

**Guidance and Procedures Number: 70**  
**Title: IRB Office Records**  
**Date of Last Revision: February 26, 2009**

**I. IRB Record Documentation**

The IRB shall prepare and maintain adequate paper or electronic documentation of the following:

**A. IRB Applications.**

Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

**B. IRB Minutes.**

Copies of the minutes of all IRB Committee meetings (See [HRPP Guidance & Procedure #69: IRB Meeting Minutes](#)).

**C. Continuing Review.**

Records of continuing review activities. (See [HRPP Guidance & Procedure #10: IRB Review Process—Continuing Review](#)).

**D. Correspondence with Investigators.**

Copies of all correspondence between the IRB and the investigators and key personnel, including substantive email correspondence. (See [HRPP Guidance & Procedure #12: IRB Review Process - Communication of IRB Actions](#)).

**E. IRB Member Rosters.**

A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member (or an immediate family member of the member) and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Rosters will also document scientific/nonscientific status, as well as whether the member is an alternate rather than a primary member. If the member is an alternate, then the roster shall specify for whom the member is an alternate.

**F. IRB Policies and Procedures.**

Written procedures which the IRB will follow (i) for conducting its initial and continuing

review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

**G. New Findings.**

Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, any department or agency head, and OHRP of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with 45 CFR 46 or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval.<sup>1</sup>

**II. Individual Protocol Records**

The IRB will prepare and maintain adequate documentation of IRB activities for each protocol under review. Each protocol is assigned a unique number and documentation is maintained in a separate file. The IRB records are organized to allow reconstruction of a complete history of all IRB actions related to the review and approval of the protocol and clearly indicate what the IRB actually approved.

Records for each protocol will include the following (as applicable):

- A. All materials as described in [HRPP Guidance & Procedure #7: Materials Required for IRB Review](#).
- B. Documentation resulting from any reviews by the expedited procedure. See Section IX of [HRPP Guidance & Procedure #8: IRB Review Process—Expedited Review](#).
- C. Copies of all correspondence between the IRB and the investigators and key personnel, including substantive email communications, as described in [HRPP Guidance & Procedure #12: IRB Review Process - Communication of IRB Actions](#).
- D. Copies of study-related correspondence between the IRB and other entities, including regulatory authorities, other review committees and study subjects.
- E. Any additional documents deemed appropriate on a case-by-case basis.
- F. For those protocols OPRS certifies to be exempt from IRB review, the records will include all materials, including documentation of exemption category, as described in [HRPP Guidance & Procedure #5: Certification of Exemption from IRB Review](#).

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<sup>1</sup> For research subject to FDA regulations, such information would also be reported to the FDA. Serious or continuing non-compliance with 21 CFR 50 and 21 CFR 56 would be reported to the FDA.

### **III. IRB Record Retention**

- A. The IRB will retain all records for at least three years.
- B. The IRB will retain all records regarding an application (regardless of whether it is approved) for at least three years.
- C. For applications that are approved, the IRB will retain records relating to the research for at least three years after completion of the research.
  - 1. Records for all research that has current IRB approval will remain in the locked OPRS file room.
  - 2. Six months to one year following official closure of a protocol, whether the IRB or investigator initiates the closure, records for the protocol will be shipped to a secure off- site storage facility and may be retained indefinitely.

### **IV. Access to Documents**

All records shall be accessible for inspection and copying by authorized representatives of Federal agencies or departments at reasonable times and in a reasonable manner. All other access to records shall be in accordance with applicable law and University policy.

#### **Regulations:**

45 CFR 46.115  
21 CFR 56.115

#### **References:**

OHRP Guidance on Written IRB Procedures – January 15, 2007.  
<http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd107.pdf>

FDA Information Sheets: Frequently Asked Questions: IRB Records.  
<http://www.fda.gov/oc/ohrt/irbs/faqs.html#IRBRecords>

University of California Office of the President, *Contract and Grant Manual*, Chapter 18-272.  
<http://www.ucop.edu/raohome/cgmanual/chap18.html#18-272>

University of California Office of the President, *Administrative Records Relating to Research: Retention and Disposition Requirements*, August 2006.  
[http://www.ucop.edu/research/about/documents/letter\\_matrix\\_august2006\\_000.pdf](http://www.ucop.edu/research/about/documents/letter_matrix_august2006_000.pdf)