

Appendix

Storage and Retention of Clinical Research Records

Approval Date: 09 APR 2009

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LOGICAL PATHWAYS IN DETERMINING IF A “DOCUMENT” IS A CLINICAL RESEARCH RECORD, AND FOR HOW LONG TO RETAIN IT.

Important Clarification Note Number 1:

From this point forward, the Division of Acquired Immunodeficiency Syndrome is abbreviated as Division of AIDS.

This appendix, as it is for the Storage and Retention of Clinical Records Policy and the Storage and Retention of Clinical Records Flowchart, applies to clinical research records that are generated, stored and retained at the Division of AIDS funded and, or sponsored clinical research sites.

This appendix is the accessible version of Storage and Retention of Clinical Records Flowchart, a visual flowchart, in which content is not accessible. Thus, the following pathways are discerned from that flowchart and describe, using simple and logical questions, the process for determining if a “document” is, or is not a clinical research record.

Additionally, these pathways give guidance on the length of time a document or a clinical research record should be retained. This guidance is based on the applicable laws, regulations, policy, or other requirements for each document or clinical research record.

Important Clarification Note Number 2:

For complete information on clinical research records for the Division of AIDS, go to the internet web link

<http://daidsportal.niaid.nih.gov/C13/DAIDS%20Home%20Page/default.aspx> ; where, the Division of AIDS Policy "Requirements for Essential Documents at Clinical Research Sites Conducting the Division of AIDS Funded and, or Sponsored Clinical Trials", and its appendix "Essential Documents Recordkeeping Requirements" can be found.

Pathway Number 1:

Is this ‘document’ a clinical research record?

Yes, it is a clinical research record.

Is this clinical research record part of a United States Food and Drug Administration, Investigation New Drug Application Study, also abbreviated as U.S. FDA IND study?

Yes, it is part of an US FDA IND study.

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Then, retain clinical research record for two years after the FDA Approval or Disapproval, IND Withdrawal, or Study Discontinuation as per the U.S. FDA 21 Code of Federal Regulations §312.62 c.

In addition to Pathway Number 1, the following question should be considered:

Is this U.S. FDA IND study related clinical research record, subject to any other U.S. Federal or State, country or local laws, regulations, policy, or other requirements?
If the answer is yes; then, the strictest of any applicable laws, regulations, policy, or other requirements for record retention of clinical research records must be followed.

Pathway Number 2:

Is this 'document' a clinical research record?

Yes, it is a clinical research record.

Is this clinical research record part of an U.S. FDA IND study?

No, it is not part of an U.S. FDA IND study.

Then, retain clinical research record for at least three years after completion of research as per the Health and Human Services 45 Code of Federal Regulations §46.115 b.

In addition to Pathway Number 2, the following question should be considered:

Is this clinical research record subject to any other U.S. Federal or State, country or local laws, regulations, policy, or other requirements?

If the answer is yes; then, the strictest of any applicable laws, regulations, policy, or other requirements for record retention of clinical research records must be followed.

Important Clarification Note Number 3:

For definition of completion of research for the Division of AIDS clinical research studies, please refer back to the actual language in the body of the policy.

Pathway Number 3:

Is this 'document' a clinical research record?

No, it is not a clinical research record.

DAIDS
Bethesda, MD USA

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Is this 'document' subject to any other U.S. Federal or State, country or local laws, regulations, policy, or other requirements?

Yes, it is subject to other applicable laws, regulations, policy, or other requirements for record retention. Then, the strictest of any of them must be followed.

Pathway Number 4:

Is this 'document' a clinical research record?

No, it is not a clinical research record.

Is this 'document' subject to any other U.S. Federal or State, country or local laws, regulations, policy, or other requirements?

No, it is not. Then, any applicable other internal policy or procedure of the institution, if available, for record retention must be followed.