

eIRB: Submit a Continuing Review

As of July 31, 2010, all continuing reviews must be submitted electronically in eIRB.

If you have not converted your study via ERGO you will need to do so before submitting the Continuing Review. For more information on how to convert a paper study, access the following link:

<https://ais.swmed.edu/ergo>

For new and converted studies, the eIRB system will send auto-generated 30, 60 and 90-day notifications to the study team (Principal Investigator , Primary Research Coordinator and Primary Administrative Contact) when the study is approaching the deadline for continuing review.

Note: Continuing Reviews and Modifications must now be submitted separately. If a modification to the approved protocol is needed, please either submit the modification prior to the continuing review submission, or after the continuing review receives final IRB approval.

Step 1: Log in to eIRB

1. Log in to eIRB using this URL:
<https://eresearch.swmed.edu/eIRB>
2. Type your **User Name** and **Password** in the corresponding fields.
3. Click Login.

Step 2: Search and Locate Study

1. Click the **My Home** link located at the top right hand corner of the screen.
2. Locate the study in the **Studies** tab.
3. Click the hyperlinked study title to access the study workspace.

Step 3: Complete Continuing Review

1. Click the **New Continuing Review** button at the bottom left hand side of the screen.
2. Complete all 6 pages of the Continuing Review SmartForm and then click **Finish**.

The Continuing Review will remain in Draft state until submitted by the Principal Investigator.

Reviewing and Submitting the Continuing Review (Principal Investigator Instructions)

Note: Only the Principal Investigator can submit the Continuing Review. The Continuing Review will remain in Draft state until submitted by the Principal Investigator.

1. Log in to eIRB using this URL:
<https://eresearch.swmed.edu/eIRB>
2. Click the **My Home** link located at the top right hand corner of the screen.
3. Under **My Tasks**, locate the Continuing Review.
4. Click on the hyperlinked CR title to access the continuing review workspace.
5. To review the Continuing Review before submitting, click the **Edit Continuing Review** or the **Printer Friendly Version** button located on the left hand side of the screen in the study workspace. **Note:** Changes can only be made when viewing the SmartForm using **Edit Study Review**.
6. To submit the CR, click the **Submit Continuing Review** button on the left hand side of the screen.
7. A confirmation window displays, indicating you will no longer be able to make changes. Click **OK** to confirm.

Reviewing and Submitting the Continuing Review—continued

The state of the continuing review will change from **Draft** to **Awaiting IRB Assignment**.

The Continuing Review is now submitted. If the IRB requires changes, the study team is notified via email.

If there are no changes required, the study team will receive the approval letter via email.

Once the Continuing Review is approved, the reapproved documents (i.e. Consent Form and/or HIPAA Authorization) will be available under the **Documents** tab of the study workspace.

Responding to Stipulations at Continuing Review

1. Log in to eIRB using this URL:
<https://eresearch.swmed.edu/eIRB>
2. Click the **My Home** link located at the top right hand corner of the screen.
3. Under **My Tasks**, locate the Continuing Review that requires changes.
4. Select the **Continuing Review** that requires changes.

Changes to the Continuing Review SmartForm only

1. Click the **Edit Continuing Review** button on the left hand side of the Continuing Review workspace.
2. Select the appropriate sections on the CR SmartForm that correspond to the changes requested by the IRB.
3. To submit the revised CR, the PI will need log-in to the CR workspace and click the **Submit Changes** button on the left hand side of the screen.

All other changes require the submission of a related Modification (i.e. parent study SmartForm, protocol, consent form, etc.)

1. Click the **New Modification** button at the bottom left hand side of the study workspace.
2. Select the appropriate sections on the Modification Form that correspond to the changes requested by the IRB.

For example, if changes to the consent form were requested, check 'Consent Form' in question 1.1 of the Modification Form. If the information requested by the IRB does not fall into one of these categories, please select 'Other'.

Responding to Stipulations at Continuing Review—continued

3. Complete the Modification Form. Please insert **'Response to IRB requested changes'** in the fields where a description of the change is requested.
4. Revised redlined documents (i.e., Consent, HIPAA Authorizations, Protocols, etc.) may be uploaded in the new Modification workspace. If you need to modify the SmartForm, this can be done by clicking the link to the SmartForm on the last page of the modification workspace.
5. To submit the related Modification, the PI will need log into eIRB, open the Modification workspace and click **Submit Modification** button on the left hand side of the screen.

Note: The CR will remain in your workspace until the IRB has approved the continuing review-related modification.

Once the related Modification has been approved, the PI may then re-submit the CR back to the IRB for final approval.

Contacts

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eResearch Link

<http://www.utsouthwestern.edu/eIRB>

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**eResearch
Quick Reference
Guide
eIRB
Submitting Continuing
Reviews**