

**INSTITUTIONAL REVIEW BOARD
SOP 405: Study Completion**

POLICY

The completion or termination of the study is a change in research activity that must be reported to the IRB. Although participants will no longer be “at risk” under the study, submission to the IRB allows the IRB to close its files as well as provide information that may be used by the IRB in the evaluation and approval of related studies.

PROCEDURES

1. Determining When a Project Can be Closed

- 1.1 When individually identifiable follow-up data are no longer being collected on participants and/or all analyses have been completed, the study may be closed. Sometimes, it may also require waiting on a close-out visit from the sponsor or their CRO, or approval by the sponsor in general.
- 1.2 There should be no outstanding mailings that require IRB approval.

2. Study Closure

- 2.1 A change in research activity form should be submitted within 30 days after completion or termination of the study. Attachments may be submitted in any format that provides adequate information about the status of the study, such as computer print-outs, telephone reports, letters, etc. The IRB administrator will review all reports of study completion and, if needed, request further information from the Investigator to clarify any questions that may arise.

3. IRB Administrative Closure

- 3.1 If a study is expired and a continuing review submission form or change in research activity form has not been submitted to the IRB, the study will be administratively closed by the IRB. The IRB administrator will document the reason for the closure in IMEDRIS and a letter to the Investigator will be generated.

4. Completion Report

- 4.1 A listing of closed studies will be posted to the IRB agenda each month, and the submission forms and attachments can be viewed by all IRB members in IMEDRIS.

SCOPE

This SOP applies to all IRB members, the IRB administrator, and members of the research community.