

SOP: 408
STUDY COMPLETION

1. POLICY

The completion or termination of a study is a change in activity and must be reported to the IRB. The investigator shall report completion or termination of a study to the IRB on an Application for Continuing Review or Final Closure Report.

Specific Policies

1.1 Determining When a Project is to be Closed

Investigator-initiated protocols may be closed when individually identifiable follow-up data are no longer being collected about participants and analysis that could indicate new information has been completed.

Multi-site industry studies may be closed when the Investigator submits the Application for Continuing Review requesting inactivation or closure.

1.2 Closure of Studies

Completion of the Application for Continuing Review requesting activation shall be accepted by the IRB for closure of Expedited and convened Board studies.

Exempt studies shall be closed through the Exempt status letter, email, or other form of communication from the investigator requesting closure.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. RESPONSIBILITY

The IRB Administrator is responsible for verifying all study completion documentation is received, reviewed, presented to the IRB, and filed appropriately. For exempt studies, the IRB Administrative Staff will send a letter yearly to the investigator requesting the status of the study.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.108, 56.109

45 CFR 46.103, 46.109

5. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs.

6. ATTACHMENTS

203-H Continuing Review Reviewer Checklist
301-B Application for Continuing Review or Final Closure Report
301-B-1 Continuing Review of Approved Research

7. PROCESS OVERVIEW

The IRB Staff confirms all documents are reviewed for submission, per SOP 301, Research Submission Requirements.

The IRB Administrator provides to the IRB Chair or designee the item to be reviewed and the tools to conduct the review.

7.1. Convened Board and Expedited Projects

The Final Closure Report is accepted by the IRB during mid-cycle of the project. An Application for Continuing Review is accepted during the anniversary period at the time the study must receive continuing review and re-approval from the IRB. These reports are processed similarly in the IRB.

- 7.1.1 The Investigator submits the Final Closure Reports to the IRB within 30 days after completion or termination of the study. The IRB Administrator reviews all reports of study completion and, if needed, requests further information from the Investigator to obtain missing data or to clarify any questions that arise.
- 7.1.2 The IRB Chair reviews and approves the Final Closure Report in accordance with SOP 402, Expedited Review. The IRB Administrator changes the study status in the IRB database to inactive and updates the next IRB meeting agenda to reflect the study closure.
- 7.1.3 The IRB Administrator generates a final closure letter and presents it to the IRB Chair for signature. The IRB Administrator sends the letter to the Investigator and files the Final Closure Report and a copy of the final closure letter in the study file.
- 7.1.4 The IRB staff stamps the file with the inactivated date on the front cover and files it with the inactivated study files.

7.2. Exempt Projects

Inactivation of exempt projects is processed in accordance with SOP 401, Research Exempt from IRB Review, Section 7.2.

APPROVED BY: _____ **DATE:** 09/01/2009

NEXT ESTABLISHED REVIEW DATE: MAY 2012