

APPLIES TO

This Policy applies to all Ohio State University faculty and staff involved in the design, conduct, or reporting of research at or under the auspices of the university, and it shall apply to all research projects on which those individuals work, regardless of the source of funding (if any) for the project. This policy also applies to students involved in the design, conduct, or reporting of research that involves sponsored programs, or research using university resources or facilities, other than those typically used for academic instruction.

POLICY

Issued: 09/18/2009 Revised:

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 employees of The Ohio State University. Under this policy and practice, the PI has the right and authority to control the appropriate use-of and access-to his/her research data, including the use of data in scholarly publications and presentations. Under Ohio law and federal regulation, however, tangible research property, including the data and other records of research conducted under the auspices of Ohio State University, belongs to the university. The purpose of this Research Data Policy is to describe the rights and responsibilities of investigators and the institution in the use, retention and maintenance of data produced as a result of the research enterprise of the university.

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Definitions

Research data include 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

Ownership

University ownership and stewardship of the scientific record for projects conducted by university faculty and staff, through the use of university facilities and resources, is based on state law (ORC 3345.14), federal regulation (OMB Circular A-110, Sec. 53), and sound management principles.

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, students, postdoctoral scholars, and staff, 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.

Collection and Retention

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.

The PI is responsible for the collection, management, and retention of research data, and should adopt an orderly system of data organization, and should communicate the chosen system to all 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.

The collection, retention, and sharing of research data that incorporates individually-identifiable patient information from the University Health System must comply with all applicable Health Insurance Portability and Accountability Act (HIPAA) policies and processes, including security standards.

Research data should be archived for a minimum of five years¹ after the final project closeout, with 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 Ohio State University Research Foundation or Office of Sponsored Programs require 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 university Office of Technology Licensing and Commercialization;
- 3) If any charges regarding the research arise, such as allegations of scientific misconduct or conflict of interest, data must be retained for a minimum of seven years as required by federal regulation, or until such charges are fully resolved; and

^{1.} Maintaining records for five years after final project closeout is based on the longest required retention period under the various applicable federal regulations.



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.

Beyond the period of retention specified here, the destruction of research records is at the discretion of the PI according to his or her college or department policy. Records will normally be retained in the unit where they are produced. Research records must be retained in Ohio State 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 General Records Retention Schedule (<u>http://library.osu.edu/sites/archives/retention/general-schedule.pdf</u>).

Data Security

Research data that incorporates personally identifiable or sensitive elements (such as Social Security numbers), or proprietary university information and trade secrets, must have adequate security protections and be treated as "Restricted Data" under The Ohio State University Policv on Institutional Data (http://cio.osu.edu/policies/institutional data/). It is the responsibility of the PI to provide such 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).

It is the responsibility of the PI to immediately report any suspected or proven disclosure or exposure of personal information 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 CIO Director of Information Security. Additional information on handling data disclosures or releases can be found in the university's policy on Disclosure or Exposure of Personal Information (<u>http://cio.osu.edu/policies/disclosure.html</u>). The PI should also report any suspected or proven disclosure of any personally-identifiable HIPAA information to their unit's HIPAA Privacy Officer.

Publication

As per national practice, the PI has the right and responsibility to ensure that research is 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-principal investigator(s), the co-PI(s) shall jointly share the right and responsibility to ensure that research is reported to the scientific and academic community as well as to select the vehicle for publication or presentation of research data and responsibility to ensure that research is 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.

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 investigators, students, and/or research staff members who do not meet the criteria for authorship, yet have provided special assistance or contributions to the research, should be listed in an acknowledgments section, if available in the publication.

It is the policy of the university to handle disputes regarding authorship as an academic issue. Such disputes shall be handled according to the procedures described in this Policy below.



Access

To ensure needed and appropriate access, for example, to facilitate response to an allegation of research misconduct, the university has the option to take custody of the primary data in a manner specified by the Vice President for Research.

