IRBManager Manual For Researchers

Contents

1.0 IRBManager

1.1 What is IRBManager?

IRBManager is an online submission, workflow, and data management system for the California Health and Human Services Agency (CalHHS), Institutional Review Board. The electronic forms provided within this system will allow users to submit new studies for review as well as submit other forms for continuing review, amendments, unanticipated problems or adverse events, and final reports. These forms are then used to electronically route the study through the required review process.

Through IRBManager, investigators have access to see the projects they are investigating as well as any separate project-sites. Each project's project-site will provide a list of events. Events can be viewed as folders for the separate submission events required for each project-site such as the initial submission, amendments, and continuing reviews. Each event will contain all associated forms, documents, and letters along with a listing of review steps, which are updated to notify the investigators where the submission is within the review process. Study personnel indicated on the project application will have access to IRBManager.

IRBManager is a fully web-based system, which means that users can log in anywhere they have internet access.

1.2 How can I obtain access to IRBManager?

- If you were previously registered in Calprotects, you have access to IRBManager. See 1.3 for details on logging in.

- If you are a new researcher submitting to CalHHS for the first time, you will need to register for IRBManager at: https://chhs.my.irbmanager.com/ by clicking on 'Click here to register'

1. Enter your email address on the first screen

2. You will be required to answer all the questions in the registration form

3. Once you register, you will receive an email with a link to reset your password. You must use this link within 24 hours. If you do not change your password within 24 hours, you will need to click on 'Forgot password?' to have a new link sent.

1.3 Initial Login for users with Calprotects accounts

If you had an approved (and not closed) project in Calprotects as of August 31, 2017, your contact has been created within IRBManager. To activate that account, do the following:

1. Go to https://chhs.my.irbmanager.com/
2. Click on 'forgot password'
3. Enter the email address on file with Calprotects
4. You will receive an email with a link to reset your password
5. Note if you do not use the email address on file in Calprotects, you will not be able to reset the password. Should this occur, contact CPHS Administration to verify the email address on file. Do not create a new account. Duplicate accounts will not be tied to the projects migrated from Calprotects. If you need to update your email address on file, contact CPHS IRB Administration.

1.4 How do I log-in?

1. Go to https://chhs.my.irbmanager.com/
2. Enter your username and password. Hint: Your username will always be an email address.
3. Enter CHHS as the Client (check box 'Remember Client' to set the client permanently for the computer you are working on).
4. Click Login.
5. If you are uncertain if you have an IRBManager account, contact cphs@chhs.ca.gov

1.5 How do I reset my password?

Click on the 'Forgot password?' to reset your password. You will receive an email with a link to reset your password. This link will expire within 24 hours. If you do not receive this email, check your 'spam/junk' folder.

As a security precaution, IRBManager locks your account after three incorrect password attempts. It is recommended that you reset your password after two incorrect attempts. If your account is locked, use the 'forgot password' to reset your password and unlock your account.

2.0 Navigating the Home Page (also known as the Dashboard)

2.1 Actions

Under actions, you can start either a Determination of Not Research/Exempt form or a New Project Application. (Note that the Amendment Form for Studies Approved in Calprotects, Continuing Review form, Final Report, Unanticipated Problem or Adverse Event Form cannot be started from this area as they must be started from within the project. See section 3.0 on how to start an xForm)

