

Policy Number: 20

Title: Completion of Study/Study Closure

Date of Last Revision: 01/21/07, 08/24/10, 01/29/15, 04/22/15, 10/01/16, 02/28/2018

Definitions:

Policy:

It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) to require reporting of study closure. In addition, the IRB may require an administrative study closure for studies that have been submitted to the but have not met the requirements for IRB review.

I. Final Closing Reports

- A. Investigators are required to submit a Final Closing Report to the IRB as soon as possible but no later than three months after the following has occurred:
 - 1. All subject accrual (i.e., recruitment and enrollment) is complete;
 - 2. All subject specimens, records, data have been obtained (i.e., no further collection of data/information from or about living individuals is required);
 - 3. No further contact with subjects is necessary (i.e., all interactions or interventions are complete and no further contact with enrolled subjects is necessary); and
 - 4. Analysis of subject identifiable data, records, and specimens are complete (i.e., use or access to subject identifiable data and review of source documents by study sponsors is no longer necessary).
 - B. If a study is canceled without participant enrollment, Investigators are still required to submit a Final Closing Report to the IRB.
- II. An electronic Closing report is available on the OR/HRPP website. The Closing Report is completed and submitted electronically to the Human Research Protections staff. In addition, the Continuing Protocol Application (CPA), available on the OR/HRPP website as well, allows the option to submit a Closing Report at the time of continuing review.
- III. Investigators are required to report unanticipated problems involving risks to participants or others even if a closing report has been filed. The Investigator is required to submit the form to the IRB within 5 business days of the Investigator's awareness of the problem (See IRB Policy 19).
- IV. Additional items relating to the study, such as the Sponsor's Completion Summary are accepted for the protocol file after the study has been closed.

V. Administrative Closing

- A. Full Committee: It is necessary for Investigators to submit to and address various ancillary committee requirements, along with Human Research Protections (HRP) requirements upon submission of a new study. When a new study submission is determined not ready for IRB review (e.g., signatures not provided, major appendices not provided, ancillary committee clearance not provided) it may take several weeks or months, over multiple IRB agendas for an item to be placed on an agenda.
- B. Expedited / Exempt: Likewise, for minimal risk research, sometimes it may take months for a researcher to respond to requests for required documentation (e.g., signatures not provided, major appendices not provided).

- C. Studies that are not ready for IRB review will remain pending in the queue for a maximum of six (6) months from the date of submission. If the study is not ready for IRB review after six months, it will be administratively closed out in the IRB database (HPS).

Procedure:

This procedure outlines the process for reporting study closures and completing an administrative closure.

I. Lead Researcher (LR) Responsibilities

- A. The LR is required to submit a Closing Report to the IRB once all of the following have occurred:
 - 1. All subject accrual (i.e., recruitment and enrollment) is complete;
 - 2. All subject specimens, records, data have been obtained (i.e., no further collection of data/information from or about living individuals is required);
 - 3. No further contact with subjects is necessary (i.e., all interactions or interventions are complete and no further contact with enrolled subjects is necessary);
 - 4. Analysis of subject identifiable data, records, and specimens are complete (i.e., use or access to subject identifiable data and review of source documents by study sponsors is no longer necessary) or, if
 - 5. The study is canceled without participant enrollment.
- B. Investigators are required to report unanticipated problems involving risks to participants or others even if a closing report has been filed. The Investigator is required to submit the form to the IRB within 5 business days of the Investigator's awareness of the problem (See IRB Policy 19).

II. IRB Chair/Designated Committee Member Responsibilities

- A. The IRB Chairperson, Vice-Chair or Designated Committee Member will review Closing Reports for protocols involving greater than minimal risk. The IRB Chairperson, Vice-Chair or Designated Committee Member will acknowledge study closure by signing and dating the report.
- B. When there is a discrepancy between the closing report and the protocol file the IRB Chair may request clarification.

III. IRB Analyst or Higher Responsibilities

- A. All Closing Reports are reviewed by the Analyst for completeness.
- B. The Analyst will assist in obtaining any additional information requested by the Committee Chairperson.
- C. The Analyst will process the Closing Report, prepare the protocol file for archives and make the appropriate HPS database entries.
- D. For an administrative closure, five months after initial submission, the LR will be sent a notice informing him/her that the study will be administratively closed within thirty days if it has not been placed on an IRB agenda.
 - 1. The Administrator will review and confirm that the new study has been pending review for 6 months. Upon confirmation that IRB review requirements have not been met during that period, the study will be administratively closed out in HPS. A note will be added in HPS to document the administrative closure.
 - 2. If the LR wishes to pursue the research after it has been administratively closed, a new application (APP) must be submitted and will be re-assigned to the pending queue.
 - a) Human Research Protections (HRP) staff will use discretion with this process should the LR be able to provide justification for the delay and a concrete date in which review requirements will be met.