

Record Retention

Entity	What to maintain	How	How long
<p><u>DHHS</u> <u>(Department of Health and Human Services)</u></p> <p>IRB Records</p> <p>45 CFR 46.115</p>	<p>Copies of research proposals reviewed and any respective scientific evaluations, approved sample consent forms, Investigator progress reports, and subject injury reports.</p> <p>IRB Meeting Minutes detail inclusive of attendance, actions taken, tallies of voting, logic for requiring changes in or disapproving research, and a written summary of discussions of controverted issues and their resolution.</p> <p>Records of continuing review activities, correspondence between the IRB and Investigators, a list of IRB members per 46.108(a)(2), written procedures for the IRB, and statements of significant new findings provided to subjects.</p> <p>Added in 2018: Rationale for an expedited reviewer’s determination under §46.110(b)(1)(i) that research appearing on the expedited review list described in §46.110(a) is more than minimal risk.</p> <p>Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of this policy, as described in §46.103(e).</p>	<p>Format – The Institution or IRB may maintain the records in printed form, or electronically.</p> <p>All records shall be accessible for inspection and copying by authorized representatives of the Federal department or agency at reasonable times and in a reasonable manner.</p> <p>Retention of multiple copies of each record is not required.</p>	<p>Three (3) years after completion of research.</p>
<p><u>FDA (Food and Drug Administration)</u></p> <p>IRB Records</p> <p>21 CFR 56.115</p>	<p>Documentation of IRB activities.</p> <p>Copies of research proposals reviewed and any respective scientific evaluations, approved sample consent forms, Investigator progress reports, and subject injury reports.</p> <p>IRB Meeting Minutes detail inclusive of attendance, actions taken, tallies of voting, logic for requiring changes in or disapproving research, and a written summary of discussions of controverted issues and their resolution.</p> <p>Records of continuing review activities, correspondence between the IRB and Investigators, a list of IRB members per 46.108(a)(2), written procedures for the IRB, and statements of significant new findings provided to subjects.</p>	<p>Format - Silent (Default to DHHS requirements).</p> <p>Must be accessible for inspection and copying by authorized representatives of the Food and Drug Administration at reasonable times and in a reasonable manner.</p>	<p>The records required by this regulation shall be retained for at least 3 years after completion of the research.</p>

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<p data-bbox="117 646 327 743"><u>FDA (Food and Drug Administration)</u></p> <p data-bbox="117 776 327 841">Investigational Devices</p> <p data-bbox="107 878 327 911">21 CFR 812.140</p>	<p data-bbox="380 180 1094 245">Accurate, complete, and current records relating to the participation in an investigation.</p> <p data-bbox="380 266 1121 331">All correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required reports.</p> <p data-bbox="380 352 1209 547">Records of receipt, use or disposition of a device that relate to: The type and quantity of the device, the dates of its receipt, and the batch number or code mark. The names of all persons who received, used, or disposed of each device. Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of.</p> <p data-bbox="380 568 1209 1234">Records of each subject's case history and exposure to the device. Case histories include 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. Such records shall include: Documents evidencing informed consent and, for any use of a device by the investigator without informed consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent. The case history for each individual shall document that informed consent was obtained prior to participation in the study. All relevant observations, including records concerning adverse device effects (whether anticipated or unanticipated), information and data on the condition of each subject upon entering, and during the course of, the investigation, including information about relevant previous medical history and the results of all diagnostic tests. A record of the exposure of each subject to the investigational device, including the date and time of each use, and any other therapy.</p> <p data-bbox="380 1255 1209 1320">The protocol, with documents showing the dates of and reasons for each deviation from the protocol.</p> <p data-bbox="380 1341 1121 1438">Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigations or a particular investigation.</p>	<p data-bbox="1245 639 1587 704">Format - Silent (Default to DHHS requirements).</p> <p data-bbox="1245 742 1598 979">Must be accessible for inspection and copying by authorized representatives of the Food and Drug Administration at reasonable times and in a reasonable manner.</p>	<p data-bbox="1652 358 1976 586">An investigator shall maintain the records required during the investigation and for a period of 2 years after the latter of the following two dates:</p> <p data-bbox="1652 623 1982 721">The date on which the investigation is terminated or completed.</p> <p data-bbox="1652 758 1703 790">OR</p> <p data-bbox="1652 828 1986 1260">The date that the records are no longer required for purposes of supporting a premarket approval application, a notice of completion of a product development protocol, a humanitarian device exemption application, a premarket notification submission, or a request for De Novo classification.</p>

