

**Committee for the
Protection of
Human Subjects**



IRBMANAGER MANUAL FOR RESEARCHERS

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1.0 IRBManager

1.1 What is IRBManager?

IRBManager is an online submission, workflow, and data management system for OSHPD's 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 OSHPD for the first time, you will need to register for IRBManager at: <https://oshpd.my.irbmanager.com/> by clicking on 'Click here to register'
 - Enter your email address on the first screen
 - You will be required to answer all the questions in the registration form
 - 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. In order to activate that account do the following:

1. Go to <https://oshpd.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 in order 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://oshpd.my.irbmanager.com/>
2. Enter your username and password. Your username will always be an email address (this is the email address you initially registered with or the email address you had on file with Calprotects).
3. Enter OSPHD 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-mail@oshpd.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

The screenshot shows the OSHPD dashboard with the following sections:

- Actions:** Start a new Determination for Exempt Research/Not Research form, Start a New Project application, Start xForm.
- Recent Items:** 2017-007-Brown University, 2017-003-CSUSM, 16-10-2745-CalPoly San Luis Obispo.
- Messages:** If you have any questions about the submission and review processes email the CPHS Office at cphs-mail@oshpd.ca.gov.
- My Documents & Forms:** 0 User Attachments, 3 xForms.
- My Projects (3 Active):**
 - Projects (3 Active):** You are associated with 3 active Projects and 3 total Projects. You are the PI for 3 active and 3 total Projects.
 - xForms (2 Active):** You have 1 unsubmitted xForms. You have 1 xForm being processed at a later stage.
 - Events (4 Open):** Only show events where I am: [dropdown]. You have 4 Initial Submission events. You have 4 Total Open events.
- My Projects (3 Active) Table:**

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

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 of 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)

- You are associated with [3 active](#) Projects and [3 total](#) Projects.
- 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 (web based).

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.
 - The user currently started 2 xForms (submissions), but clicked "Save for Later" or closed out of the form without submitting the form.
 - Note: By clicking the underline link, "2 unsubmitted" the user can go straight to the unsubmitted xForms.
- You have 3 xForms being processed at a later stage.
 - The user has submitted 3 form that is currently awaiting review and signature by the PI, Responsible Official, or is being processed by the IRB.
- You have xForms in error (not shown in screenshot).
 - The 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.
 - 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
 - The user has 1xForms 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 allow you to show the events according to your 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 with 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 PI name.
- The project title.
- Expiration date of the project (if blank study has not yet been approved).
- 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 link 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

HELP – Under Help you can contact the CHPS Administrator by choosing ‘Contact Administrator’. Page help is currently disabled. Use this manual for assistance with using IRBManager.

2.10 Test’s Settings

Allows the user to edit their profile settings. “Test” will be replaced with your first name. By clicking on Test’s Settings, you will access My Settings.

Under My Settings you can:

1. Change your password
2. Change your profile
3. Change your phone number
4. Change your address
5. View last 25 logins
6. Create an email signature

2.10.1 Change Password

1. 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	<input type="password"/>
New Password	<input type="password"/>
New Password Confirm	<input type="password"/>
<input type="button" value="Update"/>	

2. Enter old password.
3. Enter new password that meets requirements and then enter new password again to confirm.
Your password must meet the following requirements:
 1. Be 6 or more characters
 2. Be different from the username
 3. Contain any 3 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.

My Profile

Change User Information

First Name	<input type="text" value="Test Generic"/>
Last Name	<input type="text" value="Coordinator Login"/>
Degree	<input type="text"/>
Specialty	<input type="text"/>
Email Address	<input type="text"/>

You will then see this view:



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.

My Phone Numbers


Numbers

Action	Primary	Type	Number
 	<input checked="" type="checkbox"/>	Business	3-2693

You will then see this view:

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:	<input type="text" value="Test Generic Coordinator Login"/>
Phone Book	
Phone Type:	<input type="text"/> 
Primary Number:	<input checked="" type="checkbox"/>
<input type="button" value="Add Phone"/> <input type="button" value="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:

Address Book (1)								
Action	Primary	Type	Street	City	State	Zip	Country	
 	<input checked="" type="checkbox"/>	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: <input checked="" type="checkbox"/>	
<input type="button" value="Update Address"/> <input type="button" value="Reset"/> <input type="button" value="Cancel"/>	

