

Approved by IRB Executive Committee: December 10, 2008
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POLICY

The completion or termination of the study is a change in activity and must be reported to the IRB. A final project report is submitted by the Investigator to notify the IRB of the completion or termination of a project. A final project report provides information to the IRB regarding the final status of the project and allows the IRB to close the study file. In the event that the Investigator fails to apply for continuing review or fails to submit a final project report, the IRB must administratively close the study. When final project reports are acknowledged by the IRB, the study file is closed and no further activity related to the study may be conducted. Study files are retained as described in SOP 308 (Document Management).

Guidance for determining when a final project report should be submitted is posted on the IRB website. Additionally, the Investigator may not submit a final project report in the ERICA system if he/she is unable to verify such criteria are met.

PROCEDURES

1. Procedures for Submission of Final Project Reports

- 1.1. Final project reports should be submitted within 30 days after completion or termination of the study.
- 1.2. The following documentation is required for IRB Review.
 - Final project report application (available in the ERICA system).
 - Preliminary or final results, if available.
 - Sponsor documentation of study completion or termination, if it exists.

2. Procedures for IRB Review of Final Project Reports

- 2.1. A designated member of the IRB Staff reviews all final project reports and, if needed, requests further information from the Investigator to clarify any questions that may arise.
- 2.2. Once the IRB has determined that sufficient information is provided, the Investigator will receive acknowledgement of the final project report and closure of the study.

3. IRB Administrative Closure

- 3.1. If a study is expired and an application for continuing review or a final project report has not been submitted, the study will be administratively closed by the IRB. See SOP 307 (Approval Period and Determination of Expiration) for a description of procedures regarding expired studies.