2.2 Recent Items

The hyperlinks under this heading will show the most recent items you have viewed in IRBManager. You can just click on any link under "Recent Items" to go directly to that item.
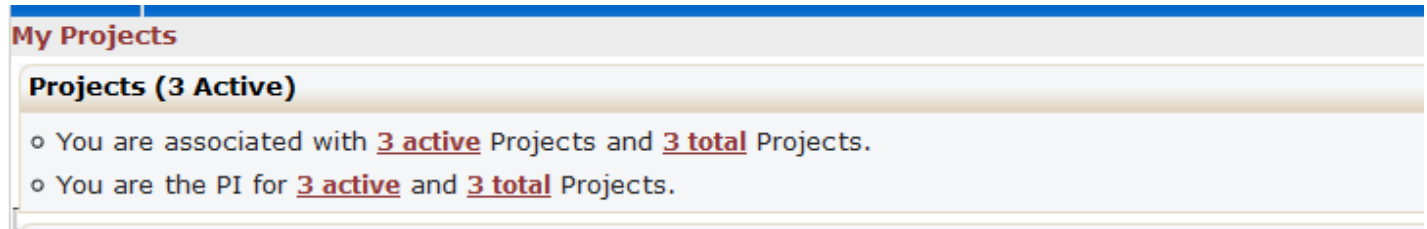
2.3 Messages

This heading is an area that the IRB will use for general communication to all the users within the system

2.4 Projects

This area shows any projects with which the user is associated as Principal Investigator, Coordinator, Sub-Investigator, Responsible Official, Administrative Contact, or other research staff.
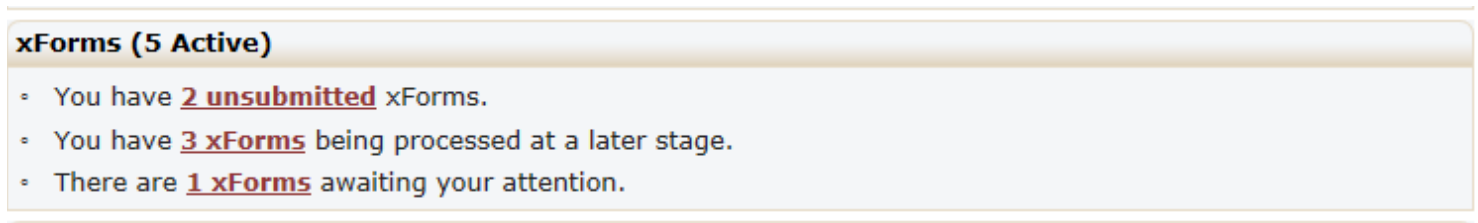
Note: By clicking on the underlined link, you will be able to view the details of the projects with which you are associated.

My Projects

Projects (3 Active)

o You are associated with **3 active** Projects and **3 total** Projects.

o You are the PI for **3 active** and **3 total** Projects.

2.5 xForms section of Dashboard

The xForms section shows the forms or applications currently being processed at this time for the user. Note that an xForm is an electronic form.

xForms (5 Active)

• You have **2 unsubmitted** xForms.

• You have **3 xForms** being processed at a later stage.

• There are **1 xForms** awaiting your attention.

In this view of the Dashboard:

- You have 2 unsubmitted xForms.
    - o Explanation: The IRBManager user started two xForms (submissions) but clicked "Save for Later" or closed out of the form without submitting the form.
    - o Note: By clicking the underlined link, "2 unsubmitted" the user can go straight to a page where all the unsubmitted xForms are listed.
- You have 3 xForms being processed at a later stage.
    - o Explanation: The IRBManager user has submitted three xForms that are currently awaiting review and signature by the PI, Responsible Official, or are being processed by the IRB.
- You have xForms in error (not shown in screenshot).
    - o Explanation: The IRBManager user has some forms that have errors. This is a software issue, and the user must notify the IRB office if they receive this notification.
    - o Note: If the user has an xForm in error, the user can click the underline link and go straight to the xForm in error.

- There are xForms currently awaiting your attention
  - Explanation: The IRBManager user has one xForm that currently need action by the user (i.e., review and signature required, revisions requested by the IRB)
  - Note: By clicking the underline link, "xForms" the user can go straight to the xForms that need the user's attention.

2.6 Events

The events section of the Dashboard shows the total number of open events and the number of events categorized by name, such as Continuing Review, Initial Submission, Continuing Review and Amendment. The dropdown following "Only show events where I am:" will display the events according to the IRBManager User role in the associated study.

Events (4 Open)

Only show events where I am: [▾]

■ You have **4 Initial Submission** events.