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<p><u>FDA (Food and Drug Administration)</u></p> <p>Investigational Drugs</p> <p>21 CFR 312.62</p>	<p>Records of the disposition of the drug, including dates, quantity, and use by subjects.</p> <p>Adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation.</p> <p>Case histories include 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.</p> <p>The case history for each individual shall document that informed consent was obtained prior to participation in the study.</p>	<p>Format - Silent (Default to DHHS requirements).</p> <p>Must be accessible for inspection and copying by authorized representatives of the Food and Drug Administration at reasonable times and in a reasonable manner.</p>	<p>For 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated.</p> <p>OR</p> <p>If no application is to be filed OR if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.</p>

Record Retention

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<p data-bbox="107 662 331 792"><u>GCP E6R2 – Guidance for Industry (Good Clinical Practice)</u></p> <p data-bbox="142 829 296 894">Essential Documents</p> <p data-bbox="92 927 348 992">Sections 4.9.0, 4-5, 8.1</p>	<p data-bbox="380 391 1163 488">Trial documents as specified in Essential Documents for the Conduct of a Clinical Trial and as required by applicable regulatory requirement(s).</p> <p data-bbox="380 529 1167 659">The sponsor should inform the investigator(s)/institution(s) in writing of the need for record retention and should notify the investigator(s)/institution(s) in writing when the trial related records are no longer needed.</p> <p data-bbox="380 699 1209 894">The minimum list of essential documents that has been developed follows. The various documents are grouped in three sections according to the stage of the trial during which they will normally be generated: (1) before the clinical phase of the trial commences, (2) during the clinical conduct of the trial, and (3) after completion or termination of the trial.</p> <p data-bbox="380 935 1209 1130">The sponsor and investigator/institution should maintain a record of the location(s) of their respective essential documents including source documents. The storage system used during the trial and for archiving (irrespective of the type of media used) should provide for document identification, version history, search, and retrieval.</p> <p data-bbox="380 1170 1209 1268">The investigator/institution should have control of all essential documents and records generated by the investigator/institution before, during, and after the trial.</p>	<p data-bbox="1245 545 1587 708">Recorded, handled, and stored in a way that allows accurate reporting, interpretation, and verification.</p> <p data-bbox="1245 748 1608 976">When a copy is used to replace an original document (e.g., source documents, CRF), the copy should fulfill the requirements for certified copies.</p> <p data-bbox="1245 1016 1608 1114">Accurate, legible, contemporaneous, original, attributable, and complete.</p>	<p data-bbox="1654 180 1976 375">The investigator/institution should take measures to prevent accidental or premature destruction of essential documents.</p> <p data-bbox="1654 399 1976 732">Essential documents should be retained until at least 2-years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region.</p> <p data-bbox="1654 756 1703 781">OR</p> <p data-bbox="1654 805 1976 967">At least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product.</p> <p data-bbox="1654 992 1976 1252">These documents should be retained for a longer period, however, if required by the applicable regulatory requirements or by an agreement with the sponsor.</p> <p data-bbox="1654 1276 1976 1471">It is the responsibility of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained.</p>

Record Retention

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<p><u>UH</u></p> <p>UH Policy GM- 1, Records Management</p>	<p>All records are maintained and retained in accordance with federal and Ohio laws and regulations.</p>	<p>Electronic must be backed-up On site or offsite with approved vender.</p>	<p>Research papers, published – Permanent</p> <p>Human experimentation records – 30 years</p> <p>IRB documentation – 3 years</p> <p>Research Reports – 10 years</p>
<p><u>Sponsor</u></p>	<p>Check Clinical Trials Agreement</p>	<p>Check Clinical Trials Agreement</p>	<p>Check Clinical Trials Agreement</p>
Entity	Details		
<p><u>GCP E6R2 – Guidance for Industry (Good Clinical Practice)</u></p> <p>IRB Documents</p> <p>Section 3.4</p>	<p>The IRB/IEC should retain all relevant records (e.g., written procedures, membership lists, lists of occupations/affiliations of members, submitted documents, minutes of meetings, and correspondence) for a period of at least 3 years after completion of the trial and make them available upon request from the regulatory authority(ies).</p> <p>The IRB/IEC may be asked by investigators, sponsors or regulatory authorities to provide its written procedures and membership lists.</p>		

Entity	Details
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Record Retention

DHHS
(Department of
Health and Human
Services)

HHS Awards

45 CFR 75.361
45 CFR 75.364

Retention requirements for records.

Financial records, supporting documents, statistical records, and all other non-Federal entity records pertinent to a Federal award must be retained for a period of three years from the date of submission of the final expenditure report or, for Federal awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report, respectively, as reported to the HHS awarding agency or pass-through entity in the case of a sub-recipient. HHS awarding agencies and pass-through entities must not impose any other record retention requirements upon non-Federal entities.

