

Creating a New Study Application

Training Course for Investigators and Study Staff

This training will cover...

- Navigating the OHRPP website
- Requesting a webIRB account
- Creating a New Study application
- Responding to IRB Requests
- Additional resources

This training will NOT cover...

- Detailed review of the IRB application
- Protocol development/questions within the application
- Post-approval applications (AM, CR & PAR)

Before getting started

Visit the [OHRPP website](#) for the following resources:

- Guidance and policy
- Forms and templates
- Decision trees
- More information about the UCLA IRBs

OHRPP Website

To access this information:

Click here to access guidance and templates

UCLA Research Administration
Human Research Protection Program

The UCLA IRB Office ▾

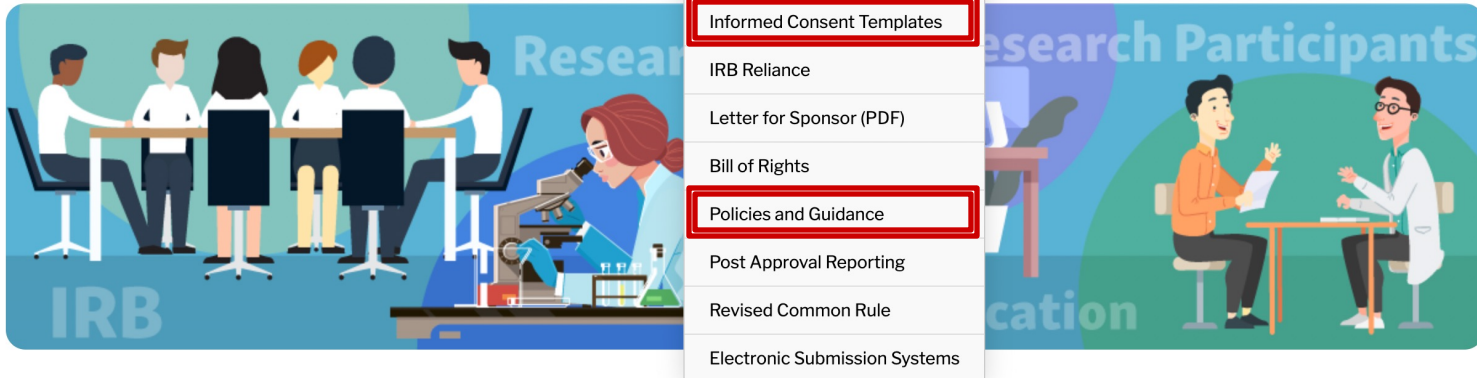
For Researchers ▾

Quality Improvement and Education ▾

For Research Participants ▾



Welcome to OHRPP



The Office of the Human Research Protection Program (OHRPP) is the administrative arm of the UCLA Human Research Protection Program (HRPP). The OHRPP in partnership with the research community is responsible for ensuring the safety and welfare of participants in Human Research Projects conducted under the aegis of UCLA. The OHRPP, which is a Division within the Office of Research Administration, provides the campus and the five UCLA Institutional Review Boards (IRBs) with professional guidance and administrative support.

Guidance Documents

Policies and Guidance

1. Authority and Overview of the Human Research Protection Program
2. OHRPP Educational Outreach and Requirements
3. Activities that Require IRB Review
4. Applying to the IRB
 - Pre-IRB Submission
 - Levels and Types of IRB Review
 - Post-IRB Submission
5. Recruitment, Screening and Informed Consent
6. Protection of Privacy, Confidentiality and Data
7. Research Involving Use and Storage of Data and/or Human Biological Specimens
8. Types of Research and Procedures
 - Biomedical
 - Social, Behavioral and Educational Research
9. Populations

4. Applying to the IRB

Pre-IRB Submission:

- Getting Started with an IRB Application-A Guide for Investigators and Research Staff
- Brief Overview of webIRB Submission Procedures
- Conducting Risk-Benefit Assessments and Determining Level of IRB Review
- Describing Research Design and Methods
- Scientific or Scholarly Review of Human Subjects Research Protocols
- Tip Sheet: Minimal Risk
- Funding Considerations for Federally-Funded and Industry Sponsored Human Research
- Funding Applications and UCLA IRB Review
- Tip Sheet: Delayed Onset Determinations
- Research Supported by the Department of Defense
- Additional Requirements for Federally Supported Research

Learn about the acceptable informed consent and recruitment methods, and how to incorporate required information into recruit material

Social, Behavioral and Educational Research

- Research Involving the Internet
- Tip Sheet: Online Survey Protection Considerations
- Deception or Incomplete Disclosure
- Research Involving Students and/or Conducted in Educational Settings

CITI Training



Visit the OHRPP CITI training help page to determine the appropriate training required:
<https://ohrpp.research.ucla.edu/citi-training/>

Before you can submit your project, all persons listed in the study application (Section 1.1) who will engage in human subjects research must complete either the Human Subjects Research Training ***OR*** the Good Clinical Practice (GCP) training. Both trainings are valid for three years.

- NIH-funded clinical trials *require* GCP training
- If accessing medical records, UCLA research HIPAA training is required. Research HIPAA training is only required once, no expiration.

How to request a webIRB account

To request a webIRB account, email:
weblirbhelp@research.ucla.edu

If you are not qualified to be a PI under UCLA [Policy 900](#), you must secure a *faculty sponsor* and have them email the following information:

- Your full name
- Your email address
- Your UCLA Logon ID
- Your 9-digit UID
- Your department/division

webIRB Official Site

Once you are ready to set up your webIRB account and create a *New Study* application visit:

<https://webirb.research.ucla.edu>

The screenshot shows the webIRB Official Site interface. At the top left, the logo reads "webIRB UCLA Research Administration". A navigation menu on the left includes: Login, Training Information, webIRB Accounts (highlighted in red), Schedule of System Maintenance and Upgrades, Quick Reference Guides & Training Materials, Forms to Upload in webIRB, webIRB Frequently Asked Questions (FAQ), and Contact Us. Below the menu is a "Return to" button with the OHRPP UCLA logo. The main content area is titled "webIRB Home" and contains a yellow box with information about the new OHRPP submission system, BruinIRB, and a red box for "Weekly Maintenance and/or Upgrades". A "Login" button is highlighted with a red box in the top right corner, with a black arrow pointing to it from a callout box.

Select "LOGIN" to access your webIRB account

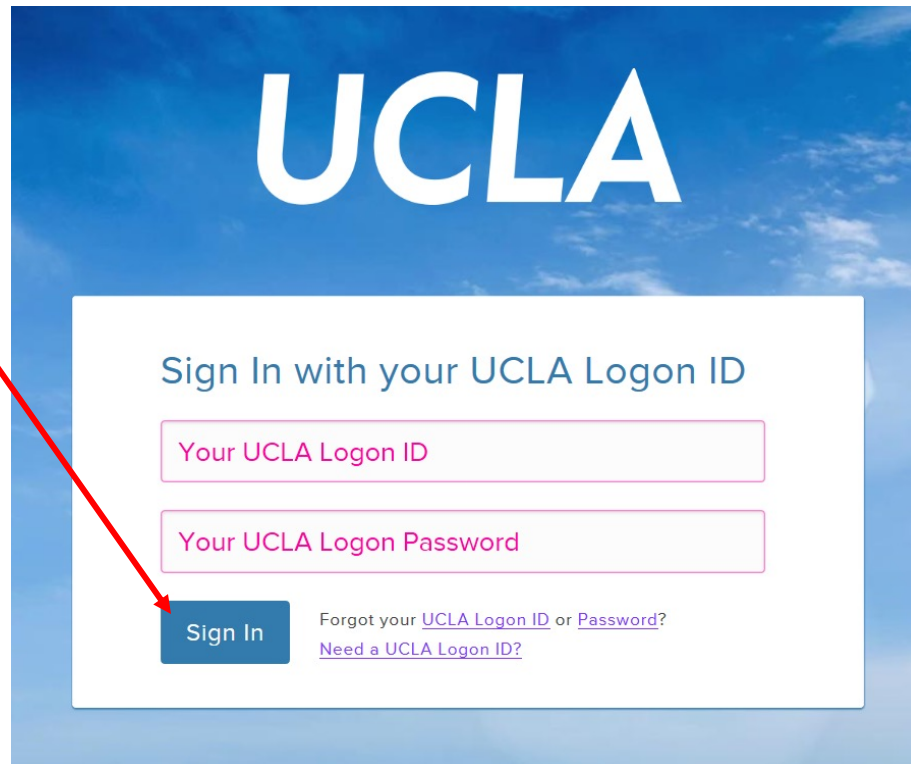
Welcome to webIRB

webIRB is UCLA's internet-based software application for the submission and review of research projects involving human subjects. All levels of review use the same webIRB application, which is designed to branch in response to information provided about the study procedures. [Click here](#) for the OHRPP guidance document "Brief Overview of webIRB Submission Procedures."

To begin using webIRB, click the Login button at the top right of the screen. Please note that you must have a webIRB account to log on. To obtain an account, please select **webIRB Accounts** from the menu to the left.

Login

1. Enter your UCLA Logon ID and password
2. Click **Sign In**



The image shows a screenshot of the UCLA login page. At the top, the word "UCLA" is displayed in large white letters against a blue sky background. Below this, a white box contains the login form. The form has the heading "Sign In with your UCLA Logon ID". It features two input fields: "Your UCLA Logon ID" and "Your UCLA Logon Password". Below the password field is a blue "Sign In" button. To the right of the button, there are two links: "Forgot your [UCLA Logon ID](#) or [Password](#)?" and "[Need a UCLA Logon ID?](#)". A red arrow from the "Sign In" button in the instructions points to the "Sign In" button on the form.

"My Home" Page

The screenshot shows the 'My Home' page for a PI1 user. The page includes a navigation bar with 'A PI1 | My Home | Logoff', a breadcrumb trail 'webIRB Home | IRB Protocols | Page for A PI1', and a 'Study Team' section. The main content area is titled 'Page for A PI1' and contains a 'Welcome to your Home Page.' message, a list of links for 'Inbox' and 'Other Tabs', and a 'webIRB Survey' section. Below the survey is a 'My Inbox' section with tabs for 'My IRB Studies', 'Archived', and 'Profile'. A table of IRB studies is displayed at the bottom, with columns for ID, Name, State, Last State Change, and PI.

Breadcrumb: Find your way through the study workspaces

Navigation Bar
My Home: find your way home
Your Name: Update your contact information

My Inbox: contains links to submissions that need your attention:
NS = New Study
PAR = Post-Approval Reports & Single Subject Exception
AM = Amendment
CR = Continuing Review or Closure

Archived: contains studies that have been withdrawn, closed, and don't require UCLA IRB review.

Filter by	ID	Name	State	Last State Change	PI
NS	IRB#12-000006	Sample Approved Study for webIRB Training - 1 - DO NOT TOUCH	Pre Submission	7/18/2012 7:34 AM	PI1
CR	IRB#12-000004-CR-00006	2013 Review for IRB#12-000004	Pre Submission	7/19/2012 2:43 PM	PI1
AM	IRB#12-000004-AM-00006	Example of linked AM	Pre Submission	7/19/2012 2:05 PM	PI1
AM	IRB#12-000004-AM-00005	Amendment #5 for webIRB Study IRB#12-000004	Pre Submission	7/18/2012 11:18 AM	PI1
PAR	IRB#12-000004-PAR-00000001	test	Pre Submission	5/1/2012 1:47 PM	PI1

My IRB Studies: contains all open studies

Create a "New Study" application

webIRB | UCLA Research Administration

A PI1 | My Home | Logoff

webIRB Home | IRB Protocols

Page for A PI1

Study Team

My Roles
Study Team

Create New Study

NS New Study

Page for A PI1

Welcome to your Home Page.

This page has links to all of the items applicable to your account.

- Inbox:** Displays your studies that have a task requiring completion.
- Other Tabs:** Provide links to your studies and personal profile.

Click here for a Quick Reference Guide.

webIRB Survey

We are interested in your feedback about webIRB. After you have used the program to submit a study, please click [here](#) to respond to a user survey.

