IRB Records and Retention

Policy Content Applies To

Mayo Clinic Human Research Protection Program

Purpose

The purpose of this document is to describe the essential records that are prepared and maintained by the IRB. This document also lists their retention requirements.

Key Terms

IRBe: IRB Electronic System

Policy Statements

The IRB maintains adequate documentation of IRB activities as defined by Federal regulations 45 CFR 46 and 21 CFR 56.

With the exception of research proposals in the 'Pre-Submission' state, the IRB records required by this policy are retained for a minimum of 3 years.

All records are accessible for inspection by authorized representatives of the FDA, OHRP, Department of Defense, AAHRPP, any other authorized agency or internal departments.

Records are only destroyed after IRB management approval.

Investigators should contact Legal Contracts or their sponsors to determine retention of study records.

IRB Records

1. The electronic IRB Record system (IRBe) is used to prepare, document, maintain and store the following records:
    a. Research project proposals, modifications, continuing review reports and reportable events
    b. Scientific evaluations
    c. Biospecimens Committee Minutes and Approvals
    d. Radiation Safety Committee and Radioactive Drug Research Committee Minutes and Approvals
    e. Department Research Committee Minutes and Approvals
    f. Approved consent, assent and HIPAA authorization documents and recruitment materials

g. Reportable events of unanticipated problem involving risk to subjects or others and related review determinations (UPIRTSO)
h. Data and Safety Monitoring Reports
i. OHRP Reporting letters Statements of significant new findings provided to subjects
j. Minutes of convened IRB meetings including attendance; actions taken by the IRB; the vote on these actions; 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.
k. Investigator notifications
l. Correspondence between the IRB and the research project team
m. Emergency Use submission and correspondence
n. IRB member and Investigator's Conflict of Interest records
o. NSR determinations
p. Accreditation approvals and associated records

2. Office Human Research Protection - IRB Rosters
3. IRB records may be found in electronic form in the IRBe system, IRB department server or in paper form that is stored at the Mayo Clinic North Warehouse (paper form prior to 2007).
4. The Mayo Clinic Content Management System (UCM) is used to review and publish IRB policies and procedures.

IRB Record Retention Requirements

The IRB will retain the following:

Three (3) Years at least after completion of research:

- Ancillary Committee Reviews
- Biospecimens Committee Reviews
- Radiation Safety Committee Reviews
- Investigator's Department Approval
- Department of Defense (DoD) Agreements

Ten (10) Years:

- Accreditation approval and support documentation (based on Accreditation approval date)

Indefinitely:

- Convened IRB Meeting Records

    - Meeting Agenda and Minutes
    - Principal Investigator Notifications/Additional Minutes
    - Member Attendance
    - Number of members voting for, against, and abstaining
    - Approved Consent Documents
    - Recruitment Materials
- Convened IRB Membership Rosters
- Reportable Events
    - UPIRTSO determinations/UPIRTSO correspondence with regulatory agencies.
- Investigator Compliance
    - Reports and Correspondence with research project teams related to the research project along with any records of evaluation
- Federalwide Assurance
- Authorization Agreements
- Certificate of Records Destruction (Mayo Clinic)
- IRBe records of research proposals in the "**Closed**" state (system status) where a final report has been submitted and approved by the IRB
- IRBe records of research proposals that have been "**Deferred**" or "**Tabled**".

Delete after 365 days:

- Records of research proposals in the "Pre-Submission" state. New research project applications that are in the pre-submission state with no history or activity
- IRBe records of research proposals in the "Withdrawn" state. New research project applications submitted to the IRB and withdrawn by the research project team prior to any IRB review either by convened IRB or expedited procedure.

Effective Date

March 22, 2014