Series 412 Documentation of Review Activities | Institutional Review Board

Documentation of Review Activities from Series 412 of the Standard Operating Procedures

I. General Requirement

The IRB must maintain accurate and thorough documentation of its review activities. This includes discussions (between IRB members as well as between the IRB and researchers), decisions, and findings. In the case of review conducted by the Convened IRB, that documentation shall be maintained in the form of meeting minutes. In the case of lesser levels of review, detailed files shall be maintained on each protocol.

II. Minutes of the Convened IRB

IRB meeting minutes should be clear about the actions and approvals of the Board. Minutes should specify the modifications required to secure approval and the reason the IRB is requesting the modifications, via a thorough recounting of the contributions that were material to the determinations. Minutes should indicate the motions voted upon by the IRB, and the results of each vote. Minutes should contain the following information:

- Attendance at the meeting
- Actions taken by the IRB and corresponding discussion summaries supporting those actions
- Votes for each protocol as numbers for, against, or abstaining
- Designation of members as Full or Alternate members
- The modifications required by the IRB as well as the basis for requiring them
- The basis for disapproving research, if an action is to be disapproved
- A written summary of the discussion of controverted issues and their resolution
- The names of IRB or EC members who leave the meeting because of a conflict of interest along with the fact that a conflict of interest is the reason for the absence.
- Any pertinent discussions related to the required determinations and protocol-specific findings justifying those determinations for:
  - Waiver or alteration of the consent process;
  - Research involving pregnant women, fetuses, and neonates;
  - Research involving prisoners; and/or
  - Research involving children;

All of which are located in the Reviewer’s Checklist for that protocol. Where there are differences between the Reviewer’s Checklist and the minutes, the minutes override the determinations documented in the Reviewer’s Checklist.

At the next available opportunity (usually, the next regularly scheduled meeting), members of the IRB shall request changes in the draft minutes from the previous meeting if any parts of the minutes require clarification or correction. Controverted issues should be resolved via discussion during the meeting. Minutes stand as approved following the opportunity for review, correction, and clarification in the subsequent IRB meeting where they have been made available. Minutes include the Reviewer’s Checklist for the Primary and Secondary, if applicable, Reviewers who submitted a checklist for review by other members of the IRB prior to the meeting where the protocol is to be considered.

III. Review Documentation Other than Convened IRB Reviews

The IRB delegates many of its review activities to members of the IRB for most items not requiring Convened IRB review. Those review activities must also be thoroughly documented by: using communication features present in Kuali Protocols, accurate and thorough completion of the Reviewer's Checklist for Expedited protocol reviews, maintaining accurate records of discussions and review actions that take place outside of the Kuali Protocols system, and ensuring that written records match the understandings of the parties.

A complete and thorough record for each and every protocol and reliance review process consists of the documentation maintained in the protocol itself as well as the supplemental documentation maintained in USU's cloud-based storage system in a file that clearly identifies the protocol (or reliance agreement) with which it is associated.

IV. Documentation Retention

In order to facilitate a reconstruction of a complete history of any given protocol review and the IRB actions taken during that protocol review and through its completion, the following documents shall be maintained in a secure and confidential file storage system:

1. The protocol submission
2. Records related to the scientific evaluation of the protocol
3. Recruitment plans and materials
4. Documentation related to the informed consent process
5. Status reports submitted by the research team
6. Participant contacts related to the study
7. Records of reportable events
8. Records of continuing review or post approval monitoring activities
9. Amendments to the approved protocol
10. Documentation related to noncompliance
11. Summaries of new findings
12. Correspondence between the IRB and the research team
13. Data & safety monitoring reports
14. Actions taken by the IRB reviewer
15. IRB meeting minutes related to the protocol's review

Documentation related to a protocol's review, approval, and subsequent implementation shall be maintained for three years beyond the date of closure. After that, they may be disposed of, unless sponsor or institutional requirements require a longer time frame for retention.

Records relating to a protocol's review, approval, and subsequent implementation may be subject to release under federal and state laws governing information requests. Such requests are handled by Utah State University's Office of General Counsel, and all requests received by any member of the IRB or HRP staff should be expeditiously forwarded to the appropriate office for disposition.