My Inbox | My IRB Studies | Archived | Profile

Displays all items which require action by the study team. Click on links for more information.

Filter by ID [dropdown] [Go] [Clear] Advanced

ID	Name	State	Last State Change	PI
NS IRB#12-000006	Sample Approved Study for webIRB Training - 1 - DO NOT TOUCH	Pre Submission	7/18/2012 7:34 AM	PI1
CR IRB#12-000004-CR-00006	2013 Review for IRB#12-000004	Pre Submission	7/19/2012 2:43 PM	PI1
AM IRB#12-000004-AM-00006	Example of linked AM	Pre Submission	7/19/2012 2:05 PM	PI1
AM IRB#12-000004-AM-00005	Amendment #5 for webIRB Study IRB#12-000004	Pre Submission	7/18/2012 11:18 AM	PI1
PAR IRB#12-000004-PAR-00000001	test	Pre Submission	5/1/2012 1:47 PM	PI1

Click to create a **New Study**

The account you logged into will appear here.

"General Information" Page

webIRB | UCLA Research Administration New: Study

<< Back Save | | Print... Continue >>

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Smartform FAQ

General Information

All items marked with a red asterisk (*) are required. Items without an asterisk may or may not be required depending on whether the items are applicable to this study.

1.0 *Full Title of the Submission: ?

1.1 Protocol Version Date and/or Number: ?

2.0 *Working or Lay Title: ?

3.0 Principal Investigator:

3.1 *Name: [None] Select...

3.2 UCLA Title:


3.3 Affiliation(s): There are no items to display
Other Affiliations: (if provided)

Note: The information for items 3.2 through 3.4 will automatically appear after you click **Save**.

The **General Information** Section of the Study Smartform will appear.

Provide a response to each question.

The questions with a red asterisk (*) are required.

For help with answering a question, click on  or refer to the guidance in the grey text box.

Insert the descriptive title. Avoid using generic titles like, "My Thesis" or "New Study".

Tip: Save your work!

webIRB | UCLA Research Administration

New: Study

<< Back Save | Print... Continue >>

Smartform FAQ

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

General Information

All items marked with a red asterisk (*) are required. Items without an asterisk may or may not be required depending on whether the items are applicable to this study.

1.0 *Full Title of the Submission:

1.1 Protocol Version Date and/or Number:

2.0 *Working or Lay Title:

3.0 Principal Investigator:

3.1 *Name: [None] Select...

3.2 UCLA Title:

3.3 Affiliation(s): There are no items to display
Other Affiliations: (if provided)

3.4 Department:

3.5 *Will the Principal Investigator conduct the informed consent process with potential study participants?

Note: The information for items 3.2 through 3.4 will automatically appear after you click Save.

After completing **all required** items on this page, click **Save** after completing the entire General Information section.

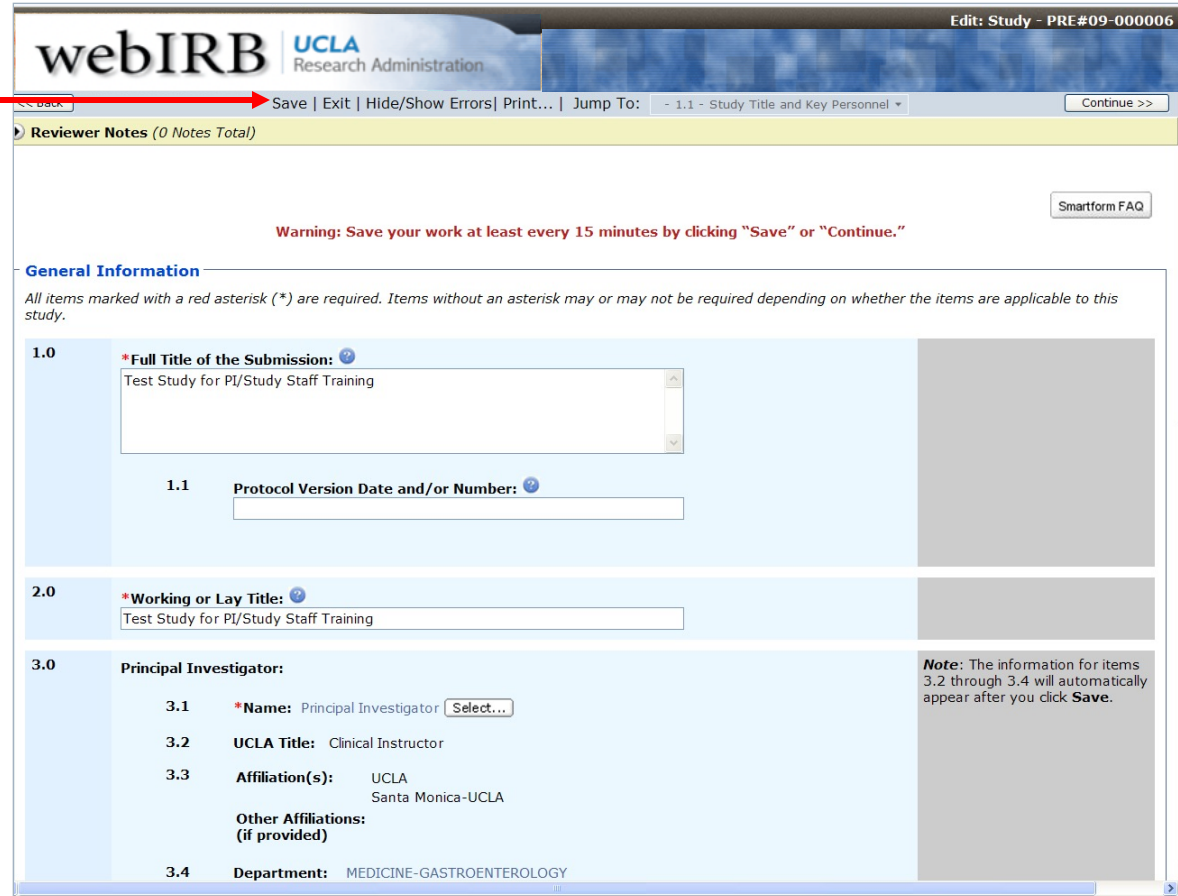
Before moving to the next page or logging off, select **"Save"**. After clicking "Save" more activities will appear at the top of the page.

Tip: Save your work!

Note the additional actions that will appear in the menu bar after clicking **Save**.

Important Note:

- webIRB does not have an auto-save feature.
- Click **Save** periodically (every 15 minutes) to ensure that your work is saved.



The screenshot shows the webIRB interface for editing a study (PRE#09-000006). The top navigation bar includes a menu with options: Save, Exit, Hide/Show Errors, Print..., and Jump To: 1.1 - Study Title and Key Personnel. A red arrow points from the 'Save' option in the menu to the 'Save' button in the text box below. A yellow banner at the top of the form area contains the text: 'Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."'.

The form is titled 'General Information' and contains the following fields:

- 1.0 *Full Title of the Submission:** Text box containing 'Test Study for PI/Study Staff Training'.
- 1.1 Protocol Version Date and/or Number:** Text box.
- 2.0 *Working or Lay Title:** Text box containing 'Test Study for PI/Study Staff Training'.
- 3.0 Principal Investigator:**
 - 3.1 *Name:** Principal Investigator (Select...)
 - 3.2 UCLA Title:** Clinical Instructor
 - 3.3 Affiliation(s):** UCLA, Santa Monica-UCLA
 - Other Affiliations: (if provided)**
 - 3.4 Department:** MEDICINE-GASTROENTEROLOGY

A note on the right side of the form states: 'Note: The information for items 3.2 through 3.4 will automatically appear after you click Save.'

Navigation Tools

The screenshot displays the webIRB interface for editing a study (IRB#09-000003). At the top, there is a navigation bar with options: << Back, Save, Exit, Hide/Show Errors, Print..., Jump To: 1.1 - Study Title and Key Personnel, and Continue >>. Below this is a yellow bar for Reviewer Notes (0 Notes Total) with Add and Delete buttons. A warning message states: "Warning: Save your work at least every 15 minutes". The main content area is titled "General Information" and contains a table of contents with sections 1.0 through 9.4. A red asterisk is next to sections 1.0 and 2.0. A "Jump To" dropdown menu is open, showing a list of sections with "1.1 - Study Title and Key Personnel" selected. A "Continue >>" button is also visible.

Use **Exit** to go to the Study workspace.

The **Jump To** Menu can be used to go to specific sections of the application.

- **Red Title** - where you are
- **Black Titles** - sections that will be required

Note: More sections may appear as you answer items in the form

Use **Continue** to navigate forward through the form to the next section (this activity will also save the changes made in the current section)

Checking Your Progress

1. Click **Hide/Show Errors**

DEVELOPMENT
UCLAwebIRB

Edit: Study - IRB#09-000148

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 1.1 - Continue >>

Study Title and Key Personnel

Reviewer Notes (0 Notes Total)

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Smartform FAQ

General Information

All items marked with a red asterisk (*) are required. Items without an asterisk may or may not be required depending on whether the items are applicable to this study.

1.0 *Full Title of the Submission: Mark & Anthony - Case #18 NSWF

1.1 Protocol Version Date and/or Number: June 25, 2009

2.0 *Working or Lay Title: Sample study for Anthony and Mark for case #18

3.0 Principal Investigator: Note: The information for items 3.2 through 3.4 will

Error/Warning Messages Refresh

Message	Field Name	Jump To
This is a required field; therefore, you must provide a value.	PI Will Obtain Consent	1.1 - Study Title and Key Personnel
This is a required field; therefore, you must provide a value.	Funding Source.Type of Award	6.2 - Funding - Description
This is a required field; therefore, you must provide a value.	Select All That Apply to Access or Included Identifiers	9.2 - Information about Study Data
This is a required field; therefore, you must provide a value.	Subjects Incur any Financial Obligations	16.3 - Costs Related to Study Participation

2. A screen will appear with links to pages needing completion. Click the links to go to the pages.

3. Remember to click **Save** after providing your response(s).

DEVELOPMENT
UCLAwebIRB

Edit: Study - IRB#09-000275

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 1.1 - Continue >>

Study Title and Key Personnel

Reviewer Notes (1 Note Total) Add Delete

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Smartform FAQ

General Information

All items marked with a red asterisk (*) are required. Items without an asterisk may or may not be required depending on whether the items are applicable to this study.

1.0 *Full Title of the Submission: Mark & Anthony - Case #18 NSWF

1.1 Protocol Version Date and/or Number: June 25, 2009

2.0 *Working or Lay Title: Sample Study for Anthony and Mark for case #18

3.0 Principal Investigator: Note: The information for items 3.2 through 3.4 will automatically appear after you click Save.

3.1 *Name: Rebecca Simms (PI) Select...

Error/Warning Messages Refresh

No Errors Found

4. Update the list of items needing completing by clicking **Refresh**. The error screen will update.

Click **Hide/Show Errors** again to hide the screen

Navigation Tools

The screenshot displays the webIRB interface for a study titled "Training- Basic 1". The top navigation bar includes "webIRB Home" and "IRB Protocols". The left sidebar contains "Current State" (Pre Submission) and "My Activities" (Send Notification to FS for FS Assurances, Submit Study, Send Training Reminder, Withdraw, Edit PI Proxy, Study Team - Log Private Comment). The main content area shows study details: Principal Investigator (A PI1), Faculty Advisor (A PI3), PI Proxy (Rebecca Simms (PI) A PI2), PI Assurances (Pending...), and FS Assurances (Pending...). A callout box with a green border and arrow points to the "Edit Study" button in the Current State section, containing the text: "Click **Edit Study** to go back to the Smartform". A larger grey callout box on the right contains the text: "If you need to logoff, save your work, first. Upon returning, you can continue working where you left off by selecting 'Edit Study' on your dashboard." The bottom section features tabs for "History", "Attachments", "IRB Requests", "Training Log", and "Change Log". The History table shows the following data:

Activity	Author	Activity Date
Notification Sent to FS for FS Assurances	PI1, A	3/5/2012 2:48 PM PST
Edited PI Proxy	PI1, A	3/5/2012 11:58 AM PST
Reactivated	PI1, A	3/1/2012 10:25 AM PST

Study Workspace

The screenshot shows the webIRB Study Workspace interface. At the top, there is a navigation bar with 'webIRB Home' and 'IRB Protocols'. The main header includes the 'webIRB' logo and 'UCLA Research Administration'. The user is logged in as 'A PI1' with options for 'My Home' and 'Logoff'. The current study is 'Test Study for webIRB Training- Basic 1'. The 'Current State' is 'Pre Submission'. The main content area displays study details: Full Title of Study, Protocol ID, Principal Investigator, Study Contact Person, Faculty Advisor, PI Proxy, PI Assurances, and FS Assurances. At the bottom, there are 'Information Tabs' for History, Attachments, IRB Requests, Training Log, and Change Log.

