

DAIDS
Bethesda, MD USA

POLICY

Storage and Retention of Clinical Research Records

Approval Date: 09 JUN 2016

No.: DWD-POL-CL-006.02

Effective Date: 11 JUL 2016

CHANGE SUMMARY NOTE: This Policy has been reviewed for accuracy and updated to meet 508 compliance guidelines. The new FDA Guidance on Electronic Record Keeping, Electronic Signatures and Electronic Informed and Guidance on Withdrawal of Subjects from: Data Retention and Other Related Issues has been added to the references. This version supersedes version 1.0 dated 09 APR 2009.

1.0 PURPOSE

This policy defines the minimum requirements for retaining clinical research records to ensure compliance with applicable regulations, laws, and policies.

2.0 SCOPE

The policy applies to clinical research records that are generated, stored and retained at National Institute of Allergy and Infectious Disease (NIAID) Division of AIDS (DAIDS) supported and/or sponsored clinical research sites.

3.0 BACKGROUND

All NIAID (DAIDS) supported and/or sponsored clinical research falls under the clinical research record retention requirements found in the Department of Health and Human Services (HHS) regulations for Protection of Human Research Subjects at 45 CFR 46. In addition to these requirements, research subject to U.S. Food and Drug Administration (FDA) regulations must comply with record retention requirements at 21 CFR 312, 21 CFR 56 and 21 CFR 812, as applicable.

U.S. Federal regulations establish the minimum standard for management of records. However, NIAID (DAIDS) supported and/or sponsored research is conducted in domestic and international settings, and may be subject to other applicable laws, regulations, policies, or other requirements (e.g., State, country-specific, and local laws, and sponsor or institutional policies). These additional requirements may extend the record retention time longer than that is required by U.S. regulations. In these circumstances, the most stringent retention period must be followed. Investigators are advised to contact their local Institutional Review Board (IRB)/Ethics Board (EC) or legal counsel at their institution for guidance on additional requirements in their jurisdiction.

NOTE: This policy does not address the Federal requirements for retention of **administrative and financial records related to funding**. This includes supporting documents, statistical records and all other records pertinent to a Health and Human Service Agency award (45 CFR 74.53). For information about records retention policies

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of administrative records related to funding, please refer to the National Institutes of Health (NIH) Grants Policy Statement.

4.0 DEFINITIONS

For definitions, see [DAIDS glossary](#).

5.0 RESPONSIBILITIES

Institution

Under the Terms of the Grant Award, clinical research records are the property of the awardee institution. Records relating to research and IRB/EC records are required by HHS regulations 45 CFR 46.115(b) to be retained for at least three [3] years after completion of the research.

Delegation of institution responsibility

The institution/IRB/EC may delegate responsibility to investigators to retain certain records (e.g., informed consent documents signed by subjects, study data) on behalf of the institution. The institution/IRB/EC should document this designated responsibility in writing and the investigator must retain these records in some form. Investigators should follow the institution's policies and procedures for retaining the records. If investigators who have been designated to retain records on behalf of the institution leave that institution, the investigators and the institution should identify the successor responsible for maintaining those institutional records, either at the original institution or wherever the records are relocated. See the OHRP [Investigator Responsibilities FAQs](#) for additional information.

Investigator

For research also subject to FDA IND regulations at 21 CFR 312.62(c), the Investigator is required to retain research records, case histories, safety reports, final reports and financial disclosure reports and records of drug disposition. Case histories include case report forms and supporting data. (e.g. signed and dated consent forms, medical records, doctors progress notes, nurse's notes, and individual's hospital charts).

For research subject to FDA IDE regulations 21 CFR 812.140(a), the Investigator is required to retain records of case histories and exposure to the device, correspondence with another investigator, sponsor, monitor, or FDA, records of

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receipt, use or disposition of device, and the protocol, as well as deviations from the protocol.

6.0 POLICY

6.1 Records

The clinical research records are the property of the awardee institution.

