

Submitting Amendments and Continuing Reviews in webIRB

Creating Amendments & Continuing Reviews in webIRB

- After approval of a study in webIRB Amendments (AMs) and Continuing Reviews (CRs) are submitted through webIRB.
- AMs and CRs are created in the approved study workspace using:



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
- Copy Study
- 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=09-000016

Principal Investigator: A PI1
Faculty Sponsor:

Study Contact Person: Study Staff75
Initial Submission Date: 12/26/2009
Committee: Medical IRB 2

Review Type: Full IRB Review
Approval Date: 1/4/2011
Expiration Date: 1/4/2012
Letter of Approval: [\[View\]](#)

PI Proxy:

PI Assurances: Completed
FS Assurances: Not Required

Request to Continue Participants during Approval Lapse:

History	Amendments	Continuing Reviews	Post-Approval Reports & Single Subject Exception	Approved Documents	Completed IRB Requests	Conditions and Determinations	Correspondence	Training Log	Change Log
Activity							Author		
Project Snapshot Generated							Michelle Leonard		
<input type="checkbox"/> View Project Snapshot									
<input type="checkbox"/> Amendment Completed - Approved							Michelle Leonard		
<input type="checkbox"/> Continuing Review Deadline Reminder							System Administrator		
<input type="checkbox"/> Amendment Opened							A PI1		

Amendments in webIRB

How many AMs can I submit at the same time?

- Only one amendment can be created at a time.
- 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.

Steps for preparing an AM application

- **Step 1:** Start the AM application by clicking  in the approved study workspace of the study you are modifying.
- **Step 2:** Describe the amendment (i.e., proposed changes to the study application).
- **Step 3:** Revise the study application and study documents, if applicable.
- **Step 4:** Submit the Amendment.

Step 1: Create an AM

- In the approved study workspace click on:



- The **Description of Amendment** section will appear.

Current State
 Approved

Study: Sample Approved Study for webIRB Training (1)

Full Title of Study: Sample Approved Study for webIRB Training (1)
 Protocol ID: IRB#09-000016

Principal Investigator: A PI
 Faculty Sponsor: Study Contact Person: Study Staff75

Review Type: Full IRB Review
 Approval Date: 1/4/2011
 Expiration Date: 1/4/2012
 Initial Submission Date: 12/26/2009
 Committee: Medical IRB 2
 Letter of Approval: [View]

My Activities

- Send Notification to FS for FS Assurance
- PI Assurances
- Send Training Reminder
- edit PI Proxy
- Copy Study
- Send Inquiry or Reply to IRB
- PI Suspend
- Study Team - Log Comment
- New Post-Approval Report or Single Subject Exception**
- New Amendment**
- New Continuing Review

PI Proxy

PI Assurances: Completed
 FS Assurances: Not Required

Request to Continue Participants during Approval Lapse:

History	Amendments	Continuing Reviews	Post-Approval Reports & Single Subject Exception	Approved Documents	Completed IRB Requests	Conditions and Determinations	Correspondence	Training Log	Change Log
Activity								Author:	
Project Snapshot Generated								Michelle Leonard	
View Project Snapshot								Michelle Leonard	
Amendment Completed - Approved								System Administrator	
Continuing Review Uealdine Reminder								A PI	
Amendment Opened									

Note: there is 1 open Amendment for this study.

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

Description of Amendment

1.0 * **Short Title:**
 Amendment #8 for webIRB Study IRB#11-000045

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**

Step 2: Describe the Amendment

Complete the **Description of Amendment** section:

Note: there is 1

Warning: Save your work at least e

Description of Amendment

1.0 * Short Title:
 Amendment #8 for webIRB Study IRB#11-000045

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 ro
 [Empty text area]

4.0 * Minor Amendment - Types of change(s) proposed.
Check all that apply:

- **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.

Step 2: Describe the amendment (cont'd)

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).

Step 2: Describe the amendment (cont'd)

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

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

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.

7.0- 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 to describe the changes that apply to the study.
- Do not attach new or modified study documents.

Step 2: Describe the amendment (cont'd)

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://ora.research.ucla.edu/OHRPP/Pages/ConsentTemplates.aspx#addendum>

Step 2: Describe the amendment (cont'd)

9.0

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

Yes No

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 “Continue” to go to the next section.

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 application smartform, click “Finish” to return to the amendment workspace. Then click “Submit Amendment” under “My Activities” to submit the amendment to the IRB.

Finish

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

Step 3: Modify the study application

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

Reviewer Notes (0 Notes Total)

Warning: Save your work at least every 15 minutes

General Information
 All items marked with a red asterisk (*) are required. Items without an asterisk may or may not be required depending on the study.

1.0 *Full Title of the Submission:
 Sample Approved Study for webIRB Training (1)

1.1 Protocol Version Date and/or Number:

2.0 *Working or Lay Title:
 Sample Approved Study for webIRB Training (1)

3.0 Principal Investigator:

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
 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
 9.2a - Privacy
 9.3 - Data Security
 9.4 - Data Security Plan

- Review all sections of the study application. Use **Jump To** or **Continue** to navigate through the sections.
- Modify all relevant sections of the study application.
- Click **Save** after revising each section.
- DO NOT modify the response in the CRC sections. Studies converted to webIRB at the time of continuing review contain the CRC sections.

Step 3: Modify the study application (cont'd)

2.0

Upload copies of the advertisements/flyers/information sheets/internet postings below. If you will be using announcements on the radio, TV, etc. provide a copy of the script, or a video or audio clip.

Add		Delete	
Document Name			
<input type="checkbox"/>	[Edit]	print ad.Prob.6.30.09.doc	
<input type="checkbox"/>	[Edit]	OCRC Radio script.6.30.09.doc	
<input type="checkbox"/>	[Edit]	Opioid Radio script.7.29.09.doc	

Revised Documents:

- Use **Edit** to replace previous versions of documents with the updated versions.
- Use **Add** to upload new documents in the application.
- 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”).
- To remove documents, click on the checkbox of the document you want to remove. Then click on **Delete**.

Step 3: Modify the study application (cont'd)

Example: The PI is adding a youth assent and revising the HIV consent form in section 20.3.

Modify the consent form and save the marked and clean copy on your desktop. Name them “HIV Consent Form-marked 081211” and “HIV Consent Form- clean 081211”.

Section 20.3 before uploading the youth assent and revised consent forms.

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.

Document Name	Document Version #
<input type="checkbox"/> [Edit] HIV Consent Form - marked.docx	0.01
<input type="checkbox"/> [Edit] HIVconsent.6.30.09.doc	0.01

Use **Add** to upload the youth assent.

Use **Edit** to upload the updated marked and clean version of the consent form.

Step 3: Modify the study application (cont'd)

Section 20.3 before uploading the youth assent and revised consent form.

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.**

Document Name	Document Version #
<input type="checkbox"/> [Edit] HIV Consent Form - marked.docx	0.01
<input type="checkbox"/> [Edit] HIVconsent.6.30.09.doc	0.01

Section 20.3 after uploading the new youth assent and revised consent form.

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.**

Document Name	Document Version #
<input type="checkbox"/> [Edit] HIV Consent Form - marked 081211.docx	0.02
<input type="checkbox"/> [Edit] HIV Youth Assent 81211.docx	0.01
<input type="checkbox"/> [Edit] HIV Consent Form - clean 081211.docx	0.02

Note document version # of the updated documents.

Step 3: Modify the study application (cont'd)

<< Back Save | **Exit** | Hide/Show Errors | Print... | Jump To: 1.1 - Study Title and

Reviewer Notes (0 Notes Total)

Warning: Save your work at least every 15 minutes

General Information

All items marked with a red asterisk (*) are required. Items without an asterisk may or may not be required depending

1.1 - Study Title and
1.1a - Other Person
1.2 - Conflict of Int
2.1 - Project Ident
2.2 - Lay Summary
5.1 - Type of Study
6.1 - Funding and
7.1 - Study Location

- Click **Exit** when you are done updating the study application.
- You will return to the **Finish** section of the Amendment Smartform.

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

Reviewer Note (0 Notes Total)

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 application smartform, click "Finish" to return to the amendment workspace. Then click "Submit Amendment" under "My Activities" to submit the amendment to the IRB.

<< Back Save | Exit | Hide/Show Errors | Finish

Click **Finish** to go to the Amendment workspace to submit.

Step 4: Submit

The screenshot shows the 'SANDBOX UCLA webIRB' interface. The main content area displays details for 'Amendment: Amendment #12 for webIRB Study IRB#09-000016'. The 'Current State' is 'Pre Submission'. A 'My Activities' sidebar on the left lists several actions, with 'Submit Amendment' highlighted. A blue arrow points from this button to a callout box on the right.

Callout Box Content:

- 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.

Send Ready Notification

Continuing Reviews

Steps for preparing a CR application

- **Step 1:** Start the CR application by clicking in the approved study workspace. 
- **Step 2:** Complete the CR application.
- **Step 3:** Submit the CR.
 - If you are modifying the study application at the time of continuing review, create and submit a separate amendment.
 - If you are submitting a PAR at the time of continuing review, create a PAR in the approved study workspace. The PAR will be reviewed with the CR.