Current State

Views of the Study

Study Activities

Summary information about the Study

Information Tabs

Field	Value
Full Title of Study:	Test Study for webIRB Training- Basic 1 (NOTE: For Use in WebIRB Training Class only)
Protocol ID:	IRB#11-000001
Principal Investigator:	A PI1
Study Contact Person:	Study Staff1
Faculty Advisor:	
PI Proxy:	Rebecca Simms (PI)
PI Assurances:	Pending...
FS Assurances:	Not Required

Current State of the Application

Current State

Pre Submission



Edit Study



Printer Version



View Differences

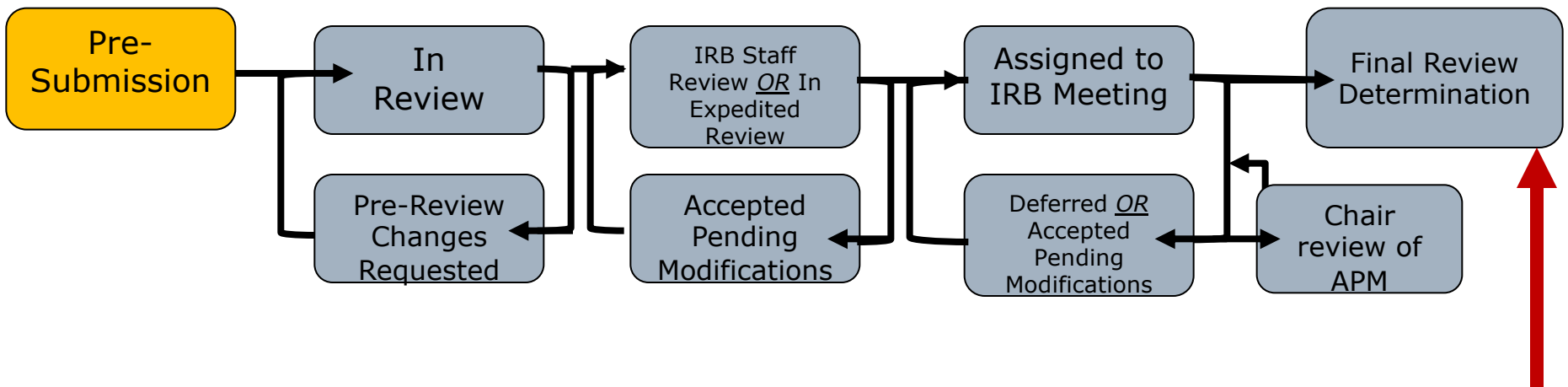


View SmartForm Progress

As your application is triaged through the IRB review process, the **Current State** of your application will change.

Note: Your study application may remain in the same current state for several days or weeks depending on various factors including your response time, the volume of submissions or the type of review (exempt, expedited or full board).

Current State of the Application



As your study application undergoes the IRB review process, the IRB might ask for additional clarification or information prior to moving your application along to the next phase of the review process. To avoid delays, please respond to any requests for clarification or additional information within a timely manner.

IRB final review determinations can be:

- Approved
- Approved-No CR
- Certified Exempt
- External Review Accepted
- Disapproved

Note: IRB#

- **Before submission**, studies get a PRE#.
For example, PRE#21-000010
- **After submission**, studies get an IRB#.
For example, IRB#21-000325

Note: The PRE# and the IRB# will not match

It is important to note your assigned IRB# for the study. When corresponding with the IRB, the staff may ask for your IRB# to easily identify your study.

Study Workspace

The screenshot shows the webIRB interface for a study. At the top, there is a navigation bar with 'webIRB Home' and 'IRB Protocols'. The current page is 'Test Study for webIRB Training- Basic 1'. The main content area is divided into two sections: 'Current State' and 'My Activities'. The 'Current State' section shows the study is in 'Pre Submission' status and provides buttons for 'Edit Study', 'Printer Version', 'View Differences', and 'View SmartForm Progress'. The 'My Activities' section lists actions like 'Send Notification to FS for FS Assurances', 'Submit Study', 'Send Training Reminder', 'Withdraw', 'Edit PI Proxy', and 'Study Team - Log Private Comment'. The right side of the page displays study details: 'Full Title of Study: Test Study for webIRB Training- Basic 1 (NOTE: For Use in WebIRB Training Class only)', 'Protocol ID: IRB# 11-000001', 'Principal Investigator: A PI1', 'Study Contact Person: Study Staff1', 'Faculty Advisor:', 'PI Proxy: Rebecca Simms (PI)', 'PI Assurances: Pending...', and 'FS Assurances: Not Required'. At the bottom, there are tabs for 'History', 'Attachments', 'IRB Requests', 'Training Log', and 'Change Log'.

webIRB | UCLA Research Administration

A PI1 | My Home | Logoff

webIRB Home | IRB Protocols

IRB Protocols > Test Study for webIRB Training- Basic 1

Current State

Pre Submission

Edit Study

Printer Version

View Differences

View SmartForm Progress

My Activities

Send Notification to FS for FS Assurances

Submit Study

Send Training Reminder

Withdraw

Edit PI Proxy

Study Team - Log Private Comment

Study: Test Study for webIRB Training- Basic 1

Full Title of Study: Test Study for webIRB Training- Basic 1
(NOTE: For Use in WebIRB Training Class only)

Protocol ID: IRB# 11-000001

Principal Investigator: A PI1

Study Contact Person: Study Staff1

Faculty Advisor:

PI Proxy: Rebecca Simms (PI)

PI Assurances: Pending...

FS Assurances: Not Required





History | Attachments | IRB Requests | Training Log | Change Log

Study Activities

My Activities



Study Staff

My Activities

-  Send Ready Notification
-  Send Training Reminder
-  Withdraw
-  Study Team - Log Private Comment






PI Proxy

My Activities

-  Submit Study
-  Send Training Reminder
-  Withdraw
-  Study Team - Log Private Comment

PI

My Activities

-  Send Notification to FS for FS Assurances
-  Submit Study
-  Send Training Reminder
-  Withdraw
-  Edit PI Proxy
-  Study Team - Log Private Comment

Available activities differ by the current state of the protocol and role of the person.

Faculty Sponsor

My Activities

-  Submit Study
-  Faculty Sponsor Assurances
-  Send Training Reminder
-  Withdraw
-  Study Team - Log Private Comment

My Activities: Send Notification to FS

- If you have a Faculty Sponsor (FS) for the study, his/her assurances are required **before** the study can be submitted.
- Click on the activity **Send Notification to FS for FS Assurances** to send an email notification to your FS.
- The email will provide a link to the study workspace.
- This activity is only available to the PI.

The image shows a screenshot of a web application interface. On the left, a 'My Activities' menu is visible with several options: 'Send Notification to FS for FS Assurances', 'Submit Study', 'Send Training', 'Withdraw', 'Edit PI Proxy', and 'Study Team - Comment'. A green arrow points from the first option in the menu to a larger window on the right. This window is titled 'Send Notification to FS for FS Assurances' and contains the following text: 'Send notification to FS for his/her assurances', 'Executing this activity will notify the Faculty Sponsor that this protocol is ready for his/her assurances.', 'You may also add comments using the area provided below.', and 'Click OK to send your notification to FS, or Cancel to exit without saving.' Below this text is a large text area for 'Comments to Faculty Sponsor:'. At the bottom right of the window are 'OK' and 'Cancel' buttons. The browser's address bar shows the URL: 'https://webirbtest.research.ucla.edu/sandbox/ResourceAdministration/Activity/form?_webrNew=all&A&'. The browser's status bar at the bottom shows 'Done', 'Internet', and '100%' zoom.

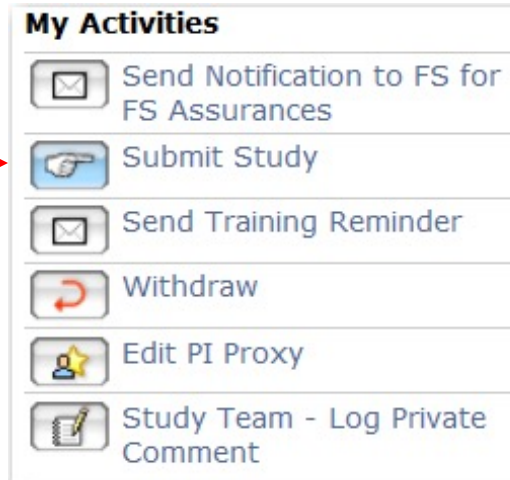
My Activities: Submit Study & Send Ready Notification

Click on the activity **Submit Study** when the application is complete.






This activity is only available to the PI, PI Proxies, and FS.

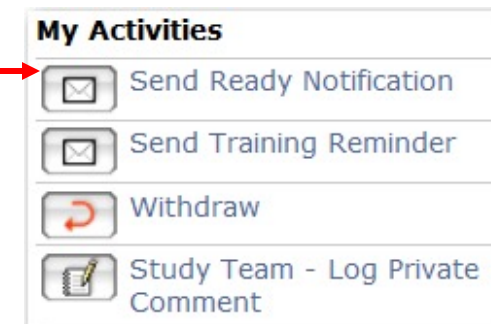
Send Ready Notification is available to all personnel listed in section 1.1.

An email will be sent to the PI, PI Proxies, and FS that contains a link to the study workspace.







My Activities

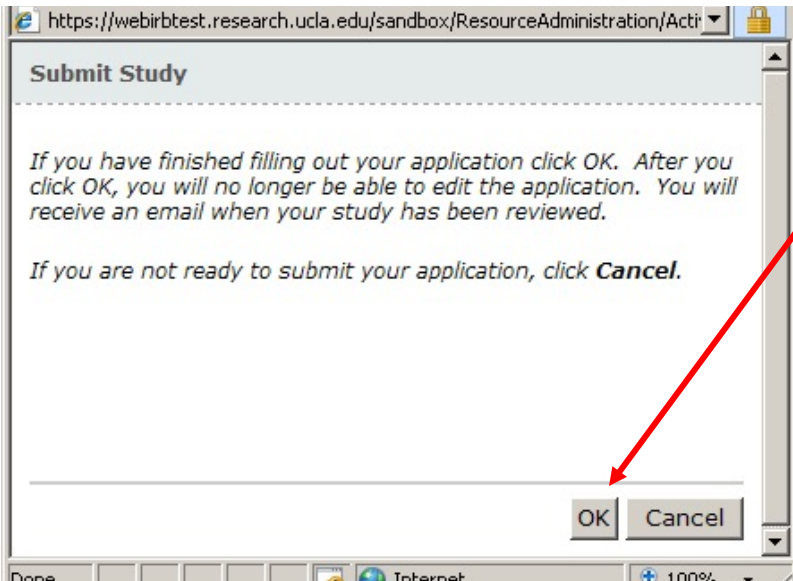
-  Send Notification to FS for FS Assurances
-  **Submit Study**
-  Send Training Reminder
-  Withdraw
-  Edit PI Proxy
-  Study Team - Log Private Comment



My Activities

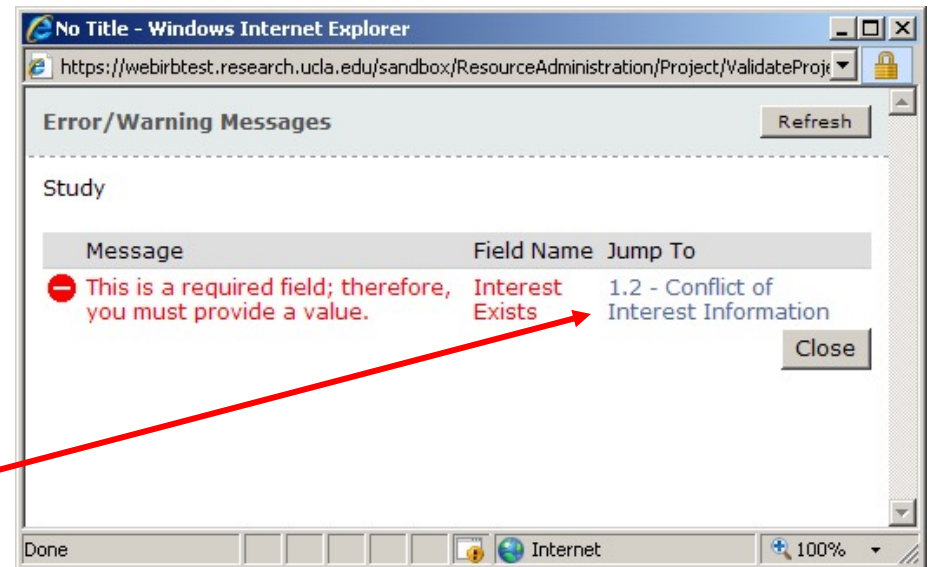
-  **Send Ready Notification**
-  Send Training Reminder
-  Withdraw
-  Study Team - Log Private Comment

My Activities: Submit Study or Send Ready Notification



If the application is complete, you will get a **Submit Study** screen.
Click **OK** to submit.