Students, postdoctoral associates, 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. Researchers given access to research data from any source shall be subject to all university rules, state and federal laws, and contractual obligations relevant to the data. Faculty and staff who give Researchers access to data shall inform them, in writing where appropriate, of any limitations or restrictions on the use or dissemination of the data. Researchers shall retain access to data resulting from research projects they themselves have initiated, and to data acquired by processes for which they were primarily responsible. 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. Concerns or disputes concerning access to data shall be handled according to the procedures described below.

Transfer in the Event an Investigator Leaves Ohio State University

In general, when the principal 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. As required by academic practice, the use of such data (for example, to conduct additional research, or for presentation or publication) is dependent on the agreement with the PI, or as may be formally agreed-upon beforehand by the PI and other co-investigators in a data use agreement. In all cases, the PI must retain the primary research data at the university. 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.

Export Control

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.

PROCEDURES

Issued: 09/18/2009 Revised:

Authorship Disputes

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. The chair or director shall 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. For concerns raised by graduate or professional students, the student should initially contact the graduate studies chair of their program.

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 his/her designee in the respective college shall investigate the dispute.

If a dean or his/her 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 his/her 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.

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 university's Policy and Procedures Concerning Research Misconduct. 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.

Data Access Disputes

If a dispute arises concerning a researcher's access to data, an initial effort to resolve the dispute shall 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). Any subsequent appeals shall 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.

Data Transfer in the Event an Investigator Leaves Ohio State University

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 Health System (for data that incorporates patient information with personal identifiers), and with written agreement from the new institution, which, at a minimum, shall provide:

- 1) Adoption by the new institution of all custodial responsibilities for the data, including acceptance of all Ohio State University and federal security requirements for restricted data that is transferred;
- 2) Formal recognition of Ohio State University's continued ownership of the data by the new institution; and
- 3) Guaranteed access by Ohio State University to the primary data, should such access become necessary.

Responsibilities

Position, or Office	List of Responsibilities			
Principal Investigator (PI)	(PI) Primary responsibility for the collection, management, and retention of research data for the required by this policy; to control access to research data; and to select the vehicle for publica presentation of the data.			
Office of Research	Responsible for notifying the PI of any sponsor requirements for retention of research data beyond the minimal period specified in this policy; securing the intellectual property rights in research data; approving off-campus archival and transfer of research data; and for conducting research integrity investigations involving research data.			
Chairs, Deans and the Provost	Responsible for managing disputes concerning access to and authorship of publications and presentations involving research data.			



Resources

- Health Insurance Portability and Accountability Act HIPAA (<u>http://aspe.hhs.gov/admnsimp/pl104191.htm</u>)
- International Traffic in Arms Regulations (ITAR) 22 CFR sections 120-130 (<u>http://www.fas.org/spp/starwars/offdocs/itar/index.html</u>)
- Export Administration Regulations (EAR)- 15 CFR sections 730-774 (<u>http://www.access.gpo.gov/bis/ear/ear_data.html</u>)
- Ohio Revised Code ORC 3345.14 (<u>http://www.legislature.state.oh.us/bills.cfm?ID=123_SB_286</u>) and ORC149.43 (<u>http://codes.ohio.gov/orc/149.43</u>)
- Office of Management and Budget OMB Circular A-110, section 53 (http://www.whitehouse.gov/omb/rewrite/circulars/a110/a110.html#53)
- The Ohio State University General Records Retention Schedule (<u>http://library.osu.edu/sites/archives/retention/general-schedule.pdf</u>)
- The Ohio State University Policy on Institutional Data (<u>http://cio.osu.edu/policies/institutional_data/Institutional_Data.pdf</u>)
- The Ohio State University Policy on Disclosure or Exposure of Personal Information (<u>http://cio.osu.edu/policies/disclosure.html</u>)

Contacts

Individual or Office	Office	Telephone	E-mail/URL
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History

Issued: 09/18/2009

Revised: