

Approving University Official: Provost

Responsible Offices: Office for Sponsored Research; Office for

Research Integrity

Effective date: December 2012 Next review date: January 2021

RESEARCH DATA: OWNERSHIP, RETENTION, AND ACCESS

Policy Statement

Individual researchers and the University have rights and responsibilities with respect to research data. This Policy describes the basis of data ownership and the standards for the collection and retention of data, in addition to requirements for data access. This Policy also provides guidance with respect to transfer of research data in the event a researcher leaves Northwestern.

This Policy does not address ownership of intellectual property, which is governed by Northwestern's Patent and Invention and Copyright Policies.

Purpose

This Policy assures that research data are appropriately recorded and archived, and available for review under appropriate circumstances.

Audience

Faculty, students, other trainees, staff, and all other members of Northwestern's research community.

Definitions

Research data: for purposes of this Policy, all information in whatever form (e.g., both physical and electronic) collected and/or generated in the course of a research project conducted at the University, under the auspices of the University, or with University resources. This includes original and derivatives of research data, including recordings of such data. Examples of research data include, but are not limited to:

- Data, analytical programs, procedures, and records necessary for the reconstruction and evaluation of the results of research;
- Data contained in laboratory notebooks;
- Data collected using instrumentation or systems and stored in an electronic format; or

• Case report forms and source documentation for human participant research studies.

Records: pursuant to Northwestern's <u>Policy on Retention of University Records</u>, "recorded information of any kind and in any form including writings, drawings, graphs, charts, images, prints, photographs, microfilms, audio and video recordings, data and data compilations, and electronic media, including e-mail."

Policy Implementation

1.0 Ownership and Responsibilities

As a federally funded research institution, the University, in order to meet the requirements of research sponsors, asserts ownership over the research data for projects conducted at the University, under the auspices of the University or with University resources. Although the University as owner of the research data must meet the requirements of sponsors, good management practice and practical considerations necessitate that the University and researchers act in partnership to fulfill these obligations.

As custodians of research data, Principal Investigators (PIs) and other researchers are stewards of research data. At the same time, no matter how such responsibilities are delegated, the flow of accountability runs from the PI being responsible to the institution for the stewardship of research data, just as the institution is ultimately responsible to the research sponsor.

Research data are to be accessible to members of the University community, external collaborators and others as appropriate (*e.g.*, for patent applications or journal submissions). Where necessary to assure needed and appropriate access (*e.g.*, for research misconduct investigations), the University may take custody of research data in a manner specified by the Vice President for Research.

Northwestern's responsibilities with respect to research data include, but are not limited to:

- 1. complying with the terms of sponsored project agreements;
- 2. ensuring the appropriate use of project resources, *e.g.*, animals, human participants, recombinant DNA, biological agents, radioactive materials, etc.;
- 3. protecting the rights of researchers, including, but not limited to, their rights to access to data from research in which they participated;
- 4. securing intellectual property rights;
- 5. facilitating the investigation of charges, such as research misconduct or conflict of interest:
- 6. maintaining confidentiality of research data, where appropriate; and
- 7. complying with applicable state and federal laws and regulations.

The PI's responsibilities with respect to research data include, but are not limited to:

- 1. ensuring proper management and retention of research data in accordance with this Policy;
- 2. establishing and maintaining appropriate procedures for the protection of research data and other essential records, particularly for long-term research projects;
- 3. ensuring compliance with program requirements;
- 4. maintaining confidentiality of research data, where appropriate; and
- 5. complying with applicable state and federal laws and regulations.

2.0 Data Retention

Research data must be retained for a minimum of three years after the financial report for the project period has been submitted or, for non-sponsored projects, a minimum of three years after the project has ended and, if applicable, the budget reconciled. In addition, any of the following circumstances may justify longer periods of retention:

- 1. research data must be kept for as long as may be necessary to protect any intellectual property resulting from the work;
- 2. if litigation or other dispute resolution, claims, financial management review, or audit related to the research project is started before the expiration of the three-year period, or commenced after the three-year period but the relevant data and records have not been destroyed, the research data and other project records must be retained until all such litigation/dispute resolution, claims, financial management review, or audit findings involving the records have been resolved and final action taken:
- 3. if any charges regarding the research arise, such as allegations of research misconduct, research data must be retained consistent with Northwestern's <u>Policy on Retention of University Records</u>, or as otherwise instructed by Northwestern's Office for Research Integrity or Office of General Counsel;
- 4. if a student is involved, research data must be retained at least until the student's degree is awarded (or the student otherwise leaves Northwestern) and any resulting papers are published;
- 5. when research is funded by an award to or contract with Northwestern that includes specific provision(s) regarding ownership, retention of, and access to technical data, the provision(s) of that agreement will supersede this Policy;
- 6. research data from human participant research studies must be maintained consistent with the <u>IRB Investigator Manual</u> and the <u>Policy on Retention of University Records</u>;
- 7. if other regulations, federal oversight, sponsor policies or guidelines, journal publication guidelines, or other University policies require longer retention, all applicable sources must be reviewed and the research data must be kept for the longest period of time applicable.

Beyond the period of retention specified in this Policy, the destruction of research data is at the discretion of the PI. Destruction of research data must follow applicable federal regulations, Northwestern policies on record retention and data disposal, sponsor requirements, and other applicable guidelines.

Research data normally will be retained in the unit where they are produced. Please refer to the <u>Policy on Retention of University Records</u> for additional guidance on responsibilities related to the retention of research data and records.

3.0 Transfer in the Event a Researcher Leaves Northwestern

When individuals other than the PI involved in research projects at Northwestern leave the University, they may take copies of research data for projects on which they have worked, subject to relevant confidentiality restrictions. However, original data must be retained at Northwestern by the PI.

If the PI leaves Northwestern and a project is to be moved to another institution, ownership of the original data may be transferred from Northwestern to the PI's new institution upon request from the PI, subject to: (a) the prior written approval of the Vice President for Research; (b) written agreement from the PI's new institution that guarantees (1) its acceptance of ongoing custodial responsibilities for the data and (2) Northwestern having access to the original data, should such access become necessary for any reason; and (c) relevant confidentiality restrictions, where appropriate. The Office for Sponsored Research should be contacted to coordinate the transfer of data to another institution.

For additional information about transferring clinical trial records, please refer to the guidance of the National Institutes of Health (NIH) available at www.clinicaltrials.gov.

Related Information

University Policies

Copyright

Patent and Invention

Retention of University Records

Reviewing Alleged Research Misconduct

Other Information

2 CFR 200.333 Retention requirements for records

Data Management Planning Tool

IRB Investigator Manual

NIH guidance on clinical trials

Northwestern Libraries Data Management Guide

Contacts

If you have any questions about this policy, you may contact:

- 1. Executive Director, Office for Sponsored Research (312) 503-7955 or osr-chicago@northwestern.edu.
- 2. Director, Office for Research Integrity (312) 503-0054 or researchintegrity@northwestern.edu.

History

Origination Date: December 18, 2012 Last Amended Date: January 25, 2018 Next Review Date: January 2021

Policy URL:

http://www.research.northwestern.edu/policies/documents/research_data.pdf