

OHSU Summary of Regulatory Retention Requirements For Records Associated with Research

Note: Award terms with research sponsors may mandate retention longer than the timeframes specified in regulation and/or notification of the sponsor prior to destruction of records. Please examine the associate award terms prior to destroying research related records.

- NIH Sponsored Research: “Financial records, supporting documents, statistical records, and all other records pertinent to an award shall be retained for a period of three years from the date of submission of the final expenditure report or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report.” (45CFR74.53.b)
- FDA regulated drug research (all sites in the US): “An investigator 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)
- FDA Regulated Device Research (all sites in the US): “An investigator...shall maintain the records required by this subpart during the investigation and for a period of 2 years after the latter of the following two dates: 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.” (21CFR812.140.d)
- FDA regulated research for investigational drugs and devices being developed for marketing submission in the US and European Economic Union (EEU) member countries and/or Japan: Records “...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 or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product.” (ICH GCP 4.9.5)
- Protected Health Information (PHI) Included in Research Data: “A covered entity must retain...for six years from the data of its creation...” (45CFR164.530 (j)(2))