IRB Records and Retention Policy

Scope

Mayo Clinic Human Research Protection Program

Purpose

This document describes the essential records prepared and maintained by the Mayo Clinic Institutional Review Board.

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 (below) (Department of Health and Human Services) 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 (below) (Food and Drug Administration) 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 Record system (IRBe) is used to prepare, document, maintain and store records related to IRB activities.
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:
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> > (1) 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.
> >
> > (2) 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.
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> > (3) Records of continuing review activities.
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> > (4) Copies of all correspondence between the IRB and the investigators.
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> > (5) A list of IRB members in the same detail as described is § 46.103(b)(3).

(6) Written procedures for the IRB in the same detail as described in § 46.103(b)(4) and § 46.103(b)(5).

(7) Statements of significant new findings provided to subjects, as required by § 46.116(b)(5).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 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.

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:

(1) 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.

(2) 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.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) 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.

(6) Written procedures for the IRB as required by 56.108 (a) and (b).

(7) 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. Mayo Clinic IRB records, such as IRB rosters, may also be stored on the IRB department server or in paper form. Paper records (prior to 2007) are stored at the Mayo Clinic North Warehouse.

5. The Universal Content Management System (UCM) is used to review and publish Mayo Clinic IRB policies and procedures.
6. 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 Procedure(s)

N/A

Related Document(s)

N/A

Definitions

IRBe: IRB Electronic System

References

N/A

Owner

Pam Kwon on behalf of Office for Human Research Protection

Contact

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Revision History

Date	Synopsis of Change
8/15/2017	Updated to new policy template. Editorial changes for consistency with federal regulations.
3/2/2016	Scheduled review - Added "Revision History"