You have **4 Total Open** events

2.7 My Projects

This is a list of all the active projects with which the user is associated. NOTE: A project is not created when a user submits an xForm. A project is created when the IRB determines that the project is ready for review. From your Dashboard, you can view the following information regarding your projects:

- The project number;
- The main site where the project is taking place;
- Note: If the project is taking place at more than one site, the project will be listed twice with each site listed.
- The Principal Investigator's (PI) name;
- The project title;
- Expiration date of the project (if blank study has not yet been approved) and
- Status: This will depend on whether the project is still under initial review or if elsewhere within the project's lifecycle. Statuses can include New (if not yet approved), Active, Active-Exempt, Active-NHSR, Expired, Suspended.
    - Note that inactive projects will not display here).

Note: By clicking on the blue hyperlink under "Project" the user can go straight to the project.

My Projects (3 Active)

Project ▾	Site ⬍	PI ⬍	Title ⬍	Expires ⬍	Status ⬍
16-10-2745-CalPoly San Luis Obispo	California Polytechnic State University San Luis Obispo	Researcher, Test DrPH	Test Study	04/05/2018	Active
2017-003-CSUSM	California State University San Marcos	Researcher, Test DrPH	Test Application For Expedited Review	07/06/2018	Active
2017-007-Brown University	Brown University	Researcher, Test DrPH	TEST Common Rule Data Only	08/09/2018	Active

By clicking the small arrow to the right of Project, Site, PI, Title, Expires, and Status, you can sort the studies accordingly.

- Project can be sorted by project number
- Site can be sorted alphabetically
- PI is sorted alphabetically
- Title is sorted alphabetically
- Expiration dates are sorted by numerical date
- Status is grouped and sorted alphabetically

2.8 Find Project

User can search by PI name or project number to find a project with which the user is associated.

2.9 Help

Under Help you can contact the CPHS Administrator by choosing 'Contact Administrator'. If page help is currently disabled, use this manual for assistance.

2.10 Your Settings

Allows the user to edit profile settings. In the examples "Test" is used but upon sign in the top right-hand corner will be replaced with "[your first name] Settings". By clicking on "[your first name] Settings", you will access My Settings.

Under My Settings you can:

- Change your password
- Change your profile
- Change your phone number
- Change your address
- View last 25 logins
- Create an email signature

2.10.1 Change Password

Step 1: Click on "Change My Password" link. You will then see this view:

Change Password

User	Test Generic Coordinator Login
Username	Coordinator
Old Password	
New Password	
New Password Confirm	

Update

1. Enter old password.
2. Enter new password that meets requirements and then enter new password again to confirm.
   Your password must meet the following requirements:
   - Be 6 or more characters
   - Be different from the username
   - Contain any three of the following: upper case letter(s), lower case letter(s), number(s), and special characters (e.g. !, @, #)
4. Click "Update".

2.10.2 Change Your Profile

1. Click on "Change My Profile" link. You will then see this view:

My Profile

Change User Information

First Name	Test Generic
Last Name	Coordinator Login
Degree	
Specialty	
Email Address	

[Update]

2. Update your name, degree, specialty, or email address.
3. Click "Update."

2.10.3 My Phone Numbers

1. Click on "My Phone Number(s)" link. You will then see this view:

My Phone Numbers

Numbers

Action	Primary	Type	Number
🖉❌	✓	Business	3-2693

2. Click the icon that appears to be a hand holding a piece of paper. You will then see this view:

Contact Name

Full Name:	Test Generic Coordinator Login

Phone Book

Phone Type:	[▼]
Primary Number:	☑

[Add Phone] [Cancel]

3. Update or add your phone number.
4. Click "Update Phone." Or "Add Phone".

2.10.4 My Address

1. Click on "My Address(es)" link. You will then see this view:

Action	Primary	Type ▾	Street ⬍	City ⬍	State ⬍	Zip ⬍	Country
🖊 ✖	✓	Business	10 Anywhere St	Anywhere	California	11111	United States

