

University Policy

Applies to: Faculty, staff (includes postdoctoral researchers), and students involved in the design, conduct, or reporting of research using university resources or facilities other than those typically used for academic instruction.

Responsible Office

Office of Research

POLICY

Issued: 09/18/2009 Revised: 06/09/2021 (minor revision)

Accurate and detailed research records are an essential component of any research project. Both the university and the principal investigator (PI) of a research project have responsibilities and rights concerning access to, use of, and maintenance of data resulting from research conducted by faculty, students, or staff of The Ohio State University. Under this policy, the PI has the right and authority to control the appropriate use of, and access to, any research data conducted under their management or supervision, including the use of data in scholarly publications and presentations. Under Ohio law and federal regulation, any tangible research property, including data and/or other records of research conducted under the auspices of the Ohio State University, belongs to the university.

Purpose of the Policy

The purpose of this policy is to describe the rights and responsibilities of the university, faculty, staff and students in the collection, use, retention, and maintenance of data produced as a result of the research enterprise of the university.

Definitions

Term	Definition
Research data	Laboratory notebooks, as well as any other primary 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 of the media on which they may be recorded.

Policy Details

- I. Ownership
 - A. University ownership and stewardship of the scientific record for projects conducted by university faculty, staff, and students through the use of university facilities and resources, is based on state law (<u>ORC</u> <u>§3345.14</u>), federal regulation (<u>OMB Circular A-110, Sec. 53</u>), and sound management principles.
 - B. The responsibilities of the university in this regard include, but are not limited to
 - 1. Complying with the terms of sponsored project agreements;
 - 2. Ensuring the appropriate use of animals, human subjects, recombinant DNA, biological agents, radioactive materials, and the like;
 - 3. Protecting the rights of faculty, staff, and students, including, but not limited to, their rights to access to data from research in which they participated for their programs of study;
 - 4. Securing the intellectual property rights of the university; and
 - 5. Facilitating the investigation of charges, such as scientific misconduct or conflict of interest.
- II. Collection and Retention
 - A. Under federal regulations, the 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.
 - B. The principal investigator (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



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members of a research group and to applicable administrative personnel, where appropriate. Particularly for long-term research projects, the PI should establish procedures for the protection of essential records in the event of a natural disaster or other emergency.

- C. The collection, retention, and sharing of research data that incorporates individually-identifiable patient information from the Wexner Medical Center must comply with the <u>Protected Health Information and HIPAA</u> <u>policy</u>.
- D. Research data should be archived for a minimum of five years after the final project closeout (this is based on the longest required retention period under the various applicable federal regulations), with original primary data retained wherever possible. In addition, any of the following circumstances may justify longer periods of retention:
 - 1. If the terms of a sponsored research agreement administered by the Office of Sponsored Programs or other university unit requires a longer retention period;
 - 2. Data must be kept for as long as may be necessary to protect intellectual property resulting from the work. Data used to support a patent or copyright application must be archived for a minimum of twenty years or such other time as required by the Corporate Engagement Office;
 - 3. If any charges regarding the research arise, such as allegations of research misconduct or conflict of interest, data must be retained for a minimum of seven years as required by federal regulation, until such charges are fully resolved, or as required by applicable university policy; and
 - 4. If a student is involved, data must be retained at least until the degree is awarded, or until it is clear that the student has abandoned the work.
- E. Beyond the period of retention specified here, the destruction of research records is at the discretion of the PI according to their college or department policy. Records will normally be retained in the unit where they are produced. Research records must be retained in university facilities, unless the Vice President for Research grants specific permission to do otherwise. For additional information regarding specific records retention procedures see the Ohio State University <u>General Records Retention Schedule</u>.
- III. Data Security
 - A. Research data that incorporates personally identifiable or sensitive elements (such as Social Security numbers), or proprietary university information or trade secrets or includes controlled unclassified information or export controlled information, must have adequate security protections and be treated as "restricted data" under the <u>Institutional Data</u> policy. It is the responsibility of the PI to properly identify the classification of their data and to provide appropriate protections, as well as any additional data security that may be specifically required under the terms of a sponsored program agreement (such those in the Federal Information Security Management Act or the Food and Drug Administration's electronic records regulations).
 - B. It is the responsibility of the PI to immediately report any suspected or proven disclosure or exposure of personal information or other restricted data in the custody of the PI, co-investigator(s), research staff or students, which is stored in a university computer, system, or data network resource to the Office of the Chief Information Officer, Director of Information Security. Additional information on handling data disclosures or releases can be found in the <u>Information Security Incident Response Management policy</u>. The PI should also report any suspected or proven disclosure of any personally-identifiable HIPAA information to their unit's <u>HIPAA Privacy Officer</u>.

