Records Retention

Purpose

The purpose is to describe the policy for the retention of human subject research records by the Institutional Review Board (IRB) and investigators.

Definition

Records relating to research that is conducted refers to an investigator's records for a particular, approved study. Regulations do not specify the exact content of investigator records, but they typically contain:

- Evidence of human research training
- Approved application forms
- Approved informed consent, parental permission or assent forms (signed versions when applicable)
- Approved advertisements
- Approved instrumentation or questions
- Approved continuing review forms or acknowledged check-in reports
- Site or data access permission letters
- Other report forms (closure, deviation, adverse event, unanticipated problem)
- Clinically-relevant documents, where applicable (e.g., CV, license, certification, etc.)
- IRB correspondence
- Grant applications, where applicable
- Data/results

Research proposals refer to submission packages (i.e. study records) transmitted to the IRB for review and approval prior to implementation.

Policy

Records retained by both the IRB and investigators may be preserved in electronic or printed format and must be accessible for inspection and copying by authorized representatives of the US Department of Health and Human Services or other applicable Federal department of agency at reasonable times and in a reasonable manner [45 CFR 46.115(b)].

IRB Records

The IRB prepares and maintains adequate documentation of IRB activities, including the following:

1. Copies of all research proposals reviewed (including consent/assent forms and ancillary documents), scientific evaluations, if any, that accompany proposals, progress reports submitted by investigators, and reports of injuries to subjects.
2. Minutes of IRB meetings, 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 official continuing review activities, including the rationale for conducting it when not required under the regulations.
4. Copies of all correspondence between the IRB and the investigators.
5. A list of IRB members in detail, as described in applicable regulations.
6. Written procedures for the IRB, as described in applicable regulations.
7. Statements of significant new findings provided to subjects, when appropriate.
8. The rationale for an expedited reviewer's determination that research appearing on the expedited review list is more than minimal risk.
9. Documentation of reliance on any other IRB, specifying the responsibilities that each institution will undertake to ensure compliance with the requirements of this policy.

Under the regulations at 45 CFR part 46.115 and 21 CFR part 56.115(b), the records required by this policy shall be retained **for at least three years**. The IRB retains its

minutes permanently in electronic format. The IRB maintains its study records electronically, and in some cases, also in printed form (e.g., all full and federally-funded studies; expedited studies approved prior to January 21, 2019). After the required retention period, all electronic study records are deleted and all printed copies are shredded. IRBNet purges its IRB records on January 1 of each year following the third anniversary of each project's official closure.

Investigator Records

Records relating to research that is conducted shall be retained **for at least three years** after completion of the research, unless otherwise indicated in the chart below.

Regulation or Entity	Minimum Retention for Investigator Records after Research Completion
Office of Human Research Protections (OHRP) 45 CFR part 46.115(b)	3 Years
Food & Drug Administration (FDA)	2 Years following marketing application approval for indication, OR
Drugs 21 CFR 312.62.c	2 Years after discontinuation of investigation and notification of FDA
Food & Drug Administration (FDA) Medical Devices 21 CFR 820.180	Period of time equivalent to the design & expected life of the device, but no less than 2 years from the manufacturer's date of release for commercial distribution

Food & Drug Administration (FDA) Biologic 21 CFR 600.12(b)	A period beyond the expiration date as is necessary for the individual product, to permit the return of any clinical report of unfavorable reactions, but no less than 5 years after the manufacturer's records have been completed or six months after the latest expiration date for the individual product, whichever is later
Health Insurance Portability & Accountability Act (HIPAA)	6 years
Professional Organization (e.g. APA)	Period described so long as it is not less than applicable regulation(s)
Sponsored Grant or Contract	Period described so long as it is not less than applicable regulation(s); Some sponsors may require that they notify the investigator first.

An investigator must state the approximated retention period, or if it is indefinite (beyond minimum), and the method of destruction (e.g. shredding, burning, tape erasure) in the application form and any consent form(s) or process.

Exemption

Research qualifying for exemption under 45 CFR part 46.104 does not have a minimum retention requirement unless a separate law, regulation or contract requires otherwise. However, investigators of such studies must state the approximated retention period, or if indefinite, and the method of destruction in the application form and any consent form(s) or process. IRBNet purges its exempt records on January 1 of each year following the third anniversary of each project's official closure.

Related Policy

- Informed Consent and Assent

History

11/17/2020: Updated for formatting and inclusion of Revised Common Rule content