2. Click the "hand holding a piece of paper" You will then see this view:

Contact Name

Full Name: Investigator, Test MSc	**Email:** test@oshpd.ca.gov

Address Book

Address Type: Business ⌄		**Country:** United States ⌄
Street: 10 Anywhere St		
Line 2:		
Line 3:		
City: Anywhere		
State/Province: CA - California ⌄		**Zip/Postal Code:** 11111
Primary Address: ☑		

Update Address | Reset | Cancel

3. Update your address.
4. Click "Update Address."

2.10.5 Log-In Information

Clicking on this link will provide a list of the time and date of the last 25 times you logged into IRBManager.

3.0 Managing forms in IRBManager (xForms)

IRBManager uses web-based forms called xForms. Users submitting to the CPHS IRB will submit the xForm appropriate to the type of request. Types of requests may include new projects, amendments, continuing reviews, exemptions, final reports and unanticipated problems/adverse events.

3.1 New project applications

1. On the home page (the view when a user logs in), under the action menu on the far-left side there are three options:

   a. Start a new Determination for Exempt Research/Not Research Form

      i. This application is for requesting a determination of exempt or not research only.

   b. Start a New Project Application

      i. This application is for requesting review of a project at the expedited or full board level

   c. Start xForm

      i. Gives the option to start one of the above forms or to start the 'Create New Contact' form, which is used to create a username and login for a contact not in the IRBManager system.

2. Click on the name of the form to start the form.

Actions	Projects (0 Active)
Start a new Determination for Exempt Research/Not Research form	○ You are not associated with any Projects.
Start a New Project application	**xForms (0 Active)**
Start xForm	○ You have **0 unsubmitted** xForms.
	○ You have **0 xForms** being processed at a later stage.

   a. This will start the applicable form that you have requested.

3.2 Amendment Form for an Existing Study that has Received Initial Approval through IRBManager

Amendments for projects that submitted a 'New Project Application' and were approved in IRBManager require updating the approved application using the 'Copy for Amendment' feature. There are two different ways to access the application for copy for amendment.

Option 1: From within the project

Project	Site	PI	Title	Expires	Status
My Projects (3 Active)					
16-10-2745-CalPoly San Luis Obispo	California Polytechnic State University San Luis Obispo	Researcher, Test DrPH	Test Study	04/05/2018	Active
2017-003-CSUSM	California State University San Marcos	Researcher, Test DrPH	Test Application For Expedited Review	07/06/2018	Active
2017-007-Brown University	Brown University	Researcher, Test DrPH	TEST Common Rule Data Only	08/09/2018	Active

On the home page under 'My Projects', click on the project number for the project that needs amending

1. Click on the 'Initial Submisson' event

   a. If a project application has been previously copied for an amendment it is recommended to make a copy of the most recent amendment to capture all recent changes.

Project-Site

Site(s): Brown University - Brown University		**PI:** Researcher, Test DrPH	
Status: Active		**Additional:** N	
Approval: 10 August 2017 for 12 months		**Expiration:** 09 August 2018	
Initial Approval: 10 August 2017		**Other Expirations:**	
Comments:			

▶ **Contacts (3)**

▼ **Events (1)**

Event	Att	FE	Instance/UDF	Start	Complete	Last Mtg
Initial Submission	11			09/08/2017		

2. Click on 'xForms'

Actions
Attachments (11)
Send EMail
Start xForm
xForms (1)

Done

3. Click on the '🗎' icon

Action	Form	Identifier	Stage/Status	Started	Submitted
🗎	Project Application	Researcher, Test DrPH	Complete	11/08/2017 at 18:27	11/08/2017 at 18:34

