

## **Introduction to webIRB**

Training Course for Investigators and Study Staff

# You will learn to...

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1. Navigate webIRB
2. Create a new Study application
3. Respond to IRB Requests
4. Create an Amendment application
5. Create a Continuing Review application
6. Update your Contact Information and Profile

# webIRB Official Site

Use this site to create and submit protocols for review by the UCLA IRB:

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

**UCLAwebIRB** Login

webIRB Home Help

webIRB Home > Training Information > Accessing Training Accounts (Sandbox)

- ▷ Training Information
  - ▷ Training Schedule
  - ▷ Accessing Training Accounts (Sandbox)
- ▷ webIRB Accounts
- ▷ Schedule of System Maintenance and Upgrades **NEW!**
- ▷ Quick Reference Guides & Training Materials
- ▷ Forms to Upload in webIRB
- ▷ webIRB Frequently Asked Questions (FAQ)
- ▷ Contact Us

### Accessing the Training Accounts

The webIRB training site is called the "webIRB Sandbox". The webIRB Sandbox site is available for training and demonstration purposes only.

**Important Note:** Any practice studies prepared on the Sandbox site *cannot* be transferred to the official site for review by the IRB. Also, the Sandbox site will be cleaned periodically and the practice studies may be erased.

Access the webIRB Sandbox site and training at:  
<https://webirbsandbox.research.ucla.edu/sandbox>

A security message will appear. It is safe to continue to the webIRB Sandbox. The security message contains a link that takes you to the webIRB Sandbox. Please click on the link "Continue to this website (not recommended)" to go to the webIRB Sandbox.

Once on the Sandbox site, check under the "Accessing the Training Accounts" tab for a list of training accounts.

# Training Site- webIRB Sandbox

## When using Internet Explorer:

- It is safe to continue to the webIRB Sandbox.
- Click on "Continue to this website (not recommended)"



There is a problem with this website's security certificate.

The security certificate presented by this website was not issued by a trusted certificate authority.  
The security certificate presented by this website was issued for a different website's address.

Security certificate problems may indicate an attempt to fool you or intercept any data you send to the server.

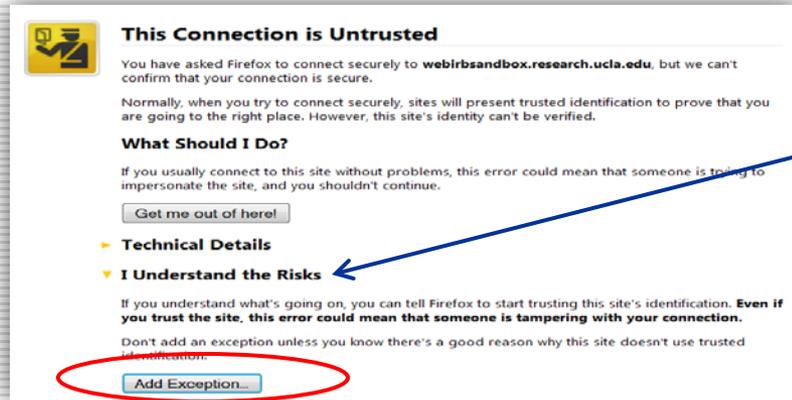
**We recommend that you close this webpage and do not continue to this website.**

 [Click here to close this webpage.](#)

 [Continue to this website \(not recommended\).](#)

 [More information](#)

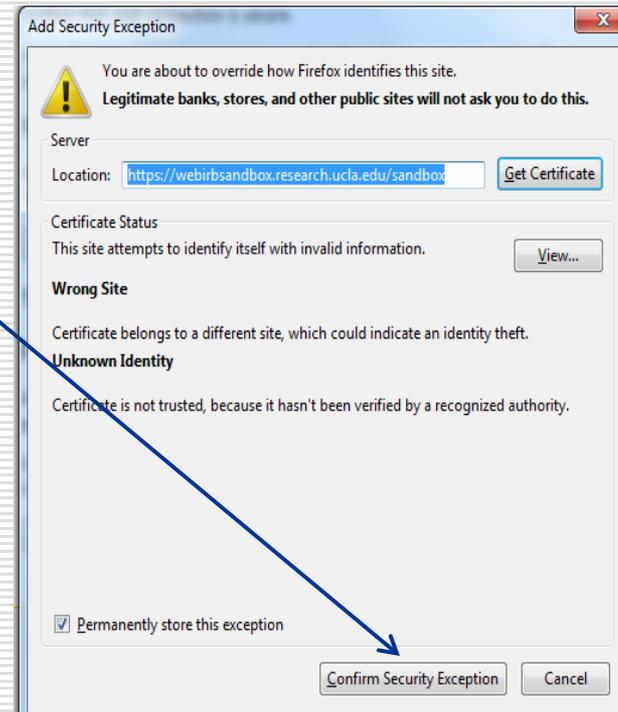
# Training Site- webIRB Sandbox (cont'd)



**When using Mozilla Firefox, follow these steps to access the Sandbox:**

1. Click on "I Understand the Risks" to see "Add Exception.."
2. Click on "Add Exception..."

3. In the "Add Security Exception" pop-up window click on "Confirm Security Exception"

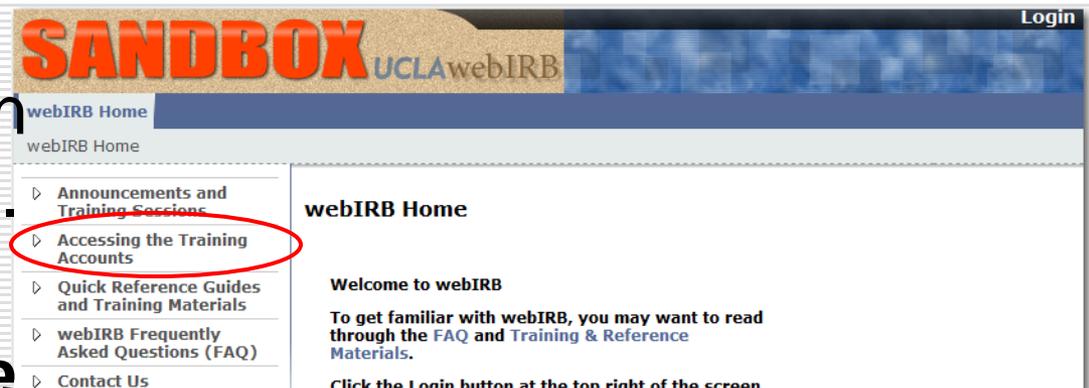


# Training Site- webIRB Sandbox (cont'd)

Use this site for ***practice only***:

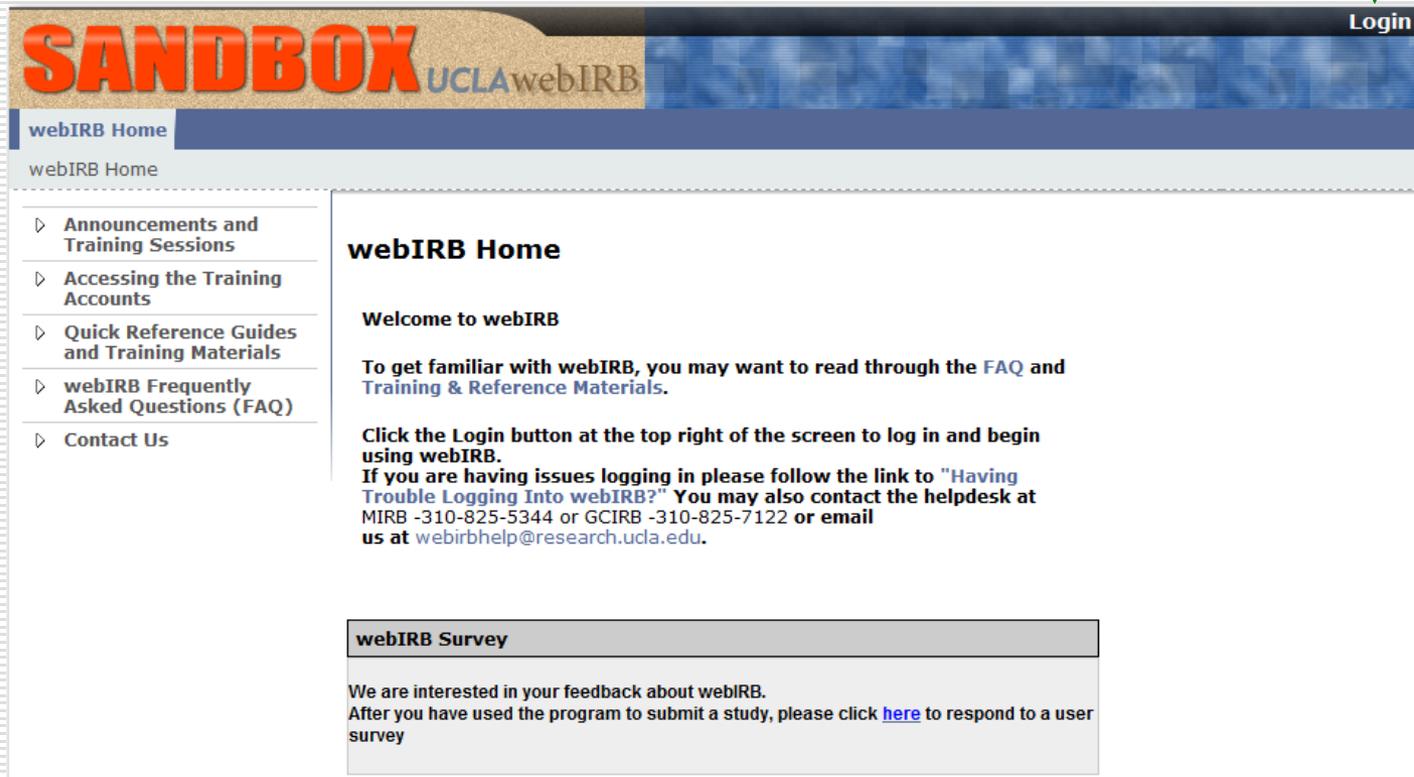
<https://webirbsandbox.research.ucla.edu/sandbox>

- ***Do not*** use it for studies that you plan to submit to the IRB.
- Studies in the Sandbox ***cannot be processed.***



# How to Create a New Study: Login

Click **Login**



The screenshot shows the webIRB Home page. At the top left is the logo "SANDBOX UCLAwebIRB". In the top right corner, there is a "Login" button. A green box with the text "Click Login" and a green arrow points to this button. Below the logo, there is a navigation bar with "webIRB Home" and a sub-menu with the following items:

- Announcements and Training Sessions
- Accessing the Training Accounts
- Quick Reference Guides and Training Materials
- webIRB Frequently Asked Questions (FAQ)
- Contact Us

The main content area is titled "webIRB Home" and contains the following text:

**Welcome to webIRB**

To get familiar with webIRB, you may want to read through the [FAQ](#) and [Training & Reference Materials](#).

Click the **Login** button at the top right of the screen to log in and begin using webIRB.

If you are having issues logging in please follow the link to "[Having Trouble Logging Into webIRB?](#)" You may also contact the helpdesk at MIRB -310-825-5344 or GCIRB -310-825-7122 or email us at [webirbhelp@research.ucla.edu](mailto:webirbhelp@research.ucla.edu).

Below this is a section titled "webIRB Survey" with the following text:

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

# How to Create a New Study: Login

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Enter the *Training Account* User Name and Password (1234) and click **Login**

UCLA webIRB

Login As

User Name:

Password:

Remember me

After signing into this site, you are bound by the terms and conditions set forth when you received your account.

# My Home

**Breadcrumb** - Find your way through the study workspaces

**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

**My IRB Studies** – contains all open studies

The screenshot shows the 'My Home' page for a PI1 user. The page includes a breadcrumb trail (webIRB Home > IRB Protocols > Page for A PI1), a navigation bar with 'My Home' and 'Logoff' links, and a main content area with a 'Study Team' section, a 'My Roles' section, and a 'Create New Study' button. The main content area also features a 'Page for A PI1' section with a welcome message and a list of links (Inbox, Other Tabs). Below this is a 'webIRB Survey' section and a 'My Inbox' section with tabs for 'My IRB Studies' and 'Archived'. The 'My IRB Studies' tab is selected, showing a table of studies with columns for ID, Name, State, Last State Change, and PI. The table contains five rows of study data.

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

**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-0000001	test	Pre Submission	5/1/2012 1:47 PM	PI1

# My Home (cont'd)

**SANDBOX** UCLAwebIRB

A PI1 | My Home | Logoff

webIRB Home | IRB Protocols

Page for A PI1

**Study Team**

**My Roles**  
[Study Team](#)

**Create New Study**

**Page for A PI1**

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

Filter by	ID		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-0000001	test	Pre Submission	5/1/2012 1:47 PM	PI1

Click to  
create a  
New Study

# Navigating the Smartform

**SANDBOX** UCLAwebIRB 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]

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 grey text box.

# Tips for Completing the first page

**SANDBOX** UCLAwebIRB

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.

- Make up a study for training purposes.
- Enter your name in either Item 3.1 (PI); Item 4.0 (Study Contact); or Item 5.0 (Key Personnel)

Click **Save** after completing the General Information section.

After clicking **Save** more activities will appear at the top of the page.

# Navigating the Smartform (cont'd)

Activities that will appear in the menu bar after clicking **Save**.

## Important Note:

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

**SANDBOX** UCLAwebIRB

Edit: Study - PRE#09-000006

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

Reviewer Notes (0 Notes Total)

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: Principal Investigator

3.2 UCLA Title: Clinical Instructor

3.3 Affiliation(s): UCLA  
Santa Monica-UCLA

Other Affiliations:  
(if provided)

3.4 Department: MEDICINE-GASTROENTEROLOGY

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

# Navigating the Smartform (cont'd)

The screenshot shows the SANDBOX UCLAwebIRB interface. At the top, it says "Edit: Study - IRB#09-000003". Below that is a navigation bar with buttons: "<< Back", "Save | Exit | Hide/Show Errors | Print...", "Jump To:", a dropdown menu showing "1.1 - Study Title and Key Personnel", and "Continue >>". Below the navigation bar is a yellow bar for "Reviewer Notes (0 Notes Total)" with "Add" and "Delete" buttons. A warning message reads: "Warning: Save your work at least every 15 minutes". The main content area is titled "General Information" and contains a table of contents. The table of contents lists sections from 1.0 to 9.4. Section 1.1 is highlighted in red, and section 1.0 is highlighted in black. A red box highlights the "Continue >>" button and the "Jump To:" dropdown menu. A green box highlights the "Exit" button. A red box highlights the "Jump to Menu" section of the table of contents.