3. Update your address.
4. Click “Update Address.”

2.10.5 Log-In Information

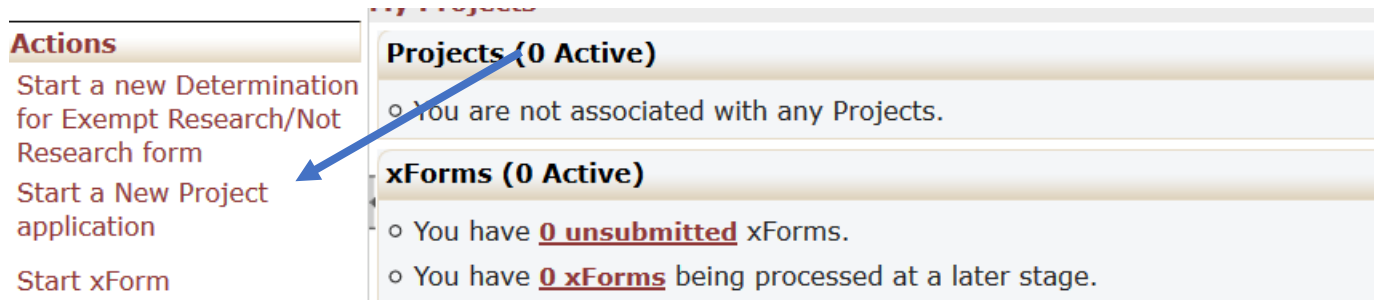
Clicking on this link will provide a list of the time and date of the last 25 times you logged into IRBManager.

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 (i.e. new project, amendment, continuing review)

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.



- 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 requires 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

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	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	

2. Click on the 'Initial Submission' event

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

3. Click on 'xForms'

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

4. Click on the '📁' icon

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

5. A window prompt will open asking 'Copy for Amendment?', click OK.

This site says...

Copy for Amendment?

OK Cancel

Option 2: From within 'My Documents & Forms'

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

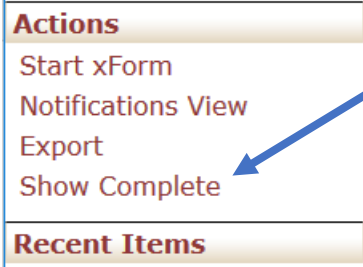
Messages

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'

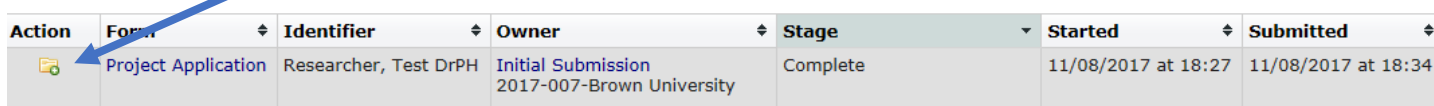



Actions

- Start xForm
- Notifications View
- Export
- Show Complete

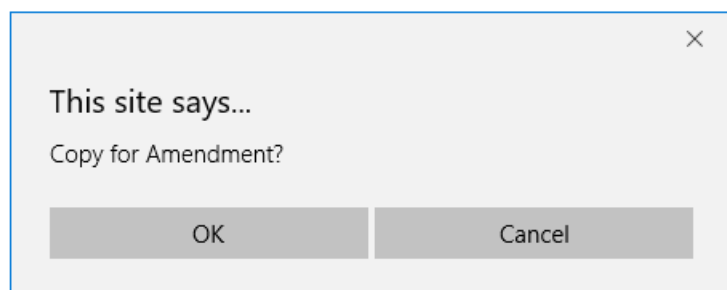
Recent Items

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



Action	Form	Identifier	Owner	Stage	Started	Submitted
	Project Application	Researcher, Test DrPH	Initial Submission 2017-007-Brown University	Complete	11/08/2017 at 18:27	11/08/2017 at 18:34

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, an 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	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

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 xForms 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."

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.

Study Information ▼ Page 2 of 11

Information

Created by:

PH

Email: oshpdtestresearcher@gmail.com Phone:

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.

Add Attachment

Name: (leave blank to use name of uploaded file)

Type: Assent ▼

File:

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 will appear. “Submit” will need to be clicked to complete the submission.

You've completed the form. You can now either save the form for later revision, or submit it.

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 (either as a PI, administrative contact, coordinator, et cetera).

i 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 sent the project for review) and then the form is owned by the project
- 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 review—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
 - IRB 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
 - Under Full Board Review—the project is being reviewed by the convened board
 - Decision Processing—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/determination letter will be attached.

4.0 Navigating the Project Protocol Page

From the home page, you can access a protocol 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, Non-Compliance, 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 link 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:** Principal investigator’s name

Event:

- **Type:** the type of event, which could include New Submission, Continuing Review, Adverse Event/Unanticipated, 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: New submission	Started: 01/28/2016
Instance:	Completed:
Committee: Inherited from Study	

4.7 Steps

This shows the actions that take place as part of the event with the dates. 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), actual date.

Event					
Type:	Initial Submission			Started:	08/21/2017
Instance:				Completed:	
Committee:	Inherited from Study				
Review Cycle:					
▶ Notes (1)					
Steps (10) <input checked="" type="checkbox"/> 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 applicable to that project.

4.8 Actions in the Event Details

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
- 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-mail@oshpd.ca.gov or by phone at (916) 326-3660.