4. A window prompt will open asking 'Copy for Amendment?', click OK.
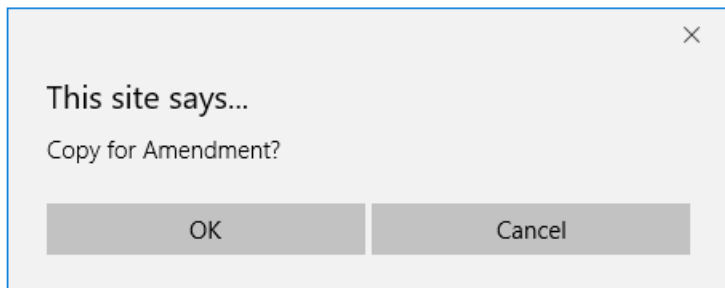
Option 2: From within 'My Documents & Forms'

1. On the home screen, under 'My Documents & Forms' click the 'xForms.'

Messages

If you have any questions about the submission and review process email the CPHS Office at cphs-mail@oshpd.ca.gov

My Documents & Forms

0 User Attachments
3 xForms
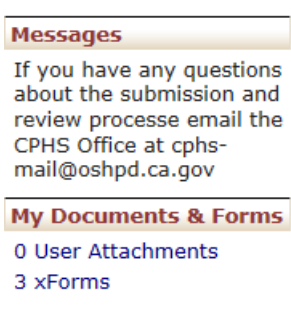
2. Under actions on the left side of the screen click 'Show Complete'

Actions

Start xForm
Notifications View
Export
Show Complete

Recent Items
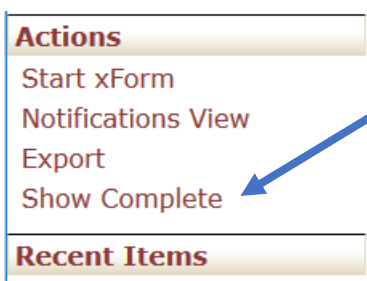
3. Find the application that needs amending
4. Click on the '📁' icon.

Action	Form	Identifier	Owner	Stage	Started	Submitt
📁	Project Application	Researcher, Test DrPH	Initial Submission 2017-007-Brown University	Complete	11/08/2017 at 18:27	11/08/20
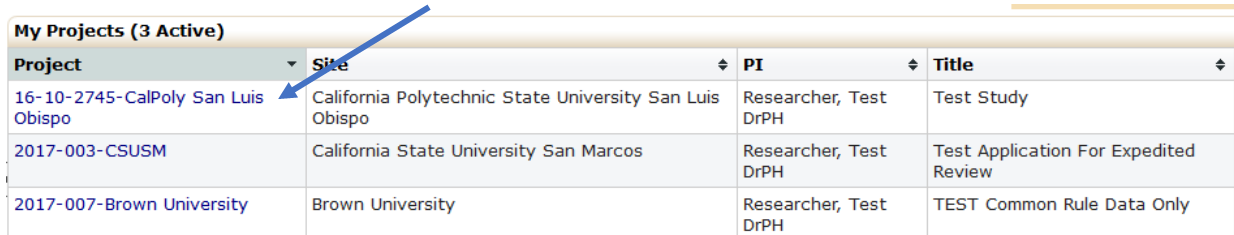
5. A window prompt will open asking 'Copy for Amendment', click OK.
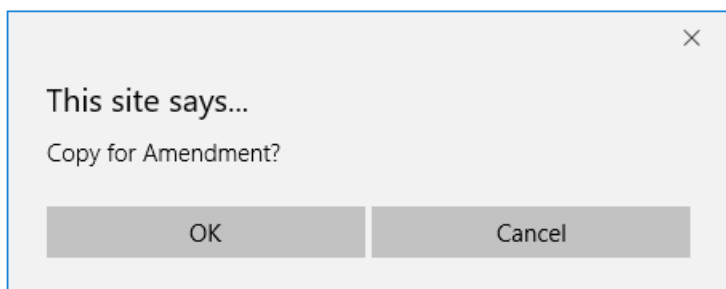
3.3 Amendment for a study submitted and approved through Calprotects, (IRBManager xForm not originally submitted)

For projects not submitted and approved in IRBManager, a separate amendment xForm needs to be submitted. This form must be started on the project. To access a project:

1. On the home page under 'My Projects', click on the project number for the project that needs amending.

My Projects (3 Active)			
Project ▼	Site ⬍	PI ⬍	Title ⬍
16-10-2745-CalPoly San Luis Obispo	California Polytechnic State University San Luis Obispo	Researcher, Test DrPH	Test Study
2017-003-CSUSM	California State University San Marcos	Researcher, Test DrPH	Test Application For Expedited Review
2017-007-Brown University	Brown University	Researcher, Test DrPH	TEST Common Rule Data Only

2. Once in the project, click 'Start xForm' (do not open an event; stay on the project).
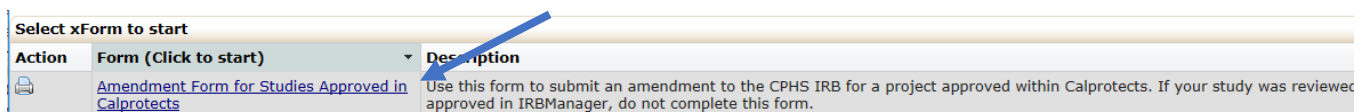
3. Click on the 'Amendment Form for Studies Approved in Calprotects'

3.4 Continuing Review form, Unanticipated Problem or Adverse Event, or Final Report Form

Follow the steps in 3.3 (see above) to start a continuing review request, unanticipated problems or adverse event, or final report form for projects either approved within Calprotects or IRBManager.

3.5 Completing an xForm
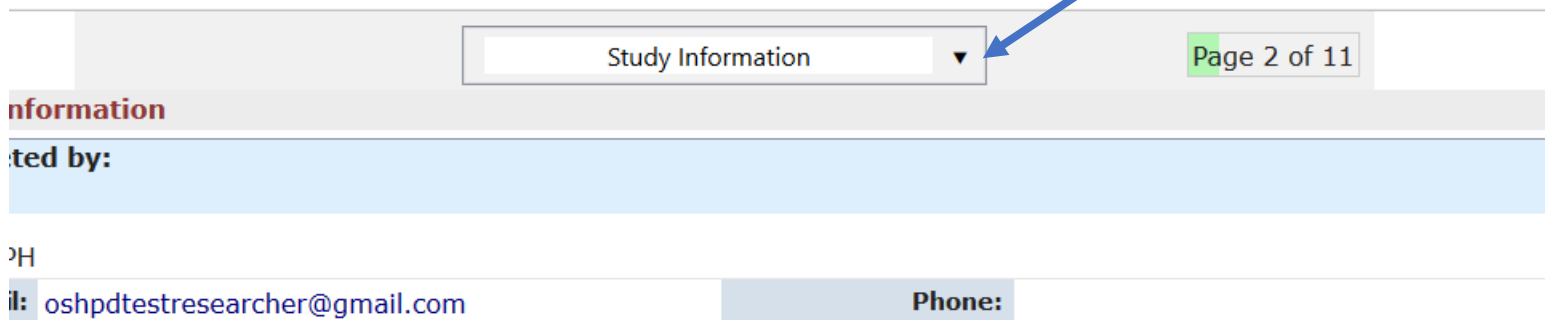
After entering basic study details, the next questions in the xForm are directed by the answers given. For example, research involving death data will not ask about human subjects in research and vice versa. Changing responses on the form will enable subsequent questions that were hidden or hide questions that are no longer applicable.

To navigate an xForm, click "Next" to move on to the next page of the xForm. Click "Save for Later" to stop working on the form. The xForm can then be reopened by going to the xForm link under "Actions."

| Previous | Next | Save for Later | View Attachment Questions | View Questions with Notes | PDF |

Most questions on the form are required (the question will be labelled "Required"). Optional questions will indicate they can be skipped in the question text. All required questions on the form must be completed before submitting. If they are not, a red error message will appear. The system will not allow you to continue until the field has been populated.