- If there are still items to complete, you will get an **Error/Warning Message**.
- Use the blue link to jump to the Section with the incomplete item(s).



My Activities: PI Assurances

webIRB | UCLA Research Administration

A PI1 | My Home | Logoff

webIRB Home | IRB Protocols

IRB Protocols > Training Study for MIRB1&3 Staff (Y)

Current State

In Review

View Study

Printer Version

View Differences

Owner (IRB Staff):

My Activities

PI Assurances

Study: Training Study for MIRB1&3 Staff (Y)

Full Title of Study: Training Study for MIRB1&3 Staff (Y)
Protocol ID: IRB#10-000163

Principal Investigator: A PI1
Faculty Sponsor:
Committee: Medical IRB 1
Initial Submission Date: 4/22/2010

Study Contact Person:
Review Type:

PI Assurances: Pending...
FS Assurances: Not Required

History | Attachments | IRB Requests | Correspondence | Training Log | Change Log

Activity	Author	Activity Date
Study Submitted for Review	CARRIE FISHER	4/22/2010 12:12 PM PDT
Created Study	CARRIE FISHER	4/22/2010 12:08 PM PDT

- **After** the study is submitted, the **PI Assurances** activity will become available to the PI.
- The PI Assurances must be completed by the PI (and only the PI) before the study can be approved.

The study team can check to see if the assurances are completed on the summary screen

My Activities: PI Assurances

PI Assurances

Please select the applicable assurance(s) for your submission. Select either the assurance for submitting Review or Study Closure. There are 3 of these and click the "OK" button.

Existing Review

1.0 I certify that the information provided in this application is complete and correct.
Agree

1.1 I understand that as Principal Investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the IRB.
Agree

1.2 I agree to comply with all FDA policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human subjects in research, including, but not limited to, the following:

- Ensuring that the principal performing the project are qualified, appropriately trained, and all willing to the provisions of the approved protocol.
- Implementing no changes to the approved protocol or research process or deviations without your IRB approval (except in an emergency, if necessary to safeguard the well-being of human subjects and then notifying the IRB as soon as possible afterwards).
- Obtaining the inquiry & feedback responses (except from human subjects or their legally responsible representatives) and using only the currently approved consent process and approved research documents, as appropriate, with human subjects.
- Reporting serious or unexpected adverse events as well as protocol violations or other incidents related to the protocol to the IRB in writing within 30 working days.
- Ensure that adequate resources to protect research participants (i.e., personnel, funding, time, equipment and space) are in place before implementing the research project, and that the research will stop if adequate resources become unavailable.
- Assigning the Principal Investigator to assume direct responsibility of the study if at any time it will be unfeasible to conduct this research personally. For example, when on sabbatical leave or vacation or other absence. When the person is called as a co-investigator in the application, s/he will submit IRB to help in interest of such arrangements.

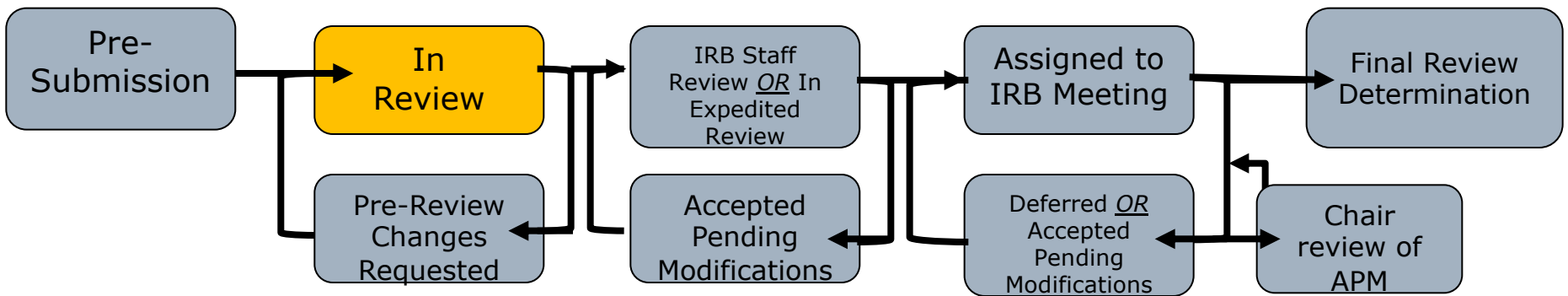
Agree

Study Closure

1.0 I certify that all study activities involving contact with study participants, as well as access to personal identifiable information has ceased and the information provided in this report is complete and correct.
Agree

Carefully read all assurances before selecting "OK".

Current State of the Application



Once your application has been submitted, the current state of the application will change to "**Pre-Review**". At this time, if the IRB analyst assigned to your project determines that you are missing documents or information or requests clarification, then the status will change to "**Pre-Review Changes Requested**".

My Activities

webIRB | UCLA Research Administration

A PI1 | My Home | Logoff

webIRB Home | IRB Protocols

IRB Protocols > Training Study for MIRB1&3 Staff (Y)

Current State

Pre-Review Changes Requested

View Study

Printer Version

View Differences

Owner (IRB Staff):

My Activities

- PI Assurances
- Send Training Reminder
- Withdraw
- Edit PI Proxy
- Copy Study
- Send Inquiry or Reply to IRB
- Study Team - Log Private Comment

Study: Training Study for MIRB1&3 Staff (Y)

Full Title of Study: Training Study for MIRB1&3 Staff (Y)
Protocol ID: IRB#10-000163

Principal Investigator: A PI1
Faculty Sponsor:
Committee: Medical IRB 1
Initial Submission Date: 4/22/2010
Study Contact Person:
Review Type:
Meeting Date-Time: - N/A

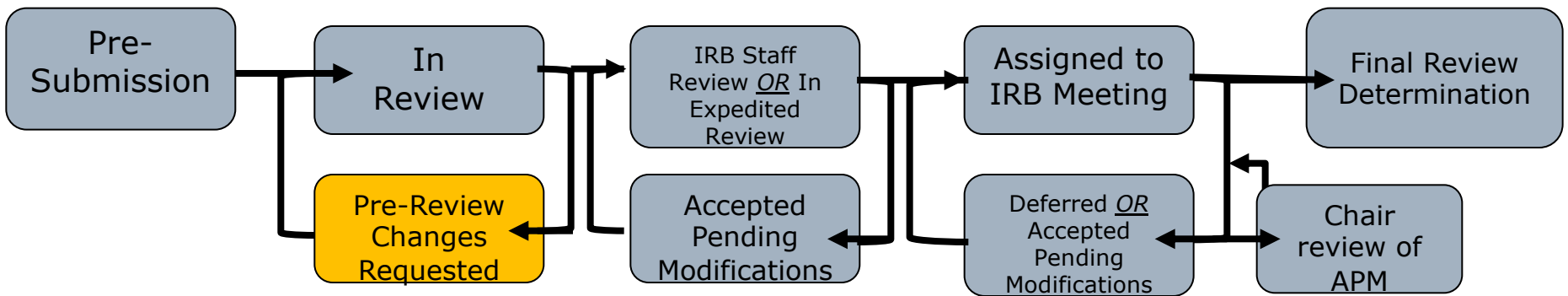
PI Assurances: Pending...
FS Assurances: Not Required

History | Attachments | IRB Requests | Correspondence | Training Log | Change Log

Activity	Author	Activity Date
Study Submitted for Review	CARRIE FISHER	4/22/2010 12:12 PM PDT
Created Study	CARRIE FISHER	4/22/2010 12:08 PM PDT

If OHRPP staff request modifications or additional information, the current state of the study will change.

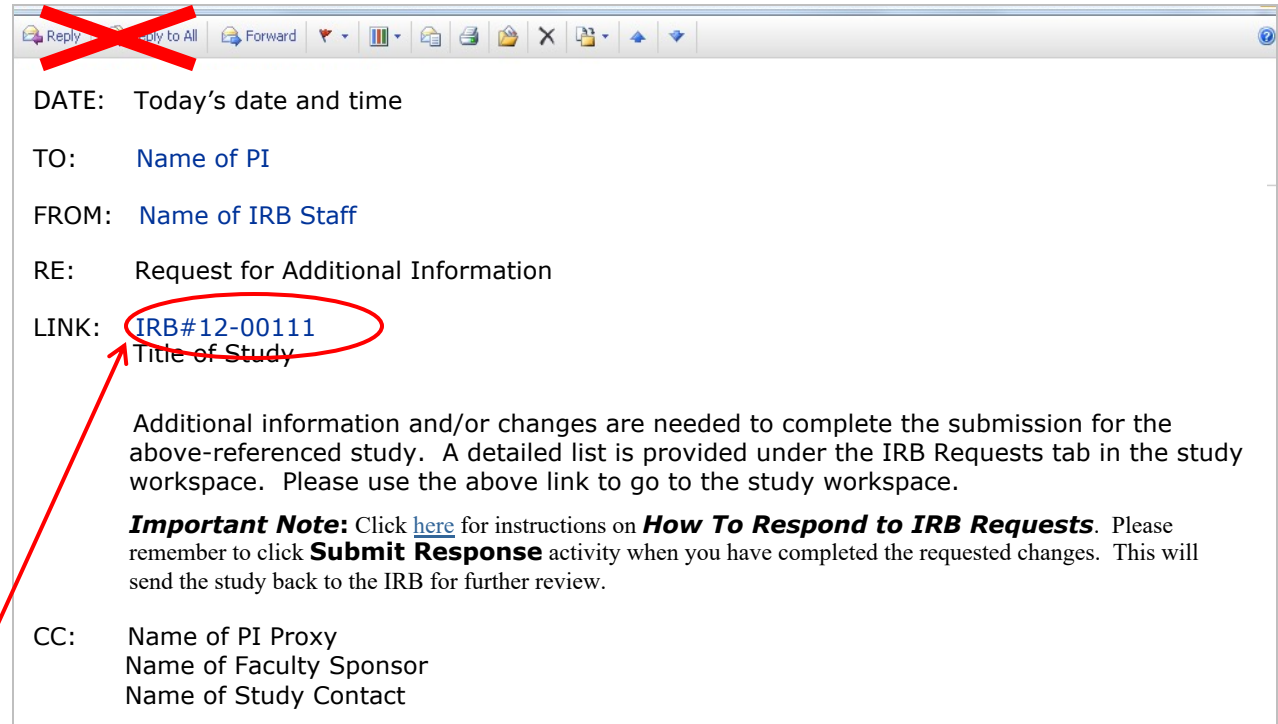
Current State of the Application



During the review process, the current state of your application will change. If your application is in any of the states at the top, it means the IRB has your application. If your application is any of the bottom states, it means action is required on your part to move your application along.

