

**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. This final regulatory action allows the IRB to close its file. The information provided may also be used by the IRB to consider approval other related studies.

PROCEDURES

1. Determining When a Study Can be Closed

- 1.1 When individually identifiable follow-up data are no longer being collected on subjects and/or all analyses have been completed, the study may be closed. However, IRB closure may not occur right away if a close-out visit is required by the sponsor, or the research base has to grant approval.
- 1.2 The change form should be submitted within 30 days after completion or termination of the study.

2. Supporting Documentation

- 2.1 The change in research activity form should accompany an email, a closure notice, or some other document related to the close out visit or closure.

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.
- 3.2 IRB administrative closures are not reportable events since the study is already expired, and there is no withdrawal of IRB approval.

4. Committee Notification

- 4.1 Closed studies will be posted to the IRB agenda under expedited review, and the submission forms and attachments can be viewed at any time by all IRB members.

SCOPE

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