All required questions on a page must be completed before clicking 'Next'. To skip to another page on the form without answering all questions on the page at that time, use the navigation drop down at the top of the page.

3.5.1 Attaching Documents

To attach a document:

1. Click "Add Attachment" on specified attachment questions.

2. Enter name for your attachment. If you want to just use the name of the uploaded file, leave this field blank.

3. Select the type of attachment if that option is available. On some questions, only a certain type of document is intended to be attached, and the type is pre-set.

4. Click the "Select" button to locate the file on your computer (files can also be attached from Dropbox or box)

5. Click "Attach" to finish the process.

3.5.2 Submitting the xForm

Before submitting an xForm, review the form completely. Changes cannot be made once an xForm is submitted unless the IRB, PI, and/or the RO request changes.

After all pages on the form have been completed, the submission screen with appear. "Submit" will need to be clicked to complete the submission.

3.6 Checking the status of an xForm

Click on 'xForms' under 'My Documents & Forms' on the left-hand side of the screen to see a list of all xForms with which you are associated (as a PI, administrative contact, coordinator, etc.).

What's this?
This table shows xForms associated with you as a user of IRBManager across the entire system.

Action	Form	Identifier	Owner	Stage	Started	Submitted
✖	Project Application		Researcher, Test DrPH (testPI)	Data entry	28 minutes ago	
	Project Application	Researcher, Test DrPH	Researcher, Test DrPH (testPI)	Notify IRB for Pre-Screening	08/11/2017 at 6:42 PM	
📁	Project Application	Researcher, Test DrPH	Initial Submission 2017-007-Brown University	Complete	08/11/2017 at 6:27 PM	08/11/2017 at 6:34 PM
✖	Project Application		Researcher, Test DrPH (testPI)	Data entry	08/08/2017 at 7:04 PM	

- Action: If a form can be deleted or copied for an amendment those options will display in this column. Note: that an xForm can only be deleted when in data entry
- Form: Name of the form
- Identifier: This is generally the PI associated with the project
- Owner: The owner of the form will be the user who started the xForm until a project is created (a project will be created within IRBManager after the IRB has assigned the project for review) and then owner column will show the type of submission and project number.
- Stage: This is the current stage that the form is in. Stages will vary by form, but in general will have the following
  - Data entry—form is currently with the user either to complete or make changes
  - PI Signature for Coordination Submission—if the PI did not complete the xForm, this is the stage the PI reviews and submits the form
  - Responsible Official Signature—Stage that the RO will sign the form and submit to the IRB
  - Notify IRB for Pre-Screening—Stage that the IRB Office will screen the application for completeness and either request further information/documentation or assign for review
  - Under Expedited Review—the project is being reviewed at the expedited level
  - Full Board Review & Office Processing—the project is being reviewed by the convened board

- Notify Researcher of Approval—The IRB has completed the review and the IRB Office is preparing the decision notification to the research team

You can also check the status of the xForm from within the event (see 3.2 for finding an xForm on an event). Note: the xForm will be 'owned' by the type of event with which it is associated (i.e. initial submission, continuing review, amendment [once the amendment is submitted])

3.7 Decision Notification

Once the IRB Office or the IRB reviewer(s) have completed their review, the research team will receive an email detailing the IRB decision. If approved, the appropriate approval/determinaton letter will be attached.

4.0 Navigating the Project Page

From the home page, you can access a project page for each of your projects. Click on the blue project number link to access this page.

4.1 Project

This section notes all sorts of basic information about the project, such as:
- IRB number

- Sponsor (if applicable)

- Committee

- Sponsor ID: will be blank as functionality not used

- Category of study: will be blank as functionality not used

- Grants (if applicable)

- Agent Type: type of research

- Title

- Year: year of first review

- Level of Review: level at which the study was reviewed (note this is used instead of Last Review and Next Review)

- Comments: description of the project as entered on the new project application.

4.2 Project-Site

This section notes information about the project and the project-site, such as:
- Site(s): the primary location of the research

- PI: Principal Investigator of the project

- Status: Active, Expired, Closed, etc.