IRB Correspondence

- The PI, PI Proxies, FS, and Contact Person will receive an email notification when the IRB:
 - ❖ requests pre-review changes
 - ❖ issues a letter (i.e., IRB Determination)
- Use the link in the email to go to the project workspace and respond to the IRB requests.
- **Do Not Reply to the email.**



Example of webIRB email notification the PI will receive when the IRB requests Pre-Review Changes to his/her study application.

Responding to IRB Requests

- When responding to an IRB request for a Study click **"Edit Study"**
- Section 1.1 of the Study Smartform will appear.

webIRB | UCLA Research Administration

webIRB Home | IRB Protocols

IRB Protocols > Test Study for PI13 (lucky thirteen)/Study Staff13(lucky thirteen) Training

Current State

Pre-Review Changes Requested

Edit Study

Printer Version

View Differences

Study: Test Study for PI13 (lucky thirteen)/Study Staff13(lucky thirteen) Training

Full Title of Study: Test Study for PI13/Study Staff13 Training



Protocol ID: IRB#09-000015

Principal Investigator: A PI13

Study Contact Person:

Faculty Sponsor:

Review Type:

- To view the IRB requests in Section 1.1, click the arrow  so that it points down .
- If there are no IRB requests for Section 1.1 you will see the message:
"There are no items to display".

webIRB | UCLA Research Administration

<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To: 1.1 - Study Title and Key Personnel

Reviewer Notes (0 Notes Total)

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Study Title and Key Personnel

Next

Click on **"Next"** to view the next section with an IRB request.

webIRB | UCLA Research Administration

<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To: 1.1 - Study Title and Key Personnel

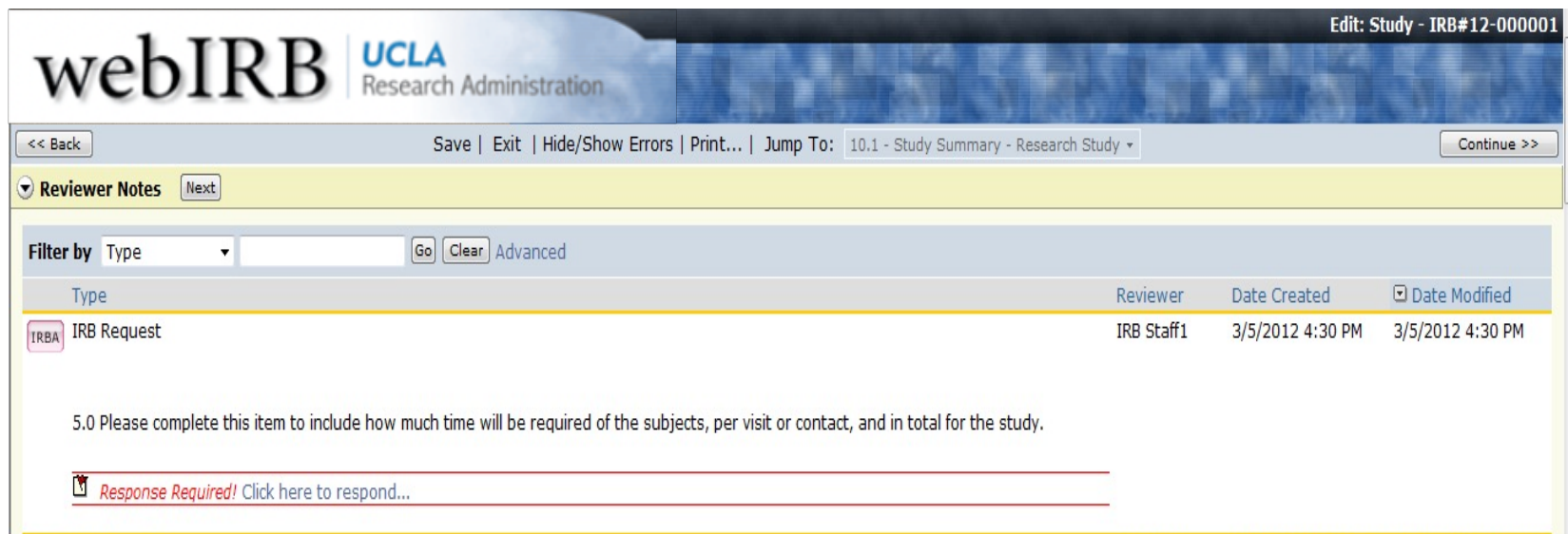
Reviewer Notes

Next

Type	Reviewer	Date Created
There are no items to display		

33

Responding to IRB Requests (cont'd)



The screenshot shows the webIRB interface for UCLA Research Administration. The top navigation bar includes the logo, navigation links (Back, Save, Exit, Hide/Show Errors, Print..., Jump To: 10.1 - Study Summary - Research Study, Continue >>), and the current study ID (Edit: Study - IRB#12-000001). Below the navigation bar is a 'Reviewer Notes' section with a 'Next' button. A filter section allows filtering by 'Type' with 'Go' and 'Clear' buttons, and an 'Advanced' link. A table lists IRB requests with columns for Type, Reviewer, Date Created, and Date Modified. The table contains one entry: IRBA IRB Request, reviewed by IRB Staff1, created on 3/5/2012 4:30 PM, and modified on 3/5/2012 4:30 PM. Below the table, a message states: '5.0 Please complete this item to include how much time will be required of the subjects, per visit or contact, and in total for the study.' A red-bordered box contains the text: 'Response Required! Click here to respond...'

Type	Reviewer	Date Created	Date Modified
IRBA IRB Request	IRB Staff1	3/5/2012 4:30 PM	3/5/2012 4:30 PM

DO NOT select "Click here to respond..." yet, instead:

1. Make all the requested changes in the Smartform.
2. Click **Save** after making changes to the Smartform.
3. When the changes are complete (make sure to **SAVE** your changes), click - **Click here to respond...** A dialogue box will open.

Responding to IRB Requests (cont'd)

When the dialogue box opens:

- Use the drop-down menu to indicate how you are responding.
- Write a response to the IRB in the text box (e.g., Done, Complete). You do not need to repeat the response provided in the Smartform.
- Click **OK**

Respond to Reviewer Notes

Author: IRB Senior Staff Test
Section 18.1/Item 1. Sample IRB Request

* User: Rebecca Simms (PI)

* Type: Change Request Completed a

* Response: b

c

OK Cancel

* Required

Your response will appear in a green text box.

Type	Reviewer	Modified
OPRS-IRB Request	IRB Senior Staff Test	4/28/2009 2:15 PM
<input checked="" type="checkbox"/> Paul Investigator - Change Request Completed - 4/28/2009 2:15 PM xyz		

Responding to IRB Requests (cont'd)

When the response has been completed, the color of the notes will change from **red** to **green**.

When there is more than one request, click **Next** to complete the additional requests.

BEFORE RESPONSE

Reviewer Note

Filter by Type [dropdown] [input] Go Clear Advanced

Type	Reviewer	Modified
IRBA OPRS-IRB Request	IRB Senior Staff Test	4/28/2009 9:51 AM

Response Required! [Click here to respond...](#)

Item #6 - Please provide a description of the requested amendment and reason for the change in item 6.

AFTER RESPONSE

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: 1.0 - Description of Amendment | Continue >>

Reviewer Note

Filter by Type [dropdown] [input] Go Clear Advanced

Type	Reviewer	Modified
IRBA OPRS-IRB Request	IRB Senior Staff Test	4/28/2009 2:15 PM

Item #6 - Please provide a description of the requested amendment and reason for the change in item 6.

Paul Investigator - Change Request Completed - 4/28/2009 2:15 PM
xyz

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: 10.1 - Study Summary - Research Study | >>

Reviewer Notes **Next**

Filter by Type [dropdown] [input] Go Clear Advanced

Type	Reviewer
IRBA IRB Request	IRB Staff

Responding to IRB Requests (cont'd)

Click **Exit** to go back to the Study Workspace

Click **Hide/Show Errors** to view any incomplete Sections

The screenshot displays the webIRB interface for UCLA Research Administration. The top navigation bar includes a breadcrumb trail: << Back | Save | Exit | Hide/Show Errors | Print... | Jump To: 20.3 - Description of the Consent Process | Continue >>. Below this is a 'Reviewer Notes' section with a 'Previous' button. A filter bar shows 'Filter by Type' with a dropdown menu, 'Go', 'Clear', and 'Advanced' options. A table lists reviewer notes:

Type	Reviewer	Date Created	Date Modified
IRB Request	IRB Staff1	11/21/2011 1:53 PM	11/21/2011 1:53 PM

Below the table, a note reads: 'Please revise the consent form to remove the footer. Attach both a marked and clean copy of the revised consent form.' A green box highlights a note: 'Change Request Completed - A P13 - 3/5/2012 4:23 PM done'. At the bottom, a red warning states: 'Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."' The main content area is titled 'Description of the Consent Process'.

Responding to IRB Requests (cont'd)

- When all of the requests have been completed, your response will appear in a green text box in the **IRB Requests** tab.
- All IRB requests must be completed/addressed before the response can be submitted.

The screenshot displays the webIRB interface for UCLA Research Administration. The main content area shows details for the study "Test Study for PI13 (lucky thirteen)/Study Staff13(lucky thirteen) Training". The "IRB Requests" tab is selected and highlighted with a red box. Below the tab, a table lists IRB requests. One request, "A PI13 - Change Request Completed - 8/9/2010 10:28 AM", is highlighted in green, indicating it has been completed. The text "5.0 The response to this item is not complete. Please indicate how much time will be required of the subjects, per visit or contact, and in total for the study." is visible above the green box. The footer of the page reads "© 2010. UCLA Office of Research Administration".

webIRB UCLA Research Administration

IRB Protocols > Test Study for PI13 (lucky thirteen)/Study Staff13(lucky thirteen) Training

Current State

Pre-Review Changes Requested

Edit Study
Printer Version
View Differences
SS-Print All Request Notes

Owner (IRB Staff): CARRIE FISHER

My Activities

Submit Response
PI Assurances
Send Training Reminder
Withdraw
Edit PI Proxy
Copy Study
Send Inquiry or Reply to IRB
Study Team - Log Private Comment

Study: Test Study for PI13 (lucky thirteen)/Study Staff13(lucky thirteen)

Full Title of Study: Test Study for PI13/Study Staff13 Training
Protocol ID: IRB#09-000015

Principal Investigator: A PI13
Faculty Sponsor: Medical IRB 2
Initial Submission Date: 12/26/2009

Study Contact Person: Study
Review Type:
Meeting Date-Time: - N/A

PI Assurances: Completed
FS Assurances: Not Required

History Attachments **IRB Requests** Correspondence Training Log Change Log

Filter by Type [dropdown] Go Clear Advanced

Type	Reviewer	M
IRBA IRB Request Jump To: 10.1 - Study Summary - Research Study	CARRIE FISHER	8/

5.0 The response to this item is not complete. Please indicate how much time will be required of the subjects, per visit or contact, and in total for the study.

A PI13 - Change Request Completed - 8/9/2010 10:28 AM
x

© 2010. UCLA Office of Research Administration

IRB Requests – Tips (cont'd)

The OHRPP Staff working on your study is listed here. Click their name for contact information.

- Use the **Send Inquiry or Reply to IRB** activity to communicate with IRB staff.

- An email notification will be sent to the Owner (IRB Staff).

