Introduction to webIRB

Training Course for Investigators and Study Staff

You will learn to...

Navigate webIRB by:
1. Creating a New Study application
2. Responding to IRB Requests
3. Creating Post-Approval webIRB Applications (Amendments, Continuing Reviews)
4. Updating your Contact Information, webIRB Profile, and accessing the OHRPP website

You will NOT learn...

IRB review process overview

Please contact OHRPP for general IRB inquiries and/or specific questions regarding your submission at:

North & South General Institutional Review Boards (GIRB)
Telephone: (310) 825-7122
Email: griib@research.ucla.edu

The Medical Institutional Review Boards 1, 2, & 3 (MRB)
Telephone: (310) 825-5344
Email: mirb@research.ucla.edu

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)"

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 or reviewed by the IRB.

1. How to Create a New Study: Login

Enter the Training Account User Name (located on the sheet in front of you) and Password (1234) and click Login.

Note: For users accessing the Sandbox outside of the training session, please use one of the following account: Sandbox Accounts

My Home

My Home (cont'd)

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 the grey text box.
• Make up a study for training purposes.
• Enter your Training Account User Name in Item 3.1.
Tips for Completing the first page

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

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

Navigating the Smartform (cont'd)

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

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

Navigating the Smartform (cont'd)

Use Exit to go to the Study workspace.

The Jump To Menu can be used to go to specific sections of the application.
- Red Text = you are here
- Black Text = sections that will be required
- Note: Sections may appear as you answer items in the form

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

Study Workspace

Common Project States

A Note About the Protocol ID

- Before submission, studies get a PRE#. For example, PRE#19-000010
- After submission, studies get an IRB#. For example, IRB#19-000325

Note: The PRE# and the IRB# will not match
Common Project States (cont'd)

<table>
<thead>
<tr>
<th>Current State</th>
<th>What the &quot;Current State&quot; Means</th>
</tr>
</thead>
<tbody>
<tr>
<td>Withdrawn</td>
<td>The project is no longer in review.</td>
</tr>
<tr>
<td>Approved</td>
<td>Research procedures may begin/continue.</td>
</tr>
<tr>
<td>Approved – No CR Required</td>
<td></td>
</tr>
<tr>
<td>Certified Exempt</td>
<td></td>
</tr>
</tbody>
</table>

Common "Current State" for Studies

<table>
<thead>
<tr>
<th>Current State</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expired</td>
<td>The Study has expired. Create and submit a Continuing Review (CR) application.</td>
</tr>
<tr>
<td>Expired – Continuation in Progress</td>
<td>The Study has expired, but a CR application has been created.</td>
</tr>
<tr>
<td>Closed</td>
<td>The Study is closed, all human subjects research activities should cease.</td>
</tr>
</tbody>
</table>

My Activities

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

Do Not Click "Reply" on webIRB Emails

- Many activities generate an email notification.
- Use the link in the email to go to 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 an email notification to your FS.
- 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 only available to the PI, PI Proxies, and FS.
- Send Ready Notification is available to all personnel listed in section 1.1.
- An email will be sent to the PI, PI Proxies, and FS that contains a link to the study workspace.

My Activities: Submit Study or Send Ready Notification

- If the application is complete, you will get a Submit Study screen.
- Click OK to submit.
- If there are still items to complete, you will get an Error/Warning Message.
- Use the blue link to jump to the Section with the incomplete item(s).
My Activities: PI Assurances

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

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

My Activities: Training Log

- Click the Training Log tab to see the current status of your study team member's CITI training (listed in section 1.1 only).

My Activities: Withdraw

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

My Activities: Edit PI Proxy

- Only the PI can add a PI Proxy using the activity Edit PI Proxy. A study team member must be listed as the Study Contact Person or Key Personnel in order to be added as a PI Proxy.

My Activities: Log Private Comment

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

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 completion 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.

2. Responding to IRB Requests

Click on the Study in your inbox titled "Test Study for webIRB Training - Basic..."

