



University of California
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Study Closeout Report

Closing Your Study

Submitting a Study Closeout Report

Closing Your Study

You must submit a Study Closeout Report for ALL types of studies. The report updates the IRB on the conduct and outcomes of the study, including any risks or problems that may have arisen since the last continuing review and may need to be disclosed to the study participants or others.

Do NOT close out a study if any of the following conditions apply. These studies must remain active and receive ongoing IRB review and approval.

- Any of the following activities are ongoing:
 - Local enrollment,
 - Local research-related interventions or
 - Local participant follow-up.
- Data analysis or manuscript preparation that involves use or access to individually identifiable information.
- Biological specimens containing individually identifiable information are being maintained in a repository that has been approved as part of this study or upon which analysis or research continues. If specimens were transferred to a separate repository that has ongoing IRB approval, then the study may be closed.

- You have not received permission from the study sponsor to close the study with the IRB.

Submitting a Study Closeout Report

1. Open your study in iRIS

In iRIS, go to **My Studies** under IRB Study Assistant. Open your study.

2. Add a new Study Closeout Report and complete it

Click on the **Study Closeout Report** link. Click on the Add New Form button and complete the form.

3. Submit the form to the IRB

Anyone listed on the study can **sign off and submit** the form.

Once a study is closed, the IRB will not accept any additional submissions for the study.

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