Section	Title
1.0	*Full Title of the Study
1.1	Study Title and Key Personnel
2.0	*Working or Lay Title
1.1a	Other Personnel
1.2	Conflict of Interest Information
2.1	Project Identification Information
2.2	Lay Summary and Keywords
5.1	Type of Study Review
6.1	Funding and Other Study Characteristics
6.2	Funding - Description
7.1	Study Locations
7.2	UCLA or UCLA Network Sites
8.1	Methods/Procedures - Descriptors
8.3	Clinical Trial of a Behavioral Intervention, Drug, Biologic
8.6	Drugs/Biologics/Dietary Supplements
8.10	Regulatory and Committee Approvals
9.2	Information about Study Data
9.3	Data Security
9.4	Data Security Plan

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 be added as you answer items in the form

Use **Continue** to navigate forward through the form

# Study Workspace

**SANDBOX** UCLA webIRB

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

**Information Tabs**

- History
- Attachments
- IRB Requests
- Training Log
- Change Log

Current State

Views of the Study

Study Activities

Summary information about the Study

Information Tabs

# A Note About the Protocol ID

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- **Before submission**, studies get a PRE#. For example, PRE#10-000010
- **After submission**, studies get an IRB#. For example, IRB#10-000325
  - The PRE# and the IRB# will not match

# Common Project States

Current State

???

## Common “Current State” for All Project Types

Current State	What the “Current State” Means
Pre-Submission	Project has not been submitted.
In-Review	Project or response has been submitted. The IRB is reviewing the project or response.
<ul style="list-style-type: none"><li>• Pre-Review Change Requested</li><li>• Deferred - Changes Required by IRB</li><li>• Accepted Pending Modifications</li></ul>	Additional information is required to review and approve the project.
Assigned to IRB Meeting	The project will be reviewed at the next Full Board meeting.

# Common Project States (cont'd)

## Common “Current State” for All Project Types (cont'd)

Current State	What the “Current State” Means
Withdrawn	The project is no longer in review.
<ul style="list-style-type: none"><li>• Approved</li><li>• Certified Exempt</li></ul>	Research procedures may begin/continue.

## Common “Current State” for Studies

Expired	The Study has expired. Create and submit a CR.
Expired – Continuation in Progress	The Study has expired and the CR is in review by the IRB.
Closed	The Study is closed. A CR was submitted to close the study.

# Common Project States (cont'd)

## Common “Current State” for PARs

Current State	What the “Current State” Means
Completed – Amendment Required	An Amendment is required. Link the PAR to an existing Amendment.
Completed	The PAR is complete.

# My Activities

PI

## My Activities

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

Faculty Sponsor

## My Activities

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

PI Proxy

## My Activities

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

Study Staff

## My Activities

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

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

# A Note About “My Activities”

- Activities generate an email notification.
  - ❖ Use the link in the email to go the protocol workspace.
  - ❖ **DO NOT** reply to the email.

**Notification to FS for FS Assurances**  
webIRB@research.ucla.edu [webIRB@research.ucla.edu]  
Sent: Monday, February 13, 2012 1:08 PM  
To: ORA ORIS Webirb Test Notify

**UCLA OHRPP**  
Office of the Human Research Protection Program

University of California Los Angeles  
11000 Kinross Avenue, Suite 211  
Los Angeles, CA 90095-1694  
<http://ohrpp.research.ucla.edu>  
GC-IRB: (310) 825-7122  
M-IRB: (310) 825-5344

DATE: 2/13/2012 1:08 PM  
TO: [Faculty Sponsor1](#)  
FROM: [Principal Investigator1](#)  
LINK: [PRE#12-000002](#)  
testing changes to Study Smartform

The above-referenced study is ready for review and completion of the Faculty Sponsor Assurances. Please click on the above link to go to the study workspace.

CC: Context.loggedFor.Study Staff - Faculty Sponsor

# 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 a message to your FS.
- An email will be sent to your Faculty Sponsor. 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 dialog box on the right. The dialog box 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 the text is a large text area for 'Comments to Faculty Sponsor:' and 'OK' and 'Cancel' buttons at the bottom right. The browser's address bar shows the URL: 'https://webirbtest.research.ucla.edu/sandbox/ResourceAdministration/Activity/form?\_webrNew=all&Ac'.

# My Activities: Submit Study & Send Ready Notification

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

This activity is available to the PI, PI Proxies & FS.

**My Activities**

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

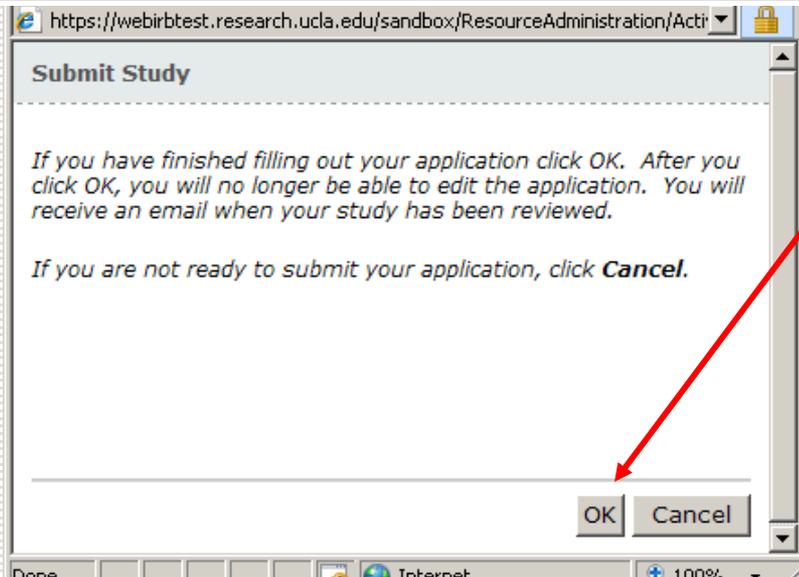
**Send Ready Notification** is available to all other Study Staff.

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

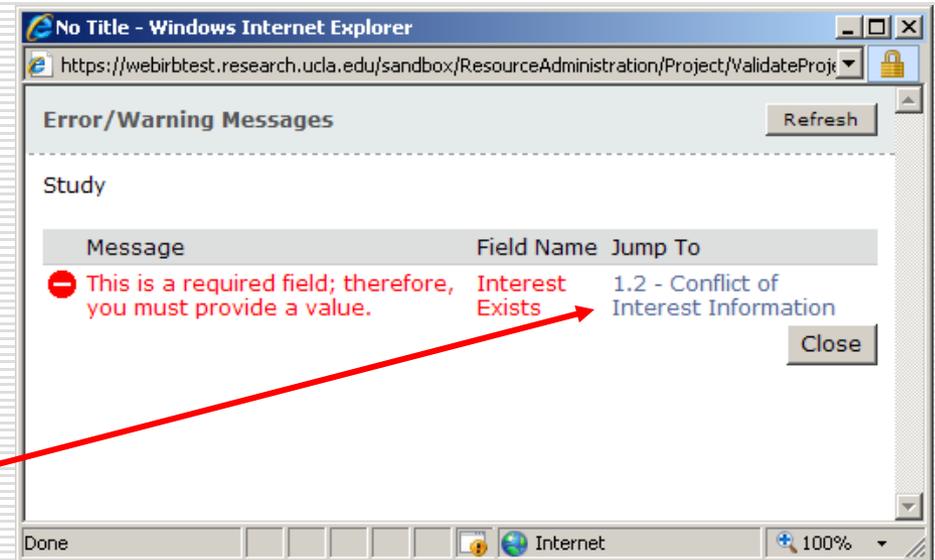
**My Activities**

-  **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 go to the Section with the incomplete item(s).

# My Activities: PI Assurances

The screenshot shows the SANDBOX UCLA webIRB interface. The top navigation bar includes 'webIRB Home', 'IRB Protocols', and 'Logoff'. The main content area is titled 'Study: Training Study for MIRB1&3 Staff (Y)'. It displays various study details such as 'Full Title of Study', 'Protocol ID', 'Principal Investigator', 'Faculty Sponsor', 'Committee', and 'Initial Submission Date'. A red box highlights the 'PI Assurances' status, which is 'Pending...'. A red arrow points from this box to a text box on the right that says 'The study team can check to see if the assurances are completed on the summary screen'. Below the study details is a 'History' table with columns for 'Activity', 'Author', and 'Activity Date'. The table shows two entries: 'Study Submitted for Review' and 'Created Study', both by 'CARRIE FISHER' on '4/22/2010'. A red box on the left contains a list of instructions, with a red arrow pointing to the 'PI Assurances' link in the 'My Activities' section of the interface.

**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

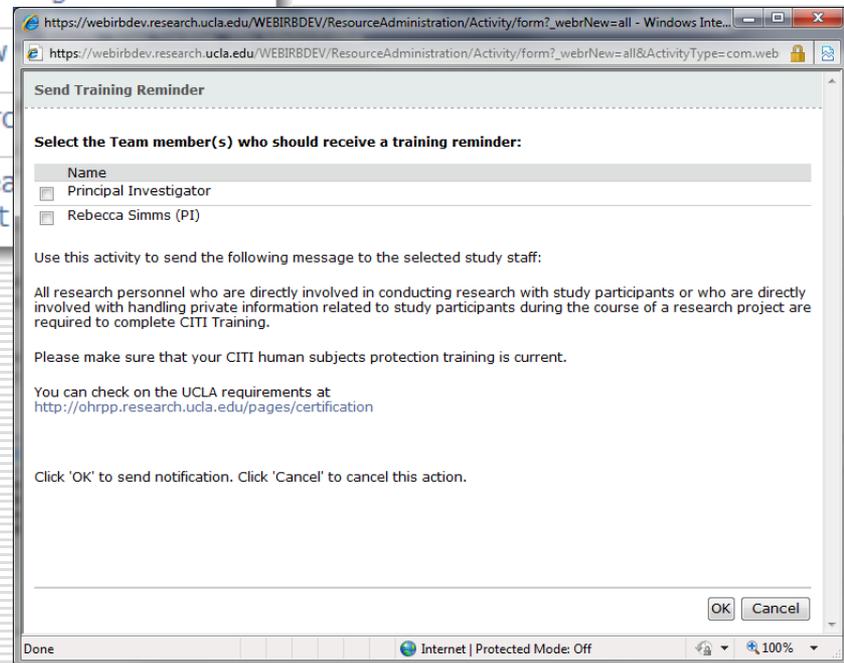
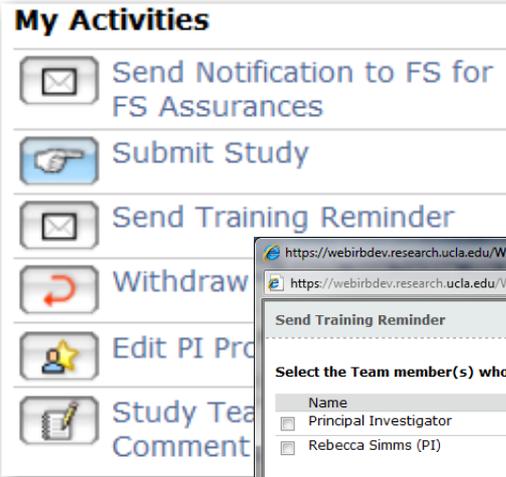
**History** | Attachments | IRB Requests | Correspondence | Training Log | Change Log

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 becomes available.
- The PI Assurances must be completed by the PI (and only the PI) before the study can be approved.

# My Activities: Send Training Reminder

- Use the **Send Training Reminder** activity to remind your staff to complete their training.
- Select member(s) who should receive a training reminder email (see next slide).
- This activity is available to the PI, PI Proxies, FS & Contact Person.



# Training Log

The screenshot shows the webIRB interface for a study titled "Test Study for webIRB Training- Basic 1". The interface includes a navigation menu on the left with options like "Pre Submission", "My Activities", and "Study Team - Log Private Comment". The main content area displays study details such as "Full Title of Study", "Protocol ID", "Principal Investigator", and "Faculty Advisor". Below this, there are tabs for "History", "Attachments", "IRB Requests", "Training Log", and "Change Log". The "Training Log" tab is selected, showing a table of training information for study team members.

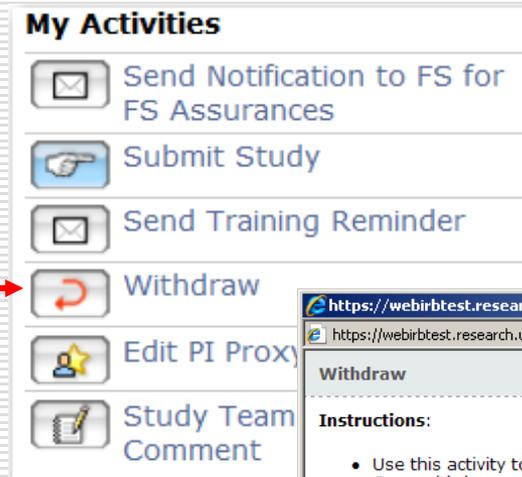
Name	Clinical Privileges Documents	Human Subjects Training Expiration Date	Human Subjects Protection Documentation	HIPAA Training Completion Date	HIPAA Training CV/Biosketch Documentation/Resume	Other Documentation
A PI1						
A PI2						
A PI3						
Study Staff1						
Rebecca Simms (PI)		9/28/2011	Training Documentation	0.01	6/14/2010	

- Each member of your research team can upload his/her training certificates in their webIRB profile.
- The training certificates will appear in the **Training Log** tab.

Click the **Training Log** tab to see your study team member's training certificate.