Notes About IRB Requests

IRB Requests can be either:
- Pre-review changes
- Official letters after review

IRB Requests are located:
- Under the History Tab
- Under the IRB Requests Tab

Or Within SmartForms:
- For the Study use "Exit Study"
- For the Amendment summary page use "Exit Amendment"
- For the Modified Study use "Exit Modified Study"

Notes About IRB Requests (cont'd)

- The PI, PI Proxies, FS, and Contact Person will receive an email notification when the IRB:
  - issues 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.

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/continuation 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.
Responding to IRB Requests (cont’d)

- When responding to an IRB request for a Study, click "Edit Study" or for an AR, click "Edit Modified Study".
- Section 1.1 of the Study SmartForm will appear.
- To view the IRB requests in Section 1.1, click the arrow to the left of the section title.
- 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 drop-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.
- If there is more than one request, click Next to complete the 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.

When all of the requested changes have been completed, your responses 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.
3. 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

Approved Study Workspace

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

Click on the link to "Sample Approved Study for webIRB Training - 10". The status should be "Approved".

Click on the My IRB Studies tab.

Click on My Home.

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

Send Inquiry or Reply to IRB activity to communicate with IRB staff.

An email notification will be sent to the Owner (IRB Staff).
Workspaces: PAR, CR, and AM
Each type of application has its own workspace after it is created.
- PAR Workspace
- CR workspace: For continuing review, the FS and PI: Ancillaries must be persisted to the CR workspace.
- Amendment Workspace

Where Are the Documents Stored?
- Click on the Approved Documents tab to see all currently approved documents.

Where Are the Documents Stored? (cont’d)
- Links to documents that have been approved with an IRB stamp with an approval and expiration date (if applicable).
- Important Note: Do not add footers to documents that will be stamped by the IRB

Create an Amendment
- Only one amendment 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 on Summary Page
- Complete the Description of Amendment section.
  - 1.0: Provide a short title. The title will appear on the approval notice.
  - 2.0: Indicate whether or not there is a change in study staff and/or key personnel. New study staff personnel will have access to the study after the AM is approved.
Update 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 set 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_102819", "child assent_clean_102819").
- 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 need to upload a revised document please use the "Upload Revision" feature. The document version number will change automatically.

Updating the Currently Approved Protocol

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

Submit the Amendment

- Remember to click Submit Amendment.
- The Withdraw button can be used to withdraw the amendment application. Please note that an amendment cannot be reactivated and you can only withdraw applications in webIDX before they have been approved.

Approved Amendment Workspace

- Unique features:
  1. View final action and AM approval notice (includes approved documents)
  2. Contains snapshot of AM (cover letter) and Modified Study application

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

Submit the CR

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

Faculty Sponsor Assurances

The Faculty Sponsor must provide the appropriate FS Assurances for either Continuing Review or Closure (both cannot be selected at the same time) in the CR workspace.

Submit the CR (cont'd)

- Click 'Submit Continuing Review or Closure' (or 'Send Ready Notification')

- When you reach Section 4.0 - Continuing Review or Closure Report click Finish to go to the CR workspace.
Submit the CR (cont'd)

The CR must be submitted from its respective workspace.

Remind: 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 OR Closure).

Continuing Review Assurances: 1.0-3.3

Study Closure Assurance

Click OK

Updating Your Contact Information and Profile

Go to the official webIRB website:
https://webirb.research.ucla.edu

UCLAwebIRB

Login

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

Update Your Contact Information

1. Click on your name.
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 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!) New!
- Completing FS Assurances for a New Study (New!) New!
- Completing PI Assurances for a Continuing Review or Closure (New!) New!
- Completing PI Assurances for a New Study (New!) 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!) Updated!
- Managing your Document in webIRB
- Navigating webIRB
- Submitting Amendments, CRs (including study closures) and PARs
- Updating your webIRB Profile and Contact Information (Updated!) 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 Helpdesk**
- Hours: 8:00AM - 5:00PM weekdays
- Phone:
  - General Campus IRB: 310-825-7122
  - Medical IRB: 310-825-5344
- Email: webIRBHelp@research.ucla.edu

**The OHRPP Office**
- Office of the Human Research Protection Program (OHRPP)
  - 10899 Wilshire Blvd, Suite 830
  - Los Angeles, CA 90095-1406
- Website: http://ora.research.ucla.edu/ohrpp