

University of California, San Diego  
Human Research Protections Program  
Institutional Review Board  
Standard Operating Policies and Procedures

Section 1.4  
Documentation and Records Retention

***Policy***

The Institutional Review Board (IRB) Director or his/her designee will prepare and maintain adequate documentation of IRB/Human Research Protections Program (HRPP) activities, including the following:

1. Copies of all original research proposals reviewed; scientific evaluations, if any, that accompany the proposals; investigator brochure, if any; approved consent/permission/assent documents, if any; recruitment materials; applications for study re-approval; study progress reports and interim reports; modifications; adverse event report forms submitted by investigators; documentation of non-compliance; reports of injuries to subjects; and other reports, such as data and safety monitoring reports, unanticipated problems involving risks to participants or others, case histories, if requested, submitted to the studies.
2. Minutes of IRB meetings in sufficient detail to show the following:
  - a) The presence of a quorum throughout the meeting including the presence of one member whose primary concern is in a non-scientific area.
  - b) Attendance at the meetings including those members who are participating through video or teleconference.
  - c) Alternate members attending the meeting and members participating by video or teleconference have received and reviewed all required information.
  - d) The approval of previous meeting minutes.
  - e) Discussion of expedited reviews and determinations.
  - f) Information and advisement of expedited review activity since the last IRB meeting.
  - g) Actions taken by the IRB.
  - h) Separate deliberations for each action.
  - i) The vote on actions including the number of members voting for, against, and abstaining.
  - j) That the informed consent document was reviewed in accordance with applicable criteria and contains all of the required elements if the study is approved. If not approved, a description of the missing elements.
  - k) The justification for waiving any or all of the required elements of informed consent.
  - l) A determination of risk level of investigational devices.
  - m) The names of IRB members who left the meeting because of a real or potential conflict of interest with the proposal under consideration and the

reason for the conflict of interest. The minutes will also state that the IRB member was absent from the meeting room for the discussion and voting (and that the quorum was maintained). Minutes must document the fact that a conflict of interest was the reason for the absence.

- n) The basis for requiring changes in or disapproving research.
  - o) A written summary of the discussion of controverted issues and their resolution.
  - p) Review of additional safeguards to protect vulnerable populations if entered as study subjects.
  - q) The frequency of continuing review of each proposal as determined by the IRB.
  - r) Any significant protocol-specific finding that may alter risk/benefit ratio.
  - s) Decisions regarding privacy including use or disclosure of protected health information, including HIPAA decisions.
  - t) Any significant new finding provided to participant, if reviewed by the IRB.
  - u) Justification for any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document associated with DHHS multi-site studies such as cooperative oncology trials, cardiology trials, and behavioral studies..
  - v) The approval period for initial and continuing review.
3. Copies of draft minutes available to regulatory agencies, VA Research and Development (R&D) Committee and members of internal and external audit teams, as requested, for reviewing IRB deliberations and decisions regarding UPRs and non-compliance. The IRB minutes will be prepared, reviewed, and approved in a timely manner. Minutes will be available as draft within three weeks of the meeting date. Once approved by the IRB, minutes may not be altered by anyone including a higher authority unless “reapproval” is granted by the appropriate IRB, such as if substantive errors are found upon review of approved minutes. Corrections may be made to the minutes, and the “revised” minutes will be provided to the appropriate IRB for review and “reapproval.” Once the final minutes are approved they shall supercede the draft minutes and copies of the draft minutes shall be destroyed and not kept in the ordinary course of business.
  4. Copies of all logs, audit reports, expedited reviews and continuing review activities, as appropriate.
  5. For initial and continuing review of research reviewed using expedited procedure, the specific permissible category, description of action taken by the reviewer, and any findings required under the regulations.
  6. Copies of documentation associated with the justification for exemption determinations.
  7. Copies of all correspondence between the IRB and the investigators.
  8. A roster of regular and alternate IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each regular and alternate member's chief anticipated contribution to the IRB’s deliberations; and any

- employment or other relationship between each member and the IRB and/or institution (e.g., full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant).
9. Copies of SOPPs.
  10. Statements of significant new findings provided to subjects.
  11. Reports of any complaints received by subjects.
  12. Access to current conflict of interest statements from IRB members.
  13. Training for IRB members and staff.
  14. Copies of informed consent/assent documents.
  15. HIPAA authorization forms.

IRB records for a protocol are organized to allow a reconstruction of a complete history of IRB actions related to the review and approval of the research protocol.

Consistent with resources available, the UCSD HRPP will attempt to maintain records indefinitely wherever possible. At a minimum, IRB records will be retained for three years after completion of the research at the site or sites over which the IRB has jurisdiction for the study. In addition in accordance with VA requirements, if a protocol is cancelled without subject enrollment, IRB records are maintained for at least five years after cancellation. Records will be retained longer if required by applicable FDA, DHHS University of California, and UCSD regulations or by the sponsor. These records will be accessible for inspection and copying by authorized representatives of the FDA, VA (VA R&D Committee), OHRP, or other appropriate federal departments or agencies at reasonable times and in a reasonable manner.

The IRB Director, IRB Assistant Directors, and the IRB administrative staff will securely store and maintain these documents as required to protect the privacy and confidentiality of subjects and sponsor data. All electronic access to these files will be limited to authorized individuals.

Access to electronic records in computer systems will be limited by appropriate access control measures, and comply at a minimum with Class C2 level security restrictions (i.e., will require individual user ID and password for system access) as defined by Department of Defense Trusted Computer System Evaluation Criteria. Electronic systems will be backed up and have a data recovery and disaster management plan compliant with the DHHS/NIH Automated Systems Security Handbook. User actions with respect to creating, modifying, and deleting data from automated systems will be logged for audit purposes.

### ***Procedures***

1. IRB Director, IRB Assistant Directors or designated HRPP staff
  - a) Maintain full and complete files for all research studies.
  - b) Maintain roster of regular and alternate IRB members.
  - c) Establish archive method for files that are not in current use but must still be retained.

- d) Establish technical and administrative procedures for maintenance of and access to physical and electronic records systems.

***Applicable Regulations***

[21 CFR 56.103\(a\)](#)

[21 CFR 56.108\(a-b\)](#)

[21 CFR 56.115](#)

[45 CFR 46.103 \(b\)\(4-5\)](#)

[45 CFR 46.108 \(a\)](#)

[45 CFR 46.115](#)

[ICH 3.2.2](#)

***References, Forms and Links***

[DHHS Automated Information Systems Security Program Handbook \(Release 2.0, dated May 1994\).](#)