

Washington University in St. Louis Research Data & Materials Policy

Washington University (WU) deems appropriate stewardship of research data as fundamental to high-quality research and academic integrity. It therefore seeks to attain high standards in the generation, management, retention, preservation, curation, and sharing of research data. Recording and maintaining accurate and appropriate research records is necessary for the following reasons:

- Support and substantiate findings;
- Protect intellectual property rights;
- Facilitate the management of the research program of WU; and
- Ensure compliance with federal regulations, sponsor requirements and other applicable policies including data sharing, management, retention, and public accessibility to published results.

Additionally, WU has rights and obligations regarding the dissemination and commercialization of knowledge resulting from WU research. To meet its obligations and protect its rights, WU must ensure that original research data and materials are secure and appropriately accessible.

DEFINITIONS

Research Data and Materials: *Research Data & Materials* is defined as the recorded factual material, regardless of the form or media on which it may be recorded, that is commonly accepted in the research community as necessary to validate research findings. This includes original and derivatives of research data (including secondary research as well as primary data collected for other purposes (e.g., operational, clinical) and then replicated for research use) and also includes the metadata necessary to recreate the processes used to manipulate and analyze the data. Research data can take a variety of forms and can include but are not limited to:

- Field notes, sample data, survey results, images, laboratory notebooks, measurement data capturing the state of a system, be it physical or engineered, e.g., internet traffic traces
- Gene sequences, chromatograms
- Reagents, cell lines, plasmids, vectors, chemical compounds, photographs, films, digital images
- Climate models, economic models
- Data from public documents, 3D models, computer code, data derived or compiled from other sources, including data such as citations to articles or books used to conduct analyses including, but not limited to meta-analyses, systematic reviews, or other integrative analyses

APPLICABILITY

This guidance applies to all WU employees and faculty members, staff, trainees of all types (including fellows and students) and any other persons (including visiting researchers, affiliate and adjunct faculty, industrial personnel, consultants, fellows, etc.) involved in the conduct of research at or under the auspices of WU. It also applies to all research projects on which those individuals work, regardless of the source of funding for the project.

OWNERSHIP AND ROLES

WU owns all Research Data and Materials generated by, or derived from, research projects conducted at or with the resources of WU regardless of funding source, unless specific terms of sponsorship or other agreements supersede these rights.

Principal Investigators and Program Directors (PIs) and other researchers, including faculty supervisors of students and trainees, have overall responsibility for management of Research Data and Materials. PIs may choose to delegate responsibility within their research groups, provided such delegation is clearly established and responsibilities understood within the research team. Any such delegation should be consistent with any applicable data management plans for that project. In the event PIs choose to delegate responsibility within their research groups, the PIs remain accountable for the stewardship of Research Data and Materials.

RETENTION

WU must retain original Research Data and Materials to enable appropriate responses to questions about accuracy, reproducibility, integrity, authenticity, and compliance with sponsor agreements and funding agency requirements, laws and regulations governing the conduct of the research, and to establish priority for patentable items.

At a minimum, Research Data and Material retention is required for **six years** following the final project close-out. A longer retention period may apply depending on applicable requirements, such as funding agency requirements, FDA requirements, journal guidelines, sponsor agreements, etc. Data supporting patent applications must be retained for the life of the patent. Clinical records used in research have unique retention requirements and need to be retained in accordance with WU policy and applicable law. In addition, centers, divisions and departments may have related policies on data management that apply. In each case, the Research Data and Materials must be kept for the longest period-of-time applicable. See [Attachment I](#) for examples of retention requirements for specific circumstances.

Requirements for recording and storing Research Data and Materials will vary by discipline. Research Data and Materials, as well as the metadata concerning how Research Data and Materials have been managed, analyzed, accessed, and shared, should be stored using a method that permits a complete retrospective audit, if necessary. PIs should determine appropriate documentation for tangible Research Materials that cannot be retained for a minimum of six years (e.g., due to degradation) to enable complete responses to questions about accuracy and reproducibility. Such tangible Research Materials should be maintained in accordance with the accepted standards of the particular academic field or discipline.

RESPONSIBILITIES

University

WU's responsibilities with respect to Research Data and Materials include:

- Facilitating compliance with the terms of research grants and agreements
- Protecting the rights of researchers to access Research Data and Materials involving research in which they participated
- Securing intellectual property rights
- Facilitating the resolution of disputes involving Research Data and Materials (e.g., investigation of allegations of misconduct)
- Educating research personnel of the appropriate confidentiality and security protections of Research Data
- Providing options and support for data sharing

School/Department

Responsible for ensuring:

- Research Data and Materials are retained and stored in accordance with this guidance
- Proper management of Research Data and Materials when a researcher leaves WU (as specified in the [PI Departure](#) process) and this guidance
- Compliance with any retention requirements as required by any applicable grants or agreements

Principal Investigator (PI)

While the university is the owner of the data, the PI is the steward and custodian of Research Data and Materials. Therefore, the PI holds original Research Data and Materials in trust for WU, and is responsible for the maintenance and retention in accordance with this guidance and any other applicable requirements. Specific responsibilities and resources include but may not be limited to those listed below.

