

**Guidance and Procedures Number: 17**  
**Title: Closure of Human Subjects Research Studies**  
**Date of Last Revision: April 27, 2009**

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**I. Overview**

The following table describes the IRB's Study Close-Out reporting requirements for various types of IRB-approved studies:

Type of IRB Review	When to Report	Reporting Form
<ul style="list-style-type: none"> <li>• Any study that received Full Committee Review at some point in its approval.</li> <li>• Any study reviewed using the expedited procedures.</li> </ul>	Report within 30 days of study close-out.	<a href="#">Final Study Close-Out Report Form</a>
<ul style="list-style-type: none"> <li>• Any Exempt study</li> </ul>	No study close-out report required, but it is strongly recommended that you notify the IRB by mail or e-mail when the study is completed.	<a href="#">Final Study Close-Out Report Form</a> may be used, but is not required

**IMPORTANT NOTE:** *Do not* close-out a study 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

**II. Final Study Close-Out Reporting Form Requirement**

To allow for substantive and meaningful review of research activities at the close of a study, the investigator is required to submit the [Final Study Close-Out Report Form](#) for all studies that

were reviewed and approved by the IRB. This report updates the IRB on the conduct and outcomes of the study, including any risks or problems that may have arisen since the last study renewal and which may need to be disclosed to the study participants or others.

For studies that were certified as exempt, investigators should notify the OPRS IRB office by mail or e-mail that the study is closed. However, investigators may use the Final Study Close-Out Report Form if they wish.

### III. Principal Investigator Responsibilities

- **Use the Final Study Close-Out Report Form:**

1. Submit the Final Study Close-Out Report Form, which is available on the forms page of the [OPRS/Human Research website](#), to the UCLA IRB within 30 days of completion or termination of all research activity, even if the current approval period has expired.

**Note:** This form is not required for studies that were certified as exempt, though it may be used. Otherwise, please send an e-mail or letter to the OPRS IRB office.

2. The Principal Investigator need not wait for the end of the study approval period to submit a Final Report Form to the UCLA IRB.
3. The form 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.

- **Store the research records 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 **HRPP Guidance & Procedures**:

[#2: Determining Which Research Activities Require UCLA OPRS/IRB Review](#),  
[#39: Research Collection, Use and Secondary Analysis of Human Specimens and/or Data](#)  
[#40: Data and Specimen Repositories](#)

- **Continue to provide confidentiality protections** for data and other commitments made, such as the communication of research results or any financial obligations to subjects.
- **If terminating employment** or other association with UCLA, he or she is obligated to either:
  1. Close the study and submit a Final Study Close-Out Report Form to the UCLA IRB  
*or*
  2. 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.

#### IV. IRB Responsibilities and Procedures

- The UCLA IRB will review all Final Study Close-Out Report Forms, and if needed, request further information from the investigator if questions arise.
- The UCLA IRB may close projects without UCLA investigator approval in the following circumstances:
  1. If it is determined that the investigator is no longer affiliated with UCLA.
  2. If the approval period for the research has expired, the study is closed to subject accrual and the IRB has not permitted ongoing research procedures for the safety of continuing subjects.
  3. If the investigator has not responded to the IRB's requests for revisions and/or clarifications within a timeframe determined on a case-by-case basis, based upon the vulnerability of the subject population and the risk of the research. If the IRB approval has not expired, such closure is a termination of IRB approval. Termination of IRB approval is reportable to the appropriate federal department or agency head(s) and institutional officials. See Section V below.
- In any of the situations described above, the IRB office will notify the Principal Investigator of the study closure,

#### V. IRB Reporting Requirements

Termination of IRB approval is reportable to the appropriate federal department or agency head(s) and institutional official (45 CFR 46.103(b)(5) and 21 CFR 56.108(b)) and will be reported according to [HRPP Guidance and Procedures #60: IRB Reporting Procedures for Unanticipated Problems, Noncompliance, Suspension, or Termination](#).

#### Regulations:

45 CFR 46.103  
45 CFR 46.109  
45 CFR 46.115  
21 CFR 56.108  
21 CFR 56.109

#### References:

FDA, *IRB Information Sheets: [Frequently Asked Questions, Questions 19](#)*, September 1988.

University of California Office of the President Research Administration Office Contract and Grant Manual, [Chapter 17, Records/Paperwork Access and Management](#).

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