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, 02/28/18, 03/26/22, 09/14/22; 11/25/24

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 Closing Report to the IRB.

II. A Closing report is completed and submitted electronically to the Human Research Protections (HRP) staff.

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 HRP requirements upon submission of a new study. When a new study submission is determined not ready for IRB review (e.g., major information 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.

C. Studies that are not ready for IRB review will remain pending in the queue for a maximum of three (3) months from the date of submission. If the study is not ready for IRB review after 3 months, it will be administratively closed out.

D. An administrative closing is neither a termination or suspension per 21 CFR 56.113 and / or 45 CFR 46.113. An administrative closing occurs for studies that remain pending IRB review after 3 months or in response to a protocol lapse with no renewal submission. It is not an IRB action resulting from research conducted contrary to IRB requirements nor associated with unexpected serious harm to subjects.

Procedure Number 20.A
Title: Procedure for Reporting of Study Closure

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 when:

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 via their agreement to close the study in the electronic IRB submission and management system.

B. When there is a discrepancy, 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, and make the appropriate database entries.