Research Data and Materials Policy

Scope
This policy applies to all research data and materials generated with the support of Yale resources, and it applies to all Yale faculty members, staff members, post-doctoral appointees, trainees, students, consultants and any others involved in the design, conduct or reporting of research. The policy does not change current copyright, patent, and record retention policies, which also apply to research.

Policy Statement
Accurate and appropriate research records are an essential component of any research project. Both the University and Yale researchers have responsibilities and rights concerning access to, use of, and maintenance of original research data.

Yale researchers are custodians of research materials and data generated with the support of Yale resources. Yale researchers have the academic freedom to determine the course and publication of any research, subject to legal requirements, Yale policy, ethical standards, and the terms and conditions of sponsored awards. Yale’s ownership and stewardship of research data and materials for projects conducted at the University, under the auspices of the University, or with University resources are based on both regulation and sound management principles and is in support of its mission of outstanding research and scholarship, education, preservation and practice, and the free exchange of ideas.

Research data and materials that are commonly accepted in the scientific community as necessary to validate research findings must be retained by Yale researchers for three (3) years after publication of the findings or until all required final reports (e.g., progress and financial) for the project have been submitted to the sponsor, unless a longer period is provisioned. PIs or co-PIs have a right to access and may generally take copies of the data when they leave Yale. Other co-investigators involved in the creation of research data may access and take copies of research data for projects (or the portions of projects) on which they have worked with the permission of the PI or PIs. Sharing of research data and materials that are commonly accepted in the scientific community as necessary to validate research findings with members of the University community, external collaborators, and others for legitimate purposes, is encouraged, often required by law, and subject to Yale policy and to legislative, regulatory, contractual, ethical or other obligations.

Reason for the Policy
As part of its core mission, “Yale is committed to improving the world today and for future generations through outstanding research and scholarship, education, preservation, and practice.” The University deems appropriate stewardship of research data as fundamental to both high-quality research and academic integrity and therefore seeks to attain the highest standards in the generation, management, retention, preservation, curation, and sharing of research data.
Yale has an obligation to ensure that its resources are used appropriately and that research conducted at Yale meets standards of integrity imposed by law and Yale policy. Yale also has rights and obligations regarding the dissemination and commercialization of knowledge resulting from research conducted with Yale resources. Federal agencies, including the National Institutes of Health and the National Science Foundation among others, have expectations of grantees for providing public access to research data and materials, notably policies for data sharing, management and public accessibility to published results. In order to meet its obligations and protect its rights, the University must ensure that original research data and materials are secure and appropriately accessible.

By relying on established principles for determining the ownership of research data and materials the University seeks to avoid and resolve disputes so that disagreements over ownership need not impede research or Yale’s mission for the dissemination of new knowledge.

**Definitions**

**Co-Investigator**

This title designates key personnel for a project, but without the oversight responsibility of a PI.

**Co-Principal Investigator**

This designation refers to individuals who share the responsibility for the project with the PI.

**Principal Investigator**

The principal investigator (PI) is the individual (or in the case of co-principal investigators, the individuals) directly responsible for the overall design and conduct of a research project and is accountable to the University, and to external sponsors if any, for the proper programmatic, scientific, or technical conduct of the project, and its financial and day-to-day management. For sponsored projects, this role is formally defined by University Policy to be the individual designated by the University and approved by the sponsor to direct a project funded by the external sponsor. For research conducted by students, trainees, or postdoctoral fellows, this role is generally vested in the faculty advisor.

- The PI is ultimately responsible for the data used and generated in the project, and is responsible for managing research data and materials in accordance with the principles and requirements outlined in this policy. The PI may choose to delegate the management responsibility of the data and materials to a co-investigator of the project.

- Where research is conducted in collaboration with external research partners, responsibility for the management of data and materials for the project is still held by a Yale University PI, co-investigator, or delegate.

- The PI is responsible for ensuring continuity of the data and materials management and, should the PI leave the university or end association with the project, is responsible for making appropriate arrangements for the data and materials at the end of the project.

**Research**

A systematic study intended to increase knowledge or understanding of the subject studied; a systematic study specifically directed toward applying new knowledge to meet a recognized need; or a systematic application of knowledge to the production of useful materials, devices, and systems or methods.