IV. Publication

A. As per national practice, the PI has the right and responsibility to ensure that research is accurately reported to the scientific and academic community, as well as to select the vehicle for publication or presentation of research data and results. In the case of research conducted with a co-PI(s), the co-PI(s) jointly share the right and responsibility to ensure that research is accurately reported to the scientific and academic community as well as to select the vehicle for publication or presentation of research data and results unless they agree otherwise in writing.



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 - B. It is the responsibility of the PI to ensure that all persons listed as authors on publications or presentations meet accepted criteria in their field for authorship credit, and that only such persons are listed as authors. The PI is responsible for ensuring that faculty, students, and/or research staff members who do not meet the criteria for authorship, yet have provided special assistance or contributions to the research, be listed in an acknowledgments section, if available in the publication.
 - C. The university handles disputes regarding authorship as an academic issue. Such disputes will be handled according to the procedures described below.
 - V. Access
 - A. To ensure needed and appropriate access as, for example, to facilitate a response to an allegation of research misconduct, the university has the option to take custody of the primary data and research records in a manner specified by the Vice President for Research.
 - B. Students, postdoctoral researchers, research associates and fellows, or other research trainees (hereinafter "researchers") may be granted access to research data by a PI for academic or research purposes in connection with a course of study or degree program or in their capacity as employees.
 - 1. Researchers given access to research data from any source are subject to all university rules, state and federal laws, and contractual obligations relevant to the data.
 - 2. Faculty and staff who give researchers access to data must inform them, in writing where appropriate, of any limitations or restrictions on the use or dissemination of the data.
 - 3. Researchers must retain access to data resulting from research projects they themselves have initiated, and to data acquired by processes for which they were primarily responsible.
 - 4. Researchers previously given access to research data in connection with a course of study, degree program, or contract may be denied such access by the PI or other responsible university official for reasonable cause.
 - 5. Concerns or disputes concerning access to data will be handled according to the procedures described below.
 - VI. Transfer in the Event an Investigator or Researcher Leaves the University
 - A. In general, when the PI or co-investigators involved in research projects at Ohio State leave the university, they may take copies of research data for projects on which they have worked.
 - B. As required by academic practice, the use of such data (for example, to conduct additional research, or for presentation or publication) is dependent on agreement with the PI, or as may be formally agreed-upon beforehand by the PI and other co-investigators in a data use agreement.
 - C. In all cases, the PI must retain the primary research data at the university unless specifically authorized pursuant to Procedure III below.
 - D. If a PI leaves the university or a project is moved to another institution, the primary research data may be transferred according to the procedure described below.
 - VII. Export Control
 - A. The PI is responsible for assuring compliance with any agreed-upon restrictions from sponsors (including publication and sharing with non-U.S. citizen collaborators and/or students) when using data that is controlled under federal International Traffic in Arms Regulations or Export Administration Regulations.
 - B. For more information, see the university Export Control policy.



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PROCEDURE

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I. Authorship Disputes

- A. Faculty, staff, or students who believe that they were not appropriately included on a publication or presentation should initially contact (in writing) the PI and the chair or director of the academic unit(s) involved, for review of such concerns.
 - 1. The chair or director will investigate whether appropriate authorship or acknowledgment was provided, based on accepted criteria for authorship or acknowledgment in the academic discipline/field, and mediate a resolution to the dispute.
 - 2. For concerns raised by graduate or professional students, the student should initially contact the graduate studies chair of their program.
- B. If a chair or director is potentially conflicted (e.g., he/she is a co-author on the publication or presentation at issue, is a collaborator of the PI, or has other close personal or professional ties), or if review of the chair or director's determination is requested, then the dean or their designee in the respective college will investigate the dispute.
- C. If a dean or their designee in the involved college(s) is potentially conflicted, or if the faculty, staff or student reasonably believes that the department and/or college failed to appropriately follow the above procedure for reviewing an authorship dispute, then the provost or their designee in the Office of Academic Affairs, in consultation with the Dean of the Graduate School for concerns involving graduate students, shall provide final institutional review and mediation of a resolution.
- D. In the event that a credible allegation of plagiarism exists in addition to the authorship dispute, the chair, dean, provost, or their designees should consult with the Vice President for Research and/or the Research Misconduct Coordinator regarding the allegation(s). Plagiarism allegations will be reviewed under the <u>Research Misconduct</u> policy. The Vice President for Research shall otherwise not participate in the above academic process for resolving authorship disputes, unless the authorship dispute involves an Office of Research Center.