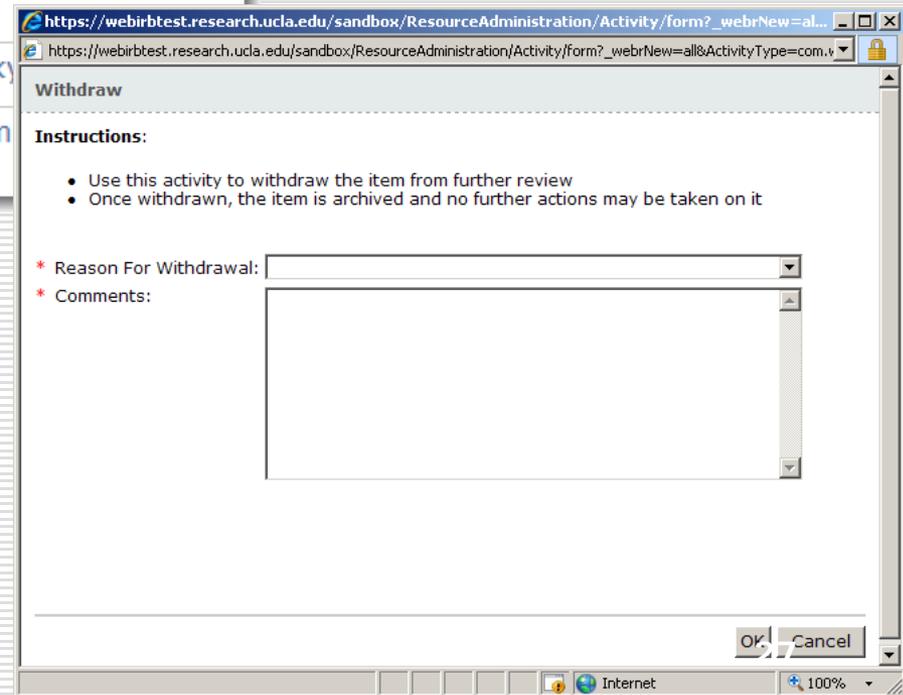
# My Activities: Withdraw

- **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 activity **Reactivate**. The Reactivate activity is only available only to the PI, PI Proxies & 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](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

# My Activities: Edit PI Proxy

Only the PI can add a PI Proxy using the activity **Edit PI Proxy**.

## My Activities

-  Send Notification to FS for FS Assurances
-  Submit Study
-  Send Training
-  Withdraw
-  Edit PI Proxy

Execute "Edit PI Proxy" on IRB#11-000001 - Mozilla Firefox

ucla.edu | https://webirbsandbox.research.ucla.edu/SANDBOX/ResourceAdministration/Activity/form?ActivityType=com.webrid

### Edit PI Proxy

**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.

**Study Staff - PI Proxy:** Rebecca Simms (PI)

**Study Staff - PI Proxy:** A PI2

**Comments:**

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.

# 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 member who should receive your message.
- An email will be sent to the study team member with a link to the study workspace.
- This activity is available to all study team members only.

**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?\_webirbNew=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
<input type="checkbox"/> Principal Investigator
<input type="checkbox"/> Rebecca Simms (PI)

**Comments:**

**Attachments (if needed):**

Document Name	Document Version #
There are no items to display	

OK Cancel

# Returning to the Smartform

The screenshot shows the webIRB interface for a study titled "Training- Basic 1". The "Current State" is "Pre Submission". A green box highlights the "Edit Study" button in the "Current State" section, with an arrow pointing to it. A text box next to the button says "Click Edit Study to go back to the Smartform".

**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 Information**

**Principal Investigator:** A PI1

**Faculty Advisor:** A PI3

**Study Contact Person:** Study Staff1

**PI Proxy:** Rebecca Simms (PI) A PI2

**PI Assurances:** Pending...

**FS Assurances:** Pending...

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

This area shows instructions and questions and important notifications regarding this Study.

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

# Checking Your Progress

1. Click **Hide/Show Errors**

DEVELOPMENT  
UCLAwebIRB

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."

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

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

Save | Exit | Hide/Show Errors | Print... | Jump To: - 1.1 -  
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 Swans (PI) [Select...]

Error/Warning Messages

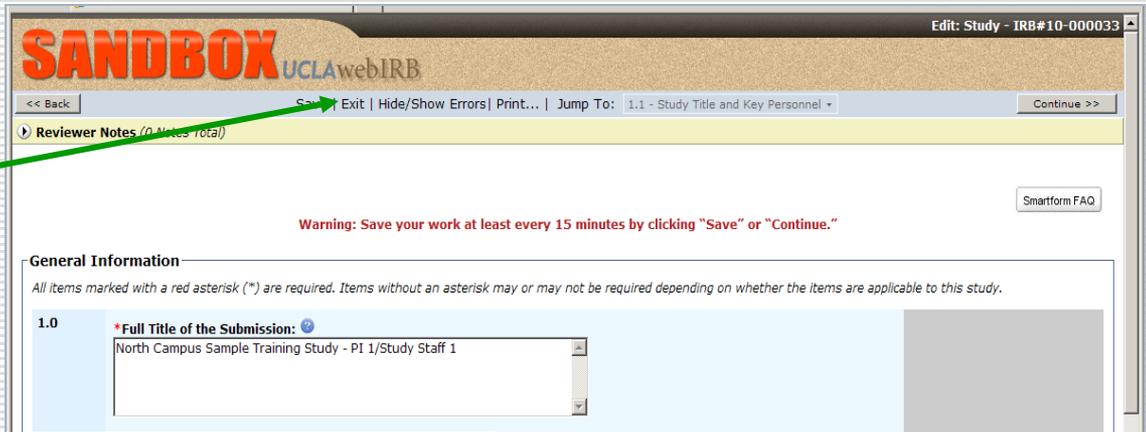
No Errors Found

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

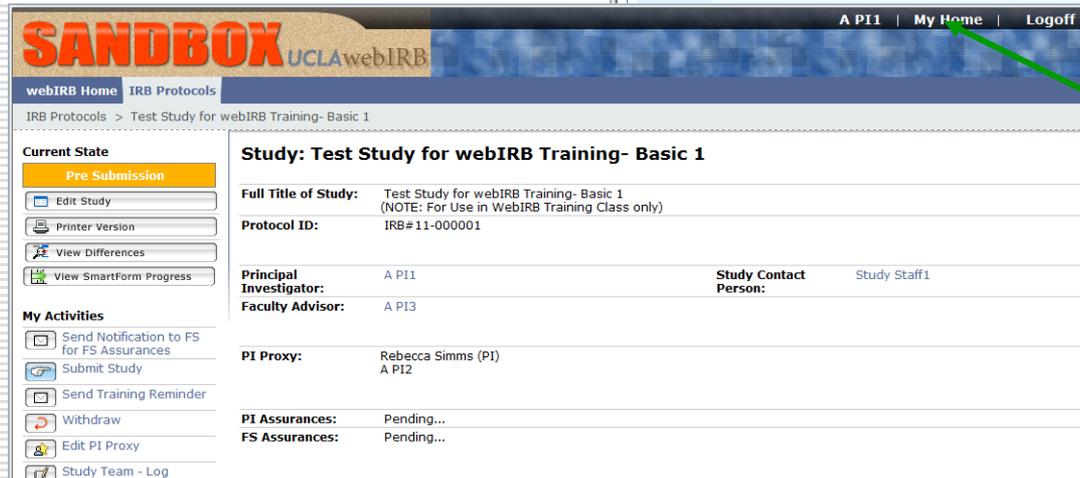
Click **Hide/Show Errors** again to hide the screen

# Exit the Application & Return to your Homepage

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



Click **My Home** to return to your webIRB homepage



# Responding to IRB Requests

**SANDBOX** UCLAwebIRB

A PI3 | My Home | Logoff

webIRB Home | IRB Protocols

Page for A PI3

**Study Team**

**My Roles**  
Study Team

**Create New Study**  
NS New Study

**Page for A PI3**

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

Filter by ID    Advanced

ID	Name	State	Last State Change	PI
NS IRB#12-000007	<a href="#">Test Study for webIRB Training- Basic 3</a>	Pre-Review Changes Requested	6/13/2012 3:15 PM	PI3

Click on the Study in your Inbox titled "Test Study for webIRB Training – Basic ...."

# Notes about IRB Requests

## IRB Requests are:

- Pre-review changes
- Official Letters

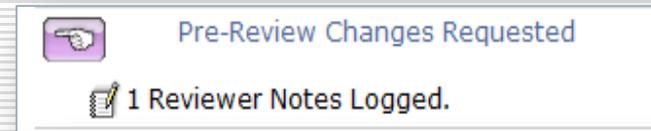
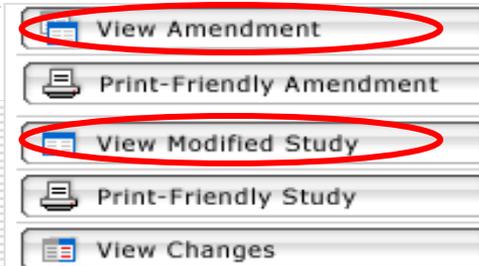
## IRB Requests can be viewed in

### • Information tabs:

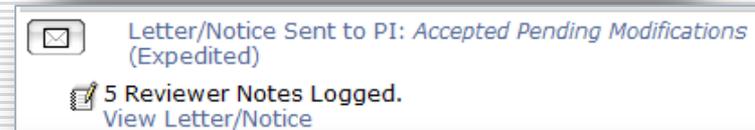
- History
- IRB Requests
- Correspondence

### • Smartforms:

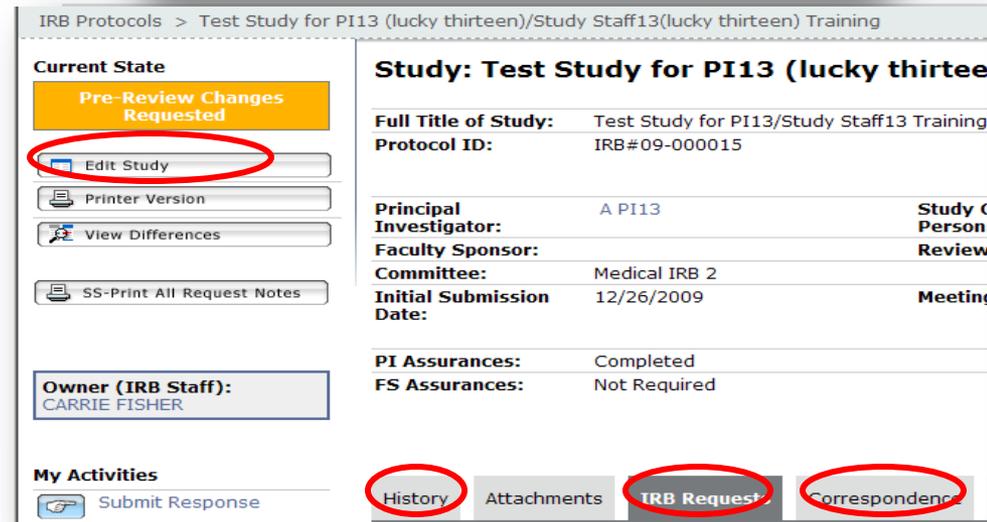
- For the Study use "Edit Study"
- For the Amendment use "View Amendment"
- For the Modified Study use "View Modified Study"



Pre-Review Changes Requested  
1 Reviewer Notes Logged.



Letter/Notice Sent to PI: *Accepted Pending Modifications (Expedited)*  
5 Reviewer Notes Logged.  
[View Letter/Notice](#)



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](#)

**Study: Test Study for PI13 (lucky thirteen)**

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

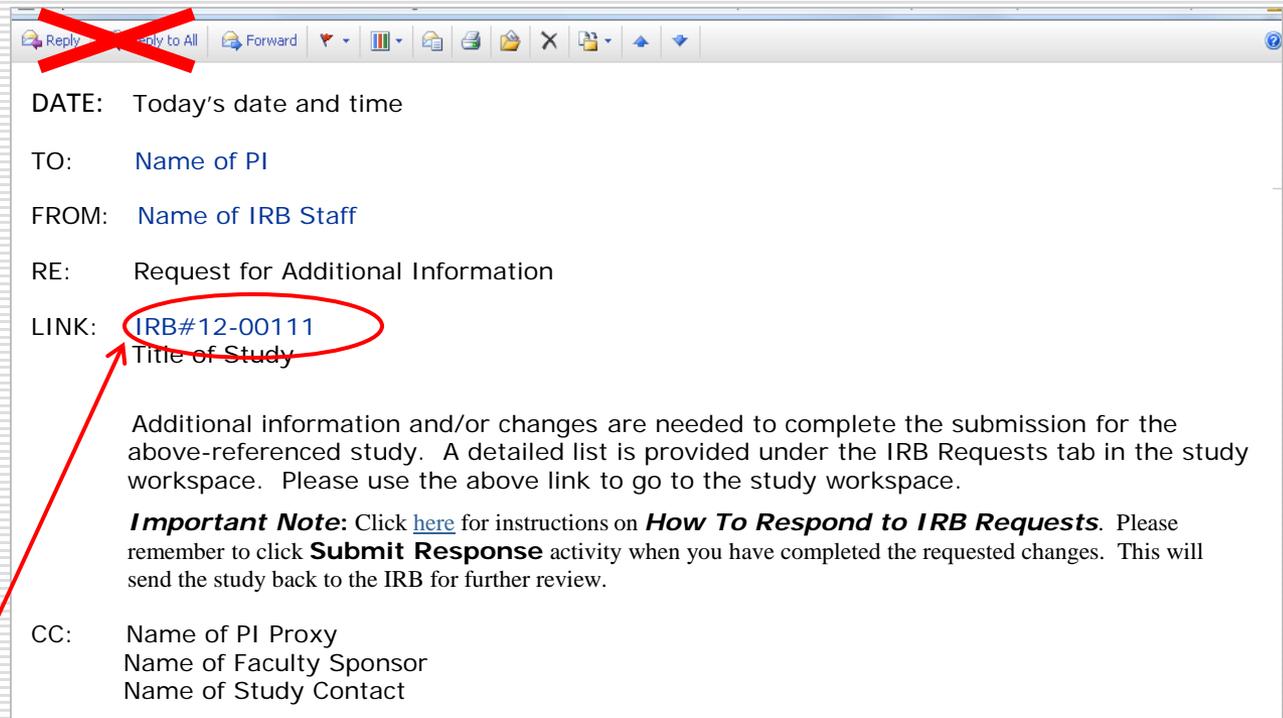
**Principal Investigator:** A PI13  
**Faculty Sponsor:** Medical IRB 2  
**Committee:** Medical IRB 2  
**Initial Submission Date:** 12/26/2009