**Research Data**

The recorded factual information associated with the research, including, but not limited to, all records necessary for the reconstruction and evaluation of the results of research, regardless of the form or medium on which the material is recorded (such as lab notebooks, photos, digital images, data files, data processing or computer programs (software), statistical records, etc.).

Research data does not include books, articles, papers, or other scholarly writings that are published or publicly presented; drafts of such scholarly writings; plans for future research; peer reviews; or communications with colleagues.
Research Materials

Tangible items that are the product of research or that are used to conduct research. Examples of research materials include reagents, cell lines, plasmids, vectors, chemical compounds, and some kinds of devices and software.

Yale Researcher

A Yale faculty member, staff member, post-doctoral appointee, trainee, or student who generates research data or materials with the support of Yale resources.

Yale Resources

Yale funds (including, for example, sponsored awards to Yale, salaries, gifts, endowment funds, and travel grants), facilities, staff, or equipment.

Policy Sections

1. Roles and Responsibilities

In their role as custodians of research data and materials, and in keeping with academic practice, Yale researchers are responsible for:

- Recording, collecting, managing, retaining, and sharing research data and materials according to legal requirements, Yale policy, and the terms and conditions of sponsored awards.
- Ensuring the retention of original data and materials.
- Where research involves the use of data owned by a third party, abiding by licenses or terms of use governing that data.

Yale’s responsibilities include but are not limited to:

- Protecting the rights of Yale Researchers as provided in this policy including, but not limited to, their right to academic freedom, rights to access data from research in which they participated, and rights to take copies of their data when they leave the University.
- Developing and implementing compliance systems, consistent with applicable legal requirements, to address scientific misconduct and conflict of interest.
- The University is accountable to sponsors for meeting all obligations concerning research data, and for supporting an environment in which the objectives of its policies and principles are met.

2. Ownership

Yale’s ownership and stewardship of research data and materials for projects conducted at the University, under the auspices of the University, or with University resources are based on both regulation and sound management principles and apply in all cases except where precluded by the specific terms of sponsorship or other agreements.

Similarly, any intellectual property rights in research data and related materials shall remain with the University unless otherwise specified by law or in a duly executed agreement. The Yale Copyright Policy provides that generally, books, articles and other scholarly writings by a faculty member are deemed the property of the writer, who is considered to be entitled to determine how the works are to be disseminated and to keep any income they produce, unless otherwise provided by law.
3. Retention

Generally, research data and materials that are commonly accepted in the scientific community as necessary to validate research findings must be retained by Yale researchers for three (3) years after publication of the findings or all required final reports (e.g., progress and financial) for the project have been submitted to the sponsor.

Longer retention periods may be required by Yale policy, publishers, sponsors, and applicable law. Yale researchers are responsible for consulting these requirements and research data must be retained in accordance with those more stringent requirements. Some key provisions and circumstances are as follows:

- Research data must be kept until any patentable invention resulting from the work is protected by the filing of a patent application or, if a decision is made by the University not to file for patent protection, until rights to the invention are returned to the inventor.
- If charges of academic misconduct or conflict of interest have been made in relation to a research project, the research data must be retained by the University as long as required by any sponsoring agency’s requirements, but at least until all charges have been resolved and final action taken. If the research data were the subject of litigation or investigation, the research data must be retained until the Office of the General Counsel has issued instructions regarding their disposition.
- Research data involving human subjects presents special requirements. Yale researchers must consult University policy as well as federal and state laws and regulations related to research data retention, including but not limited to HIPAA, as applicable.
- If a student is involved in a research project, the research data must be retained until the student has been awarded a degree or it is clear that the student has abandoned the work.
- If the research data or materials are appraised by the University to have long term cultural, historical, economic, environmental, or other acknowledged value, then the University may require a longer retention period.
- If the research project involves FDA regulated articles, then, consistent with 21 C.F.R. §§ 312.6 and 812.140, the investigator must keep records for two years following the date a marketing application is approved for the product; or if a marketing application is not filed or FDA approved, for two years after the investigation is terminated, completed, or otherwise discontinued and the FDA is notified. If other regulations, sponsor policies, or guidelines require longer retention periods, research data must be kept in accordance with those more stringent requirements.