The screenshot displays the webIRB interface for a study titled "Test Study for PI13 (lucky thirteen)/Study Staff13(lucky thirteen) Training". The interface includes a navigation menu, a "Current State" section with a "Pre-Review Changes Requested" status, and a "My Activities" list. The "My Activities" list includes "Send Inquiry or Reply to IRB", which is highlighted by a red arrow. The "IRB Requests" tab is active, showing a table of requests with columns for "Type", "Reviewer", and "Modified". The table contains one entry: "IRB Request" with reviewer "CARRIE FISHER" and modified date "8/9/2010 10:31 AM". Below the table, a message states: "5.0 The response to this item is not complete. Please indicate how much time will be required of the subjects, per visit or contact, and in total for the study." A green box below the message contains the text: "A PI13 - Change Request Completed - 8/9/2010 10:31 AM Done".

webIRB | UCLA Research Administration

A PI13 | My Home | Logoff

webIRB Home | IRB Protocols

IRB Protocols > Test Study for PI13 (lucky thirteen)/Study Staff13(lucky thirteen) Training

Current State

Pre-Review Changes Requested

Edit Study

Printer Version

View Differences

SS-Print All Request Notes

Owner (IRB Staff):
CARRIE FISHER

My Activities

Submit Response

PI Assurances

Send Training Reminder

Withdraw

Edit PI Proxy

Copy Study

Send Inquiry or Reply to IRB

Study Team - Log Private Comment

Study: Test Study for PI13 (lucky thirteen)/Study Staff13(lucky thirteen) Training

Full Title of Study: Test Study for PI13/Study Staff13 Training
Protocol ID: IRB#09-000015

Principal Investigator: A PI13
Study Contact Person: Study Staff13

Faculty Sponsor:
Review Type:

Committee: Medical IRB 2
Initial Submission Date: 12/26/2009
Meeting Date-Time: - N/A

PI Assurances: Completed
FS Assurances: Not Required

History | Attachments | **IRB Requests** | Correspondence | Training Log | Change Log

Filter by Type [dropdown] [Go] [Clear] [Advanced]

Type	Reviewer	Modified
(IRBA) IRB Request Jump To: 10.1 - Study Summary - Research Study	CARRIE FISHER	8/9/2010 10:31 AM

5.0 The response to this item is not complete. Please indicate how much time will be required of the subjects, per visit or contact, and in total for the study.

A PI13 - Change Request Completed - 8/9/2010 10:31 AM
Done

Responding to IRB Requests

webIRB Home | IRB Protocols

IRB Protocols > Test Study for webIRB Training- Basic 1

Current State

Pre-Review Changes Requested

Edit Study | Printer Version | View Differences | SS-Print All Request Notes

Owner (IRB Staff): IRB Staff1

My Activities

Send Ready Notification | Send Training Reminder | Request Extension to Respond | Withdraw

Study: Test Study for webIRB Training- Basic 1

Full Title of Study: Test Study for webIRB Training- Basic 1
(NOTE: For Use in WebIRB Training Class only)

Protocol ID: IRB# 12-000001

Principal Investigator: A PI1 | **Study Contact Person:** Study Staff1

Faculty Sponsor: | **Review Type:**

Committee: Medical IRB 1

Initial Submission Date: 3/5/2012 | **Meeting Date-Time:** - N/A

PI Proxy: Rebecca Simms (PI) A PI2

PI Assurances: Pending...

FS Assurances: Not Required

Request to Continue Participants during Approval Lapse:

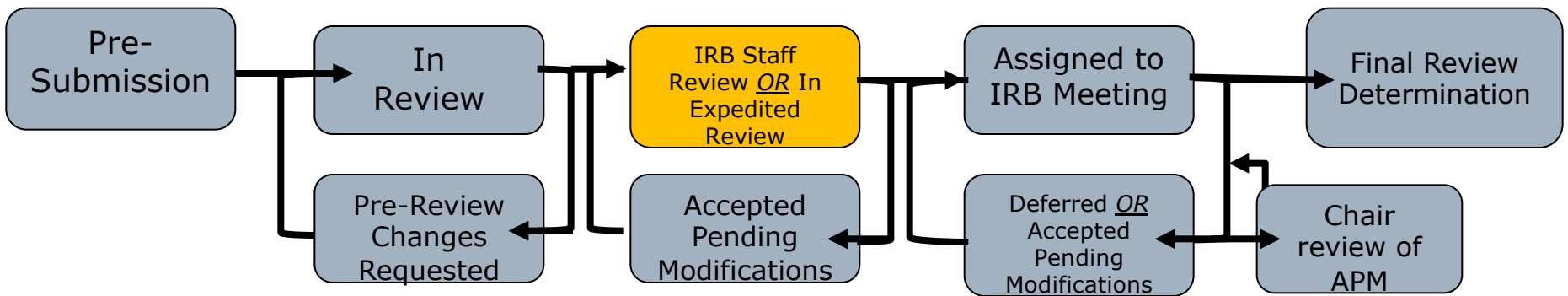
PI, PI Proxy, and FS:

Click **Submit Response** to submit the revised application to the IRB for review.

Study Staff:

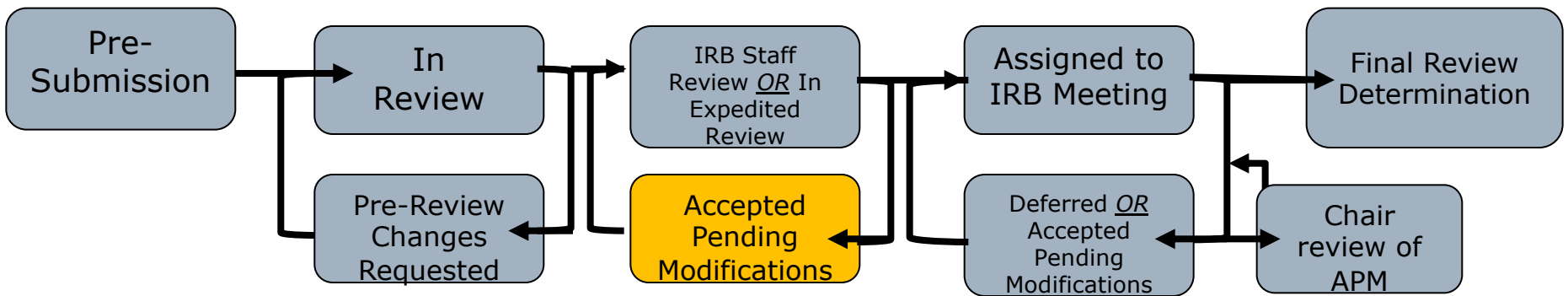
Use the **Send Ready Notification** to let the PI know that the response is ready to be submitted.

Current State of the Application



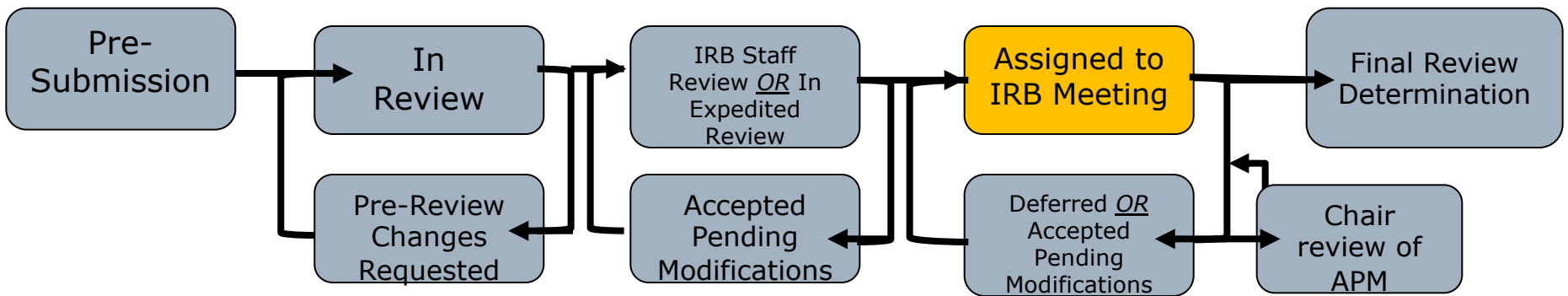
Once all requested changes are made, the current state of your application may return to, **"In Review"** on your end. However, during this current state, your study has been assigned to a designated reviewer. If the designated reviewer or the IRB have any changes they would like you to make, the current status will change to **"Accepted Pending Modifications"**.

Current State of the Application



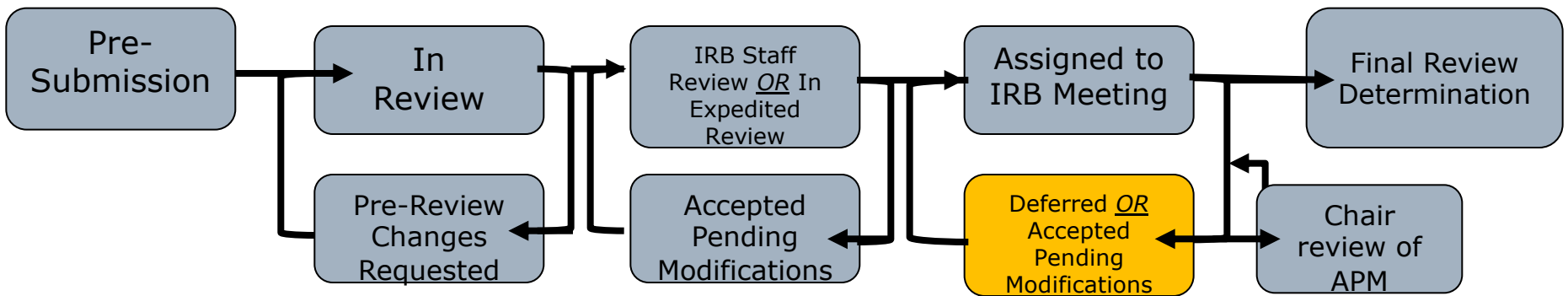
If the current state changes to “**Accepted Pending Modifications**”, it means the designated reviewer requests changes to your application.

Current State of the Application



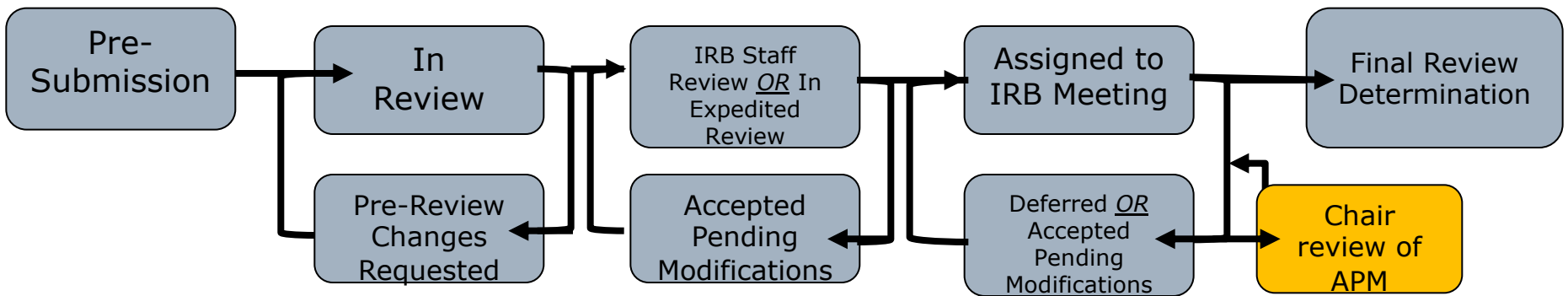
If your study requires review by the full board, the current state will change to “**Assigned to IRB Meeting**”. After the IRB reviews your project, they will issue a review determination.

