

Office of the Vice Chancellor for Research

Research Data/Record Retention Requirements

Record Retention Requirements:

Research data that are commonly accepted in the scientific community as necessary to validate research findings must be retained by WashU researchers for a minimum period required by applicable laws and regulations, funding agency requirements, or other agreements. The University and the Principal Investigator have rights and responsibilities concerning access to, use of and maintenance of original research data and records ("Records"). Records should be retained in the unit where the records and data were produced. The Principal Investigator is responsible for determining what needs to be retained in sufficient detail to enable appropriate responses to questions about accuracy, authenticity, primacy and compliance with laws and regulations governing the conduct of the research. Research data should be stored using a method that permits a complete retrospective audit, if necessary.

Federal Research Record Retention Requirements:

DHHS Federal Grants 3 years after the expiration of the funding period [final financial report]

45 CFR 74.53

FDA 2 years after the last marketing approval <u>21 CFR 312.62(c)</u>

HIPAA Authorizations/Waivers 6 years after completion of the study 45 CFR 164.530(j)(1)

IRB Records 3 years after study completion 45 CFR 46.115(b); 21 CFR 56.115(b)

Other Circumstance that may justify retaining records for longer periods could include:

Intellectual Property (<u>WashU policy</u>): Records must be kept for as long as necessary to protect intellectual property and complete patenting and licensing procedures

Funding agencies/sponsors: Records must retained as required by the sponsoring entity or as specified in the agreement

Students: Records must be retained for [one-year] after the student's degree is awarded

Publications: Records must be retained as required by journal policies

Research Compliance/Integrity Investigations: If any allegations of wrongdoing regarding the research arise, such as allegations of scientific misconduct or conflict of interest, data must be retained until such allegations are fully resolved or as required by the Office of the Vice Chancellor for Research

Administrative/Legal Proceedings: Records must be retained until the final resolution of the proceeding or as required by the Office of the General Counsel

Transfer Records/Data/Materials when departing WashU

Follow the PI Departure Checklist, as applicable