Study Records Retention

The requirement for retention of study records depends on which regulations apply to the research. Please refer to the table below for required years of retention for study records.

Type of Research	Record Retention Period
IRB records	3 years after study completion
Research with a federal grant	3 years after expiration of the grant period
FDA-regulated research (Investigational Drugs or Devices)	2 years after the investigation is discontinued and FDA is notified, following the date a marketing application is approved; need written confirmation from FDA or sponsor.
ICH-GCP (E6) (for all clinical trials)	Two (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 or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. However, these documents should be retained for a longer period if required by the applicable regulatory requirements or by an agreement with the sponsor.
HHS-regulated research	3 years after study completion
Non-funded research	3 years after study completion (best practice); if it involves children, 6 years after study completion (best practice)
Research including HIPAA authorizations	6 years (see below for document retention requirements)

IRB Records

HHS regulations at 45 CFR 46.115(b) and FDA regulations at 21 CFR 56.115(b) require that all IRB records be retained for at least 3 years, and records relating to research which is conducted be retained for at least 3 years after completion of the research. All records must be accessible for inspection and copying by authorized representatives of HHS or the FDA at reasonable times and in a reasonable manner. IRB records may be retained electronically or in printed hard copy. For more information about retention of IRB records, refer to the IRB Records and Retention policy.

Research Regulated by FDA

An investigator involved in the research of drugs, devices, or biologics being tested in humans for FDA approval shall retain records for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, 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 (21CFR312.62(c)). Records should be retained until there is written confirmation from the sponsor or FDA granting permission to destroy them.

Research with HIPAA Authorizations

HIPAA requires a **6 year retention period** for the documents listed below (45CFR163.530(j)(1):

- **Written HIPAA Authorizations:** If the research involves Protected Health Information (PHI), the Principal Investigator must retain the permission (i.e. the consent form or authorization) to use the PHI for 6 years beyond the expiration date of the authorization (completion of the research).
- **IRB Determinations for Waiver of HIPAA authorization:** Records documenting that a request for waiver of HIPAA Authorization met all the requirements of 45 CFR 164.512(i.)(2)(ii) must be retained for 6 years from the completion of the research.
- **Disclosures of PHI:** An accounting of all disclosures of PHI (not listed in the consent/authorization) must be retained for 6 years after the disclosure.

Signed consent forms

HIPAA Authorizations must be retained for 6 years; otherwise, signed consent forms should be retained for 3 years.