Role

- 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).

▼ Events (9)			
Action	Event	Att	Instance/UDF
	Continuing Review	3	
	Annual Progress Report	1	
	Reportable Events	1	
	Amendment	14	
	Amendment	35	
	Annual Progress Report	0	
	Continuing Review	2	
	Amendment	10	
	Initial Submission	23	

▼ Reviews on Open Events (4)



- 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.

Attachments

Project-Site

PI Kwon, Alysia

Attachments on Amendment Started 03/24/2023 on 2022-04-995-DPH

Attachments (4)	Action	Name
Generated Docs (1)		Attachment 11. Health Equity SOP Evaluation Pre&Post.pdf
		Health Equity ProtocolDetail TrackedChanges Feb2023.docx
		Health Equity ProtocolDetail CLEAN Feb2023.docx
		RATE Review Documentation March 2023.pdf



