



UNIVERSITY OF CALIFORNIA, SAN DIEGO  
HUMAN RESEARCH PROTECTIONS PROGRAM

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## Study Withdrawal/Closure

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### **Policy**

By federal regulation, changes in research activity require reporting to the IRB. Study closure is one such activity. As stated by the FDA, “Although subjects will no longer be ‘at risk’ under the study, a final report/notice to the IRB allows it to close its files as well as providing information that may be used by the IRB in the evaluation and approval of related studies.”

The Principal Investigator must report closure of a research study to the IRB within 30 days.

Additional information must be provided to the IRB should the study be associated with a device. If the device is associated with an IDE, the investigator will within 3 months after termination or completion of the investigation or the investigator's part of the investigation, submit a final report to the IRB. Further, if a device is determined to be either a Significant Risk or Non-Significant Risk device, the sponsor's final report must be provided to the IRB for review within 6 months after completion or termination of the study.

A research study may not be closed and must remain “active” if any of the following are true:

- 1) Local enrollment, research-related interventions and/or participant following are ongoing.
- 2) Use or access of individually identifiable information for analysis or manuscript preparation is ongoing and/or the analysis may indicate new information may be required.
- 3) Biological specimens containing individually identifiable information in a repository that has been approved as part of the study or upon which analysis or research is ongoing at the local site.
- 4) Permission from an external sponsor to close the study has not been received.

Investigators are expected to continue to honor confidentiality protections for data and other commitments made to the subject such as notifying the subject of study completion; communicating research results and/or additional significant findings to the subject; providing compensation to subject; notifying the subject's primary care physician and ensuring appropriate follow-up and treatment, as needed.

Subsequent use of data from closed research, whether by the original investigator or other investigators, may constitute human subjects research requiring IRB approval or Certification of Exemption of IRB review.

Investigators and the IRB must retain all research records for a minimum of three years after the completion of the research (five years for VA studies). University of California, General Counsel, recommends additional requirements for retention of research records including the following:

- 1) Research records where children are the research subjects should be kept until the subjects are 25 years of age.
- 2) Research records for in vitro studies or where pregnant women are included as research subjects should be kept for 25 years after completion of the research.

The following is a summary of current FDA requirements governing record retention which may change over time as the FDA adopts amendments. It remains the PI's responsibility to comply with FDA and other regulations in effect at the time. FDA-regulated research includes the following requirements as outlined in 21 CFR 312.62.c, "An investigator shall retain records...for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified."

Further requirements for FDA-regulated research, as outlined in ICH GCP 4.9.5, include, "Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period, however, if required by the applicable regulatory requirements or by an agreement with the sponsor. It is the responsibility of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained."

Agreements between outside entities and the University may also obligate the Investigator to retain research records beyond those noted above.

### **Procedures**

To withdraw a study before initial approval has been granted by the IRB, a letter signed by the PI must be provided to the HRPP. The letter must indicate that the PI is asking for the study to be withdrawn and describe the reason(s) for the withdrawal.

To close a study that has received IRB approval, but no study procedures have been done such as enrolling participants, a letter signed by the PI must be provided to the HRPP. The letter must indicate that the PI is asking for the study to be closed and describe the reason(s) for the study closure.

Upon receipt of the letter, the IRB Administrator or HRPP staff designee will review the submission for completeness. A request to the PI may be made to clarify any questions or to provide additional information. Once any answers to questions or additional information have been provided, the study withdrawal/closure submission will be reviewed by the IRB Administrator, or by the IRB Chair's designee, and the PI will be provided with written notice of the review of the withdrawal/closure and/or acceptance of the withdrawal/closure, as appropriate.

To close a study that has received IRB approval and has performed study procedures such as enrolling participants, PI completed Study Closure Facepages and Narrative Summary of Progress at Study Closure must be provided to the HRPP. A copy of each these forms can be found on the HRPP web site "Forms" page. In addition, copies of relevant associated information such as formal study closure from sponsor, site monitoring reports, audits, other reviews, etc., must also be provided for review.

Upon receipt of the Facepages, Narrative Summary and additional information, the IRB Administrator or HRPP staff designee will review the submission for completeness. A request to the PI may be made to clarify any questions or to provide any additional information. Once any answers to questions or additional information have been provided, the study closure submission will be reviewed by the full IRB at the next appropriate IRB meeting, or by the IRB Administrator, or by the IRB Chair's designee.

Study closure submissions that will require review by the full Committee include those that describe additional study activity after IRB approval expiration or significant new findings; information that will be disclosed to study participants; unanticipated problems involving risks to participants or others (UPR); or if upon review of the study file, significant outstanding issues not resolved previously.

The PI will be provided with written notice of the review of the study closure and/or acceptance, as appropriate.

### Applicable Regulations

[21 CFR 56.108\(a\)\(3\)](#)

[21 CFR 56.115](#)

[21 CFR 312.62\(c\)](#)

[21 CFR 812.150\(b\)\(7\)](#)

[45 CFR 115](#)

[Department of Veterans Affairs Records Control Schedule 10-1](#)

[FDA Information Sheet, Frequently Asked Questions](#)

[ICH GCP 4.9.5](#)

[University of California, Office of the President, "Administrative Records Relating to Research – Retention and Disposition Requirements", August 2006](#)