Step 1: Create a CR application

- In the approved study workspace click on:

CR New Continuing Review

- The **Continuing Review-Type of Study** section will appear:

Current State
 Approved

Study: Sample Approved Study for webIRB Training (1)

Full Title of Study: Sample Approved Study for webIRB Training (1)
 Protocol ID: IRB#09-000016

Principal Investigator: A P11
 Faculty Sponsor:
 Review Type: Full IRB Review

Study Contact Person: Study Staff 3
 Initial Submission Date: 12/26/2009
 Committee: Medical IRB 2

Approval Date: 1/4/2011
 Expiration Date: 1/4/2012
 Letter of Approval: [View]

Owner (IRB Staff):
 IRB Staff 1

My Activities:

- Send Notification to FS for FS Assurances
- DT Assurances
- Send Training Reminder
- Edit PI Proxy
- Copy Study
- Send Inquiry or Reply to IRB
- DT Suspend
- Study Team - Log Private Comment

PI Proxy:

DT Assurances: Completed
 FS Assurances: Not Required

Request to Continue Participants during Approval Lapse:

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

Activity

- Project Snapshot Generated
- View Project Snapshot
- Amendment Completed - Approved
- Continuing Review Deadline Reminder
- Amendment Opened

Author: Michelle Leonard
 System Administrator: Michelle Leonard
 A P11

SANDBOX UCLAwebIRB

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

Continuing Review - Type of Study

1.0 IRB# for the study:
 IRB# 09-000016

2.0 *Indicate the type of report you are submitting:

Progress report for continuing review
 Study Closure
 Clear

Guidance: If any of the following conditions apply, the study must remain open:
 1. Local enrollment to the study is ongoing.
 2. Local research related interventions are ongoing.
 3. Local participant follow-up is ongoing.
 4. Data analysis or manuscript preparation that involved use or access to individually identifiable information is ongoing.

Step 2: Complete the CR application

SANDBOX UCLAwebIRB

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

Warning: Save you

Continuing Review - Type of Study

1.0 IRB# for the study:
IRB#09-000016

2.0 *Indicate the type of report you are submitting:

Progress report for continuing review

Study Closure

Clear

3.0 You have indicated in the Study smartform that the following apply to the study design
The research activities involve direct contact with study participants (e.g., collection of data

4.0 UCLA IRB Expiration Date of this Study:
1/4/2012

Done Internet | Protected Mode: Off 100%

- The SmartForm will branch depending on the type of report you are submitting:
 - Progress report for continuing review
 - Study Closure
- Click **Continue** to navigate through the sections.
- Complete the CR by providing a response to all the questions in each section.

Step 2: Complete the CR application (cont'd)

UCLAwebIRB

<< Back Exit | Hide/Show Errors | Print... | Jump To: 2.1 - Post-Approval Reports (Including Unanticipated Problems Involving Risks to Participants or Others) Continue >>

Review Note

Type	Reviewer	Modified
There are no items to display		

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

Post-Approval Reports (including Unanticipated Problems Involving Risks to Participants or Others)

1.0 *Did any of the following occur during the past approval period for this study?

Check all that apply:

- Unexpected or serious adverse events
- DSMB report or new information regarding the safety of the study
- Protocol violations, incidents or complaints
- Study audit or monitoring from an outside group (e.g., study sponsor, FDA, etc.)
- None of the Above

1.1 If you indicated that any of the above occurred, did you submit the required reports for those that should have been reported within 3 or 10 working days during the past approval period?

Guidance: Please click on the following link for a list of reporting requirements and timeframes. ([link](#))
 Yes No

If you answered 'No' above, create and submit a separate post-approval report(s) within webIRB referencing the IRB number of this continuing review application.

Guidance item 1.1: Please click on the following link for a list of reporting requirements and timeframes. ([link](#))

Done

If you have not submitted all the required post-approval reports during the past approval period:

- Go to the approved study workspace and create a PAR.
- The PAR will be reviewed along with the CR.
- Submit the PAR at the same time you submit the CR.

Step 2: Complete the CR application (cont'd)

The screenshot shows a web application interface with a top navigation bar containing '<< Back', 'Save | Exit | Hide/Show Errors | Print... | Jump To: 4.0 - Continuing Review or Closure Report', and a 'Finish' button. Below the navigation bar is a 'Reviewer Note' section with a table header 'Type', 'Reviewer', and 'Modified', and the text 'There are no items to display'. The main content area is titled 'Continuing Review or Closure Report' and contains 'Instructions for Submission'. A red arrow points from the 'Finish' button in the top right to a callout box. The callout box contains the text: 'Click **Finish** when you reach **Section 4.0- Continuing Review or Closure Report** to go to the CR workspace.'

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

Reviewer Note

Type	Reviewer	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 completed form within 30 days of completion or termination of all research activity, even if the current approval period has expired.

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

1. Click the "**Finish**" button on this page to return to the Continuing review/Study Closure workspace.
2. If you have any amendments to submit at the same time as the report, use the "**Create Linked 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 gairb@research.ucla.edu.
- Call the Medical IRB staff at 310-825-5344 or email mirb@research.ucla.edu.
- For exempt protocols only, contact Wendy Brunt at 310-825-4810 or email wbrunt@research.ucla.edu.

