

Title: UNIVERSITY POLICY ON CUSTODY OF RESEARCH DATA

Approved by: Board of Trustees

Date Approved: December 13, 2022

Effective date: December 13, 2022

Responsible Official: Senior Vice President for Research

Responsible University Office: Office of Research and Technology Management

Revision History: 5/18/1993, 12/14/2000, 2/26/2006, 4/21/2011, 11/22/2022

Related legislation and University policies: 2 CFR 200

Review Period: 5 years or as needed with the revision of Federal Regulations

Date of Last Review: November 2022

Relates to: Faculty, Staff, and Students

Rationale and Purpose of Policy

This policy establishes the

regardless of the form or the media on which they are recorded. This policy pertains to data and data records, and does not pertain to biomaterials or other physical research samples.

Principal Investigator (PI) is defined as the individual who is responsible for the scientific and technical planning, execution, and reporting of a research project. In the case of externally funded research projects the PI is identified in the notice of award. For student research involving human subjects or other contractual controls arising outside the University, the faculty member who is serving as the principal investigator with respect to the human subject research is considered the PI.

Rights and responsibilities

Both the University and PI have responsibilities and rights concerning access to, transfer of, use of, storage and maintenance of research data. The PI is responsible for maintenance and retention of research data in accord with this policy. Case Western Reserve University's responsibilities regarding research data include, but are not limited to:

1. Complying with terms of sponsored project agreements.
2. Ensuring that appropriate security policies and procedures are followed for data derived from animals, human subjects, recombinant DNA, etiological agents, radioactive materials, and the like.
3. Protecting the rights of faculty, students, postdoctoral scholars, and staff, including, but not limited to, their rights to access and transfer data from research in which they participated.
4. Securing intellectual property rights other than copyright.
5. Facilitating the investigation of charges, such as scientific misconduct or conflict of interest.
6. Responding to legal actions involving the University related to research carried out under its auspices.

Collection and retention of research data

Case Western Reserve University shall retain research data in sufficient detail and for an adequate period to enable appropriate responses to questions about accuracy, authenticity, primacy and compliance with laws and regulations governing the conduct of the research.

The PI is the custodian of research data unless an alternative arrangement is agreed on in writing and the agreement is on file with the University. The PI is responsible for the collection, management, and retention of research data. The PI should adopt an orderly system of data organization and should communicate the chosen system to all members of a research group and to the appropriate administrative personnel, where applicable. Particularly for long-term research projects, the PI should establish and maintain procedures for the protection and management of essential records.

Research data shall be archived for not less than three years after the final grant close-out or after publication resulting from the project, whichever occurs last, with original data retained whenever possible. It is the responsibility of the PI to determine and utilize reasonable and prudent methods of archiving, using University information technology resources where possible. Where applicable, appropriate measures to protect confidential information must be taken. In addition, any of the following circumstances may justify longer periods of retention:

1. Data shall be kept for as long as necessary to protect any intellectual property resulting from the work.
2. If any charges regarding the research should arise, such as allegations of scientific misconduct or conflict of interest, data shall be retained until such charges are fully resolved.
3. If the data involved constitute part of a student's work toward a degree, they shall be retained at least until the degree is awarded or the student has abandoned the degree program.

Beyond the period of retention specified here, the destruction of research records is at the discretion of the PI and his or her department or laboratory.

To enable the University to meet its responsibilities related to custody of research data (as previously described), the PI is obligated, upon appropriate request, to make all data available for review by the University, its officials or bodies, the external funding agency, journals in which data are published, or other external regulatory agencies. This obligation continues even after the PI leaves the University.

Questions on the interpretation of this policy may be directed to the Senior Vice President for Research and Technology Management.

Approved by the Faculty Senate Research Committee on November 17, 2000, and amended after consultation with the Faculty Senate on February 10, 2001, and amended again on June 10, 2002, and amended again on June 10, 2003, and amended again on June 10, 2004, and amended again on June 10, 2005, and amended again on June 10, 2006, and amended again on June 10, 2007, and amended again on June 10, 2008, and amended again on June 10, 2009, and amended again on June 10, 2010, and amended again on June 10, 2011, and amended again on June 10, 2012, and amended again on June 10, 2013, and amended again on June 10, 2014, and amended again on June 10, 2015, and amended again on June 10, 2016, and amended again on June 10, 2017, and amended again on June 10, 2018, and amended again on June 10, 2019, and amended again on June 10, 2020, and amended again on June 10, 2021, and amended again on June 10, 2022, and amended again on June 10, 2023, and amended again on June 10, 2024, and amended again on June 10, 2025.