

Overview

Within the Rutgers University ORSP compliance unit, the IRB support staff maintains documentation of its activities under the direction of the Sponsored Programs Administrator. This documentation includes agenda and minutes of IRB meetings and if applicable, minutes of subcommittee meetings, which report the discussion and decisions of the IRB; the written procedures the IRB follows in its review; and the full protocol file, including correspondence between the IRB and the investigator (for example, progress reports). The compliance unit maintains a current listing of all IRB members, with their credentials, the capacity in which they serve on the board, and their employment or other relationship with Rutgers University.

The following sections describe the procedures for document creation and retention:

- A) [Complete protocol file](#)
- B) [Records retention](#)
- C) [Documentation of discussion and decision](#)

REFERENCES:

AAHRPP II-3. The Research Review Unit maintains adequate documentation of its activities.

A. Complete protocol file

What records relating to protocols does the IRB staff retain?

The ORSP compliance unit maintains a complete file for each protocol submitted for review. The following documentation is retained with the file:

- The proposal, scientific evaluations, if any, that accompany the proposal, approved sample consent document(s), and copy of the grant
- Copies of all correspondence between the reviewer, the IRB Administration and the investigator
- The reviewers' Comment Sheet, which includes at a minimum the approval or disapproval decision and reasons. If the protocol was reviewed as exempt or expedited, the file also includes the criteria used to determine the status
- All records relating to amendments, progress reports and reports of unexpected events
- All records relating to continuing review
- For expedited reviews, a description of the review and any actions taken by the reviewer
- For greater than minimal risk protocols, documentation regarding the face-to-face assessment meeting conducted by the IRB or ORSP staff.

The ORSP compliance unit maintains the complete protocol file for at least three years following the end of the study. The end of the study is defined as follows:

- Subject recruitment is permanently closed
- No further follow-up is being done on subjects who were enrolled
- The data analysis is complete
- The research is published. Note that legally required reporting, such as to courts, is not considered "publication."

REFERENCES:

AAHRPP II-3.A. The RRU maintains a complete set of all materials relevant to review of the research study in each protocol file.

B. Records retention

What is the period for retaining records and keeping them available?

As required by Federal law, the ORSP compliance unit retains meeting minutes and other detailed records described in this Standard for at least 3 years. Records pertaining to human subjects research are retained for three years after the completion of the research. All such records are accessible for authorized representatives, including authorized representatives of the relevant federal Department or Agency, to inspect and copy at reasonable times and in a reasonable manner.

REFERENCES:

AAHRPP II-3.B. The RRU retains required records for a period of time sufficient to meet federal, state, local regulations, sponsor requirements and organizational policies and procedures.

OHRP B (5) In addition, records must be accessible for inspection and copying by HHS at reasonable times and in a reasonable manner.

C. Documentation of discussion and decision

What documentation of IRB discussions and decisions are retained?

Minutes of IRB full-board meetings show the following detail:

- Attendance at the meetings
- Actions taken by the IRB in regard to each item of business brought before it, and in regard to each protocol.
- The vote on the actions taken, including the number of members voting for, against, and abstaining (with the names of abstaining members)
- The basis for requiring changes in or disapproving research
- Written summary of the discussion of controversial issues and their resolution.
- If the regulations require the IRB to make certain determinations (i.e. waivers of consent or research involving children), these determinations and their justifications are documented

Minutes of subcommittee meetings are also written and retained.

REFERENCES:

AAHRPP II-3.C. The IRB documents pertinent discussions and all decisions on research studies and activities.

OHRP A(6) Documentation of expedited review should include specific permissible categories, and documentation of review and action taken by IRB reviewer

OHRP B(2) Meeting minutes document discussion for each protocol, and detailed vote counts (total, for, opposed, abstained)

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