

FAQs Clinical Record Retention

What is a clinical research record?

DAIDS defines clinical research records as the essential and source documents found on the list in the DAIDS Policy on Essential Documents Appendix 1¹; and records, in any form (including, but not limited to, written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, and the actions taken².

Who owns the clinical research records that were conducted with support from NIH?

Unlike Pharmaceutical-sponsored research, under the Terms of the NIH Award, the awardee institution retains ownership of the clinical research records that were conducted with NIH support.

Do I have to keep my clinical research records?

Yes. The regulations mandate that records related to the research must be retained for a specified number of years, regardless of status of the grant. The length of time that the records must be retained depends on the type of research that was conducted, if the records are subject to the HIPAA rule, if there are research misconduct proceedings associated with the research, and other pertinent federal, state, and local laws and regulations.

Do I have to keep the hardcopy of my clinical research records?

Records may be preserved in hardcopy, electronic or other media form³ since there is no regulatory requirement that clinical research records be retained in a certain type of format. However, investigators should check with their institution for institutional policies and procedures pertaining to record retention.

How long must I keep the clinical research records of a study that is not being conducted under an IND?

All records relating to research that is conducted must be retained for at least three years after completion of the research⁴. The three-year time period begins when the individual institution's engagement in the human subjects research activity ends.

How do I know when my research has been completed?

Human subject research activities are considered completed once all research-related interventions and interactions with human subjects have been completed, all data collection and analysis of

¹ <http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/PDF/EssentialDocAppndx.pdf>

² ICH E6 § 1.22

³ <http://www.hhs.gov/ohrp/investigatefaq.html#q11>

⁴ 45 CFR §46.115(b)

identifiable private information described in the IRB-approved research plan have been finished⁵, and primary analysis of either identifiable private or deidentified information is completed.

My institution requires that I retain research records for five years after the completion of the research activities, which is longer than the HHS regulatory requirement. Which set of requirements should I follow?

For clinical research studies not conducted under an IND, where institutional policy, U.S. state and/or regional/country specific regulations and/or laws are more protective and/or restrictive than Federal law, DAIDS advises institutions and investigators to consult legal counsel and/or regulatory advisors to determine the records retention requirements.

For example, the HHS regulations requires that IRB records be retained for at least three [3] years after the conclusion of research; however, an institutional policy may require that IRB records be retained for five [5] years. In this example, the institutional policy may govern the retention time requirements.

What is the retention period of clinical research records for a study was conducted under an IND?

The clinical research records must be retained for a minimum of two years after the marketing application is approved for the drug for the indication for which it was being investigated. Alternatively, if no application will be filed or if the application is not approved for the requested indication, the records must be retained for a minimum of two years after the investigation is discontinued and FDA is notified.⁶

Is there a DAIDS-authorized list of clinical research studies for which the clinical research records policy is no longer applicable?

Yes, the DAIDS Regulatory Compliance Center (RCC) maintains a list of DAIDS- funded and/or - sponsored clinical research studies for which the HHS and FDA regulations for record retention no longer apply. This list is available on the RCC website in the password protected area. The regulatory requirements and DAIDS policy for retention of clinical research records remain applicable for clinical research studies that are not on the RCC list.

Investigators should consult their local IRB/REC or legal counsel at their institution to determine if there are other applicable laws, regulations, policies or requirements for record retention of their clinical research records. Investigators may follow their institutions policies and procedures for record disposition of clinical research records that have no ongoing requirements for record retention.

Do I need to keep a copy of the CLIA, CAP, or other laboratory certificates within my clinical research records?

⁵ <http://www.hhs.gov/ohrp/investigatefaq.html#q10>

⁶ 21 CFR §312.62(c)

Yes, the laboratory certificates need to be retained as essential documents with the clinical research records, unless the certificates are stored elsewhere and are easily available and accessible.

The laboratory that is providing results used to clinically manage a subject is located outside the United States (U.S.). What documentation must be retained for this laboratory as part of my clinical research records?

The documents/records that must be retained in a laboratory as part of clinical research records are those that would allow the reconstruction of a study. These include records related to: personnel training and competency, specimen tracking forms/laboratory requisitions, chain of custody, laboratory reports, instrument validation and preventative maintenance, quality control/quality assurance and proficiency testing, reference ranges, raw data source documentation and policies/procedures pertinent to the conduct of the study. The complete list is described in the DAIDS Guidelines for Good Clinical Laboratory Practice Standards, issued 30 June 2008.

Do I need to keep SOPs and site MOPs for my research studies?

Yes, procedural manuals that are referenced in the protocol need to be retained for studies that are conducted under an IND. It is acceptable for someone other than the investigator to keep all versions of the manuals that were applicable during the course of the research, if the manuals are easily available and accessible. .

Once a study is completed, there is no regulatory requirement to keep procedural manuals for studies that were not conducted under an IND.

Do I need to keep a copy of the DAIDS network policy manual as part of the clinical research records?

Yes, for studies that were conducted under an IND, all procedure manuals that were referenced in a protocol must be available as part of the clinical research records. However, it is okay for another entity within or outside the institution to retain all versions of the manual that were applicable during the conduct of the research project, as long as the manual is easily available and accessible.

Must I keep the documentation pertaining to Community Advisory Board (CAB) consultations as part of my clinical research records?

No, CAB consultations are not included in the essential documents that must be retained as part of the clinical research records. However, investigators may want to contact their business official or DAIDS Grants Management person to inquire what CAB documentation should be retained under the terms of their award.

Do I need to keep quality assurance (QA) records that document the steps that were taken to assess the data integrity of my clinical research records?

No, QA records are not on the list of essential documents that must be retained as part of the clinical research records.