**PI Assurances:** Completed  
**FS Assurances:** Not Required

[History](#) [Attachments](#) [IRB Request](#) [Correspondence](#)

# Notes about IRB Requests (cont'd)

- The PI, PI Proxies, FS & 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.*

# Notes about IRB Requests (cont'd)

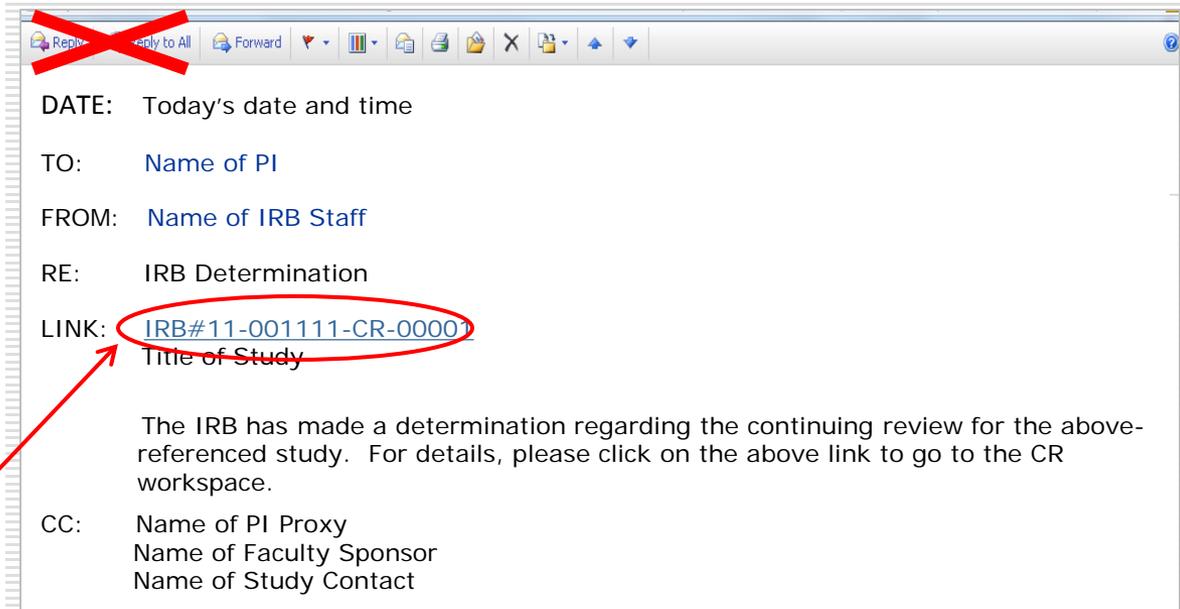
- When the IRB issues a letter the email notification will say

“The IRB has made a determination...”

The email does not state whether the letter is an approval/certification of exemption or contains IRB requests.

- Use the link in the email to go to the workspace to view the letter and if necessary respond to the IRB requests.

- **Do Not Reply to the email.**



*Example of webIRB email notification the PI will receive when the IRB issues a letter for the CR.*

# Sending Inquiry or Reply to MRSC

If your project involves Radiation, the Medical Radiation Safety Committee will also communicate with you using webIRB

To contact or reply to MRSC, please use the "Send Inquiry or Reply to MRSC" activity.

*Note: Using the "Send Inquiry or Reply to IRB" will **NOT** reach the MRSC administrator.*

**Current State**

**Approved**

[View Study](#)

[Printer Version](#)

[View Differences](#)

[SS-Print All Request Notes](#)

**Owner (IRB Staff):**  
IRB Staff1

**My Activities**

[Send Training Reminder](#)

~~[Send Inquiry or Reply to IRB](#)~~

[Study Team - Log Private Comment](#)

[Send Inquiry or Reply to MRSC](#)

[New Post-Approval Report or Single Subject Exception](#)

[New Amendment](#)

[Continuing Review or Closure](#)

**Study: Sample Approved Study for webIRB Training - 2**

**Full Title of Study:** Sample Approved Study for webIRB Training - 2  
**Protocol ID:** IRB#11-000043

**Principal Investigator:** A PI2  
**Faculty Sponsor:**

**Review Type:** Full IRB Review  
**Expiration Date:** 11/21/2016

**PI Proxy:** Rebecca Simms (PI)

**PI Assurances:** Completed  
**FS Assurances:** Not Required

**Request to Continue Participants during Approval Lapse:**

**Study Contact Person:** Study Staff2  
**Initial Submission Date:**  
**Committee:** Medical IRB 1  
**Letter of Approval:** View

**History** | Amendments | Continuing Review or Closure | Post-Approval Reports & Single Subject Exception | Approved Documents | Completed IRB Requests | Conditions and Determinations | Notices | Other Regulatory Documents | Training Log

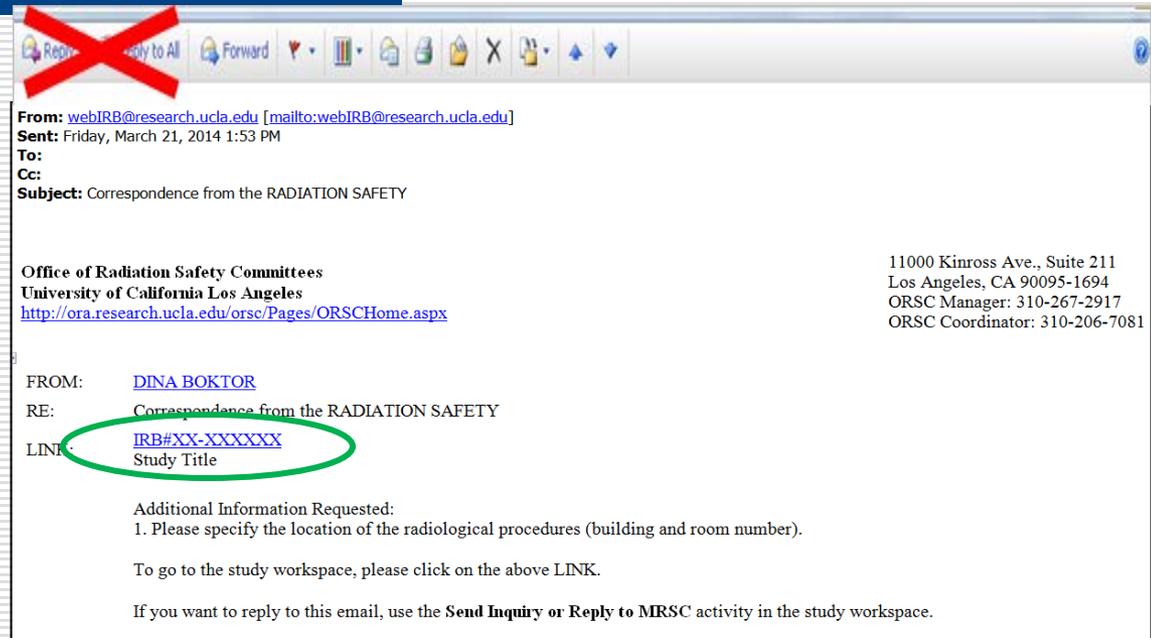
Filter by

# Notes about Inquiry or reply to MRSC (cont'd)

- When the MRSC sends a inquiry or reply, the notification will say

“Correspondence from the RADIATION SAFETY”

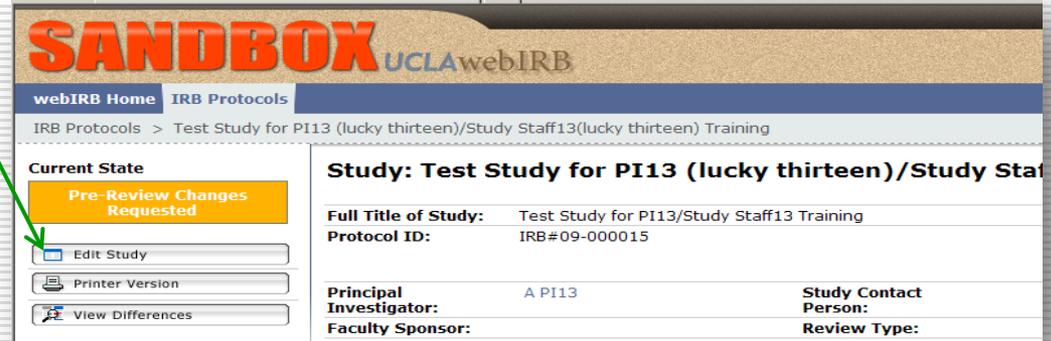
- Use the link in the email to go to the workspace to view the inquiry/reply and if necessary respond to the MRSC requests.
- **Do Not Reply to the email.**



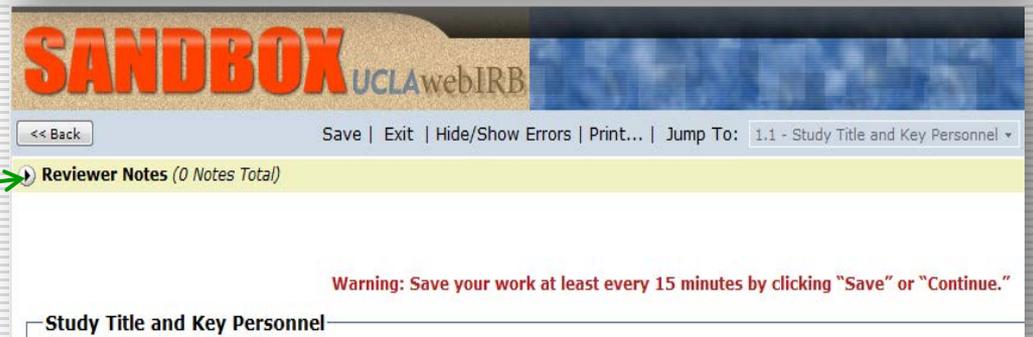
*Example of webIRB email notification the PI will receive when the MRSC administrator sends an inquiry or reply.*

# Responding to IRB Requests (cont'd)

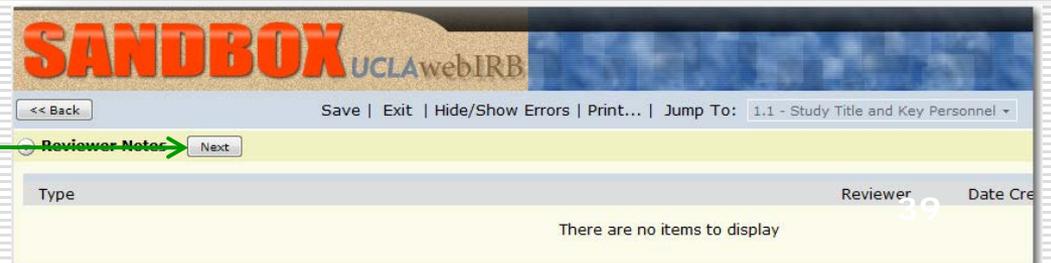
- When responding to an IRB request for a Study click **"Edit Study"** or for an AM click **"View Modified Study"**
- Section 1.1 of the Study Smartform will appear.



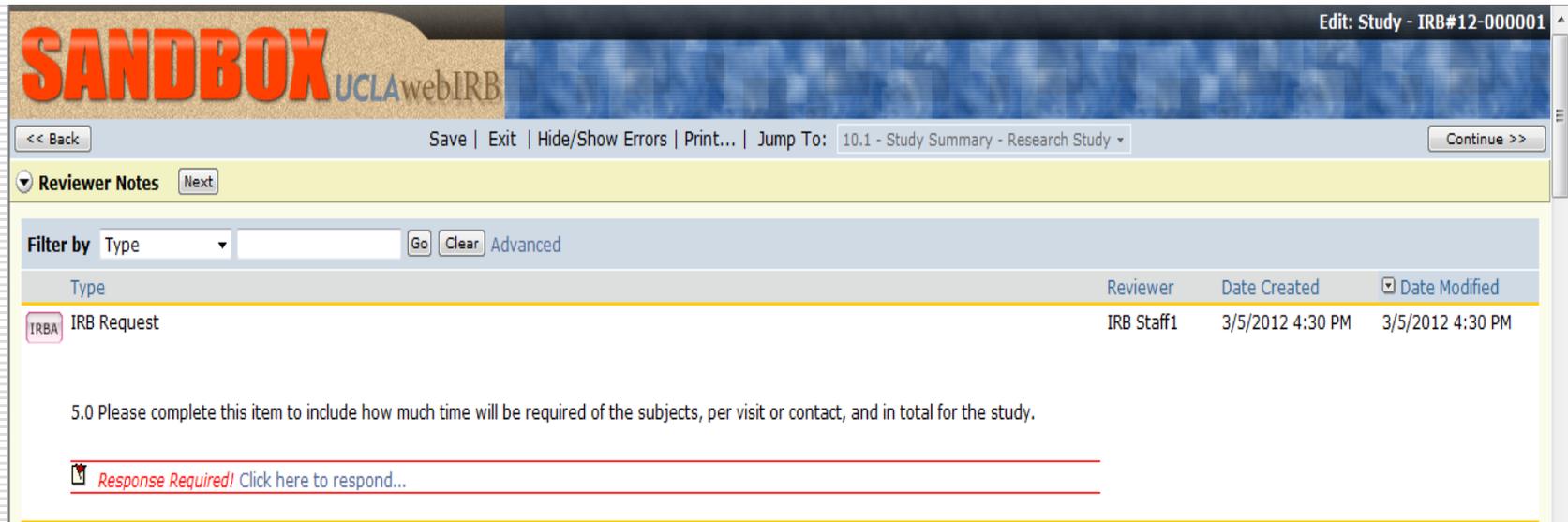
- To view the IRB Request in Section 1.1, click the arrow  so that it points down .
- If there are no IRB Requests for Section 1.1 you will see the message "There are no items to display".



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



# Responding to IRB Requests (cont'd)



The screenshot shows the SANDBOX UCLAwebIRB interface. At the top, there is a header with the logo and the text "Edit: Study - IRB#12-00001". Below the header, there is a navigation bar with buttons for "<< Back", "Save", "Exit", "Hide/Show Errors", "Print...", "Jump To: 10.1 - Study Summary - Research Study", and "Continue >>". The main content area is titled "Reviewer Notes" and includes a "Next" button. Below this, there is a filter section with a "Filter by" dropdown set to "Type", and buttons for "Go", "Clear", and "Advanced". A table displays the following information:

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

Below the table, there is a text entry field with the instruction: "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." At the bottom of the field, there is a red underline and a link that says "Response Required! Click here to respond..."

