

6. University Policy on Custody of Research Data

a. Rationale and Purpose of the Guidelines

This policy establishes the assurance that research data are appropriately recorded, archived for a reasonable period of time, and available for review under the appropriate circumstances.

1. Research support agencies, journals, clinical care sites, or colleagues in the field may need or be legally entitled to review primary research data well after publication or dissemination of results and will hold the University accountable for the availability of these data.
2. Researchers involved in multi-investigator projects have rights to access to data gathered by all members of the group.
3. The University may be required to review internally the adequacy and integrity of data if findings of university research are called into question.

b. Contact person

Vice President for Research and Technology Transfer

c. 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 as "a systematic investigation designed to develop and contribute to generalizable knowledge." Examples of activities that constitute research include any study intended to result in publication or public presentation; any activity resulting in publication or public presentation, even though it involves only review of existing data that were collected with no intent to publish; or any use of an investigational drug or device.

Research data are defined as the material, originally recorded by or for the investigator, commonly accepted in the scientific community as necessary to validate research findings. Research data include but are not limited to laboratory notebooks, 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.

The principal investigator (PI) is defined as the person responsible for the research or who is the signatory person for sponsored research. Confidential information is specified in the "Case Western Reserve University Intellectual Property Policy" and the "University Policy on the Involvement of Human Participants in Research." For student research involving human subjects, the faculty member who is serving as the responsible investigator with respect to the human subject research is considered the PI.

d. Rights and responsibilities

Both the University and principal investigator (PI) have responsibilities and rights concerning access to, use of, 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 with regard to research data include, but are not limited to:

1. Complying with terms of sponsored project agreements;
2. Ensuring the appropriate use of 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 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.

e. Collection and retention of research data

Case Western Reserve University must retain research data in sufficient detail and for an adequate period of time 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 agreed on in writing otherwise, and 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 of essential records.

Research data must be archived for not less than three years after the final close-out or publication, whichever occurs last, with original data retained whenever possible. This should include reasonable and prudent practice for off-site back-up of electronic and hard-copy data. 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 must be kept for as long as may be necessary to protect any intellectual property resulting from the work;
2. If any charges regarding the research arise, such as allegations of scientific misconduct or conflict of interest, data must be retained until such charges are fully resolved; and
3. If the data involved constitute part of a student's work toward a degree, they must be retained at least until the degree is awarded or it is clear that the student has abandoned the work.

Beyond the period of retention specified here, the destruction of the research record 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, or the external funding agency or journals, or other external regulatory agencies. This obligation continues even after the PI leaves the University.

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

Research data will normally be retained in the unit where they are produced. Research data must 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.

f. Transfer in the event a researcher leaves Case Western Reserve University

When individuals involved in research projects who are not PI's at Case Western Reserve University leave the University, they may take copies of research data for projects on which they have worked. The PI must, however, retain original data, at Case Western Reserve University, unless specific permission to do otherwise is granted by the vice president for research and technology transfer. In the case of student research where the student is not the PI, the individual who is 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 vice president for research and technology management or his/her 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.

If a PI leaves Case Western Reserve University, custody of the data may be transferred as long as there is a written agreement signed by the vice president for research and technology management or his/her designee and either the PI or (in the event the project is moved to another institution) both the PI and the new institution that guarantees:

1. acceptance of custodial responsibilities for the data, and
2. that Case Western Reserve University be given access to the data should that become necessary.

Approved by the Board of Trustees 5/18/93. Amended by the Faculty Senate Research Committee on November 17, 2000, and amended after consultation with the Executive Committee on December 7, 2000. Approved by the Faculty Senate December 14, 2000 and the Board of Trustees on June 13, 2001.