Current State of the Application



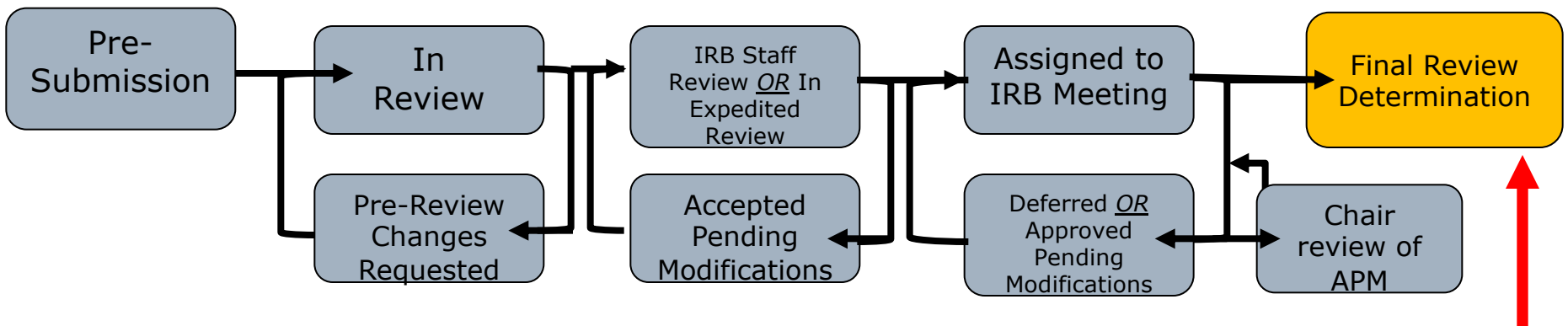
If the IRB does not approve your project after their initial review, it means they need more information for which the current state of your study will reflect either “**Deferred**” or “**Accepted Pending Modifications (APM)**”. If the IRB defers your study, it means that the IRB lacked sufficient information to make a review determination. Therefore, the IRB will have to obtain additional information from you then the IRB will re-review your study at the next IRB meeting. You will receive an email if any additional action is requested.

Current State of the Application



If the IRB determines your study is “**Accepted Pending Modifications (APM)**”, then you will be required to submit the changes requested in order to receive approval of your study. Upon submitting the changes, the IRB Chair will review and confirm these changes.

Current State of the Application



Once the designated reviewer or IRB Chair confirms that all the requested changes have been made, a final review determination will be issued.

IRB review determinations can be:

- Approved
- Approved-No CR
- Certified Exempt
- External Review Accepted
- Disapproved

Note: IRB Determinations

The “Current State” will reflect one of the following depending on your study type once the designated reviewer or the IRB determines your study may proceed:

- **Certified Exempt:** *Exempt* studies that are minimal risk and do not require review by the IRB. No Continuing Review (CR) required but annual assurance is required.
- **Approved-No CR:** Most *Expedited* studies that are minimal risk that meet certain criteria will receive approval that does not expire, no Continuing Review. Annual assurance is required.
- **Approved:** Some *Expedited* studies and studies requiring *Full Board* review which are greater than minimal risk and will have an expiration date of no greater than one year. About 2 months before expiration of IRB approval, you will need to submit a CR application.

Note: IRB Determinations

If UCLA is relying on another institution for the IRB review of your collaborative (multi-site) research study and the UCLA IRB determines it is appropriate to cede review to another institution, the IRB determination will state, “**External Review Accepted**”. The UCLA IRB may require additional documentation of the external review. When UCLA relies on another institution, continuing review is not required at UCLA however, annual assurances must be completed. For more information about collaborative research, please review [OHRPP guidance on reliance](#).

Please review [OHRPP guidance on the results of IRB review](#) for more information about IRB determinations.

Approved Study Workspace

Current State

Approved

View Study
Printer Version
View Differences
SS-Print All Request Notes

Owner (IRB Staff):
IRB Staff1

My Activities

Send Notification to FS for FS Assurances
PI Assurances
Send Training Reminder
Edit PI Proxy
Send Inquiry or Reply to IRB
PI Suspend
Study Team - Log Private Comment

Study: Sample Approved Study for webIRB Training - 10

Full Title of Study: Sample Approved Study for webIRB Training - 10
Protocol ID: IRB#11-000051

Principal Investigator: A PI10
Faculty Sponsor:
Study Contact Person: Study S
Initial Submission Date:
Committee: Medical

Review Type: Full IRB Review
Approval Date: 11/22/2011
Expiration Date: 11/21/2016

PI Proxy: Rebecca Simms (PI)
PI Assurances: Completed
FS Assurances: Not Required

Request to Continue Participants during Approval Lapse:

History | **2** Amendments | Continuing Review or Closure | Post-Approval Reports & Single Subject Exception | **3** Approved Documents | Completed IRB Request | **4** Notices

Activity	Author	Activity D
Project Snapshot Generated	Administrator, System	11/22/2011
5 View Project Snapshot		
Study - Approved	Staff1, IRB	11/22/2011
View Correspondence Letter		

1 PAR New Post-Approval Report or Single Subject Exception
AM New Amendment
CR Continuing Review or Closure

Unique features:

1. Create, **but not submit**, post-approval applications (i.e., AM, CR, and PAR).
2. All other workspaces are accessible.
3. Contains all currently approved documents
4. Contains all approval letters.
5. Contains a copy of the application.

View Active Studies

Click on **My Home**

webIRB | UCLA Research Administration

A PI5 | **My Home** | Logoff

webIRB Home | IRB Protocols

Page for A PI5

Study Team

My Roles
Study Team

Create New Study
NS New Study

Page for A PI5

Welcome to your Home Page.

This page has links to all of the items applicable to your role as an investigator or study personnel.

- **Inbox:** Displays your studies that have a task requiring completion.
- **Other Tabs:** Provide links to your studies and personal profile

Click here for a Quick Reference Guide.

webIRB Survey

We are interested in your feedback about webIRB. After you have used the program to submit a study, please click [here](#) to respond to a user survey.

My Inbox | **My IRB Studies** | Archived | Profile

Displays IRB related studies you are associated with but do not require any action by the study team at this time.

Filter by ID [dropdown] [Go] [Clear] Advanced

ID	Name	State	Last State Change	PI
NS IRB#12-000004	Text Changes (short title)	Approved	4/12/2012 7:14 PM	PI1
NS IRB#11-000005	Test Study for webIRB Training- Basic 5	Pre-Review Changes Requested	6/13/2012 3:14 PM	PI5
NS IRB#11-000046	Sample Approved Study for webIRB Training - 5	Approved	11/22/2011 10:52 AM	PI5

Click on the **My IRB Studies** tab.

You may access your approved study under this tab. All studies that you are listed on will appear here. Select the study title to view the study.

Other Considerations

During this process, you may need to make additional changes such as:

- Update contact information
- Withdraw your application
- Edit the PI Proxy
- Discuss changes amongst the study team

Update Your Contact Information

The screenshot shows the webIRB interface for a user named 'A PI5'. The navigation bar at the top includes 'webIRB Home', 'IRB Protocols', and 'Page for A PI5'. A callout box with a green border points to the user name 'A PI5' in the top right corner, with the instruction '1. Click on your name.' The main content area is titled 'Page for A PI5' and includes a 'Study Team' button, 'My Roles' section, and a 'Create New Study' button. Below this is a 'webIRB Survey' section and a 'My IRB Studies' section with a table of studies.

webIRB | UCLA Research Administration

A PI5 | My Home | Logoff

webIRB Home | IRB Protocols

Page for A PI5

Study Team

My Roles
Study Team

Create New Study
NS New Study

Page for A PI5

Welcome to your Home Page.

This page has links to all of the items applicable to your role as an investigator or study personnel.

- Inbox:** Displays your studies that have a task requiring completion.
- Other Tabs:** Provide links to your studies and personal profile

[Click here](#) for a Quick Reference Guide.

webIRB Survey

We are interested in your feedback about webIRB.
After you have used the program to submit a study, please click [here](#) to respond to a user survey.

My Inbox | **My IRB Studies** | Archived | Profile

Displays IRB related studies you are associated with but do not require any action by the study team at this time.

Filter by	ID		Go	Clear	Advanced
ID	Name	State	Last State Change	PI	
NS	IRB#12-000004	Text Changes (short title)	Approved	4/12/2012 7:14 PM	PI1
NS	IRB#11-000005	Test Study for webIRB Training- Basic 5	Pre-Review Changes Requested	6/13/2012 3:14 PM	PI5
NS	IRB#11-000046	Sample Approved Study for webIRB Training - 5	Approved	11/22/2011 10:52 AM	PI5

Update Your Contact Information (cont'd)

2. Update your information in the **Properties** tab.

4. Click **My Home** to return to your homepage.

The screenshot shows the 'webIRB' interface for 'UCLA Research Administration'. The user is logged in as 'A PI5'. The navigation bar includes 'webIRB Home' and 'IRB Protocols'. The main content area is titled 'A PI5' and contains the 'Account Profile' form. The form includes fields for 'Honorific', 'First Name', 'Middle Name', 'Last Name' (pre-filled with 'PI5'), 'Preferred Email', 'Work Phone #', and 'Degree(s)'. A legend at the bottom indicates that asterisks denote required fields. A green box with an arrow points to the 'Properties' tab, and another green box with an arrow points to the 'My Home' link in the top navigation. A third green box with an arrow points to the 'Apply' button at the bottom right.

webIRB | UCLA Research Administration

A PI5 | My Home | Logoff

webIRB Home | IRB Protocols

A PI5

A PI5

Changes to your Account Profile can be made below.

Account Profile

Honorific: -- Select ▾

* First Name:

Middle Name:

* Last Name: PI5

* Preferred Email:

Work Phone #:

Degree(s):

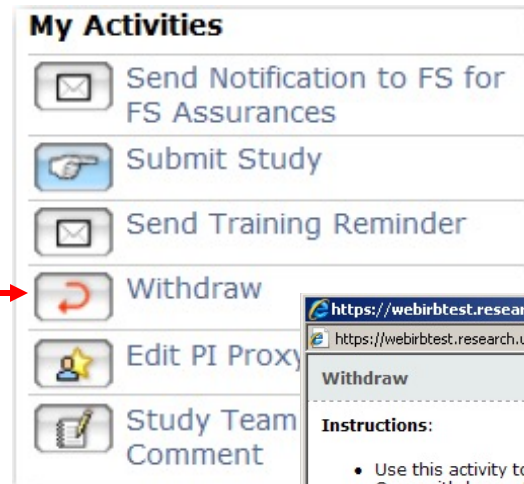
* Required

Apply

3. When you are done, click **Apply**.

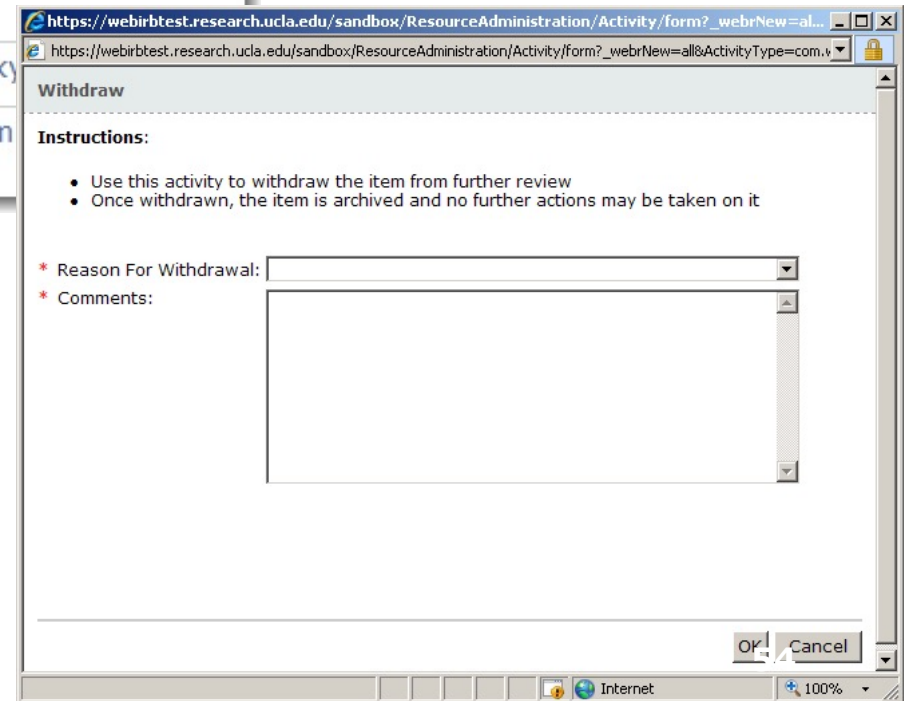
My Activities: Withdraw

- **Use carefully:** Use the **Withdraw** activity if you are no longer planning to conduct the study.
- The study will be archived.
- This activity is available to everyone.
- A withdrawn Study can be reactivated using the **Reactivate** activity. The Reactivate activity is only available to the PI, PI Proxies, and FS.