**DO NOT** click "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 pull 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:  (dropdown menu open showing: Change Request Completed, Change Request Completed, Change Request Not Completed, Information Only)

\* Response:

\* Required

OK Cancel

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

To return to the Study Workspace, Click **Save**, then **Exit**.

When there is more than 1 request, click **Next** to complete additional requests.

The image displays three screenshots of the IRB system interface, illustrating the process of responding to requests.

**BEFORE RESPONSE:** The first screenshot shows the 'Reviewer Note' section for an 'OPRS-IRB Request'. The note is highlighted in red, indicating a required response. The text reads: 'Response Required! Click here to respond... Item #6 - Please provide a description of the requested amendment and reason for the change in item 6.' The reviewer is 'IRB Senior Staff Test' and the date is '4/28/2009 9:51 AM'.

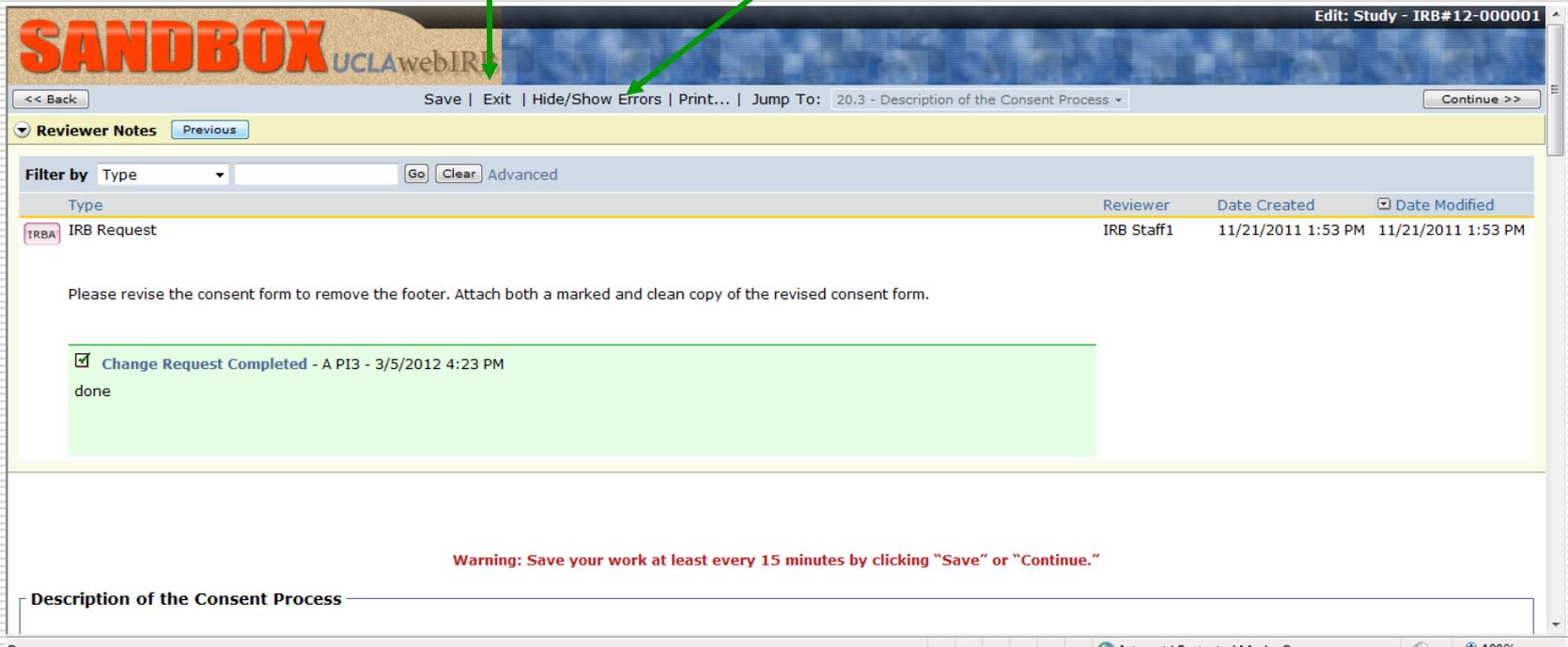
**AFTER RESPONSE:** The second screenshot shows the same 'Reviewer Note' section after the response is completed. The note is now highlighted in green. The text reads: 'Paul Investigator - Change Request Completed - 4/28/2009 2:15 PM xyz'. The reviewer is 'IRB Senior Staff Test' and the date is '4/28/2009 2:15 PM'. A green arrow points from the 'Save' button in the navigation bar to the 'Reviewer Note' section.

**Next:** The third screenshot shows the 'Reviewer Note' section for an 'IRB Request'. A 'Next' button is visible next to the 'Reviewer Note' dropdown, indicating that there are multiple requests to be processed. A green arrow points from the 'Next' button to the 'Reviewer Note' section.

# 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 SANDBOX UCLAwebIRB interface. At the top, there is a navigation bar with the following options: << Back, Save, Exit, Hide/Show Errors, Print..., Jump To: 20.3 - Description of the Consent Process, and Continue >>. The main content area is titled "Reviewer Notes" and includes a "Previous" button. Below this, there is a "Filter by" section with a dropdown menu set to "Type", a "Go" button, a "Clear" button, and an "Advanced" link. A table lists the 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 message 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" with a checked checkbox and the word "done" below it. At the bottom of the interface, a red warning message states: "Warning: Save your work at least every 15 minutes by clicking 'Save' or 'Continue.'" The page title is "Description of the Consent Process".

# Responding to IRB Requests (cont'd)

- When all of the requests have been completed/addressed, 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 'SANDBOX UCLAwebIRB' interface. The top navigation bar includes 'webIRB Home' and 'IRB Protocols'. The main content area is titled 'Study: Test Study for PI13 (lucky thirteen)/Study Staff13(lucky thirteen)'. It provides details such as '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: - N/A', 'PI Assurances: Completed', and 'FS Assurances: Not Required'. The 'My Activities' sidebar on the left lists actions like 'Submit Response', 'PI Assurances', 'Send Training Reminder', 'Withdraw', 'Edit PI Proxy', 'Copy Study', 'Send Inquiry or Reply to IRB', and 'Study Team - Log Private Comment'. The 'IRB Requests' tab is active, showing a table with columns for 'Type', 'Reviewer', and 'M'. A row is highlighted in green, indicating a completed request: 'A PI13 - Change Request Completed - 8/9/2010 10:28 AM' with a reviewer of 'CARRIE FISHER'. A green arrow points from the text box in the first bullet point to this green-highlighted row.

# Responding to IRB Requests (cont'd)

The screenshot displays the webIRB system interface for a study titled "Test Study for webIRB Training- Basic 1". The interface includes a navigation menu on the left with options like "Pre-Review Changes Requested", "Edit Study", "Printer Version", "View Differences", and "SS-Print All Request Notes". The main content area shows study details such as "Full Title of Study", "Protocol ID", "Principal Investigator", "Faculty Sponsor", "Committee", "Initial Submission Date", "PI Proxy", "PI Assurances", and "FS Assurances". A green box highlights the "Send Ready Notification" option in the "My Activities" section, with an arrow pointing to it from the text box on the right.

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	Meeting Date-Time	- N/A
Initial Submission Date:	3/5/2012		
PI Proxy:	Rebecca Simms (PI) A PI2		
PI Assurances:	Pending...		
FS Assurances:	Not Required		
Request to Continue Participants during Approval Lapse:			

## PI, PI Proxy, 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.

# IRB Requests - Tips

Click here for a printable summary of the IRB Requests and your responses.

The screenshot displays the webIRB interface in a browser window. The browser title is "No Title - Windows Internet Explorer" and the address bar shows the URL: <https://webirbsandbox.research.ucla.edu/SANDBOX/CustomLayouts/ReviewerNote-PrinterVersion?PageTy>. The page content includes a sidebar on the left with navigation options, a main content area with study details, and a table of reviewer notes.

**Study:** A PI13 | My Ho

**Full Title of Protocol ID:** IRB#: IRB#09-000015  
Title: Test Study for PI13 (lucky thirteen)/Study Staff13(lucky thirteen) Training  
PI: A PI13

**Principal Investigator Faculty Sponsor Committee:** CARRIE FISHER

**Initial Submission Date:**

**PI Assurance FS Assurance:**

**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

SmartForm Section	Reviewer Notes	Respondent Notes
10.1 - Study Summary - Research Study	<p>IRBA IRB Request</p> <p><b>Author:</b> CARRIE FISHER</p> <p><b>Date Created:</b> 09 Aug 2010 10:04:41</p> <p><b>Note:</b> 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.</p>	<p>Change Request Completed</p> <p><b>Respondent:</b> A PI13</p> <p><b>Date Responded:</b> 09 Aug 2010 10:28:20</p> <p><b>Response:</b> Done</p>

# IRB Requests – Tips (cont'd)

The IRB Staff working on your study is listed here.

- Use the **Send Inquiry or Reply to IRB** activity to communicate with IRB staff.
- An email notification will be sent to the IRB Staff (Owner).

The screenshot displays the 'SANDBOX UCLA webIRB' interface. The top navigation bar includes 'webIRB Home' and 'IRB Protocols'. The current page is titled 'IRB Protocols > Test Study for PI13 (lucky thirteen)/Study Staff13(lucky thirteen) Training'. The 'Current State' section shows a yellow box indicating 'Pre-Review Changes Requested' and buttons for 'Edit Study', 'Printer Version', 'View Differences', and 'SS-Print All Request Notes'. The 'Owner (IRB Staff):' is listed as 'CARRIE FISHER'. The 'My Activities' list includes 'Submit Response', 'PI Assurances', 'Send Training Reminder', 'Withdraw', 'Edit PI Proxy', 'Copy Study', 'Send Inquiry or Reply to IRB', and 'Study Team - Log Private Comment'. The main content area shows study details: '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: A PI13', 'Review Type: Study Staff13', 'Committee: Medical IRB 2', 'Initial Submission Date: 12/26/2009', 'Meeting Date-Time: - N/A', 'PI Assurances: Completed', and 'FS Assurances: Not Required'. Below this is a tabbed interface with 'IRB Requests' selected, showing a table with columns 'Type', 'Reviewer', and 'Modified'. The table contains one entry: 'IRBA 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 indicates 'A PI13 - Change Request Completed - 8/9/2010 10:31 AM Done'.

# Post-Approval webIRB Applications

---

Types of applications that can be submitted in webIRB *after approval of a study*:

- **Amendment**
- **Continuing Review or Closure**
- **Post –Approval Report**
- **Single subject Exception**

AM New Amendment

CR Continuing Review or Closure

PAR New Post-Approval Report  
or Single Subject Exception

# Post-Approval Activities

Click on My Home

The screenshot shows the webIRB interface for a PI5 user. The top navigation bar includes 'A PI5 | My Home | Logoff'. The main content area is titled 'Page for A PI5' and contains a 'Study Team' tab, 'My Roles' (Study Team), and a 'Create New Study' button. The main content area is titled 'Page for A PI5' and contains a 'Welcome to your Home Page.' message, a list of links (Inbox, Other Tabs), and a 'webIRB Survey' section. Below the survey is a navigation bar with 'My Inbox', 'My IRB Studies', 'Archived', and 'Profile'. The 'My IRB Studies' section displays a table of IRB related studies.

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.

Click on the link to "Sample Approved Study for webIRB Training ...". Project State should be "Approved".

# Approved Study Workspace

**Current State**

**Study:** Sample Approved Study for webIRB Training - 10

**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

**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:**

**Review Type:** Full IRB Review

**Committee:** Medical

**Approval Date:** 11/22/2011

**Expiration Date:** 11/21/2016

**3 Letter of Approval:** View

**PI Proxy:** Rebecca Simms (PI)

**PI Assurances:** Completed

**FS Assurances:** Not Required

**Request to Continue Participants during Approval Lapse:**

**History**

- Amendments
- Continuing Review or Closure
- Post-Approval Reports & Single Subject Exception
- 4 Approved Documents**
- Completed IRB Requests
- Conditions and Determinations

**Activity** | **Author** | **Activity D**

- Project Snapshot Generated | Administrator, System | 11/22/2011
- View Project Snapshot | **5**
- 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, **not submit**, post approval applications (i.e., AM, CR, and PAR).
2. All other workspaces are accessible.
3. Contains the Study or CR Approval letter only.
4. Contains all approved documents
5. Contains a copy of the approved application

# Workspaces: PAR, CR, and AM

Each type of application has its own workspace after it is created.

The screenshot displays three overlapping workspace views from the webIRB system:

- PAR Workspace:** The top-most view, titled "Post-Approval Report & Single Subject Exception: example of PAR workspace". It shows a "Current State" of "Pre Submission" and a sidebar with options like "Edit Post-Approval Report or Single Subject Exception", "Print", "View", "SS-Print", "Owner", "Parent State: A Review Review", and "My Activities" (Submit Continuing Review or Closure, FS Assurances, Withdraw).
- CR workspace:** The middle view, titled "Continuing Review or Closure: 2013 Review for IRB#12-000004". It shows a "Current State" of "Pre Submission" and a sidebar with options like "Edit Continuing Review or Closure", "Printer-Friendly Version", "SS-Print All Request Notes", "Owner (IRB Staff)", "Parent Study: State: Suspended Review Type: Expedited", and "My Activities" (Submit Continuing Review or Closure, FS Assurances, Withdraw).
- Amendment Workspace:** The bottom-most view, titled "Amendment:Amendment #1 for webIRB Study IRB#11-000042". It shows a "Current State" of "Pre Submission" and a sidebar with options like "Edit Amendment", "Print-Friendly Amendment", "Edit Modified Study", "Print-Friendly Study", "View Changes", "SS-Print All Request Notes", "Owner (IRB Staff)", "Parent Study: State: Approved Review Type: Full IRB Review", and "My Activities" (Submit Amendment, Send Training Reminder, Withdraw, Edit PI Proxy).

Red boxes highlight the workspace titles: "PAR Workspace", "CR workspace – At continuing review the FS and PI Assurances must be completed in the CR workspace.", and "Amendment Workspace".

# Where are the documents stored?

The screenshot shows the 'Sandbox' interface for UCLA webIRB. The main content area displays details for a study titled 'Sample Approved Study for webIRB Training - 5'. The study is in an 'Approved' state. Key information includes: Full Title of Study: Sample Approved Study for webIRB Training - 5; Protocol ID: IRB#11-000046; Principal Investigator: A P15; Faculty Sponsor: [blank]; Review Type: Full IRB Review; Committee: Medical IRB 1; Approval Date: 11/22/2011; Expiration Date: 11/21/2016; PI Proxy: Rebecca Simms (PI); PI Assurances: Completed; FS Assurances: Not Required. A 'Letter of Approval' link is visible with a 'View' button. At the bottom, there is a 'History' table with tabs for 'Amendments', 'Continuing Review or Closure', 'Post-Approval Reports & Single Subject Exception', 'Approved Documents', 'Completed IRB Requests', 'Conditions and Determinations', and 'Correspondence'. The 'Approved Documents' tab is selected, showing a table with columns for 'Activity', 'Author', and 'Activity Date'. A row shows 'Project Snapshot Generated' by 'Administrator, System' on '11/22/2011 10:53 AM PST'. A 'View Project Snapshot' link is present below the table.

**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 - 5**

**Full Title of Study:** Sample Approved Study for webIRB Training - 5  
**Protocol ID:** IRB#11-000046

**Principal Investigator:** A P15  
**Faculty Sponsor:**

**Review Type:** Full IRB Review  
**Committee:** Medical IRB 1

**Approval Date:** 11/22/2011  
**Expiration Date:** 11/21/2016  
**Letter of Approval:** [View](#)

**PI Proxy:** Rebecca Simms (PI)

**PI Assurances:** Completed  
**FS Assurances:** Not Required

**Request to Continue Participants during Approval Lapse:**

**History** | Amendments | Continuing Review or Closure | Post-Approval Reports & Single Subject Exception | **Approved Documents** | Completed IRB Requests | Conditions and Determinations | Correspondence

Activity	Author	Activity Date
Project Snapshot Generated	Administrator, System	11/22/2011 10:53 AM PST

[View Project Snapshot](#)

- **View** Letter of Approval to see the documents approved for the Study or CR.
- To view documents approved for the AM go to the AM workspace.

Click on the **Approved Documents** tab to see *all currently approved documents*

# Where are the documents stored? (cont'd)

The screenshot shows a webIRB application interface. At the top, there is a navigation bar with tabs: History, Amendments, Continuing Review or Closure, Post-Approval Reports & Single Subject Exception, **Approved Documents** (circled in red), Completed IRB Requests, Conditions and Determinations, and Correspondence. Below the navigation bar, there are three buttons: PAR (New Post-Approval Report or Single Subject Exception), AM (New Amendment), and CR (Continuing Review or Closure). The main content area is titled "Approved Consent Forms and Recruitment Materials:" and contains a table with columns "Name", "Version", and "Modif". The table lists a document named "HIVconsent.6.30.09.doc.pdf" with version "0.01". Below this, there is a section titled "INFORMED CONSENT (Documents uploaded by Study Staff - these are NOT necessarily approved)". This section contains two sub-sections: "Section 20.3/item 5.0 Description of Consent Process: Consent Forms/Information Sheets/Screening or Consent Scripts:" and "Section 10.1/item 1.0 Study Summary: Study Materials:". Each sub-section contains a table with columns "Document Name" and "Document Version #". The first table lists "HIVconsent.6.30.09.doc" with version "0.01". The second table lists "CBT Manual 110711" with version "0.01".

Name	Version	Modif
HIVconsent.6.30.09.doc.pdf   History	0.01	

**INFORMED CONSENT (Documents uploaded by Study Staff - these are NOT necessarily approved)**

Section 20.3/item 5.0 Description of Consent Process: Consent Forms/Information Sheets/Screening or Consent Scripts:

Document Name	Document Version #
HIVconsent.6.30.09.doc	0.01

Section 10.1/item 1.0 Study Summary: Study Materials:

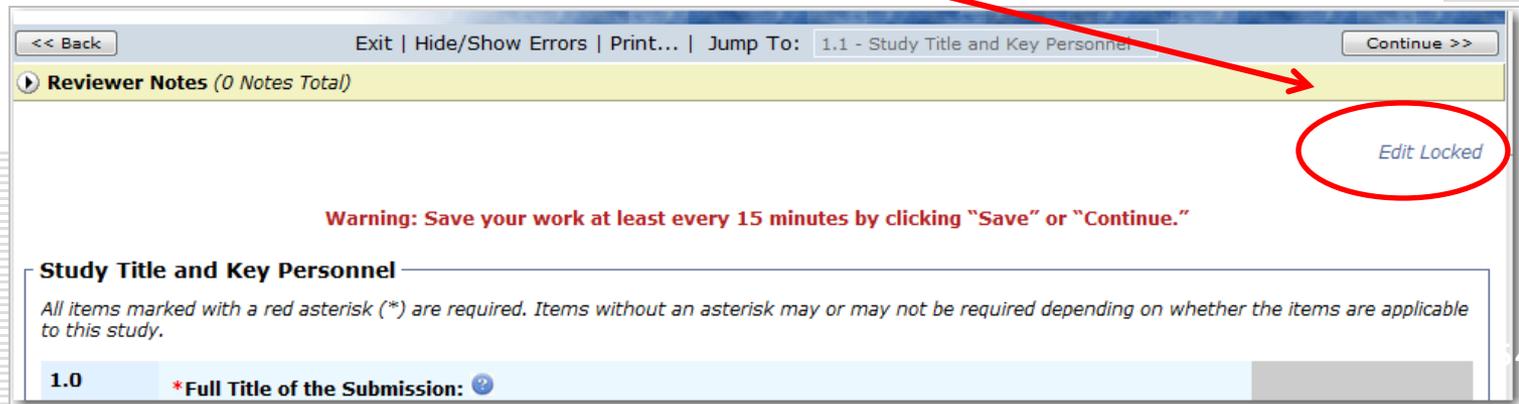
Document Name	Document Version #
CBT Manual 110711	0.01

Links to consent forms and documents that were uploaded to the application.

**Important Note:** Don't add footers to documents that will be stamped by webIRB

# Create an Amendment

- Only one AM can be created and submitted at a time.
  - An amendment can be used to revise several aspects of a study at once.



# Create an Amendment (cont'd)

The screenshot displays the 'Sandbox' interface for the 'UCLA webIRB' system. The main content area shows details for a study titled 'Sample Approved Study for webIRB Training - 1'. A green arrow points from the 'AM New Amendment' button in the 'My Activities' sidebar to a callout box. The callout box contains the following text:

- In the approved study workspace click on **New Amendment**.
- The Amendment Smartform will appear.

The interface includes a top navigation bar with 'webIRB Home' and 'IRB Protocols'. The left sidebar contains 'Current State' (Approved), '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), and a list of activity buttons (PAR, AM, CR). The main content area shows study details such as 'Full Title of Study', 'Protocol ID', 'Principal Investigator', 'Faculty Sponsor', 'Review Type', 'Approval Date', 'Expiration Date', 'PI Proxy', 'PI Assurances', 'FS Assurances', and 'Request to Continue Participants during Approval Lapse'. The bottom navigation bar includes 'History', 'Amendments', 'Continuing Review or Closure', 'Post-Approval Reports & Single Subject Exception', 'Documents', 'IRB Requests', 'Determinations', 'Log', and 'Log'.

# Describe the Amendment

**SANDBOX** UCLA webIRB

<< Back Save | Print...

Note: there are

Warning: Save your work at least every 15 minutes.

### Description of Amendment

**Attention:**

Due to the constraints of the webIRB system, it's advisable to have one amendment application under review at a time.

1. When an amendment is submitted, the sections of the application that are being modified are locked to further changes. For example, if you are submitting an amendment to change the inclusion criteria, study summary and consent sections, these sections will be locked by the system and no further changes can be made to them.
2. Instead of submitting separate amendment application for each change, try to group the changes together as much as possible.

Please plan your amendment application so that you do not have more than two undergoing reviews at a time. If you have more than two, you may be required to withdraw one or more of the amendments.

**1.0** \* Short Title:  
Amendment #3 for webIRB Study IRB#11-000004

**2.0** \* Change in study staff and/or other personnel.

Check all that apply:

- Principal Investigator
- Contact Person
- Key Personnel (Study Staff and/or Other Personnel)
- Not applicable

**3.0** If this amendment includes a change to the Principal investigator and the current person filling this role is not available to electronically submit...

Complete the **Description of Amendment** section.

- **1.0- Provide a short title**  
The title will appear on the AN.
- **2.0- Indicate whether or not there is change in study staff and/or key personnel**  
New study staff/personnel will have access to the study when the AM is approved.

# Describe the Amendment (cont')

**4.0** \* **Minor Amendment - Types of change(s) proposed.**

**Check all that apply:**

- Clarification or technical change
- Minor increase/decrease in number of Study participants
- Narrowing of the inclusion criteria
- Broadening of the exclusion criteria
- Changes in the dosage or form (e.g., tablet to liquid) but not the route of administration of an approved drug
- Increase or decrease in the number of safety monitoring visits provided that there is no impact on subject safety.
- Addition or deletion of study sites
- Change in payments to study participants
- Minor changes to recruitment materials
- Minor changes to screening procedures
- Change in funding source(s)
- Other
- None of the above**

**5.0** \* **Major Amendment - Types of change(s) proposed.**

**Check all that apply:**

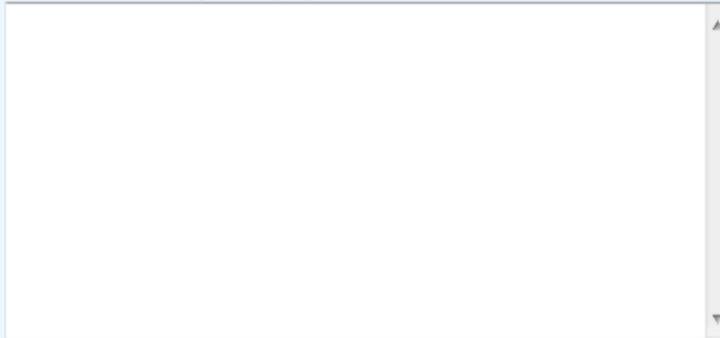
- Change in study design of a protocol approved by the full board of the IRB
- Change in status of study participants (e.g., study participant becomes prisoner, ward, or pregnant in a protocol not approved for these populations (Note: This primarily applies to medical or treatment studies.)
- Addition of a procedure not approvable using expedited review procedures (e.g., ionizing radiation)
- Changes that increase risk or discomfort to study participants
- Substantive changes to a consent form or other study documents distributed to subjects.
- Other
- None of the above**

**6.0** **If you selected "other" to any of the items above, list the type of change.**

**Select the check box(es) that best describe the proposed change(s).**

# Describe the Amendment (cont')

7.0 \* Provide a summary of the proposed modifications and describe the reason(s) for the modifications.



**7.0- Provide a description and justification for the changes you selected in Items 2.0, 4.0, and 5.0.**

- If applicable describe procedures for re-consenting subjects.

7.1 Attach a summary of changes here (if applicable).

Add

name

version

There are no items to display

*Note:* All other materials - such as consent forms, recruitment flyers, etc - must be attached to the appropriate section of the application - not here.

**7.1- If applicable, attach the summary of changes provided by the sponsor.**

- Use Item 7.0 describe the changes that apply to the study.
- Do not attach modified study documents.

# Describe the Amendment (cont')

**8.0** \* Are any participants currently enrolled in the study?

Yes

No

Not Applicable

Clear

*If yes, answer the following items:*

**8.1** Should current study participants be notified or re-consented?

Yes

No

Not Applicable - No study participants have been enrolled

Clear

**8.2** Should participants who have completed the study be notified?

Yes

No

Not Applicable - No study participants have been enrolled

Clear

**8.3** If you indicated "No" for items 8.1 and/or 8.2, indicate the rationale.

**8.0** Indicate whether there are any subjects currently enrolled in the study.

- If applicable describe procedures for re-consenting subjects in Item 7.0.

Addendum Consent Templates are available at <http://ohrpp.research.ucla.edu/pages/biomedical-informed-consent>

# Description Amendment (cont')

## 9.0- Indicate whether you are submitting a Post-Approval Report (PAR) with the Amendment.

- The application will branch with the PAR questions.
- If the PAR has been submitted as a separate application, select "No".

9.0

\* Is a Post-Approval Report included in this amendment?

Yes  No

**SANDBOX** UCLAwebIRB New: Amendment

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

Note: there are 2 open Amendments for this study.

or "Continue."

**Description of Amendment**

**Attention:**

Due to the constraints of the webIRB system, it's advisable to have one amendment application under review at a time. If, however, you need to submit a second amendment, here are some things to know:

1. When an amendment is submitted, the sections of the application that are being modified are locked to further changes until the amendment is reviewed and approved. For example, if you submit an amendment that has modifications to the inclusion criteria, study summary and consent sections, these sections will be locked by the system and no further changes will be possible until you receive your approval letter.
2. Instead of submitting separate amendment application for each change, try to group the changes together as much as possible on one amendment application.

Please plan your amendment application so that you do not have more than two undergoing reviews at a time. If you run into a bind, you can call the IRB Office for assistance.

Click **Save** when you complete this section.

Click **Continue** to go to the next section

# Description Amendment (cont')

## Finish

Please ensure you have updated the appropriate items on the original study application form  
SmartForm

If you have completed the amendment smartform and updated the appropriate items on the study amendment workspace. Then click "Submit Amendment" under "My Activities" to submit the amendment.

## Finish

- When you reach **Finish** click "SmartForm" to go to the Study application.
- Section 1.1 of the study application will appear.