Responsibilities	Resources Available
Accurately recording, maintaining and retaining Research Data and Materials	Becker Medical Library Data Management Services
Ensuring that, for all aspects of their research program, sufficient records are kept to document the experimental methods and accuracy of data collection as well as the methods and accuracy of data interpretation	Workshop on Data Management Planning (DMP) University Libraries (Danforth) Data Services Data Management Resources and Guides
Adopting an orderly and dated system of organization	RIS Data Storage Platform Institutional DMPTool (includes boiler plate WU language for funder required DMPs)
Communicating these requirements and the chosen system of data organization to all members of the research team, including appropriate administrative personnel	Checklist for Data Management from MIT
Ensuring data sharing agreements are in place prior to transferring restricted data outside of WU	Contact JROC for support with data sharing agreements
Ensuring access to the Research Data and Materials in the event of a departure from WU by any member of the research team, under terms approved by WU, including obtaining departmental and institutional approval	PI Departure Checklist procedures
Providing unfettered access to Research Data and Materials by the University; this includes facilitating access for any institutional investigations, such as allegations of research misconduct	

Complying with applicable data management requirements, such as funding agencies, agreements, and journal policies, regarding data access and retention	Attachment I DMP Tool How to use the DMP Tool
Abiding by any licenses, terms, or conditions set forth by third parties that retain ownership of data used in research (e.g., data use and access agreements, etc.)	Contact JROC for support with any agreement conditions Guide on Rights and Ownership/CC Licensing
Maintaining the confidentiality and ensuring appropriate protection and security of restricted Research Data and Materials, particularly human subject Research Data	Secure Storage and Communication Methods
Establishing and maintaining procedures, particularly for long-term research projects, for the protection of essential records in the event of a natural disaster or other emergency, and securing such records in such event	Continuity Planning
Sharing data that is findable, accessible, interoperable (FAIR) is increasingly expected. This means rather than submitting data to a repository without documentation or review by an outside entity, the data goes through a curation process.	Institutional Data Repository Open Scholarship institutional repository (University Libraries) Guides to sharing at WashU Data Curation Services FAIR data principles

DATA SHARING/ACCESS

Sharing within WU

The PI generally shall determine who has access to Research Data and Materials generated within their project but will allow access by other WU personnel upon reasonable request, including access to investigators associated with the research project, for research, academic and other legitimate purposes. PIs must provide documentation that describe the data for reuse and inform others accessing Research Data and Materials of any limitations or restrictions on its use or dissemination.

At all times, WU has the right to take physical custody of the Research Data and Materials.

Sharing Publicly

Many publishers, academic societies, government sponsors and other funders require that protocols, data sets, metadata, and code underlying researchers' published results be shared with other researchers and be deposited in public repositories and databases. See [Attachment I](#) for examples of data sharing policies required by specific sponsors. It is the responsibility of the PI to confirm the institution's ability to comply with any data sharing or data management plan incorporated into an application for support from a sponsor, particularly NIH and NSF. WU encourages the responsible sharing of Research Data and Materials in furtherance of its commitment to transparency, accountability, and reproducibility in research and in accordance with WU or other policies governing sharing of Research Data and Materials. WU recommends that researchers submit data to an established data archive or repository whenever possible. Washington University provides an institutional data repository, the Digital Research Materials Repository, which includes curation and preservation actions for long-term accessibility.

TRANSFERS

If a PI leaves WU, original Research Data and Materials may be transferred to another institution with prior approval from a Dean, Department Chair, or Director (as specified in the [PI Departure](#) process) and when other required institutional processes are put in place, such as the Office of Technology Management for materials transfer agreements. In addition, a written commitment from the PI's new institution may be necessary that guarantees: 1) the new institution's acceptance of custodial responsibilities for the Research Data and Materials, and 2) WU's access to Research Data and Materials, should that become necessary.

Removing or transferring Research Data and Materials that are subject to confidentiality or other legal restrictions (including but not limited to HIPAA, a consent form, other human subjects protections, legal holds as a result of legal proceedings, and patent prosecution) require other institutional approvals and may require an agreement with the receiving party generated by the Joint Research Office of Contracts.

When the PI is permitted to take original Research Data and Materials, he or she has an obligation to hold it in trust for WU and must provide access to it or return it if needed during the required retention periods. In addition, during the required retention period, such Research Data and Materials must be available to external sponsors, and designated governmental officials, as appropriate. Transfer of data should be done in a secure manner applying strong security controls such as access restriction via passwords, data encrypted at rest and in motion, etc.

When individuals other than the PI who are involved in research projects leave WU, they may take copies of Research Data and Materials for projects on which they have worked with permission from the PI or department unless restricted by the specific terms of the applicable agreement/sponsor or by applicable laws, regulations, and WU policies.