These records include clinical research records, IRB/EC records, and records related to investigations or proceedings of research misconduct.

Investigators and others retaining records covered under this policy should seek guidance from their institution on whether or not the records are subject to any limitations on their disposal.

6.2 Storage

Clinical research records are stored in a manner that ensures privacy, confidentiality, security, and accessibility when the clinical research is being conducted and after the research is completed. Records can be kept in hardcopy, electronic or other media form. It is permissible to transfer these documents from paper records to electronic formats and to archive this information on available media. Retention of multiple copies of each record is not required. See DAIDS Policy on the Use of Electronic Records.

6.3 Access

Clinical research records must be accessible while the clinical research is being conducted and after the research is completed. These records must be accessible for inspection and copying at reasonable times and in a reasonable manner by authorized representatives of the sponsor(s) (including site monitors), DAIDS, and regulatory agencies. These entities must have access to examine electronic records or certified copies of clinical research records for the purposes of quality assurance reviews, audits, and evaluation of the study safety and progress.

6.4 Record Keeping Requirements for DAIDS supported and/or sponsored clinical research

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- 6.4.1 The institution, or designee, must maintain adequate documentation of all IRB/EC records and clinical research records.
 - 6.4.2 Records must be retained for at least three [3] years after the completion of research.
 - 6.4.3 Records must be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner (45 CFR 46.115 b).
- 6.5 Record Keeping Requirements for studies subject to the U.S. FDA IND regulations
- 6.5.1 The institution or the IRB/EC must maintain adequate documentation of all IRB/EC activities.
 - 6.5.1.1 These records must be retained for at least three [3] years after the completion of research.
 - 6.5.1.2 The IRB/EC records must be accessible for inspection and copying by authorized representatives of the FDA at reasonable times and in a reasonable manner. (21 CFR 56.115(b))
 - 6.5.2 The investigator or designee must retain certain records for research conducted under a U.S. FDA IND (21 CFR 312.62 c):
 - 1. for two [2] years after the date a marketing application is approved for the drug for the indication for which it is being investigated; or,
 - 2. if no application is to be filed or if the application is not approved for such indication, for two [2] years after the investigation is discontinued and FDA is notified.
 - 6.5.3 Records required to be retained under 21 CFR 312.62(c) include clinical research records (including case histories).
- 6.6 Record Keeping Requirements for studies subject to the U.S. FDA IDE regulations
- 6.6.1 The institution or the IRB/EC must maintain adequate documentation of all IRB/EC activities.
 - 6.6.1.1 These records must be retained for at least three [3] years after the completion of research.
 - 6.6.1.2 The IRB/EC records must be accessible for inspection and copying by authorized representatives of the FDA at

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reasonable times and in a reasonable manner. (21 CFR 56.115(b))

6.6.2 The investigator or designee must retain certain records for research conducted under a U.S. FDA IDE (31 CFR 812.140) for two [2] years after:

1. the date on which the investigation is terminated or completed; or,
2. the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.

6.6.3 Records required to be retained under 21 CFR 812.140(a) include clinical research records (including case histories).

6.7 Special Circumstances

6.7.1 When a participant withdraws from DAIDS-supported research

Already-accrued data must be maintained in clinical research records for participants that withdraw their participation from DAIDS-supported clinical research. For further information, see [OHRP Guidance on Withdrawal of Subjects from Research: Data Retention and Other Related Issues](#). In addition, for FDA-regulated studies, see [FDA Guidance for Sponsors, Clinical Investigators, and IRBs: Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials](#).

6.7.2 Health Insurance Portability and Accountability Act (HIPAA)

Generally, clinical records subject to the U.S. Health Insurance Portability and Accountability Act (HIPAA) must be retained for six [6] years from the date of creation or the date when the records were last in effect, whichever is later (45 CFR 164.530 (j)).