# Update the Currently Approved Protocol

The screenshot shows the SANDBOX UCLAwebIRB interface. At the top, the logo 'SANDBOX UCLAwebIRB' is visible on the left, and 'Edit: Study - MS#2\_IRB#11-00004' is on the right. Below the logo, there is a navigation bar with buttons: '<< Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print...', 'Jump To:', and 'Continue >>'. The 'Save', 'Exit', 'Hide/Show Errors', 'Jump To:', and 'Continue >>' buttons are circled in red. Below the navigation bar, there is a 'Reviewer Notes' section with a table. The table has columns for 'Type', 'Reviewer', and 'Modified'. The main content area shows a warning: 'Warning: Save your work at least every 15 minutes'. A 'Jump To:' dropdown menu is open, listing sections: 1.1 - Study Title and Key Personnel, 1.1a - Other Personnel, 1.2 - Conflict of Interest Information, 2.1 - Project Identification Information, 2.2 - Lay Summary and Keywords, 5.1 - Type of Study Review, 6.1 - Funding and Other Study Characteristics, 6.2 - Funding - Description, 7.1 - Study Locations, 7.2 - UCLA or UCLA Network Sites, 8.1 - Methods/Procedures - Descriptors, 8.3 - Clinical Trial of a Behavioral Intervention, Drug, Bi, 8.6 - Drugs/Biologics/Dietary Supplements, 8.10 - Regulatory and Committee Approvals, 9.2 - Information about Study Data, 9.2a - Privacy, and 9.3 - Data Security. A red box highlights the text: 'Update the relevant sections of the currently approved protocol.'

Update the relevant sections of the currently approved protocol.

- Use the **Jump To** menu or **Continue** button to navigate through the application.
- Remember to click **Save** after revising each SmartForm page.
- Use **Hide/Show Errors** to see sections that need completion.

# Upload Revised and New Documents

5.0

\* Attach copies of the informed consent documents, information sheets, consent scripts as applicable to this study. Include copies of translated forms, if applicable.

Add

Upload Revision

Document Name

HIVconsent.6.30.09.doc

Document Version #

0.01

Delete

- Use **Upload Revision** to replace previous versions of documents with the updated versions.
  - Update the document title to distinguish between the marked and clean copy. Include the version date. (e.g., “child assent\_marked\_010111”, “child assent\_clean\_010111”).
- Use **Add** to upload new documents in the application.
- To remove documents, click **Delete** on the document you want to remove.

# Upload Revised and New Documents (cont'd)

When you upload a revised document or add a new document, the **Submit a Document** screen will open.

1. Click **Browse** to select and upload document from your computer.
2. Then click **OK**.

**Note:** You can leave the **Title** field blank. The name of your document will be used.

The screenshot shows a web browser window titled "No Title - Windows Internet Explorer" with the URL "https://webirbtest.research.ucla.edu/sandbox/ResourceAdministration/Document/FormForProperty?formID=C". The main content area is titled "Submit a Document" and contains a "Help" button. There are two input fields: "Title:" (circled in red) and "\* File:" (with a "Browse..." button circled in red). A note next to the "Title" field says "If not provided, the name of the file will be used". Below the fields is a "Show Advanced Options" button. At the bottom, there are three buttons: "OK" (circled in red), "OK and Add Another", and "Cancel". A status bar at the bottom shows "Done", "Internet", and "100%".

5.0

**\* Attach copies of the informed consent documents, information sheets, consent scripts as applicable to this study. Include copies of translated forms, if applicable.**

Add

	Document Name	Document Version #	
Upload Revision	HIVconsent.6.30.09.doc	0.02	Delete

When you upload a revised document, webIRB will update the version number on the screen.

# Updating the Currently Approved Protocol

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

Study Title and Key Personnel ▾

▼ Reviewer

Type	Created	Date Modified
------	---------	---------------

- Click **Save** when you done updating the Study SmartForms.
- Click **Exit**
- You will return to the **Finish** Section of the Amendment Smartform.

<< Back      Save | Exit | Hide/Show Errors | Print... | Jump To: Finish      Finish

▼ Reviewer Note

Type	Reviewer	Date Modified
There are no items to display		

Click **Finish**. You will go to the Amendment workspace.

# Submit the Amendment

Remember to click **Submit Amendment**

*Reminder:*

-The **Submit Amendment** activity is available only to the PI and PI Proxy.

- Study Staff can use the **Send Ready Notification** to let the PI/PI Proxy know the Amendment is ready to be submitted.

The screenshot displays the SANDBOX UCLA webIRB interface. At the top, there is a navigation bar with 'A PI1 | My Home | Logoff'. Below this is a breadcrumb trail: 'webIRB Home | IRB Protocols | IRB Protocols > Sample Approved Study for webIRB Training - 1 > Amendment #1 for webIRB Study IRB#11-000042'. A red box labeled 'Breadcrumbs' points to this trail.

The main content area is titled 'Amendment: Amendment #1 for webIRB Study IRB#11-000042'. It contains a table with the following information:

<b>Amendment ID:</b>	IRB#11-000042-AM-00001		
<b>Study Name:</b>	Sample Approved Study for webIRB Training - 1	<b>Study ID:</b>	IRB#11-000042
<b>Principal Investigator:</b>	A PI1	<b>Study Contact Person:</b>	Study Staff1
<b>Faculty Sponsor:</b>		<b>Review Type:</b>	
<b>PI Proxy:</b>	Rebecca Simms (PI)		
<b>Date Created:</b>	3/6/2012 12:38 PM		

On the left side, there is a 'Current State' section with a 'Pre Submission' button and several options: 'Edit Amendment', 'Print-Friendly Amendment', 'Edit Modified Study', 'Print-Friendly Study', 'View Changes', and 'SS-Print All Request Notes'. Below this is the 'Owner (IRB Staff):' section, followed by 'Parent Study: State: Approved, Review Type: Expedited'. The 'My Activities' section is circled in red and includes 'Submit Amendment', 'Send Training Reminder', 'Withdraw', 'Edit PI Proxy', and 'Study Team - Log Private Comment'.

At the bottom, there is an 'Information Tab' section with a red box around it, and a navigation bar with 'History', 'IRB Requests', 'New or Modified Docs', and 'Change Log'.

# Approved Amendment Workspace

**SANDBOX** UCLAwebIRB

webIRB Home IRB Protocols

IRB Protocols > Sample Approved Study for webIRB Training - 1 > Amendment #1 for webIRB Study IRB#11-000042

**Current State**  
Approved

View Amendment  
Print-Friendly Amendment  
View Modified Study  
Print-Friendly Study  
View Changes  
SS-Print All Request Notes

**Amendment: Amendment #1 for webIRB Study IRB#11-000042**

**Amendment ID:** IRB#11-000042-AM-00001  
**Study ID:** IRB#11-000042  
**Study name:** Sample Approved Study

**Principal Investigator:** A P11  
**Study Contact Person:** Study Staff1

**PI Proxy:** Rebecca Simms (PI)

**Initial Submission Date:** 4/12/2012  
**Review Type:** Expedited

**Final Action:** Approved  
**Final Action Letter:** View

**Linked to Projects:**

ID	Name	Project Type	Stat
There are no items to			

**Description:**  
There are no items to display

**My Activities**  
Send Training Reminder  
Send Inquiry or Reply to IRB  
Study Team - Log Private Comment

**History** Completed IRB Requests New or Modified Docs Correspondence Change Log

Activity	Author
Generate Project Snapshot	Administrator, System
View Amendment Snapshot View Modified Study Snapshot	
Sent Letter/Notice To PI: Approved (Expedited)	Staff1, IRB
View Approval Notice	

## Unique features:

1. View final action and AM Approval letter (includes approved documents)
2. Contains snapshot of AM (cover letter) and Modified Study application

**Note:** A snapshot of Modified Study application will also appear in the History tab of the Study workspace.

# Create a Continuing Review or Closure (CR)

**SANDBOX** UCLAwebIRB

A PI1 | My Home | Logoff

webIRB Home | IRB Protocols

IRB Protocols > Sample Approved Study for webIRB Training - 1

**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 - 1**

**Full Title of Study:** Sample Approved Study for webIRB Training - 1  
**Protocol ID:** IRB#11-000042

**Principal Investigator:** A PI1  
**Faculty Sponsor:**

**Review Type:** Expedited

**Approval Date:** 3/26/2012  
**Expiration Date:** 11/21/2016

**PI Proxy:** Rebecca Simms (PI)

**PI Assurances:** Completed  
**FS Assurances:** Not Required

**Request to Continue Participants during Approval Lapse:**

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

**History** | Amendments | Continuing Review or Closure | Post-Approval Reports & Single Subject Exception | Approved Documents | Completed IRB Requests | Conditions and Determinations | Correspondence | Training Log | Change Log

Activity	Author	Activity Date
Amendment Opened	PI1, A	7/13/2012 3:23 PM PDT

View Amendment workspace

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

- In the approved study workspace click on **Continuing Review or Closure (CR)**.
- The CR Smartform will appear.

# Complete the CR Application

**SANDBOX** UCLAwebIRB

New: Continuing Reviews

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

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

Continuing Review or Closure

1.0 IRB# for the study:  
IRB#12-000004

2.0 \*Indicate the type of report you are submitting:

Progress report for continuing review

Study Closure

- The SmartForm will branch depending on the type of report you are submitting:
  - Progress report for continuing review
  - Study Closure
- Provide a response to each question
- Remember to **Save**

- Click **Continue** to navigate through the sections.
- Complete the CR by providing a response to all the questions in each section.
- *Reminder:* Use **Hide/Show Errors** to see sections that need completion

# Complete the CR Application (cont'd)

<< Back      Save | Exit | Hide/Show Errors | Print... | Jump To: 4.0 - Continuing Review or Closure Report      Finish

▼ Reviewer Note

Type	Reviewer	Date Created	Date Modified
There are no items to display			

**Continuing Review or Closure Report**

**Instructions for Submission**

If you are closing your IRB Approved or Certified Exempt study, submit this report upon completion or termination of all research activity, even if the current report is still under review.

When you are ready to submit this report, please use the following instructions for review.

1. Click the "**Finish**" button on this page to return to the Continuing Review or Closure Report workspace
2. If you have any amendments to submit at the same time as this report, click the "**Amendment**" button under "**My Activities**."
3. Submit the report by using the "**Submit Continuing Review**" activity
4. Once the report is submitted, the state indicator at the top left of the workspace will no longer display "**Pre-Submission**."

Contact OHRPP/IRB office if you have any questions.

- Call the General Campus IRB staff at 310-825-7122 or email [gcirb@research.ucla.edu](mailto:gcirb@research.ucla.edu).
- Call the Medical IRB staff at 310-825-5344 or email [mirb@research.ucla.edu](mailto:mirb@research.ucla.edu).
- For exempt protocols only, contact Wendy Brunt at 310-825-4810 or email [wbrunt@research.ucla.edu](mailto:wbrunt@research.ucla.edu).

OHRPP Guidance #17 on this topic is posted on the OHRPP website at <http://ohrpp.research.ucla.edu>.

- When you reach **Section 4.0- Continuing Review or Closure Report** click **Finish** to go to the CR workspace
- The following must occur in the CR:
  - Submit the CR

# Submit the CR

webIRB Home IRB Protocols

IRB Protocols > Text Changes (short title) > 2013 Review for IRB#12-000004

**Project State**  
Pre Submission

Edit Continuing Review or Closure  
Printer-Friendly Version  
SS-Print All Request Notes

**Owner (IRB Staff):**  
Parent Study: State: Approved  
Review Type: Expedited

**Continuing Review or Closure: 2013 Review for IRB#12-000004**

<b>Continuing Review or Closure ID:</b>	IRB# 12-000004-CR-00006		
<b>Study ID:</b>	IRB# 12-000004	<b>Study Name:</b>	Text Changes (short title)
<b>Principal Investigator:</b>	A PI1	<b>Study Contact Person:</b>	
<b>Faculty Sponsor:</b>	A PI5	<b>Consent requires modification?:</b>	
<b>SAE since last Continuing Review:</b>		<b>Significant new findings to disclose?:</b>	
<b>Total enrolled for this site since last progress review:</b>		<b>Study expiration date:</b>	
<b>Any modifications not approved prior to implementation?:</b>		<b>Review Type:</b>	
<b>Initial Submission Date:</b>		<b>Meeting Date &amp; Time:</b>	- N/A
<b>Committee:</b>	Medical IRB 1		

If you have a Faculty Sponsor, use "Send Notification to FS for FS Assurances" to request his/her assurances.

- My Activities**
- Send Notification to FS for FS Assurances
  - Submit Continuing Review or Closure
  - Withdraw
  - Edit PI Proxy

**My Activities**

- Send Notification to FS for FS Assurances
- Submit Continuing Review or Closure
- Withdraw
- Edit PI Proxy

**PI Proxy:**

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

Error!! If you have a Faculty Sponsor his/her assurances are required before submitting the CR.

# Faculty Sponsor Assurances



## Faculty Sponsor Assurances

The Faculty Sponsor must provide the appropriate FS Assurances in the CR workspace.

Continuing Review Assurances.

Study Closure Assurances.

FS Assurances

### Faculty Sponsor Assurances

Please select the applicable assurance for your submission. Select either the assurance for Continuing Review or Study Closure. Then scroll down and click the "OK" button.

#### Continuing Review

1.0 By checking Agree as sponsor on this research application, I certify that the student or guest investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accord with the approved protocol. In addition,

- I agree to meet with the investigator on a regular basis to monitor study progress.
- Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in solving them.
- I assure that the investigator will report serious or unexpected adverse events as well as protocol violations or other incidents related to the protocol to the IRB in writing within 10 working days.
- If I will be unavailable, for example, if I am on sabbatical leave or vacation, I will arrange for an alternate faculty sponsor to assume responsibility during my absence, and I will advise the IRB by letter of such arrangements.

Agree

#### Study Closure

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

Agree

Click ok

OK Cancel

# Submit the CR (cont'd)

Click “Submit Continuing Review” (or “Send Ready Notification”)

## My Activities



Send Notification to FS for FS Assurances



Submit Continuing Review or Closure



Withdraw



Edit PI Proxy

# Submit the CR

The CR must be submitted from its respective workspace.

IRB Protocols > Text Changes (short title) > 2013 Review for IRB#12-000004

**Project State**  
Pre Submission

**Continuing Review or Closure: 2013 Review for IRB#12-000004**

**Continuing Review or Closure ID:** IRB#12-000004-CR-00004  
**Study ID:** IRB#12-000004      **Study Name:** Text Changes (short title)

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

**Faculty Sponsor:** A PI5

**SAE since last Continuing Review:**      **Consent requires modification?:**  
**Total enrolled for this site since last progress review:**      **Significant new findings to disclose?:**  
**Any modifications not approved prior to implementation?:**      **Study expiration date:** 4/12/2013

**Initial Submission Date:** 7/13/2012      **Review Type:** Expedited  
**Committee:** Medical IRB 1      **Meeting Date & Time:** - N/A

**PI Proxy:**

**PI Assurances:** Completed  
**FS Assurances:** Completed

**Request to Continue Participants during Approval Lapse:**

**Owner (IRB Staff):** IRB Staff1  
**Parent Study:** State: Approved  
**Review Type:** Expedited

**My Activities**

- Send Notification to FS for FS Assurances
- Submit Continuing Review or Closure**
- Withdraw
- Edit PI Proxy

← CR workspace

**Reminder:**  
The Submit activity is only available to the PI, FS, and PI Proxy.

# Complete the PI Assurances

The activity **PI Assurances** will become available for the PI in the CR workspace **after** submitting the CR.