SECURING RESEARCH DATA & MATERIALS

Ensuring appropriate protection of Research Data and Research Materials is a fundamental responsibility of all members of the WU research community and others who may have access to Research Data and Research Materials. The [WU Information Security](#) policies, standards and guidelines must be followed in addition to abiding by all grant and contract-related requirements and regulations. Research Data that incorporates personally identifiable or sensitive elements (such as Social Security numbers) or includes export-controlled information or controlled unclassified information (CUI) must have adequate security protections and be treated as "protected data" under the [Information Classification Policy](#). It is the responsibility of the PI to identify the classification of their Research Data and to provide appropriate protections, as well as any additional data security that may be specifically required under the terms of a sponsored program agreement (such as those in the Federal Information Security Management Act, Federal Acquisition Regulations requiring protection of CUI, or the FDA's electronic records regulations).

PIs are responsible for the confidentiality, integrity, handling, and protection of their data in accordance with WU's data security standards, applicable laws, regulations, policies, and binding commitments, such as informed consent documents, data use agreements, and any other written agreements governing security and/or confidentiality of the Research Data and Materials. See [here](#) for a list of available secure storage and communication services at WU.

Examples of basic security controls for Research Data and Materials may include the following:

- Data collection and storage devices should be password protected with a strong password
- Sensitive or protected data should be encrypted
- Use of WU provided and managed devices to collect or store data
- Data collection and storage devices should be stored and accessed in physically secure locations
- Use Box, REDCap, or other WU vetted secure tools to share data
- Share only the minimum amount of data necessary to achieve the goals of the research
- Use secure email when transmitting protected data, such as the encryption required when transmitting health information protected by HIPAA

CONTACTS

For questions regarding data management:

- [University Libraries](#) (Danforth)
- [Becker Medical Library](#) (WUSM)

For questions regarding data archival and storage:

- [Research Infrastructure Services](#)

For questions regarding data protection/security:

- [Information Security Office](#)

For questions regarding data use/sharing agreements:

- [Joint Research Office for Contracts](#)

For questions regarding research integrity issues:

- [Office of Research Integrity & Ethics](#)

For questions regarding human studies:

- [Human Research Protection Office](#)

Related Policies & Resources

- [Intellectual Property Policy](#)
- [Record Management Policy](#)
- [University Library Data Services](#)
- [Becker Library Data Management and Sharing Services](#)
- [Data Classification](#)
- [Research Infrastructure Services](#)
- [Secure Storage and Communication](#)
- [WashU Data Repository](#)
- [DMP-Tool](#)

Attachment I

Retention Requirements:

The following table includes examples of retention requirements. The Research Data & Materials Guidance requires a minimum of [6 years](#) for retention. Researchers must maintain data for the longest applicable period.

Examples	Retention Requirements
Research at Washington University	Retained at least 6 years in accordance with this Research Data & Materials guidance
Research projects involving FDA regulated articles	2 years following the date a marketing application is approved for the product; or if a marketing application is not filed or FDA approved, for 2 years after the investigation is discontinued and the FDA is notified. (See 21 CFR 312.62 and 21 CFR 812.140)
Human Subjects Research	All research records, including signed consent forms, must be kept in their original form or a certified scanned electronic form for at least 6 years beyond close of the study. (See IRB Policies and Electronic Storage of Human Research Study Documents)
Animal Research	Records of activities described in an IACUC protocol must be maintained for 6 years (the last 3 years of the project protocol approval period plus an additional 3 years), or as specified by an IACUC policy.
Uniform Guidance Requirements (applicable to any federally funded research)	3 years from the date of submission of the final expenditure report or, if any litigation or audit is started before the expiration of the 3 year period, the records must be retained until any claim or audit is resolved and final action taken. See 2 CFR 200.334
Research projects involving Protected Health Information (PHI)	6 years after completion of the study 45 CFR 164.530(i)(1)
Intellectual Property	Records must be kept for as long as necessary to protect intellectual property and complete patenting and licensing procedures
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

Data Sharing Requirements – Examples by Agency

National Institutes of Health (NIH)	NIH Policy for Data Management and Sharing NIH Scientific Data Sharing NIH Grants Policy Statement: Availability of Research Results Compilation of NIH Sharing Policies and Related Guidance NCI Moonshot Public Access and Data Sharing Policy
National Science Foundation (NSF)	Proposal and Award Policies & Procedures Guide Compilation of NSF Dissemination and Sharing Requirements
Department of Energy (DOE)	DOE Policy for Digital Research Data Management Public Access Plan
Center for Disease Control (CDC)	Policy on Public Health Research and Nonresearch Data Management and Access
NASA	Policy Directive: Research Data and Publication Access
EPA	Policy for Increasing Access to Results of EPA
Journal Requirements	Individual journals have policies and expectations for sharing data. See the CHORUS Publisher Data Availability Policies Index for many journal requirements.