My Activities

- Send Notification to FS for FS Assurances
- Submit Study
- Send Training Reminder
- Withdraw**
- Edit PI Proxy
- Study Team Comment



https://webirbtest.research.ucla.edu/sandbox/ResourceAdministration/Activity/form?_webrNew=all&ActivityType=com.v

Withdraw

Instructions:

- Use this activity to withdraw the item from further review
- Once withdrawn, the item is archived and no further actions may be taken on it

* Reason For Withdrawal:

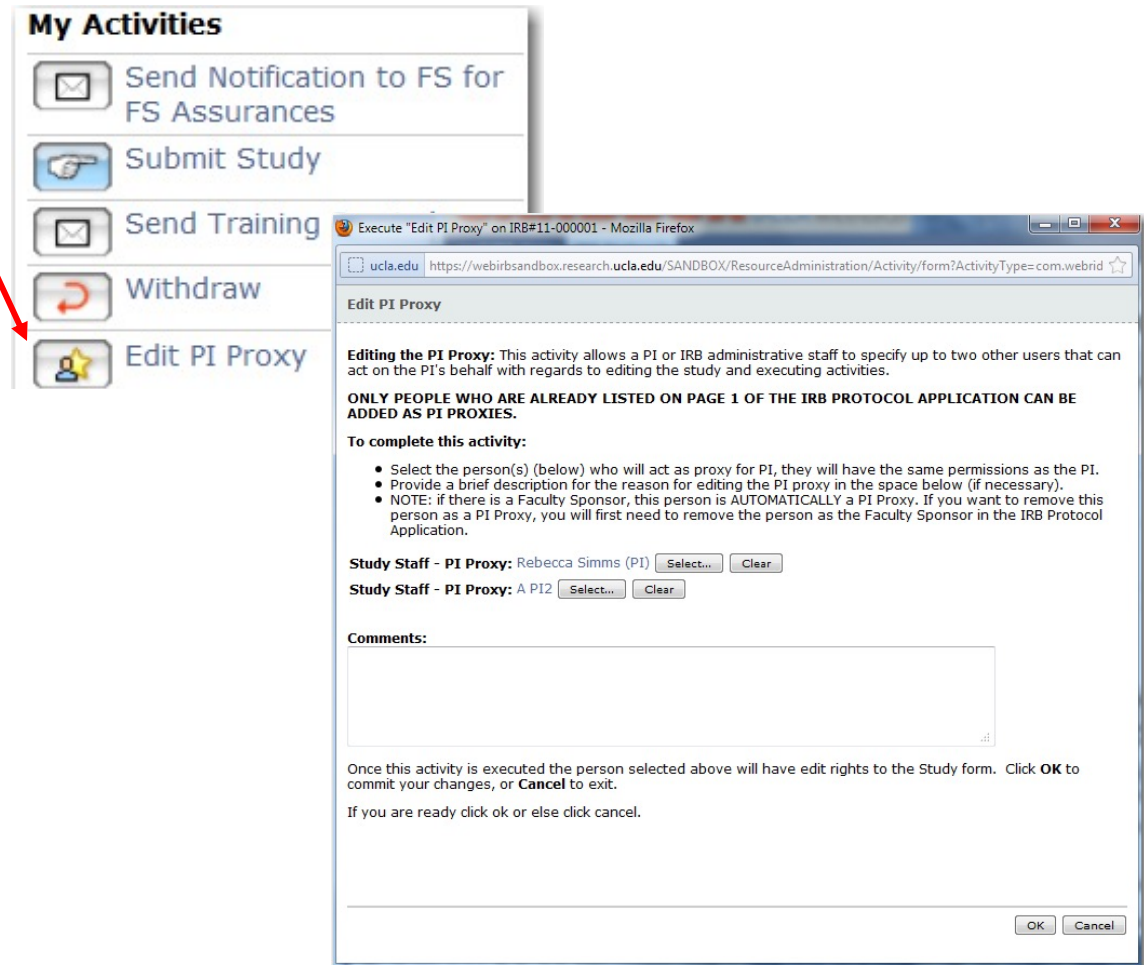
* Comments:

OK Cancel

Internet 100%

My Activities: Edit PI Proxy

Only the PI can add a PI Proxy using the activity **Edit PI Proxy**. A study team member must be listed as the Study Contact Person or Key Personnel in order to be added as a PI Proxy. To use this feature, the person on must be currently listed on the study in Section 1.1.









The image shows a screenshot of a web application interface. On the left, a 'My Activities' menu is visible with several options: 'Send Notification to FS for FS Assurances', 'Submit Study', 'Send Training', 'Withdraw', and 'Edit PI Proxy'. A red box highlights the 'Edit PI Proxy' option, with a red arrow pointing to the text box on the left. To the right, a browser window displays the 'Edit PI Proxy' form. The form title is 'Edit PI Proxy' and the URL is 'https://webirbsandbox.research.ucla.edu/SANDBOX/ResourceAdministration/Activity/form?ActivityType=com.webrid'. The form contains the following text: 'Editing the PI Proxy: This activity allows a PI or IRB administrative staff to specify up to two other users that can act on the PI's behalf with regards to editing the study and executing activities. ONLY PEOPLE WHO ARE ALREADY LISTED ON PAGE 1 OF THE IRB PROTOCOL APPLICATION CAN BE ADDED AS PI PROXIES. To complete this activity: • Select the person(s) (below) who will act as proxy for PI, they will have the same permissions as the PI. • Provide a brief description for the reason for editing the PI proxy in the space below (if necessary). • NOTE: if there is a Faculty Sponsor, this person is AUTOMATICALLY a PI Proxy. If you want to remove this person as a PI Proxy, you will first need to remove the person as the Faculty Sponsor in the IRB Protocol Application.' Below this text are two rows of 'Study Staff - PI Proxy' with 'Select...' and 'Clear' buttons. The first row is for 'Rebecca Simms (PI)' and the second is for 'A PI2'. There is a 'Comments:' section with a text area. At the bottom, there is a note: 'Once this activity is executed the person selected above will have edit rights to the Study form. Click OK to commit your changes, or Cancel to exit. If you are ready click ok or else click cancel.' and 'OK' and 'Cancel' buttons.

My Activities: Log Private Comment

- To communicate within the Study workspace use the activity **Study Team – Log Private Comment**.
- A pop-up screen will appear. Select the study team members who should receive an email notification about the comment. The email will contain a link to the study workspace.
- The comment will be visible to all study team members in the History tab and this activity is only available to study team members.

My Activities

-  Send Notification to FS for FS Assurances
-  Submit Study
-  Send Training Reminder
-  Withdraw
-  Edit PI Proxy
-  Study Team - Log Private Comment

https://webirbdev.research.ucla.edu/WEBIRBDEV/ResourceAdministration/Activity/form?_webNew=all&ActivityType=con

Study Team - Log Private Comment

Please add comments for **STUDY TEAM** in the box below and attach documents if needed. Comments and attachments will **NOT** be seen by IRB Staff or IRB Committee Members.

Select the Team member(s) who should receive an email about this comment:

Name

Principal Investigator

Rebecca Simms (PI)

Comments:

Attachments (if needed):

Add

Document Name	Document Version #
There are no items to display	

OK Cancel

Key Take-Aways

After your study has been approved/accepted by the IRB keep in mind:

- Any changes to the study will require submission of an Amendment (AM) application
- Once you have completed your research, review the OHRPP guidance on [Study Closures](#)
- Use the “[Edit Study Personnel](#)” activity to make changes to study personnel. Changes to the faculty sponsor, PI or “Others” will require submission of an AM application.
- Complete Annual Assurances within a timely manner. The IRB will administratively close any studies where assurances were not completed within three months
- Submit CR applications at least 60 days before the expiration date to prevent a lapse in approval

Resources

webIRB | UCLA Research Administration

webIRB Home | IRB Protocols | Researcher Profiles | Meetings

webIRB Home > Quick Reference Guides & Training Materials > Investigators & Research Staff

Login

Training Information

webIRB Accounts

Schedule of System Maintenance and

Quick Reference Guides & Training Materials

- Investigators & Research Staff
- IRB Committee Members

webIRB

webIRB Frequently Asked Questions (FAQ)

Contact Us

For Investigators & Research Staff

IMPORTANT NOTE: Be sure to click the **Submit** button if you want any activity to be reviewed or approved by the IRB. This button is located on the left hand side of the webIRB screen under "My Activities."

Video Tutorials *New

Follow the link to access short instructional videos on:

- Accessing Approval Notices and Other Study Documents
- Completing PI Assurances for a New Study
- New webIRB Functions Automatic Training Checks and Edit Study Personnel *New

Additional videos coming soon

Quick Reference Guides

Follow the link to access short (1-2 page) reference guides on:

- Adding a Funding Source in Section 6.2 (Funding-Description)
- Adding Key Personnel or Study Contact in Section 1.1 (Study Title-Key Personnel)
- Completing Annual Assurances in webIRB *New
- Completing FS Assurances for a Continuing Review or Closure
- Completing FS Assurances for a New Study
- Completing PI Assurances for a Continuing Review or Closure
- Completing PI Assurances for a New Study
- Create a New Study
- Guidelines for Describing Research Design and Methods in Section 10.1 of the webIRB Study Application
- How to Respond to IRB Requests
- Managing your Document in webIRB
- Navigating webIRB
- New webIRB Functions Automatic Training Checks and Edit Study Personnel *New
- Submitting Amendments, CRs (including study closures) and PARs

Select "Quick References Guides & Training Materials" then, select "Investigators & Research Staff"

<https://webirb.research.ucla.edu/WEBIRB/Rooms/DisplayPages/!avoutInitial?PageID=PAGE0000081> nation

Resources

For technical assistance with webIRB only:

Contact the webIRB Help Desk

Email: webIRBhelp@research.ucla.edu

Resources

For general inquiries about the IRB process:

Contact the appropriate IRB:

North & South General IRBs (GIRBs)

Email: gcirb@research.ucla.edu

Medical IRBs (MIRBs)

Email: mirb@research.ucla.edu

Resources

For questions specific to your submitted application, contact the OHRPP staff member assigned to your study:

The screenshot displays the webIRB interface for a study titled "Test Study for PI13 (lucky thirteen)/Study Staff13(lucky thirteen) Training". The interface includes a navigation bar with "webIRB Home" and "IRB Protocols", and a user menu with "A PI13", "My Home", and "Logoff". The main content area shows the study's current state as "Pre-Review Changes Requested" and provides options to "Edit Study", "Printer Version", "View Differences", and "SS-Print All Request Notes". A table of study details is shown below, with the "Owner (IRB Staff)" field highlighted in a red box. The owner is identified as "CARRIE FISHER".

Study: Test Study for PI13 (lucky thirteen)/Study Staff13(lucky thirteen) Training			
Full Title of Study:	Test Study for PI13/Study Staff13 Training		
Protocol ID:	IRB#09-000015		
Principal Investigator:	A PI13	Study Contact Person:	Study Staff13
Faculty Sponsor:		Review Type:	
Committee:	Medical IRB 2		
Initial Submission Date:	12/26/2009	Meeting Date-Time	- N/A
PI Assurances:	Completed		
FS Assurances:	Not Required		

Contact the OHRPP staff member assigned to your study by selecting their name, their contact information will appear.

Resources

To remain current on UCLA research policy, guidance and updates:

Sign-up for the Human Research News (HRN) Newsletter

The HRN includes updates to OHRPP guidance and policy, Learn-at-Lunch trainings on important research topics and offers other resources and important updates.

Please visit the [ORA Mailing Lists](#) page to subscribe.

Your feedback matters



Help us improve our presentation
by completing OHRPP's brief and
anonymous [SURVEY](#)