- The PI (and only the PI) can complete the PI assurances by clicking on the activity in the CR workspace.
- The PI must provide the appropriate PI Assurances.

**Continuing Review Assurances: #1-#3**

**Study Closure Assurance**

**My Activities**

 **PI Assurances**

**PI Assurances**

Please select the applicable assurance(s) for your submission. Select either the assurances for Continuing Review or Study Closure. Then scroll down and click the "OK" button.

**Continuing Review**

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

2.0 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

3.0 agree to comply with all UCLA 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 personnel performing the project are qualified, appropriately trained, and will adhere to the provisions of the approved protocol.
- Implementing no changes in the approved protocol or consent process or documents without prior 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 legally effective informed consent from human subjects or their legally responsible representative, and using only the currently approved consent process and stamped consent 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 10 working days.
- Assure that adequate resources to protection 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.
- Arranging for a co-investigator to assume direct responsibility of the study if at any time I will be unavailable to direct this research personally, for example, when on sabbatical leave or vacation or other absences. Either this person is named as a co-investigator in this application, or I will advise IRB by letter in advance of such arrangements.

Agree

**Study Closure**

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

**Click ok**

# PAR with CR

**SANDBOX** UCLAwebIRB

A PI1 | My Home | Logoff

webIRB Home IRB Protocols

IRB Protocols > Sample Approved Study for webIRB Training - 1

**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 - 1**

**Full Title of Study:** Sample Approved Study for webIRB Training - 1  
**Protocol ID:** IRB#11-000042

**Principal Investigator:** A PI1  
**Faculty Sponsor:**

**Review Type:** Expedited

**Approval Date:** 3/26/2012  
**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:** Amendments | Continuing Review or Closure | Post-Approval Reports & Single Subject Exception | Approved Documents | Comp IRB Re

**Activity**

Amendment Opened  
View Amendment workspace

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

**Letter of Approval:** View

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

If you are submitting a PAR at the time of continuing review:

- Return the Approved Study workspace to create the PAR.
- The PAR and CR must be submitted at the same times

# Updating Your Contact Information and Profile

---

Go to the webIRB Official Website

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

# Login

The screenshot shows the UCLA webIRB website interface. At the top right, there is a 'Login' button. A red box with the text 'Click Login' and a red arrow points to this button. The main content area is titled 'webIRB Home' and contains a welcome message and instructions on how to log in and find help.

**UCLAwebIRB** Login

webIRB Home

webIRB Home

- ▷ Training Information
- ▷ **webIRB Accounts**
- ▷ **Schedule of System Maintenance and Upgrades NEW!**
- ▷ Quick Reference Guides & Training Materials
- ▷ Forms to Upload in webIRB
- ▷ webIRB Frequently Asked Questions (FAQ)
- ▷ Contact Us

### webIRB Home

Welcome to webIRB

To get familiar with webIRB, you may want to read through the [FAQ](#) and [Training & Reference Materials](#).

Click the **Login** button at the top right of the screen to log in and begin using webIRB.

If you are having issues logging in please follow the link to "[Having Trouble Logging Into webIRB?](#)" You may also contact the helpdesk at MIRB -310-825-5344 or GCIRB -310-825-7122 or email us at [webirbhelp@research.ucla.edu](mailto:webirbhelp@research.ucla.edu).

# Login

---

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



The screenshot shows the UCLA Logon interface. At the top left is the UCLA logo, followed by the text "LOGON". Below this is a "Sign In" section with two input fields: "UCLA Logon ID" with a link "(Get a Logon ID)" and "Password" with a link "(Reset your password)". At the bottom of the form is a blue "Sign In >" button and a "Help" link. A red arrow points from the "Sign In" step in the list to the "Sign In >" button. At the bottom of the page, there is a footer with the text "Privacy, Security & Legal | Loaded: Mon, 05 Mar 2012 22:50:21 -0800".

**UCLA** LOGON

**Sign In**

UCLA Logon ID ([Get a Logon ID](#))

Password ([Reset your password](#))

**Sign In >** [Help](#)

[Privacy, Security & Legal](#) | Loaded: Mon, 05 Mar 2012 22:50:21 -0800

# Update Your Contact Information

The screenshot shows the webIRB interface for a user named 'A PI5'. The top navigation bar includes 'webIRB Home', 'IRB Protocols', and user options 'A PI5', 'My Home', and 'Logoff'. A green box highlights the 'A PI5' link 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 with a 'Study Team' link, and a 'Create New Study' button. Below this is a 'webIRB Survey' section and a 'My IRB Studies' section with tabs for 'My Inbox', 'My IRB Studies', 'Archived', and 'Profile'. The 'My IRB Studies' section displays a table of IRB-related studies.

**SANDBOX** UCLAwebIRB

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	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.

**Provide or update your:**

- a. Department
- b. Telephone number
- c. Degree(s)
- d. Title
- e. Email address

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

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

**SANDBOX** UCLAwebIRB

A PI5 | My Home | Logoff

webIRB Home | IRB Protocols

Root > A PI5

**A PI5**

Title: \_\_\_\_\_ E-mail: test@test.com

Division: SOCIOLOGY Business: \_\_\_\_\_

Department: ACADEMIC DEPARTMENTS Mobile: \_\_\_\_\_

Secondary Department: \_\_\_\_\_

*Note for Employees:* The information for your account was obtained from the UCLA Employee Database. Please contact your department administrator if changes are needed for the listed Division or Department. Changes to the c

Properties | Account | Notification Settings

Honorific: -- Select One --

First: A

Middle: \_\_\_\_\_

\* Last: PIS

**Degree(s):** Add

There are no items to display

**Title**

\* E-mail 1: test@test.com

Secondary Department: \_\_\_\_\_

Business: \_\_\_\_\_

Mobile: \_\_\_\_\_

Home: \_\_\_\_\_

Fax: \_\_\_\_\_

Addr 1: \_\_\_\_\_

Addr 2: \_\_\_\_\_

Addr 3: \_\_\_\_\_

City: \_\_\_\_\_

State: -- Sele Zip: \_\_\_\_\_

Country: -- Select One --

\* Required

Apply

# Update Your Profile

Your **Profile** records information that will be central to all of your IRB submissions.

1. Click the **Profile** tab.

2. Click on the link with your name to go to your Profile.

The screenshot shows the 'Sandbox' interface for UCLA webIRB. The top navigation bar includes 'A PI5 | My Home | Logoff'. The main content area is titled 'Page for A PI5' and contains a welcome message and a list of links: 'Inbox' (for studies with tasks) and 'Other Tabs' (for studies and profile). A 'webIRB Survey' section is also present. At the bottom, there are tabs for 'My Inbox', 'My IRB Studies', 'Archived', and 'Profile'. The 'Profile' tab is active, displaying a table with one row: 'A PI5's Profile' with a status of 'Active'.

name	Status
A PI5's Profile	Active

# Update Your Profile (cont'd)

**SANDBOX** UCLAwebIRB

A PI5 | My Home | Logoff

webIRB Home | IRB Protocols

Researcher Profiles > A PI5's Profile

**Current State**

Active

Edit Researcher Profile

Printer Version

**A PI5's Profile**

Department: SOCIOLOGY  
Created: 11/8/2011 1:31 PM  
Last Modified: 11/8/2011 1:31 PM

History Log | Training

No data to display.

3. Click **Edit Researcher Profile.**

# Update Profile (cont'd)

<< Back      Save | Exit | Hide/Show Errors | Print... | Jump To: 1.0 Investigator/Study Personnel      Continue >>

### Investigator/Study Personnel

**1.0**    The Investigator/Study Personnel Profile provides basic information on all study personnel. It is used by the webIRB system to identify you and to populate screens for each new study application.  
**Profile Name:** A P15's Profile

**2.0**    \* **Identify the institutions with which this investigator/study personnel is affiliated.**  
**Check as many as apply:**

- UCLA
- Cedars Sinai Medical Center
- Charles R. Drew University
- Harbor-UCLA Research and Education Institute (REI)
- Olive View - UCLA Medical Center
- Santa Monica-UCLA
- RAND
- VA Greater Los Angeles Healthcare System
- Other

**2.1**    **If Other, specify:**

**3.0**    \* **Conditions of Use of webIRB:**

To meet regulatory requirements, passwords used to access webIRB must not be shared with anyone. All actions taken in webIRB are logged and include the individual performing the action, and the date and time that it occurred. Individuals are accountable for actions initiated under their user account.

Please indicate below that you understand and agree to comply with the conditions of use of webIRB as described above.

I agree

4. Fill out first page and then click **Continue**.

# Update Profile (cont'd)

8. Click **Continue** to go to the next section

The screenshot shows a web browser window with the URL '2.0 Basic Profile Information'. The page title is 'Basic Profile Information'. The form contains several sections:

- 1.0 Name:** A P15
- 2.0 Title:**
- 3.0 Division & Department:** Division: SOCIOLOGY, Department: ACADEMIC DEPARTMENTS, Secondary Department:
- 4.0 Provide a description of your qualification, level of training and expertise related to the conduct of research.**
- 5.0 Clinical Privileges Documentation (if applicable):** Includes an 'Add' button and a table with columns 'Document Name' and 'Version'. Below the table, it says 'There are no items to display'.
- 6.0 Documentation of Human Subjects Protection Training:** Includes an 'Add' button and a table with columns 'Document Name' and 'Version'. Below the table, it says 'There are no items to display'.
  - 6.1 Training Expiration Date:** A date input field.
- 7.0 Documentation of HIPAA Training (if applicable):** Includes an 'Add' button and a table with columns 'Document Name' and 'Version'. Below the table, it says 'There are no items to display'.
  - 7.1 Training Completion Date:** A date input field.

Annotations include a green box around item 6.0 with text '6. Add your CITI training certification in Item 6.0.', a green box around item 7.0 with text '7. If applicable, add your HIPAA training certification in Item 7.0.', and a red box around items 5.0, 6.0, and 7.0 with text '• Capitalized items come from the UCLA Employee Database', '• Items on the profile will be available to the IRB for all of your future applications.', and '• Update these items as needed.'. A green arrow points from the text '8. Click Continue to go to the next section' to the 'Continue >>' button in the top right corner.

# Update Profile (cont'd)

10. Click **Save** and **Exit**

9. If you want specific study personnel to automatically populate your webIRB applications, they can be added on this page.

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

3.0 Default Information for new webIRB Submissions

**1.0 Default Principal Investigator (indicate yourself if you are usually the PI):**  
 Select...

**2.0 Default Contact Person:**  
 Select...

**3.0 Key Personnel:**  
 Add  
Person Organization  
There are no items to display

*If you complete the following items, the information will automatically populate the webIRB smartform whenever you initiate a new application. If, however, it does not apply to a specific study, it can easily be modified within the application.*

# Where to get Help

The screenshot shows the UCLA webIRB website interface. At the top right is a "Login" button. Below the header is a navigation bar with "webIRB Home" and a breadcrumb trail: "webIRB Home > Quick Reference Guides & Training Materials > Investigators & Research Staff". A "Help" button is located in the top right of the main content area. On the left is a sidebar menu with several categories, each with a dropdown arrow. The category "Quick Reference Guides & Training Materials" is circled in red, and its sub-item "Investigators & Research Staff" is also circled in red. The main content area is titled "For Investigators & Research Staff" and contains two sections: "Quick Reference Guides" and "Training Presentations".

**UCLA webIRB** Login

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

▶ Training Information

▶ **webIRB Accounts**

▶ Schedule of System Maintenance and Upgrades

▶ **Quick Reference Guides & Training Materials**

▶ Investigators & Research Staff

▶ IRB Committee Members

▶ Forms to Upload in webIRB

▶ webIRB Frequently Asked Questions (FAQ)

▶ Contact Us

## For Investigators & Research Staff

### 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 FS Assurances for a Continuing Review or Closure **New!**
- Completing FS Assurances for a New Study **New!**
- Completing PI Assurances for a Continuing Review or Closure **New!**
- Completing PI Assurances for a New Study **New!**
- 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 **Updated!**
- Managing your Document in webIRB
- Navigating webIRB
- Submitting Amendments, CRs (including study closures) and PARs
- Updating your webIRB Profile and Contact Information **Updated!**

### Training Presentations

Follow the link to access presentation (i.e., step-by-step instructions) on:

- Introduction to webIRB - Creating a New Study
- Submitting Amendments, Continuing Reviews, and Continuing Reviews with a linked Amendment
- Submitting Post-Approval Reports and Single Subject Exceptions
- Tips for Submitting a CR
- Updating your webIRB Profile and Contact Information
- webIRB Beyond the Basics: How to Start an Amendment & Continuing Review Application

NOTE: UCLA IRB approval notices do not contain an actual signature, as they are created, issued and stored electronically. Please follow the link for an official notification of electronic signature on IRB approval letters.

# Where to get Help (cont'd)



**UCLAwebIRB** Login

webIRB Home webIRB Home > Contact Us

- ▷ Training Information
- ▷ **webIRB Accounts**
- ▷ Schedule of System Maintenance and Upgrades
- ▷ Quick Reference Guides & Training Materials
- ▷ Forms to Upload in webIRB
- ▷ webIRB Frequently Asked Questions (FAQ)
- ▷ **Contact Us**

## Contact Us

### The webIRB Helpdesk

Hours: 8:00AM - 5:00PM weekdays  
Phone:

M-IRB	310-825-5344
GC-IRB	310-825-7122

Email: [webIRBHelp@research.ucla.edu](mailto:webIRBHelp@research.ucla.edu)

### The OHRPP Office

Office of the Human Research Protection Program (OHRPP)  
11000 Kinross Avenue, Suite 102  
Box 951694  
Los Angeles, CA 90095-1694  
Campus Mail Code: 169407

Website: <http://ohrpp.research.ucla.edu/>



Questions?