Creating a New Study Application

Training Course for Investigators and Study Staff
This training will cover…

- Navigating the OHRPP website
- Requesting a webIRB account
- Creating a New Study application
- Responding to IRB Requests
- Additional resources
This training will NOT cover…

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

Visit the OHRPP website for the following resources:

- Guidance and policy
- Forms and templates
- Decision trees
- More information about the UCLA IRBs
To access this information:

Click here to access guidance and templates
Learn about the acceptable informed consent and recruitment methods, and how to incorporate required information into recruit material.
Before you can submit your project, all persons listed in the study application (Section 1.1) who will engage in human subjects research must complete either the Human Subjects Research Training OR the Good Clinical Practice (GCP) training. Both trainings are valid for three years.

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

Visit the OHRPP CITI training help page to determine the appropriate training required: https://ohrpp.research.ucla.edu/citi-training/
How to request a webIRB account

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

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

• Your full name
• Your email address
• Your UCLA Logon ID
• Your 9-digit UID
• Your department/division
Once you are ready to set up your webIRB account and create a New Study application visit: https://webirb.research.ucla.edu

Select “LOGIN” to access your webIRB account
Login

1. Enter your UCLA Logon ID and password
2. Click **Sign In**
"My Home" Page

**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** Archived:** contains studies that have been withdrawn, closed, and don’t require UCLA IRB review.
Create a “New Study” application

Click to create a New Study

The account you logged into will appear here.

<table>
<thead>
<tr>
<th>ID</th>
<th>Name</th>
<th>State</th>
<th>Last State Change</th>
<th>PI</th>
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</thead>
<tbody>
<tr>
<td>IRB#12-000006</td>
<td>Sample Approved Study for webIRB Training - 1 - DO NOT TOUCH</td>
<td>Pre Submission</td>
<td>7/19/2012 7:34 AM</td>
<td>PI1</td>
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<td>Pre Submission</td>
<td>7/19/2012 2:05 PM</td>
<td>PI1</td>
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<tr>
<td>IRB#12-000004-AM-00005</td>
<td>Amendment #5 for webIRB Study IRB#12-000004</td>
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<tr>
<td>IRB#12-000000-PAR-00000001</td>
<td>test</td>
<td>Pre Submission</td>
<td>5/1/2012 1:47 PM</td>
<td>PI1</td>
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</table>
“General Information” Page

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

Provide a response to each question.

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

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

Insert the descriptive title. Avoid using generic titles like, “My Thesis” or “New Study”.
Tip: Save your work!

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

Before moving to the next page or logging off, select **Save**. After clicking “Save” more activities will appear at the top of the page.
Tip: Save your work!

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

Important Note:

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

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

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

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

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

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

1. Click **Hide/Show Errors**

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

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

Click **Edit Study** to go back to the Smartform.

If you need to logoff, save your work, first. Upon returning, you can continue working where you left off by selecting “Edit Study” on your dashboard.
Study Workspace

Current State

Views of the Study

Study Activities

Summary information about the Study

Information Tabs

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:

PI Proxy: Rebecca Simms (PI)

PI Assurances: Pending...

FS Assurances: Not Required

History | Attachments | IRB Requests | Training Log | Change Log
Current State of the Application

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

**Note:** Your study application may remain in the same current state for several days or weeks depending on various factors including your response time, the volume of submissions or the type of review (exempt, expedited or full board).
As your study application undergoes the IRB review process, the IRB might ask for additional clarification or information prior to moving your application along to the next phase of the review process. To avoid delays, please respond to any requests for clarification or additional information within a timely manner.

**IRB final review determinations can be:**
- Approved
- Approved-No CR
- Certified Exempt
- External Review Accepted
- Disapproved
Note: IRB#

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

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

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

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
Available activities differ by the current state of the protocol and role of the person.
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.
Carefully read all assurances before selecting “OK”.

My Activities: PI Assurances
Once your application has been submitted, the current state of the application will change to “Pre-Review”. At this time, if the IRB analyst assigned to your project determines that you are missing documents or information or requests clarification, then the status will change to “Pre-Review Changes Requested”.
If OHRPP staff request modifications or additional information, the current state of the study will change.
During the review process, the current state of your application will change. If your application is in any of the states at the top, it means the IRB has your application. If your application is any of the bottom states, it means action is required on your part to move your application along.
IRB Correspondence

• The PI, PI Proxies, FS, and Contact Person will receive an email notification when the IRB:
  ❖ requests pre-review changes
  ❖ issues a letter (i.e., IRB Determination)

• Use the link in the email to go to the project workspace and respond to the IRB requests.

