

ARCHIVED POLICY

DAIDS Policy on Storage and Retention of Clinical Research Records

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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 Division of AIDS (DAIDS)-funded and/or -sponsored clinical research sites.

3.0 BACKGROUND

This policy conveys the regulatory requirements for clinical research record retention of clinical site operations as mandated by the Department of Health and Human Services (HHS) Federal Policy on Protection of Human Subjects at 45 CFR §46, the Food and Drug Administration (FDA) Investigational New Drug (IND) Application at 21 CFR §312 and the FDA Investigational Device Exemption (IDE) provisions at 21 CFR §812.

U.S. Federal law establishes the minimum standard for management of records. However, DAIDS research is conducted around the world, and is subject to State, local, foreign law, and funding or institutional policies. Investigators are advised to contact their local Institutional Review Board (IRB)/Ethics Board (EC) or legal counsel at their institution for guidance about the additional requirements of local regulations, laws and institutional policies.

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.¹ For information about records retention policies of administrative records related to funding, please refer to the National Institutes of Health (NIH) Grants Policy Statement at:

http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part8.htm

¹ HHS 45 CFR §74.53

4.0 DEFINITIONS

Required Documents:

Clinical research records: The records that describe or record the methods, conduct, and/or results of a clinical trial, and the actions taken.² Examples of these documents may include, but are not limited to, all essential and source documents listed in the DAIDS Policy on Essential Documents Appendix 1³. The records may be in any form, including written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms.

Clinical research records include:

Case history: A detailed account of relevant information gathered about a subject. This information includes the case report forms and supporting data including, for example, signed and dated consent forms and medical records, including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes, as required for both IND and IDE clinical trials.⁴

Essential documents: Documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.⁵ See listing of documents at DAIDS Policy on Essential Documents Recordkeeping Requirements Appendix 1, No.: [DWD POL-RA-03.00A1](#)

Source documents: The original documents, data, and records containing clinical findings, observations, or other activities in a clinical research study that allows the reconstruction and evaluation of the study. Examples of source documents include: hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or

² ICH E6 §1.22

³ <http://www3.niaid.nih.gov/research/resources/DAIDSCLinRsrch/Regulatory/>

⁴ FDA 21 CFR 312.62(b) & 21 CFR §812.140(a)(3)

⁵ ICH E6 §1.23

magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial.⁶

IRB/EC records: The documentation maintained by the institution, or when appropriate, an IRB/EC, of IRB/EC activities, as required by HHS 45 CFR §§46.103(b)(3-5) and §46.115.

Research misconduct: Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.⁷

Research misconduct records include:

Records related to investigations of research misconduct: The records containing data or results that embody the facts resulting from scientific inquiry. These include research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to HHS or an institutional official by a respondent in the course of the research misconduct proceeding.⁸

Records of research misconduct proceedings: Records showing the actions that an institution has taken related to alleged research misconduct⁹. Examples of these records include the records that the institution secures for the research misconduct proceedings, except for duplicate records; the documentation of the determination of irrelevant or duplicate records; the inquiry report and final documents produced in the course of preparing that report, including documentation of any decision not to investigate; the investigation report and all records in support of that report,

⁶ ICH E6 §1.52

⁷ PHS 42 CFR §93.103

⁸ PHS 42 CFR §93.224

⁹ PHS 42 CFR §93.223

including the recordings
or transcriptions on each interview conducted.¹⁰

Other:

Completion of a clinical research study: Occurs when the following activities are finished:

- all research-related interventions or interactions with human subjects (e.g. when all subjects are off study);
- all protocol-required data collection of identifiable private information described in the IRB/EC-approved research plan;
- all analysis of identifiable private information described in the IRB/EC-approved research plan;
- primary analysis of either identifiable private or deidentified information.

For additional definitions see DAIDS Glossary:

<http://www3.niaid.nih.gov/research/resources/DAIDSCLinRsrch/Glossary.htm>

5.0 RESPONSIBILITIES

Institution

Under the HHS regulations¹¹, *the Institution* is required to retain IRB/EC records and records relating to research 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

¹⁰ PHS 42 CFR §93.317(a)

¹¹ HHS 45 CFR §46.115(b)

the successor responsible for maintaining those institutional records, either at the original institution or wherever the records are relocated.¹²

Investigator

Under the FDA IND regulations¹³, *the Investigator* is required to retain records of case histories and disposition of drug for a period of two [2] years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or if the application is not approved for such indication, until two [2] years aft the investigation is discontinued and FDA is notified.

Under the FDA IDE regulations¹⁴, *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 receipt, use or disposition of a device, and the protocol, as well as deviations from the protocol for a period of two [2] years after: the date on which the investigation is terminated or completed; or, 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.

6.0 POLICY

6.1 Records

The clinical research records are the property of the awardee institution¹⁵.

These records include clinical research records, IRB/EC records, and records related to investigations or proceedings of research misconduct, as defined in Section 4.0 of this policy.

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.

¹² <http://www.hhs.gov/ohrp/investigatefaq.html#q11>

¹³ FDA 21 CFR §312.62(c)

¹⁴ FDA 21 CFR §812.140(a)

¹⁵ http://grants.nih.gov/grants/policy/nihgps_2001/part_ii_a_6.htm

6.2. Storage

Clinical research records are stored in a manner that ensures privacy, confidentiality, security, and accessibility during the clinical research and after the research/trial 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.

