

STUDY COMPLETION OR TERMINATION

SOP #:	406	VERSION #:	1	EFFECTIVE DATE:	5/1/09	SUPERSEDES DOCUMENT:	/ /
THIS POLICY PERTAINS TO:		ALL RESEARCH SUBMITTED TO THE IRB					
RESPONSIBILITY FOR EXECUTING POLICY:		IRB CHAIRPERSON, IRB MEMBERS, IRB VICE CHAIRPERSON, IRB SECRETARY, INVESTIGATOR					
LAST REVIEWED ON:		/ /		RESULTS:	REVISED		
APPROVAL AUTHORITY:		Associate Vice President for Research and Economic Development					
APPROVED BY:					DATE:		/ /

1. POLICY

The completion or termination of the study is a change in activity and must be reported to the IRB by the Investigator. Although subjects will no longer be "at risk" under the study, a final report/notice to the IRB allows it to close its files and provides information that may be used by the IRB in the evaluation and approval of related studies.

2. SPECIFIC POLICIES

2.1 Determining When a Project Can Be Closed

2.1.1 When individually identifiable follow-up data are no longer being collected on subjects enrolled and when data analysis is complete, the study may be closed.

2.1.2 Multi-site industry supported studies may be closed when the Investigator submits his or her final report.

2.2 Project Closure Reports when IRB approval has expired

Investigators must submit a closure report to the IRB even when the IRB approval has expired. Failure to submit a closure report after multiple attempts may affect future submissions by the Investigators.

2.3 Administrative Closure of an Expired Project

The IRB has the authority to administratively close a research project that has expired and is closed to accrual. The IRB will notify the Investigator, the Investigator’s Adviser and/or the Chair of the Department, and any other appropriate individuals.

2.4 Notification of the IRB

When the IRB Chairperson terminates or temporarily suspends a research project, all regular members shall be informed of actions taken by the IRB at the next convened meeting.

3. RESPONSIBILITY

The IRB Staff is responsible for ensuring that all study completion documentation is received, reviewed, presented to the IRB, and filed appropriately.

The IRB Chairperson and/or Vice Chairperson are responsible for administratively closing research projects that have been terminated due to expiration.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.108, 56.109
 45 CFR 46.103, 46.109

5. ATTACHMENTS

Research Project Termination Form

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
<i>IRB Secretary</i>	Instruct Investigators to submit written notification of completion of the study, in the form of either a completed Research Project Termination Form or Research Project Review and Progress Report.
<i>IRB Secretary, IRB Vice Chairperson, IRB Chairperson, IRB Members</i>	Review Research Project Termination Form or Research Project Review and Progress Report and obtain any outstanding information or documentation from the Investigator to close the study. If there are inconsistencies or if clarification is needed, request additional information.
<i>IRB Secretary</i>	Make a list of completed studies, terminated studies, and temporarily suspended studies for presentation to the IRB at its next convened meeting.
<i>IRB Vice Chairperson, IRB Chairperson, IRB Secretary</i>	The IRB may administratively close a study when IRB approval has lapsed.