

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 assurance that research data are appropriately available and accessible for a reasonable period and are available for review under the appropriate circumstances. Examples include:

Sponsors, funding agencies, journals, clinical care sites, or colleagues in the field may need or be legally entitled to review primary research data after publication or dissemination of results and will hold the University accountable for the availability of these data.

The University may be required to conduct internal reviews of the adequacy and integrity of data if findings of university research are called into question.

Principal Investigators involved in internal multi-investigator projects have rights to access data gathered by all members of the group.

Principal Investigators can share and transfer data in accordance with sponsor guidelines and regulations and to fulfill the technical and scientific aims of a research project whether it is funded or unfunded.

Contact person

Senior Vice President for Research and Technology Management

Applicability and Definitions

This policy shall apply to all Case Western Reserve University faculty, staff, students, and other persons at Case Western Reserve University involved in the design, conduct, or reporting of research at or under the auspices of Case Western Reserve University, or with the use of university resources or facilities. It shall apply to all research projects on which those individuals work, regardless of the source of funding for each project.

Research is defined in this context as “a systematic investigation designed to develop and contribute to generalizable knowledge.”

Research data are defined as the originally recorded factual material, commonly accepted in the scientific community as necessary to validate research findings. Research data include but are not limited to laboratory notebooks, photographs, genetic sequences, test responses, slides, models, algorithms, methodologies, standard operating procedures, database contents, spectra, transcripts as well as any other records that are necessary for the reconstruction and evaluation of reported results of research and the events and processes leading to those results,

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.

Research data shall normally be retained in the unit where they were produced. Research data shall be retained in such a manner that they are accessible for inspection and copying by authorized representatives of Case Western Reserve University at reasonable times and in a reasonable manner.

Data Sharing and Transfer

For CWRU group research projects, the PI is obligated to give CWRU co-investigators access to the research data or copies thereof for review and/or use in subsequent research, with proper acknowledgement. Data sharing and custody arrangements among CWRU co-investigators or for CWRU group projects should be determined by the investigators when joining the project and preferably defined in a data use agreement.

The University and Principal Investigator are jointly responsible for ensuring compliance with sponsor data sharing policies and requirements for the expedited translation of research results into knowledge, products, and procedures.

The sharing or transfer of data by Principal Investigators with colleagues at an institution external to CWRU for the benefit of a sponsored project or an unfunded collaboration should be defined and, if necessary, negotiated and approved by the Office of Research Administration

Transfer of data when a researcher leaves Case Western Reserve University

When a PI leaves Case Western Reserve University it is the responsibility of the PI to plan for the custody, archiving, and destruction of research data in accordance with this policy. Ownership of data from closed, active, and ongoing research projects belongs with the University.

Principal Investigators wishing to transfer research data to the new institution will work with the management center and the Office of Research Administration for approval and negotiation of the transfer of requested data. Original data from active and ongoing research must remain at Case Western Reserve University with an assigned custodian, unless permission is granted by the Associate Vice President for Research, and both the PI and the new institution guarantees 1) their acceptance of custodial responsibilities for the data, and 2) that Case Western Reserve University will be given access to the data should it become necessary.

Original data from a closed project that has not been archived or destroyed may be taken by the PI without additional oversight. If the PI chooses not to take this data it must be destroyed prior to the PI leaving CWRU.

When individuals involved in research projects who are not PIs at Case Western Reserve University leave the University, they may take copies of research data for projects on which they have worked. However, the PI must retain the original data at Case Western Reserve University, unless specific permission to do otherwise is granted by the Senior Vice President for Research and Technology Management or his/her designee.

In the case of a student researcher who is not the PI, the PI may allow the student to take the original data (except for original informed consent documents if the study involves human subjects) when the student leaves the university as long as the student signs a written agreement (also signed by the PI and the Associate Vice President for Research or their designee) agreeing to accept custodial responsibilities for the data and that Case Western Reserve University will be given access to the data should that become necessary.

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 Executive Committee on December 7, 2000. Approved by Faculty Senate on December 14, 2000.

Approved, as amended by the Faculty Senate, on November 22, 2022.