Guidance and Procedure: IRB Documentation of Activities

(last updated February 26, 2019)

Overview

The IRB/OHRPP office prepares and maintains records and documents associated with its oversight of research and the administration of the boards.

These materials include, but are not limited to:

- Individual protocol records - IRB/OHRPP applications and supporting documentation
- Records of continuing review and amendment activities
- Copies of all official correspondence between the IRB and the investigators and key personnel
- Copies of the minutes of all IRB meetings.
- Rosters of the current IRB members and their qualifications
- Documentation of agreements to serve as IRB of record, or to rely upon external IRBs
- OHRPP/IRB policies and procedures

See the sections below for details.

Documentation for projects reviewed and approved by the UCLA IRB using webIRB are stored within webIRB.

Documentation for projects reviewed and approved by the UCLA IRB prior to implementation of webIRB are stored in a secure offsite storage facility (including copies of protocol documentation and IRB review communications) and in electronic records in the OHRPP office (including meeting minutes).

webIRB

Investigators and research staff submit research applications (initial, continuing, amendment, and post-approval reports) requiring UCLA IRB/OHRPP review via the online, web-based webIRB application. webIRB is used to complete exempt, expedited, and full committee reviews of research involving human participants.

IRB reviews, OHRPP staff communications of the results of IRB reviews, and investigators responses to the IRB requests are all completed online via webIRB. webIRB stores all correspondence between the study team and the IRB and serves as an electronic filing system for all study documentation.

Individual Protocol Records

The IRB prepares and maintains 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):

- All materials as described in Materials Required for IRB Review.
- Documentation resulting from any reviews by the exempt or expedited procedure.
- Copies of all correspondence between the IRB and the investigators and key personnel, including substantive email communications.
- Copies of study-related correspondence between the IRB and other entities, including regulatory authorities, other review committees and study subjects.
- Any additional documents deemed appropriate on a case-by-case basis.

Minutes

IRB staff will prepare minutes that document the proceedings of each convened IRB meeting. The Board's correspondence to investigators, outlining the basis for requiring changes in or disapproving the research, is included in the minutes, making the IRB correspondence an official part of the minutes.

The minutes of IRB meetings will be written in sufficient detail to show:

- Attendance at the meeting including when an alternate member replaces a primary board member
- The names of IRB members who leave the meeting because of a conflict of interest for the study being discussed or for other reasons but need not be specified
- Attendance for each action including verification that quorum was met and maintained throughout the meeting (majority and nonscientist present)
- For each protocol reviewed, any votes or other actions taken and the vote on that action (including number of members voting for, against, or abstaining, and the names of any abstaining members)
- Verification and summary showing the IRB considered and found all required determinations (45 CFR 46.111) for protocol and informed consent approvals
- The basis for requiring changes in or disapproving research
- A written summary of controverted issues and their resolution
- For initial and continuing review, the approval period
- Summary of any continuing education provided to board members
- Documentation that the IRB was informed of all expedited review activity since the last IRB meeting as required by 45 CFR 46.110(c)

If applicable, the minutes will identify those sections of the webIRB application that include protocol-specific information supporting the following:

- any waiver of informed consent or documentation of consent (45 CFR 46.116(c),(d))
- the inclusion of vulnerable subjects in the research [45 CFR 46 subparts B, C, D]
- determinations that an FDA-regulated device study is either significant risk or non-significant risk [21 CFR 812.2(b)(1)(ii) and 21 CFR 812.66]

If the Board disagrees with any of the above protocol-specific information in the application, that will be documented in the "Committee Discussion" section of the minutes.

Following a convened IRB meeting, the IRB staff prepares minutes consisting of the information described above. The minutes will be distributed for review by the IRB Chair/designee, who will concur or modify them. Finalized minutes are distributed to the convened board. Finalized minutes will be maintained by the IRB in accordance with applicable legal requirements and the data storage policies of the University and the IRB.

Documentation of Expedited Review

For protocols reviewed using expedited review procedures, the designated reviewer(s) designate the applicable expedited review category(ies) in webIRB when they electronically submit their Expedited Review Activity Form.

Expedited reviewers will document the following in the "Additional Comments" section of the Expedited Review Activity Form:

- Any disagreement with the protocol-specific information supporting any waiver of informed consent or documentation of consent or the inclusion of vulnerable subjects in the research.

- For research reviewed and approved after January 21, 2019 under the 2018 Revised Common Rule, written justification why continuing review would enhance protection of research participants, when applicable.

IRB Member Rosters

The UCLA OHRPP will maintain IRB member rosters that include:
- 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 specifies for whom the member is an alternate.

IRB/OHRPP Policies and Procedures

The UCLA OHRPP will maintain written procedures which the IRB will follow for:
- conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;

- 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
- 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.

IRB Record Retention

- The IRB will follow the standards of the University of California Record Retention Schedule.
- The IRB will retain all records for at least three years.
- The IRB will retain all records regarding applications that have been reviewed for at least three years.
- For applications that are approved, the IRB will retain records relating to the research for at least three years after completion of the research.
  - Electronic records for all research with current IRB approval will remain stored in webIRB.
  - Paper records for all research with current IRB approval will remain in a secure off-site storage facility.
  - Six months to one year following official closure of a protocol, whether the IRB or investigator initiates the closure, webIRB records will be archived and may be retained indefinitely. Paper records, if any, for the protocol will be shipped to a secure off-site storage facility and may be retained indefinitely.

Access to Documents

All records are 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.

References and Regulations

DHHS Regulations
- IRB Records: 45 CFR 46.115

FDA Regulations
- IRB Records: 21 CFR 56.115

DOD Regulations
- See OHRPP Checklist: DOD

References
- OHRP Guidance on Written IRB Procedures, July 1, 2011
- FDA Information Sheets: Frequently Asked Questions: IRB Records.
- University of California Office of the President, Contract and Grant Manual, Chapter 18-272.
- University of California Office of the President, Record Retention Schedule

Change history:
8/16/2016: Addition of FDA determinations to *Minutes* section; updated UC Record Retention link.
2/26/2019: Updated description of Expedited reviewers responsibilities under Revised Common Rule