• **Do Not Reply to the email.**

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

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

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

Click on “Next” to view the next section with an IRB request.
Responding to IRB Requests (cont’d)

**DO NOT** select “Click here to respond...” yet, instead:

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

When the dialogue box opens:

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.

When 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

Please revise the consent form to remove the footer. Attach both a marked and clean copy of the revised consent form.

**Change Request Completed - A PI3 - 3/5/2012 4:23 PM**
done
Responding to IRB Requests (cont’d)

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

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

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

**PI, PI Proxy, and FS:**
Click **Submit Response** to submit the revised application to the IRB for review.

**Study Staff:**
Use the **Send Ready Notification** to let the PI know that the response is ready to be submitted.
Once all requested changes are made, the current state of your application may return to, “**In Review**” on your end. However, during this current state, your study has been assigned to a designated reviewer. If the designated reviewer or the IRB have any changes they would like you to make, the current status will change to “**Accepted Pending Modifications**”. 
If the current state changes to “Accepted Pending Modifications”, it means the designated reviewer requests changes to your application.
If your study requires review by the full board, the current state will change to “Assigned to IRB Meeting”. After the IRB reviews your project, they will issue a review determination.
If the IRB does not approve your project after their initial review, it means they need more information for which the current state of your study will reflect either “Deferred” or “Accepted Pending Modifications (APM)”. If the IRB defers your study, it means that the IRB lacked sufficient information to make a review determination. Therefore, the IRB will have to obtain additional information from you then the IRB will re-review your study at the next IRB meeting. You will receive an email if any additional action is requested.
If the IRB determines your study is "**Accepted Pending Modifications (APM)**", then you will be required to submit the changes requested in order to receive approval of your study. Upon submitting the changes, the IRB Chair will review and confirm these changes.
Once the designated reviewer or IRB Chair confirms that all the requested changes have been made, a final review determination will be issued.

IRB review determinations can be:
- Approved
- Approved-No CR
- Certified Exempt
- External Review Accepted
- Disapproved
Note: IRB Determinations

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

- **Certified Exempt:** *Exempt* studies that are minimal risk and do not require review by the IRB. No Continuing Review (CR) required but annual assurance is required.

- **Approved-No CR:** Most *Expedited* studies that are minimal risk that meet certain criteria will receive approval that does not expire, no Continuing Review. Annual assurance is required.

- **Approved:** Some *Expedited* studies and studies requiring *Full Board* review which are greater than minimal risk and will have an expiration date of no greater than one year. About 2 months before expiration of IRB approval, you will need to submit a CR application.
Note: IRB Determinations

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

Please review OHRPP guidance on the results of IRB review for more information about IRB determinations.
Approved Study Workspace

Unique features:

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

Click on **My Home**

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

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

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

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

1. Click on your name.
Update Your Contact Information (cont’d)

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

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

4. Click **My Home** to return to your homepage.
My Activities: Withdraw

- **Use carefully:** Use the **Withdraw** activity if you are no longer planning to conduct the study.
- The study will be archived.
- This activity is available to everyone.
- A withdrawn Study can be reactivated using the **Reactivate** activity. The Reactivate activity is only available to the PI, PI Proxies, and FS.
Only the PI can add a PI Proxy using the activity **Edit PI Proxy**. A study team member must be listed as the Study Contact Person or Key Personnel in order to be added as a PI Proxy. To use this feature, the person on must be currently listed on the study in Section 1.1.
My Activities: Log Private Comment

• To communicate within the Study workspace use the activity **Study Team – Log Private Comment**.

• A pop-up screen will appear. Select the study team members who should receive an email notification about the comment. The email will contain a link to the study workspace.

• The comment will be visible to all study team members in the History tab and this activity is only available to study team members.
Key Take-Aways

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

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

For technical assistance with webIRB only:

Contact the webIRB Help Desk

Email: webIRBhelp@research.ucla.edu
Resources

For general inquiries about the IRB process:

Contact the appropriate IRB:

**North & South General IRBs (GIRBs)**
Email: gcirb@research.ucla.edu

**Medical IRBs (MIRBs)**
Email: mirb@research.ucla.edu
Resources

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

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

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

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

The HRN includes updates to OHRPP guidance and policy, Learn-at-Lunch trainings on important research topics and offers other resources and important updates. Please visit the ORA Mailing Lists page to subscribe.
Your feedback matters

Help us improve our presentation by completing OHRPP’s brief and anonymous SURVEY