The only exceptions are the following:

- (a) If any litigation, claim, or audit is started before the expiration of the 3-year period, the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken.
- (b) When the non-Federal entity is notified in writing by the HHS awarding agency, cognizant agency for audit, oversight agency for audit, cognizant agency for indirect costs, or pass-through entity to extend the retention period.
- (c) Records for real property and equipment acquired with Federal funds must be retained for 3 years after final disposition.
- (d) When records are transferred to or maintained by the HHS awarding agency or pass-through entity, the 3-year retention requirement is not applicable to the non-Federal entity.
- (e) Records for program income transactions after the period of performance. In some cases, recipients must report program income after the period of performance. Where there is such a requirement, the retention period for the records pertaining to the earning of the program income starts from the end of the non-Federal entity's fiscal year in which the program income is earned.
- (f) Indirect cost rate proposals and cost allocations plans. This paragraph applies to the following types of documents and their supporting records: Indirect cost rate computations or proposals, cost allocation plans, and any similar accounting computations of the rate at which a particular group of costs is chargeable (such as computer usage chargeback rates or composite fringe benefit rates).
 - (1) If submitted for negotiation. If the proposal, plan, or other computation is required to be submitted to the Federal Government (or to the pass-through entity) to form the basis for negotiation of the rate, then the 3-year retention period for its supporting records starts from the date of such submission.
 - (2) If not submitted for negotiation. If the proposal, plan, or other computation is not required to be submitted to the Federal Government (or to the pass-through entity) for negotiation purposes, then the 3-year retention period for the proposal, plan, or computation and its supporting records starts from the end of the fiscal year (or other accounting period) covered by the proposal, plan, or other computation.

Access to records.

- (a) Records of non-Federal entities. The HHS awarding agency, Inspectors General, the Comptroller General of the United States, and the pass-through entity, or any of their authorized representatives, must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts. The right also includes timely and reasonable access to the non-Federal entity's personnel for the purpose of interview and discussion related to such documents.
- (b) Only under extraordinary and rare circumstances would such access include review of the true name of victims of a crime. Routine monitoring cannot be considered extraordinary and rare circumstances that would necessitate access to this information. When access to the true name of victims of a crime is necessary, appropriate steps to protect this sensitive information must be taken by both the non-Federal entity and the HHS awarding agency. Any such access, other than under a court order or subpoena pursuant to a bona fide confidential investigation, must be approved by the head of the HHS awarding agency or delegate.
- (c) Expiration of right of access. The rights of access in this section are not limited to the required retention period but last as long as the records are retained. HHS awarding agencies and pass-through entities must not impose any other access requirements upon non-Federal entities.

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<p data-bbox="132 427 306 589"><u>NIH (National Institutes of Health) and Cooperative Agreements</u></p> <p data-bbox="128 626 310 654">Grant Awards</p> <p data-bbox="100 695 338 755">NIH Grants Policy Statement 8.4.2</p>	<p data-bbox="380 175 768 203"><u>REVISED DECEMBER 2019.</u></p> <p data-bbox="380 211 1986 573">Recipients generally must retain financial and programmatic records, supporting documents, statistical records, and all other records that are required by the terms of a grant, or may reasonably be considered pertinent to a grant, for a period of 3 years from the date the annual FFR is submitted. For awards under SNAP (other than those to Federal institutions), the 3-year retention period will be calculated from the date the FFR for the entire competitive segment is submitted. Those recipients must retain the records pertinent to the entire competitive segment for 3 years from the date the FFR is submitted to NIH. Federal institutions must retain records for 3 years from the date of submission of the annual FFR to NIH. See 45 CFR 75.361 for exceptions and qualifications to the 3-year retention requirement (e.g., if any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period, the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken). Those sections also specify the retention period for other types of grant-related records, including F&A cost proposals and property records. See 45 CFR Parts 75.361 and 75.364 for record retention and access requirements for contracts under grants.</p> <p data-bbox="380 613 1927 773">These record retention policies apply to both paper and electronic storage of applicable information, including electronic storage of faxes, copies of paper document, images, and other electronic media. Institutions that rely on an electronic storage system must be able to assure such a system is stable, reliable, and maintains the integrity of the information. When storing electronic images of paper documents, the system must also assure a full, complete, and accurate representation of the original, including all official approvals.</p> <p data-bbox="380 813 1965 1036">NIH, Inspectors General, the Comptroller General of the United States, and the pass-through entity, or any of their authorized representatives, must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the NIH award, in order to make audits, examinations, excerpts, and transcripts. The right also includes timely and reasonable access to the non-Federal entity's personnel for the purpose of interview and discussion related to such documents. The rights of access in this section are not limited to the required retention period but lasts as long as the records are retained. Pass-through entities must not impose any other access requirements upon non-Federal entities.</p>