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

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

Step 3: Submit the CR

SANDBOX UCLAwebIRB

webIRB Home IRB Protocols

IRB Protocols > Sample Approved Study for webIRB Training (1) > 2012 Review for IRB

Project State
 Pre Submission

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

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

My Activities
 Send Notification to FS for FS Assurances
 Submit Continuing Review
 Withdraw
 Edit PI Proxy
 Study Team - Log Private Comment

Continuing Review: 2012 Review

Continuing Review ID: IRB#09-000016-CR-00006
 Study ID: IRB#09-000016

Principal Investigator:

Faculty Sponsor:

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:
Initial Submission Date:	Review Type:
Committee: Medical IRB 2	Meeting Date & Time:

PI Proxy:

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

Request to Continue Participants during Approval Lapse:

History Documents Amendments Reportable Events IRB Requests Correspondence Change Log

- The **Submit Continuing Review** 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 CR is ready to be submitted.

Submit the CR

Before submitting:

- If you have a faculty sponsor (FS) use **Send Notification to FS for FS Assurances** to obtain your FS assurances.

To submit the CR:

- **Submit Continuing Review** available only to the PI and PI Proxy.
- **Send Ready Notification** - available only to study staff to let the PI/PI Proxy know the CR is ready to be submitted.

After Submitting:

- The activity  **PI Assurances** will appear.
- The PI must provide his/her assurance by clicking on this activity.

PI Assurances

The PI must provide the appropriate PI Assurances.

If Progress Report for Continuing Review was selected in Section 1.1/item 2.0, the PI must provide the Continuing Review Assurances #1-#3.

PI Assurances

PI Assurances

Continuing Review

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

2.0 I 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 I 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

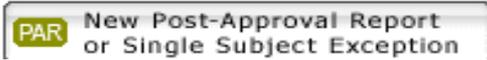
Study Closure

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

If Study Closure was selected in Section 1.1/item 2.0, the PI must provide the Study Closure Assurances.

Create and complete the PAR

- If you are submitting a PAR with the CR, go to the approved study workspace to create the PAR using:



- The PAR application will appear. Complete the application.
- When you complete the application the PAR workspace will appear.

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

Copy Study

Send Inquiry or Reply to IRB

PI Suspend

Study Team - Log Private Comment

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

[AM New Amendment](#)

[CR New Continuing Review](#)

Study: Sample Approved Study for webIRB Training (1)

Full Title of Study: Sample Approved Study for webIRB Training (1)

Protocol ID: IRB#09-000016

Principal Investigator: A PI1	Study Contact Person: Study Staff7 5
Faculty Sponsor:	Initial Submission Date: 12/26/2009
Review Type: Full IRB Review	Committee: Medical IRB 2
Approval Date: 1/4/2011	Letter of Approval: [View]
Expiration Date: 1/4/2012	

PI Proxy:

PI Assurances: Completed

FS Assurances: Not Required

Request to Continue Participants during Approval Lapse:

History
Amendments
Continuing Reviews
Post-Approval Reports & Single Subject Exception
Approved Documents
Completed IRB Requests
Conditions and Determinations
Correspondence
Training Log
Change Log

Activity

	Author Michelle Leonard
View Project Snapshot	
	Michelle Leonard
	System Administrator
	A PI1

Submit the PAR

SANDBOX UCLAwebIRB

webIRB Home | IRB Protocols

IRB Protocols > Sample Approved Study for webIRB Training (1) > tuiuir

Current State

Pre Submission

Edit Post-Approval Report or Single Subject Exception

Printer Version

View Differences

SS-Print All Request Notes

Owner (IRB Staff):

Parent Study:
State: Approved
Review Type: Full IRB Review

My Activities

Submit

Withdraw Post-Approval Report or Single Subject Exception

Copy Post-Approval Report or Single Subject Exception

Study Team - Log Private Comment

Post-Approval Report & Single Subject Exception: tuiuir

Post Approval Report / Single Subject Exception ID: IRB#09-000016-PAR-0000

Study Name: Sample Approved Study for webIRB Training (1)

Study ID: IRB#09-000016

Principal Investigator: A P11

Faculty Sponsor:

Date Reported to IRB:

Submission Type: Updated Study Safety Information / Protocol Clarification

History | Stamped Study Documents | Amendments | IRB Requests | Change Log | Corre

Activity

Created Post-Approval Report or Single Subject Exception

Submit the PAR:

- The **Submit** 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.

Summary

- Amendments and Continuing Reviews are created in the approved study workspace.
- If you are submitting a PAR the time of continuing review, go to the approved study workspace to create the PAR.

Questions?