6.3 Record Keeping Requirements for DAIDS funded and/or sponsored clinical research

The institution, or designee, must maintain adequate documentation of all IRB/EC records and clinical research records as defined in Section 4.0 Definitions of this document.

6.3.1 Records must be retained for at least three [3] years after the completion of research.

6.3.2 Records must be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.¹⁶

6.4 Record Keeping Requirements for studies subject to the U.S. FDA IND regulations

6.4.1 The investigator or designee must retain certain records for research conducted under a U.S. FDA IND¹⁷:

6.4.1.1 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,

6.4.1.2 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.

¹⁶ HHS 45 CFR §46.115(b)

¹⁷ FDA 21 CFR §312.62(c)

6.4.1.3 records required to be retained under 21 CFR §312.62(c) include clinical research records (including case histories) (See §4.0 definitions).

6.5 Record Keeping Requirements for studies subject to the U.S. FDA IDE regulations

6.5.1 The investigator or designee must retain certain records for research conducted under a U.S. FDA IDE¹⁸ for two [2] years after:

6.5.1.1 the date on which the investigation is terminated or completed;
or,

6.5.1.2 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.

6.5.1.3 records required to be retained under 21 CFR §812.140(a) include clinical research records (including case histories) (See §4.0 Definitions).

6.6 Special Circumstance

6.6.1 Treatment Use of an Investigational New Drug/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.¹⁹

HIPAA only applies to U.S. institutions. Because the record keeping regulations of HIPAA are complex, 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 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 FDA and HHS requirements.

¹⁸ FDA 31 CFR §812.140

¹⁹ HHS 45 CFR §164.530 (j)

6.5.2 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 and/or regional/country-specific regulations and/or laws to determine the regulatory requirements related to maintaining clinical research records of children.

6.5.3 Research misconduct

Legally, the institution is the entity responsible for DAIDS funded and/or sponsored research. It has a continuing obligation to ensure that it maintains adequate records related to investigations of research misconduct and research misconduct proceeding.²⁰ 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 U.S. Public Health Service (PHS) proceeding involving the research misconduct allegation as provided by law, whichever is later.²¹

6.5.4 Collaboration with other Federal department or agencies.

DAIDS may fund and/or sponsor clinical research or clinical trials with other Federal departments or agencies, including the Common Rule agencies²² 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

²⁰ PHS 42 CFR §93 Research misconduct

²¹ PHS 42 CFR §93.317(b) Maintenance of record

²² Departments of Agriculture (7 CFR Part 1c), Commerce (15 CFR Part 27), Defense (32 CFR Part 219), Education (34 CFR Part 97), Energy (10 CFR Part 745), Housing and Urban Development (24 CFR Part 60), Justice (28 CFR Part 46), Transportation (49 CFR Part 11), and Veterans Affairs (38 CFR Part 16); National Aeronautics and Space Administration (14 CFR Part 1230), Consumer Product Safety Commission (16 CFR Part 1028), and National Science Foundation (45 CFR Part 690); International Development Cooperation-Agency for International Development (22 CFR Part 225), and Environmental Protection (40 CFR Part 26)

must be met. However, the collaborating department or agency may have adopted more protective standards.²³

6.5.6 Records of Closing Sites

In general, each research institution and/or investigator is responsible for retaining study documents even if funding has been discontinued and/or the site has been closed.

When a research site is closing, the investigator will work with DAIDS to determine if any portion of the clinical research records will be transferred to DAIDS or transferred to another research site.

7.0 REFERENCES

21 CFR §312.57, *Record Keeping and Record Retention*

21 CFR §312.62, *General Responsibilities of Investigators*

42 CFR §93, *Public Health Service Policies on Research Misconduct*

45 CFR §46.115, *IRB records*

45 CFR §164, *Privacy and Security of Protected Health Information (HIPAA)*

DAIDS Policy Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials,

<http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/Regulatory/>

DAIDS Policy Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials,

<http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/ClinicalSite.htm>

Human Research Questions & Answers, Office for Human Research Protections (OHRP) "What records should investigators keep, and for how long?",

<http://www.hhs.gov/ohrp/investigatefaq.html#q11>

NIH Grants Policy Statement, part II,

http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part4.htm

Office for Human Research Protections (OHRP) IRB Guidebook

http://www.hhs.gov/ohrp/irb/irb_guidebook.htm

²³ http://www.hhs.gov/ohrp/irb/irb_guidebook.htm

Office of Management and Budget, White House Circular A-110,
<http://www.whitehouse.gov/omb/circulars/a110/a110.html#53>

8.0 INQUIRIES

Questions and comments regarding this policy may be directed to the OPCRO Policy Group at: NIAIDOPCROPOLICYGROUP@mail.nih.gov

9.0 AVAILABILITY

This policy is available electronically at the following URL:
<http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/Default.htm>

10.0 CHANGE SUMMARY

This policy is the first version. It does not supersede any other version.

11.0 APPENDICIES

Appendix 1 – Storage and Retention of CCR [Flowchart]

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

12.0 APPROVAL

/Richard Hafner, MD/
Richard Hafner