Introduction to webIRB

Training Course for Investigators and Study Staff
You will learn to…

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
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)”
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
How to Create a New Study: Login

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

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

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

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

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

- **Archived** - contains studies that have been withdrawn, closed, and don’t require UCLA IRB review.
My Home (cont’d)

Click to create a New Study
Navigating the Smartform

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

- 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.
Navigating the Smartform (cont’d)

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

Use **Continue** to navigate forward through the form.
Study Workspace

Current State

Views of the Study

Study Activities

Information Tabs

Summary information about the Study

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
Faculty Advisor: Study Contact Person:
Study Staff1
PI Proxy: Rebecca Simms (PI)
PI Assurances: Pending...
FS Assurances: Not Required

History Attachments IRB Requests Training Log Change Log
A Note About the Protocol ID

• **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

## Common “Current State” for All Project Types

<table>
<thead>
<tr>
<th>Current State</th>
<th>What the “Current State” Means</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Submission</td>
<td>Project has not been submitted.</td>
</tr>
<tr>
<td>In-Review</td>
<td>Project or response has been submitted. The IRB is reviewing the project or response.</td>
</tr>
<tr>
<td>• Pre-Review Change Requested</td>
<td>Additional information is required to review and approve the project.</td>
</tr>
<tr>
<td>• Deferred - Changes Required by IRB</td>
<td></td>
</tr>
<tr>
<td>• Accepted Pending Modifications</td>
<td>The project will be reviewed at the next Full Board meeting.</td>
</tr>
<tr>
<td>Assigned to IRB Meeting</td>
<td></td>
</tr>
</tbody>
</table>
Common Project States (cont’d)

<table>
<thead>
<tr>
<th>Common “Current State” for All Project Types (cont’d)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Current State</strong></td>
</tr>
<tr>
<td>Withdrown</td>
</tr>
<tr>
<td>• Approved</td>
</tr>
<tr>
<td>• Certified Exempt</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Common “Current State” for Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Expired</strong></td>
</tr>
<tr>
<td><strong>Expired – Continuation in Progress</strong></td>
</tr>
<tr>
<td><strong>Closed</strong></td>
</tr>
</tbody>
</table>
### Common Project States (cont’d)

<table>
<thead>
<tr>
<th>Current State</th>
<th>What the “Current State” Means</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed – Amendment Required</td>
<td>An Amendment is required. Link the PAR to an existing Amendment.</td>
</tr>
<tr>
<td>Completed</td>
<td>The PAR is complete.</td>
</tr>
</tbody>
</table>
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.
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.
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.

**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: 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).

This is a required field; therefore, you must provide a value.
• **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.

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

- 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: Edit PI Proxy

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

Click **Edit Study** to go back to the Smartform
Checking Your Progress

1. Click **Hide/Show Errors**

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).

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

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”
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.
Notes about Inquiry or reply to MRSC (cont’d)

• When the MRSC sends an 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)

**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:

a. Use the pull down menu to indicate how you are responding.

b. 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.

c. Click **OK**

Your response will appear in a green text box.
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.
Responding to IRB Requests (cont’d)

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

Click **Hide/Show Errors** to view any incomplete Sections
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.
Responding to IRB Requests (cont’d)

**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.
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).
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
Post-Approval Activities

Click on **My Home**

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

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

Project State should be “Approved”.
Approved Study Workspace

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

- **PAR Workspace**

- **CR workspace** – At continuing review, the FS and PI Assurances must be completed in the CR workspace.

- **Amendment Workspace**
Where are the documents stored?

- **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)

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)

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

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’)

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

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

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

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

<table>
<thead>
<tr>
<th>Check all that apply:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in study design of a protocol approved by the full board of the IRB</td>
</tr>
<tr>
<td>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.)</td>
</tr>
<tr>
<td>Addition of a new procedure not approvable using expedited review procedures (e.g., ionizing radiation)</td>
</tr>
<tr>
<td>Changes that increase risk or discomfort to study participants</td>
</tr>
<tr>
<td>Substantive changes to a consent form or other study documents distributed to subjects.</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>None of the above</td>
</tr>
</tbody>
</table>

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

If you selected "other" to any of the items above, list the type of change.
Describe the Amendment (cont’)

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 - 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 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
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”.

Click **Save** when you complete this section.
Click **Continue** to go to the next section.
Description Amendment (cont’)

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

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

- 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.

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

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

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.
Approved Amendment Workspace

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)

• In the approved study workspace click on **Continuing Review or Closure** (CR).

• The CR Smartform will appear.
Complete the CR Application

• 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)

- 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

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

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

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

**Continuing Review** Assurances.

**Study Closure** Assurances.

Click **ok**
Submit the CR (cont’d)

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

The CR must be submitted from its respective 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

Click **ok**
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

UCLA webIRB

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 GCIRE -310-825-7122 or email us at webirbhelp@research.ucla.edu.
1. Enter your UCLA Logon ID and Password
2. Click **Sign In**
Update Your Contact Information

1. Click on your name.
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

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

4. Click **My Home** to return to your homepage.
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.
Update Your Profile (cont’d)

3. Click **Edit Researcher Profile**.
Update Profile (cont’d)

4. Fill out first page and then click Continue.
Update Profile (cont’d)

6. Add your CITI training certification in Item 6.0.
7. If applicable, add your HIPAA training certification in Item 7.0.

- Capitalized items come from the UCLA Employee Database
- Items on the profile will be available to the IRB for all of your future applications.
- Update these items as needed.

8. Click **Continue** to go to the next section
9. If you want specific study personnel to automatically populate your webIRB applications, they can be added on this page.

10. Click Save and Exit
Where to get Help

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 5.2 (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 Updated!
- 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)

Contact Us

The webIRB Heldesk

Hours: 8:00AM - 5:00PM weekdays
Phone:
M:IRB 310-825-5344
GC-IRB 310-825-7122

Email: 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?