UCLA Research Administration
Human Research Protection Program

Guidance and Procedure: Closure of Human Subjects Research Studies

(updated March 15, 2021)

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Overview

A study closure report is required for all human research studies. Among other reasons for closing out a study, the closure report updates the IRB on the conduct and outcomes of the study, any new risks, safety issues or problems that may have arisen since the last study renewal, and informs the IRB of the final disposition of research records and data.

Closure reports should be submitted to the IRB ***within 30 days of study close-out*** by completing a closure report application.

IMPORTANT NOTES: ***Do not*** file a study closure report if any of the following six conditions apply. Such studies must remain active and continue to receive ongoing IRB review and approval:

- ***Enrollment*** at the UCLA-approved site is ongoing.
- ***Research-related interventions*** and/or follow-up at the UCLA-approved site is ongoing.
- ***Participant follow-up*** at the UCLA-approved site is ongoing.
- ***Biological specimens containing personally identifiable information are being maintained*** in a repository that has been approved as part of this study or upon which analysis or research is ongoing. If, however, specimens were transferred to a separate repository that has ongoing IRB approval, the study may be closed.
- ***Data analysis or manuscript preparation*** that involves the use or access to personally identifiable information is ongoing.
- If there is an external study sponsor and the ***sponsor has not provided permission*** to close the study with the IRB.

Closing Sponsor-Initiated Clinical Trials

After study enrollment is closed and interventions with subjects are complete, ***do not submit an IRB closing report until the sponsor has closed UCLA as a study site***. This includes:

- Sponsor close-out visit is complete and all outstanding issues have been addressed.
- Access to PHI or identifiable data and records (e.g., source documentation) is no longer needed by the UCLA study team, sponsor or sponsor representatives.
- All contractual and budgetary issues are complete (e.g., payments to subjects; billing to sponsor or third party insurance).

IMPORTANT NOTE: Clinical trials must also be updated on the clinicaltrials.gov website.

Study Closure Report Procedures

In order to close a UCLA IRB approved study, the Principal Investigator needs to submit a closure report.

- The Principal Investigator ***need not wait*** for the end of the study approval period to submit a study closure to the UCLA IRB.
- A study closure is ***not*** required if the Principal Investigator or the IRB withdraws a submission for a new study from the IRB review process ***prior*** to receiving IRB approval.

Principal Investigator Responsibilities

- ***Submit a closure report application*** to the UCLA IRB within 30 days of completion or termination of all research activity, even if the current approval period has expired.
- ***Store the research records for the required length of time*** in accordance with federal regulations, University of California policy, and any additional requirements stipulated by research sponsors and/or investigators' professional associations.
- ***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 from IRB review. For further information about storage of data for future use and about secondary uses of data, please consult any or all of the following ***OHRPP Guidance & Procedures***:
  - *Determining Which Research Activities Require UCLA OHRPP/IRB Review*
  - *Collection, Use, and Secondary Analysis of Human Specimens or Data*
  - *Data and Specimen Repositories*
- ***Continue to follow data security measures and assure confidentiality of records and data***.
- Report to the IRB ***any information learned after study closure*** that could affect subject safety or medical care, including but not limited to serious adverse events or unanticipated problems reported by the Sponsor or others responsible for study monitoring.
- ***If terminating employment*** or other association with UCLA, the Principal Investigator is obligated to either:
  - **Transfer the protocol** to another UCLA investigator (via an addendum) who must then be approved by the UCLA IRB (required) and Department or Division head (where applicable) as the new Principal Investigator, ***or***
  - **Close the study** and submit a study closure to the UCLA IRB. If closing the study, the Principal Investigator is responsible for making arrangements with the department/division to **assure data and records are stored properly** and remain confidential.

IRB Responsibilities and Procedures

- The UCLA IRB will review all study closure notifications, and if needed, request additional information from the investigator if questions arise.
- The UCLA IRB may close projects without UCLA investigator approval in the following circumstances:

- If it is determined that the investigator is no longer affiliated with UCLA.
- If the IRB approval has been terminated. This would only occur after IRB review and communication with the investigator. Termination of IRB approval is reportable to the appropriate federal department or agency head(s) and institutional officials. See OHRPP Guidance: IRB Reporting Requirements.

- In any of the situations described above, the IRB office will notify the Principal Investigator of the study closure.

OHRPP Responsibilities and Procedures

The UCLA OHRPP considers the following to be abandoned and may perform an administrative closure without UCLA investigator approval:

- Protocols that have been expired for at least six months and for which no continuing review application has been submitted.

- Protocols that have been expired for at least six months and for which a continuing review application was submitted, but the investigator has not responded to the IRB's requests for revisions and/or clarifications within a reasonable timeframe, usually 30 days, and an extension has not been requested.

- Protocols with no expiration date and the Annual PI Assurances was not completed before the anniversary date of the initial approval.

In any of the situations described above, the OHRPP will notify the Principal Investigator of the administrative closure.

Regulations and References

DHHS Regulations:

- Suspension or Termination of IRB Approval - Revised Common Rule 2018: 45 CFR 46.108(a)(4)
- Suspension or Termination of IRB Approval - pre-2018 Common Rule: 45 CFR 46.103(b)
- IRB Review of Research: 45 CFR 46.109
- IRB Records: 45 CFR 46.115

FDA Regulations:

- IRB Functions and Operations: 21 CFR 56.108
- IRB Review of Research: 21 CFR 56.109
- Suspension or Termination of IRB Approval of Research – 21 CFR 56.113

References:

- University of California Office of the President, *Administrative Records Relating to Research: Retention and Disposition Requirements*, June 2010.
- FDA Guidance for Institutional Review Boards (IRBs), Clinical Investigators, and Sponsors: Frequently Asked Questions 1998 (updated October 18, 2010).

Change history:

6/9/2016: Clarified procedure for administrative closure of protocols that have been expired for at least six months.
07/07/2020: Updated to reflect 2018 Revised Common Rule; updated links.
03/15/2021: Removed information re: webIRB.