II. Data Access Disputes

- A. If a dispute arises concerning a researcher's access to data, an initial effort to resolve the dispute will be made by the graduate studies chair (in the case of students) or the chair or director (for other researchers) of the relevant academic unit(s) involved, following stated grievance procedures for the graduate program or academic unit(s).
- B. Any subsequent appeals will be referred to the following entities, in order: the relevant college associate dean for research, or other qualified faculty administrator appointed by the dean, the Graduate School (for students), and, as a last resort, the Office of Research and the Office of Legal Affairs.
- III. Data Transfer in the Event an Investigator Leaves Ohio State
 - A. If a PI leaves the university or a project is moved to another institution, the primary research data may be transferred with the approval of the dean of the college employing the PI, the Vice President for Research, and the Wexner Medical Center (for data that incorporates OSUWMC patient information with personal identifiers), and with written agreement from the new institution.
 - B. Such written agreement, at a minimum, must provide:
 - 1. Adoption by the new institution of all custodial responsibilities for the data, including acceptance of all university and federal security requirements for restricted data that is transferred;
 - 2. Formal recognition by the new institution of the Ohio State University's continued ownership of the data; and



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3. Guaranteed access by the Ohio State University to the primary data, should such access become necessary.

Responsibilities

Position or Office	Responsibilities
Principal investigator (PI)	 Primary responsibility for the collection, management, and retention of research data for the periods required by this policy; Control access to research data; and Select the vehicle for publication or presentation of the data
Office of Research	 Notify the PI of any sponsor requirements for retention of research data beyond the minimal period specified in this policy; Secure the intellectual property rights in research data; Approve off-campus archival and transfer of research data; and Conduct research integrity investigations involving research data.
Chairs, Deans, and the Provost	Manage disputes concerning access to and authorship of publications and presentations involving research data.

Resources

University Policies Information Security Incident Response Management, <u>go.osu.edu/infosec-isirmp</u> Export Control, <u>go.osu.edu/Export-Control-Policy</u> General Records Retention Schedule, <u>go.osu.edu/retention-schedules</u> Protected Health Information and HIPAA, <u>go.osu.edu/phi-hipaa-policy</u> Institutional Data, <u>go.osu.edu/idp</u> Research Misconduct, <u>go.osu.edu/ResearchMisconductPolicy</u>

Laws and Regulations

Export Administration Regulations (EAR)- 15 CFR sections 730-774, <u>ecfr.gov/cgi-bin/text-idx?SID=1ce538802813688ad1c5a8e7d39a25d5&mc=true&tpl=/ecfrbrowse/Title15/15CVIIsubchapC.tpl</u> Health Insurance Portability and Accountability Act (HIPAA), <u>hhs.gov/hipaa/for-professionals/index.html</u> International Traffic in Arms Regulations (ITAR) - 22 CFR sections 120-130, <u>ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=2b696098de1ff50ea0b25e7959b4b0bb&r=PART&n=22y1.0.1.13.57</u> Office of Management and Budget - OMB Circular A-110, section 53, <u>whitehouse.gov/wp-content/uploads/2017/11/Circular-110.pdf</u> Ohio Revised Code §3345.14 <u>codes.ohio.gov/orc/3345.14</u> and §ORC 149.43 <u>codes.ohio.gov/orc/149.43v2</u>

Other Resources

HIPAA Privacy and IT Security Officers list, compliance.osu.edu/HIPAAprivacyITsecurity.pdf

Contacts

Subject	Office	Telephone	E-mail/URL
Policy questions	Office of Research Compliance	(614) 292-9258	<u>orc.osu.edu</u>

History

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