Short Course for PIs with Study Teams

How to Review and Submit a New webIRB Study Application
What you will learn

1. How to Review & Submit a New Study (p.14)
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Links to webIRB

1. webIRB website
   - http://webirb.research.ucla.edu

2. Training Website (Sandbox)
   - https://webirbsandbox.research.ucla.edu/sandbox
How to Review & Submit a New Study

1. Go to the webIRB Sandbox at: https://webirmbsandbox.research.ucla.edu/sandbox
   - Important Note: The Sandbox is for practice only. Do not use it for studies that you plan to submit to the IRB. Studies in the Sandbox cannot be processed by the IRB.

2. Look on your desk for a card with sandbox accounts
   - Use the PI User Name and password assigned to your desk.
When do I start a New Study Application?

1. For submissions of new studies to the IRB
2. To convert paper studies at the time of Continuing Review

Important Note: The IRB will only accept webIRB applications for new studies and CR after 9/30/10
Email Notification that Study is Ready

Your study staff will send notification that the study is ready for review.

When that occurs, you can click on the link in the email to go to the study workspace.
Login to webIRB

1. Click **Login**
Login to webIRB

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

*Note:* You will use your UCLA Login ID and password on the official site.
My Home

1. Navigation Bar
   (My Home - find your way home)

2. Breadcrumb
   (Find your way through the study workspaces)

3. My Inbox
   contains links to studies/actions that need your attention.
   1. **NS** = New Study
   2. **PAR** = Post Approval Reports
   3. **AM** = Amendment
   4. **CR** = Continuing Review

4. My IRB Studies
   All open studies

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Click the link to the study in Pre Submission
Study Workspace

1. Summary Information about the Study
2. Current State
3. Views of the Study
4. Study Activities
5. Information Tabs
Views of the Study

1. Click **Printer Version** to open a read-only copy of the study that you can scroll through.

2. Click **Edit Study** to open a copy of the study that you can modify.
Navigating the Smartform

**WARNING**
1. If you make changes, click *Save* (before you walk away from your desk or if you are on a screen for more than 15 minutes)

2. Use *Continue* to navigate forward through the form
Navigating the Smartform

1. Use the **Jump to** Menu to go to application sections
   - **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

2. **Exit** will take you to the study workspace. Click it.
My Activities
My Activities

Available activities differ by the current state and by the role of the person.
My Activities: Send Notification to FS

If you have a Faculty Sponsor for the study, his/her assurances are needed **before** the study can be submitted. **Click** here to send a message to the FS.
My Activities: Submit Study

Click **Submit Study** when the application is complete.
My Activities: Submit Study

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

2. If there are still items to complete, you will get an **Error/Warning Message**. You would use the blue link to go to the page with the needed item(s). Instead click **Close**.
My Activities: PI Assurances

**IMPORTANT:**

*After* the study is submitted, the **PI Assurances** become available. The PI must complete them **before** the study can be approved.

The study team can check to see if the assurances are completed on the summary screen.
My Activities: Withdraw

Use carefully: Click Withdraw if you are no longer planning on conducting the study.
My Activities: Edit PI Proxy

Click **Edit PI Proxy** if you need to appoint a person on the study to submit it for you.

*Note*: the PI still needs to complete the PI Assurances
My Activities: Copy Study

Click **Copy Study** if you want to copy a study as a starting point for a different study.
Feedback from the IRB

The PI, Contact Person and PI Proxies will receive an automatic email notification when the IRB sends correspondence. You will be able to click on the link to go to the study workspace.

**Note:** When the IRB first sends out feedback on a study the link will briefly disappear from your workspace while it is being copied.
Responding to IRB Feedback

1. Go to My Home

2. Click on the Study in your Inbox titled “Test Study for PI/Study Staff Training”
Where to find IRB Feedback

1. Click on the **IRB Requests** tab. A list of requested changes will appear.

2. **Note**: If there is formal correspondence, it will be listed under the **History** and **Correspondence** tabs.
Responding to IRB Feedback

2. Click on the **Section Name** next to **Jump To**. This will take you to the smartform page.

**Note:** There is a quirk in the webIRB program that displays the IRB staff names under “Reviewer.” The staff are actually the “Minutes Recorders” and “Contact People,” not the reviewers.
Responding to Feedback (cont.)

1. Once on the page, click the arrow next to **Reviewer Notes**. The note will appear.

2. Make all of the needed changes on the page.

3. When the changes are complete, click **Click here to respond**.

4. A dialogue box will open.
   a. Use the pull down menu to indicate how you are responding
   b. Write a response to the IRB in the Text box.
   c. Click **OK**
Responding to Feedback (Cont.)

1. When all of the responses are complete, the color of the notes will change from red to green.

2. To return to the Study Workspace, Click Save, then Exit.
Need More Time to Respond?

1. Responses to the IRB are due within 30 days of the date of the feedback letter. You can request additional time by clicking the **Request Extension to Respond** Activity.

2. Complete and submit the activity form. Be sure to indicate how much more time you will need to respond.
Responding to Feedback (Cont.)

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

(Note: another activity box will appear for you to complete. You will have a place to record any additional comments.)
Approved Study Workspace

The buttons to create PARs, Amendments and CR will be in the lower left corner.
Updating Your Profile

Go to the webIRB website

- http://webirb.research.ucla.edu
Logging In

Getting Started:
1. Click Login
1. Enter your **UCLA Logon ID** and Password
2. Click **Login**
Update Contact Information

1. Click your name
Update Contact Information

2. Check to make sure that the information in the text boxes is current.

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

4. Click **My Home**
Update Profile

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

1. **Click** the **Profile** tab

2. **Click** the link to your Profile
Update Profile

3. Click Edit Researcher Profile
Update Profile

4. Click Continue
Update Profile

5. Items that are in **blue** come from the UCLA Employee Database

6. Items on the profile will be available to the IRB for all of your future applications. So you only need to update them as needed.

You can complete the rest of the items, as applicable, on your own.

7. Click Continue
Update Profile

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

9. Click Exit.
Where to get Help

Click webIRB Home

UCLA webIRB

Contact Us

The webIRB Helpdesk
Hours: 8:30AM - 4:30PM weekdays
Phone: (310) 267-1887
Email: webIRBHelp@research.ucla.edu

The OHRPP Office
Office of the Human Research Protection Program (OHRPP)
11000 Wilshire Avenue, Suite 102
Los Angeles, CA 90095-1694
Campus Mail Code: 169407
Website: http://ohrpp.research.ucla.edu/
Questions?