Continuing Review

What is Continuing Review?

If you want to continue working on a study beyond its expiration date, you must submit the study to the IRB for continuing review approval. The IRB re-reviews the study to determine if it is appropriate for the study to continue, as is or with modifications.

Continuing review is required even if:

- No changes have been made since the last approval
- The only study activity is subject follow-up
- The only study activity is data analysis*

* Note: You may be able to close your study [1] if data analysis is being done by someone else, such as the sponsor or the lead site. You may also be able to close the study if data analysis or manuscript preparation no longer involves use or access to individually identifiable

information, and they key has been destroyed.

How Often Is Continuing Review is Required?

Most studies must undergo continuing review annually [2]. However, the IRB may require more frequent review. Your approval letter will clearly list the study's expiration date, and you can sort your studies by expiration date in iRIS. Please note that exempt studies [3] do not expire and do not require continuing review.

Continuing review reminders from iRIS

The iRIS system sends out a courtesy continuing review reminder to the PI and study contacts before a study expires. However, it is ultimately the PI's responsibility to submit a continuing review application, allowing 4 weeks for review and re-approval before expiration.

If Approval Expires

If approval expires, ALL RESEARCH ACTIVITIES INVOLVING HUMAN SUBJECTS MUST STOP, even if the continuing review application has been submitted to the IRB. Research activities include, but are not limited to, study visits, medical records review and data analysis. The only exception is that activities needed for participant safety should continue; contact the IRB [4] if this occurs. No new subjects may be enrolled.

If any project activity occurs or continues after the expiration date, the investigator is out of compliance with both federal regulations and University policy. Retrospective approval for work done after the expiration date cannot be granted.

Submitting in iRIS

Allow at least 4 weeks for the continuing review to be processed. Incomplete submissions will not be assigned for review.

Follow these steps to submit the continuing review. For additional assistance, read the quick guide called "Submitting Post-approval Forms" in the Help section of iRIS.

1. Open the study via the IRB Study Assistant

Go to **My Studies** under the IRB Study Assistant. Open the active study you want to renew.

2. Start and complete the new form

Click on the **Continuing Review Submission Form** link. Click Add New Form to start a blank form. If you have previously renewed this study, you can **copy a previous Continuing Review Form** by selecting the form you want to copy and clicking Copy Form. The copied form will open automatically.

3. Describe any new modifications

You can modify your study at the time of continuing review. Indicate in the first section of the Continuing Review Form that you are modifying the study, and then provide a description of the proposed changes in the "**New Modifications**" section. Attach any new or revised

documents or applications later in the form.

Caution: If a study?s expiration date is close, consider not submitting a possibly controversial modification until after the continuing review has been approved. Delayed approval and study expiration may occur if the IRB has questions or problems with the modification.

4. Attach consent forms

In the "**Attach Consent Forms**" section, you must attach all consent documents that you plan to use during the next approval period ? even if the documents are currently approved and are not being modified. The IRB will review them and give them an updated approval stamp. Follow the instructions on the form to attach the consent documents. If the study is closed to accrual and you don't need to re-consent [5], do not attach the consent forms. Note: You do not need to attach any other study documents that are currently approved and are not being modified.

5. PI must submit

The **PI must sign off and submit** the Continuing Review Form.

IRB Review Process for Continuing Reviews

Studies initially reviewed as full committee

These submissions will be reviewed by the full committee at a convened meeting unless certain conditions apply (see below).

Studies initially reviewed as full committee, now eligible for expedited review

If one of the following apply, the continuing review can be reviewed under the expedited review procedures:

1. The research is permanently closed to the enrollment of new subjects and the research remains active only for long-term follow-up, such as medical records review and telephone follow-up. (If one of the research follow-up procedures is an intervention such as a blood draw or an x-ray, the continuing review is not eligible for expedited review.)
2. No subjects have ever been enrolled and no additional risks have been identified since the last full committee review.
3. The remaining research activities are limited to data analysis.

Studies initially reviewed as expedited review

These submissions can be reviewed under the expedited review procedures if the study procedures continue to qualify for expedited review.

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Source URL: https://irb.ucsf.edu/continuing-review

Links
[1] https://irb.ucsf.edu/study-closeout-report
[2] https://irb.ucsf.edu/study-expiration-dates-and-extended-approval-criteria
[3] https://irb.ucsf.edu/levels-review
[4] https://irb.ucsf.edu/contact-us
[5] http://irb.ucsf.edu/obtaining-and-documenting-informed-consent#reconsent