MAYO CLINIC

Institutional Review Board (IRB) Records and Retention Policy

Scope

Applies to personnel in the Mayo Clinic Human Research Protection Program when involved in Human Subjects Research for which the Mayo Clinic IRB is the IRB of Record.

Purpose

To describe the essential records prepared and maintained by Mayo Clinic IRB.

Policy

- Investigators should contact Mayo Clinic Legal Contracts Administration (or their local institutions' equivalent) or the study sponsor to determine the required retention period for study records maintained by study teams.
- IRB records required under 45 CFR 46.115 (Department of Health and Human Services [DHHS]) are retained for at least 3 years, and records relating to research which is conducted shall be retained for at least three years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.
- IRB records required by 21 CFR 56.115 (Food and Drug Administration [FDA]) are retained for at least three years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.
- Records are only destroyed after IRB management approval.

IRB Records and Reports

1. The electronic IRB system (IRBe) is used to prepare, document, maintain and store records related to IRB activities, including, but not limited to, designated expedited reviewer and individual convened IRB member review notes, and minutes of IRB meetings documenting protocol-specific determinations and summarizing discussion of controverted issues and their resolution.
2. Per 45 CFR 46.115:
    a. An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:
        i. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by investigators, and reports of injuries to subjects.
        ii. Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number

of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
   iii. Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in §46.109 (f) (i).
   iv. Copies of all correspondence between the IRB and the investigators.
   v. A list of IRB members in the same detail as described is § 46.108(a) (2).
   vi. Written procedures for the IRB in the same detail as described in § 46.108(a) (3) and (4).
   vii. Statements of significant new findings provided to subjects, as required by § 46.116(c) (5).
   viii. The rationale for an expedited reviewer's determination under §46.110(b) (1) (i) that research appearing on the expedited review list described in §46.110 (a) is more than minimal risk.
  b. Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of this policy, as described in §46.103 (e). The records required by this policy shall be retained for at least 3 years, and records relating to research conducted shall be retained for at least 3 years after completion of the research. The institution or IRB may maintain the records in printed form, or electronically. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.
3. Per 21 CFR 56.115:
  a. An institution, or where appropriate, an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:
   i. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
   ii. Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
   iii. Records of continuing review activities.
   iv. Copies of all correspondence between the IRB and the investigators.
   v. 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 and the institution: for example: full-time employee, part-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.
   vi. Written procedures for the IRB as required by 56.108 (a) and (b).
   vii. Statements of significant new findings provided to subjects, as required by 50.25.
  b. The records required by this regulation shall be retained for at least 3 years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Food and Drug Administration at reasonable times and in a reasonable manner.
  c. The Food and Drug Administration may refuse to consider a clinical investigation in support of an application for a research or marketing permit if the institution or the IRB that reviewed the investigation refuses to allow an inspection under this section.
4. In order to allow a reconstruction of a complete history of IRB actions related to the review and approval of the protocol, the IRB records include copies of the following, as applicable:
  a. Investigator brochure.

   b. Recruitment materials.
   c. Data and safety monitoring reports.
   d. Unanticipated Problems Involving Risks to Participants or Others (UPIRTSO).
   e. Documentation of non-compliance.
5. IRB records for initial and continuing review of research by the expedited procedure include:
   a. The justification for using the expedited procedure.
   b. Justification that the criteria for approval are met.
   c. Actions taken by the reviewer.
   d. Documentation for conducting continuing review of research that otherwise would not require continuing review as described in §46.109 (f) (i).
   e. Rationale for an expedited reviewer's determination under §46.110(b)(1)(i) that research appearing on the expedited review list described in §46.110(a) is more than minimal risk.
   f. Any findings required by laws, regulations, codes, and guidance to be documented.
6. IRB records document the justification for Exempt determinations, as well as assessment of submitted proposals as Not Research or Not Human Subjects Research.
7. Mayo Clinic IRB records, such as IRB rosters, may also be stored in electronic or printed (paper) form. Paper records (before 2007) are stored at the Mayo Clinic North Warehouse.
8. The Policy and Procedure Management System is used to review and publish Mayo Clinic IRB policies and procedures.
9. New research applications that are in the pre-submission state, or are withdrawn, with no IRB review history or activity for one year or more will be deleted from IRBe.

Policy Notes

N/A

Related Procedures

N/A

Related Documents

Retention of and Access to Research Data Policy

Definitions

IRB Electronic System (IRBe): The electronic IRB is a system that is used to prepare, document, maintain and store records related to IRB activities, including, but not limited to, designated expedited reviewer and individual convened IRB member review notes, and minutes of IRB meetings documenting protocol-specific determinations and summarizing discussion of controverted issues and their resolution.

References

45 CFR 46.115

21 CFR 56.115

Owner

Tammy S. Neseth, M.A. on behalf of Office for Human Research Protection

Contact

Michelle K. Daiss, Heidi M. Hanf

Revision History

Date	Synopsis of Change
01/12/2021	Scheduled review. Updated contact and References. Minor edits.
01/21/2019	Updated per 2018 Revised Common Rule requirements, including documenting rationale for conducting continuing review of research when otherwise not required under 45 CFR 46.109(f)(i), and rationale for an expedited reviewer's determination under §46.110(b)(1)(i) that research appearing on the expedited review list described in §46.110(a) is more than minimal risk. Change Owner to T. Neseth.
05/23/2018	Added in per AAHRPP recommendations: • has been revised to reflect that the IRB's electronic system (IRBe) "…is used to prepare document, maintain and store records related to IRB activities, including, but not limited to, designated expedited reviewer and convened IRB member notes, and minutes of the IRB meetings documentation protocol-specific determinations and summarizing discussion of controverted issues and their resolution." • In order to allow a reconstruction of a complete history of IRB actions related to the review and approval of the protocol, what the IRB records will include • IRB records for initial and continuing review of research by the expedited procedure include: Justifications and actions. That the IRB records documents the justification for exempt determinations.
08/15/2017	Updated to new policy template. Editorial changes for consistency with federal regulations.
03/2/2016	Scheduled review - Added "Revision History"
04/03/2014	Scheduled review
07/01/2012	Scheduled review

04/28/2010	Approval for need to establish document: Office for Human Research Protection

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