4. Transfer

When Yale researchers who are PIs or co-PIs on research projects at Yale leave the University, they may generally take copies of research data for projects on which they have worked. Taking copies of data or materials subject to confidentiality or other legal restrictions, including but not limited to data and materials that are covered by HIPAA and other human subjects protections, germane to disputes and investigations, or necessary for patent protection, may be restricted and requires permission from the Office of the Provost.

Other co-investigators may take copies of research data for projects (or the portions of projects) on which they have worked only with the permission of the PI or PIs or, if the PI or PIs and the individual leaving cannot reach agreement, with the permission of the Office of the Provost. In all cases, the original data and materials must be retained at Yale.

In appropriate circumstances, Yale may transfer ownership of research data or materials to a third party pursuant to a duly executed sponsored award or other agreement. For data, the
transfer of ownership from Yale to another institution requires prior written approval of the Office of the Provost. It will generally be granted only when the research project itself is being transferred to the other institution and will be pursuant, at a minimum, to a written agreement executed by the recipient institution that guarantees (1) its acceptance of ongoing custodial responsibilities for the data, and (2) Yale having access to the original data, should access become necessary for any reason. The transfer will be in accordance with relevant confidentiality restrictions, when Yale deems them appropriate or necessary or as required by law (e.g., HIPAA). For materials, transfer requires execution of a material transfer agreement (MTA) executed by Yale and the recipient institution prior to the removal of the materials or equipment from the University premises.

5. Sharing and Access

Sharing of research data and materials that are commonly accepted in the scientific community as necessary to validate research findings with members of the University community, external collaborators, and others for legitimate purposes, is a key precept of the University.

Research data and materials shall be made publicly available to the extent feasible while minimizing harm to the legitimate interests of the University, to research subjects, and to other parties, subject to Yale policy and to legislative, regulatory, contractual, ethical or other obligations, including but not limited to whether providing such public access would be cost prohibitive.

Where necessary to assure needed and appropriate access, the University has the option to take custody of the data in a manner specified by the Provost.

Yale researchers who are PIs or co-PIs on research projects at Yale have a right to access research data for projects on which they have worked. Other co-investigators may access research data for projects (or the portions of projects) on which they have worked only with the permission of the PI or PIs, or, if the PI or PIs and the individual leaving cannot reach agreement, with the permission of the Office of the Provost.

Related Information

- Yale University Research Data Management Principles and Guidance: http://research.yale.edu/research-data
- Yale University HRPP Policy 730 Human Research Record and Biological Specimen Retention and Transfer: https://your.yale.edu/policies-procedures/policies/730-hrpp-policy-730-human-research-record-and-biological-specimen
- Yale University HRPP Procedure 730 PR1 Departing Investigator-Final for Departing Investigators https://your.yale.edu/sites/default/files/730pr1departinginvestigator.pdf
- Yale University Policy 5100 HIPAA: http://hipaa.yale.edu/sites/default/files/files/5100.pdf
- Yale University Record Retention Requirements: http://ogc.yale.edu/sites/default/files/files/Yale-Records-Retention-Schedule.xls
- Yale University Policy 1105 Retention of University Financial Records: https://your.yale.edu/policies-procedures/policies/1105-retention-university-financial-records
- Yale University HIPAA Policy 5003 Accounting for Disclosure: http://hipaa.yale.edu/sites/default/files/files/5003.pdf
- Yale Data Classification Policy: https://its.yale.edu/secure-computing/security-standards-and-guidance
• Yale University Patent Policy: http://ocr.yale.edu/faculty/policies/yale-university-patent-policy
• Yale University Copyright Policy: http://ocr.yale.edu/faculty/policies/yale-university-copyright-policy
• Yale University Policy on Incoming Material Transfer Agreements: http://ocr.yale.edu/faculty/material-transfer-agreements
• Yale University Policy 1310 Principal Investigator Eligibility Requirements on Sponsored Projects: https://your.yale.edu/policies-procedures/policies/1310-principal-investigator-eligibility-requirements-sponsored-projects
• 2 C.F.R. Part 200 Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards: http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title02/2cfr200_main_02.tpl (see also: https://www.whitehouse.gov/omb/grants_docs)
• Office of Science and Technology Policy Memo: Increasing Access to the Results of Federally Funded Scientific Research

Contacts
For assistance with questions relating to research data and materials, please see below.

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<th>Subject</th>
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<td>Sponsored Projects Administration</td>
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<td>Patent Policy and Assignment of Rights</td>
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