- Approval: Current approval date

- Initial Approval: the date that the project was first approved

- Expiration: the expiration date for expedited and full review projects (this is the day the project will expire unless a continuing review is granted)
- Comments: will be empty

4.3 Contacts

This section lists the contacts associated with the study along with their role, phone number and email address.

▼Contacts (2)	
Name ▾	**Role**
Test Generic Coordinator	Research Coordinator
Test Generic PI	Co-Investigator

4.4 Attachments

This section stores any documents associated with the project.

4.5 Events

This section lists all the IRB "events" or submissions that have been or are being conducted for the project. The event line contains the following sections:

- Event: the type of event (Initial Submission, Amendment, Study Closure, Unanticipated Problems/Adverse Event, etc.)
- Att: number of attachments associated with that event or review.
- Instance/UED: Usually this will be blank. If an amendment, a summary of the amendment appears here.
- Start: the date the event was started or loaded into IRBManager
- Complete: the date the event was completed
- Last Mtg: shows the last meeting this event or review was submitted to. Even if a submission is expedited, it shows up on a meeting expedited review report.

You can click on any blue event hyperlink to view the event details specific to the event. (See Section 5.0)

4.6 Event Details

Event Details are specific to the event or submission.

The event details contain the following:

Project Site:
- Project: Project IRB number
- Site: Location where the project is taking place
- PI: PI's name

Event:
- Type: the type of event, which could include Initial Submission, Continuing Review, Unanticipated Problem/Adverse Event etc.)
- Instance: Usually this will be blank. If an amendment, a summary of the amendment appears here.
- Started: the date the event first started
- Completed: the date the event was completed

Event			
Type:	Initial Submission	Started:	08/21/2017
Instance:		Completed:	
Committee:	Inherited from Study		
Review Cycle:			

4.7 Steps

This shows the date actions take place as part of the event. Each event will have the steps listed with a planned date (not used except for steps that involve the full board review of a study) and actual date.

Event						
Type:	Initial Submission			**Started:**	08/21/2017	
Instance:				**Completed:**		
Committee:	Inherited from Study					
Review Cycle:						

▶ **Notes (1)**

Steps (10) ☑ Hide Skipped

Step	Planned	Actual	Complete	Minutes	Micro Note
Receive Submission		08/21/2017	Yes		
Review for completeness		08/21/2017	Yes		
Assign to Reviewers		08/21/2017	Yes		
Receive Expedited Reviewer Recommendation		08/23/2017	Yes		
Notify Board of Recommended Approval			No		
Notify PI of Approval			No		

For example, in this event the following has occurred:

- The IRB received the New Submission on 08/21/2017
- The IRB staff completed an internal review/ for completion on 08/21/2017
- The Project was assigned to reviewers on 08/21/2017
- The Expedited Reviewer returned the review on 08/23/2017
- The Expedited approval has not yet been reported to the board
- The PI has not yet been notified of approval

When the CPHS IRB has completed these actions, the complete will be marked 'yes' and a completion date will occur.

Ensure 'Hide Skipped' is checked otherwise you'll see steps not appliciable to that project.

4.8 Actions in the Event Details

Actions
Attachments (17)
Send EMail
Start xForm
xForms (1)

Done

Actions in the event details screen are as follows:
- Attachments: shows the attachments related to the event detail
    - Generated Docs – shows the approval documents associated with the study
- Send Email: enables the user to send an email through the event, this email will be recorded automatically on the event page
- Start xForm: Gives the option to start an xForm or to start the 'Create New Contact' form, which is used to create a username and login for a contact not in the IRBManager system.
- xForms : shows the form used to create the event.
- Done: Returns the user to the next most logical page depending on previous actions.

4.9 Further Questions

If you have further questions regarding your project status or using IRBManager, contact the CPHS IRB Administration at cphs@chhs.ca.gov or by phone at (916) 651-5599.