Due to the complex nature of the HIPAA regulations, DAIDS advises institutions and investigators that are part of a covered entity and that conduct research as part of treatment, to consult their institution's policies and procedures, HIPAA Privacy and Security officials, and legal counsel

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and/or risk management personnel to determine the records retention requirements under HIPAA. The record retention requirements of 45 CFR 164 (HIPAA) are in addition to HHS and FDA requirements.

6.7.3 Children

In general, the record retention rules for the clinical research records of children vary by jurisdiction. Therefore, investigators and clinical research site personnel are advised to review their institutional policy and U.S. State, local and country-specific laws and regulations to determine the regulatory requirements related to maintaining clinical research records of children.

6.7.4 Research misconduct

Legally, the awardee institution is the entity responsible to retain research misconduct records per the U.S. Public Health Service (PHS) policies at [42 CFR 93](#). Research misconduct records include records related to investigations of research misconduct and records of research misconduct proceedings for DAIDS supported and/or sponsored research. Unless custody has been transferred to HHS, or the Office of Research Integrity has advised the institution in writing that it no longer needs to retain the records, an institution must maintain records of research misconduct proceedings in a secure manner for seven [7] years after completion of the institutions' proceeding or upon the completion of any PHS proceeding involving the research misconduct allegation as provided by law, whichever is later (PHS 42 CFR 93.317 b)).

6.7.5 Collaboration with other Federal department or agencies.

DAIDS may support and/or sponsor clinical research with other Federal departments or agencies, including the [Common Rule agencies](#) that have adopted the Federal Policy for the Protection of Human Research Subjects. When collaborating with another Federal department or agency, the record keeping requirements of 45 CFR 46.115 are the minimum standard that must be met. However, the collaborating department or agency may adopt more protective standards.

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6.7.6 Records of Closing Sites

Each research institution and/or investigator is responsible for retaining study documents even if support has been discontinued and/or the site has been closed.

There may be extenuating circumstances under which DAIDS may take custody of the clinical research records or recommend the transfer of records to another research site. An example of this maybe if a site is closed to research or in the case of resource-limited settings, the site is defunded. In these circumstances, the investigator will work with DAIDS to determine the research record's disposition.

7.0 REFERENCES

[HHS regulations for the Protection of Human Subjects at 45 CFR 46](#)

[HHS Regulations on Security and Privacy \(HIPAA\) at 45 CFR 164](#)

[PHS policies on Research Misconduct at 42 CFR 93](#)

[FDA regulations on Institutional Review Boards at 21 CFR 56](#)

[FDA regulations on Investigational New Drug Application at 21 CFR 312](#)

[FDA regulations on Devices at 21 CFR 800-892](#)

[International Conference on Harmonization \(ICH\) E6 Good Clinical Practice \(GCP\)](#)

[OHRP Guidance on Withdrawal of Subjects from: Data Retention and Other Related Issues](#)

[OHRP Investigator Responsibilities FAQs](#)

[OHRP Federal Policy for the Protection of Human Subjects \("Common Rule"\)](#)

[FDA Guidance for Industry Electronic Source Data in Clinical Investigations](#)

[FDA Guidance for Sponsors, Clinical Investigators, and IRBs: Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials](#)

[NIH Grants Policy Statement, section 16.7.5 Reporting and Record Retention](#)

[Office of Management and Budget, White House Circular A-110](#)

[DAIDS Critical Events Manual](#)

[DAIDS Essential Documents Guidance](#)

[DAIDS Protocol Documents Manual](#)

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8.0 INQUIRIES

Questions and comments regarding this policy may be directed to the [OPCRO Policy Group](#)

9.0 AVAILABILITY

This policy is available electronically on the [Division of AIDS \(DAIDS\) Clinical Research Policies and Standard Procedures](#) webpage.

10.0 APPENDICIES

[Appendix 1 – Storage and Retention of CCR](#) [Flowchart]

[Appendix 2 –Storage and Retention of CCR](#) [Text Only Version]

11.0 APPROVAL

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