Name of Policy: Research data and responsible conduct of scholarship and research **Policy Number**: 3364-70-02 **Approving Officer**: President **Responsible Agent**: Vice President for Research **Scope**: All University of Toledo Campuses	**Effective date:** November 18, 2020 **Original effective date**: March 25, 2008

☐	New policy proposal	☐	Minor/technical revision of existing policy
☒	Major revision of existing policy	☐	Reaffirmation of existing policy

(A) Policy statement

This policy describes the rights and responsibilities of University faculty, staff and students in the collection, use, retention and maintenance of Research Data and the standards of practice required for the conduct of scholarship and research at The University of Toledo. It is intended to complement, but be independent of existing University policies, sponsoring agency policies, and federal regulations governing certain aspects of the conduct of research including, but not limited to human subjects, animal subjects, radiation, biosafety, conflict-of-interest, and hazardous materials. A separate University policy on misconduct, which is mandated by federal regulations, describes how the University handles issues of research misconduct (University policy 3364-70-21). The University complies with all applicable laws and regulations governing aspects of the conduct of research and other scholarly activities.

(B) Scope

Scientific inquiry, scholarly contributions, creativity, and academic accomplishment can take many forms and may vary among disciplines. The issues addressed by this policy are essential to all research and scholarship and describes rights and responsibilities of the faculty, staff and students in authorship and publication, responsible conduct of research training, and in the collection, use, retention, and maintenance of data, produced as a result of the research enterprise of the University.

(C) Definitions

Corresponding Author is the author who is responsible for communicating with the publisher during the peer review and editorial process and for ensuring that all authors have reviewed and have access to the submitted or edited manuscript(s) and /or responses to reviewers. This individual is responsible for completing the administrative requirements of the publisher. In the event that there is more than one corresponding author, the corresponding authors share the responsibilities equally under this policy.

Research Director (RD) is any individual who is a dissertation or thesis advisor, laboratory director or research program director. The principal investigator on any grant/contract or sponsored project is the Research Director for the research or project(s) supported by that grant/contract.

Trainee is any individual in training. Trainees may include, but are not be limited to, undergraduate and graduate students, postdoctoral fellows, research associates or fellows, residents, and junior colleagues.

Unit Head is the immediate responsible administrator, generally a department chair, program director, center director, or dean.

Research Data is any information that has been collected, observed or generated, 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.

Electronic communications such as email and associated attachments transmitted, received or used in the course of university business, such as research projects, are considered to be public records, as stated in University 3364-65-07 Electronic communication policy, regardless of whether the communication was sent or received on a public or privately owned personnel computer or messaging system.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Scholarship is defined as the practice of advancing, preserving, and disseminating knowledge and thought through study, reflection, and engagement that extends beyond traditional instructional activities. Research and scholarship are used interchangeably in this document.

Sponsored Projects include activities originated or conducted by University faculty or staff supported wholly or in part by external restricted funds awarded to the University. Definitions of activities are found in 3364-70-23 Facilities and Administration Costs policy. Such activities include: Sponsored Instruction and Training, Organized Research and Other Sponsored Activities.

(D) Responsible Conduct of Research (RCR)

It is the responsibility of the RD to ensure that all applicable research team members are informed of sponsor RCR training requirements and that requirements have been met. It is also RD's responsibility to provide appropriate mentoring of Trainees under their direction through discussions of RCR and through oversight of the research project. RCR topics related to the research project may include:

(1) Conflicts of interest (personal, professional, and financial).

(2) Policies regarding the use of human subjects in research.

(3) Policies regarding the use of animals in research.

(4) Laboratory safety, biohazard management, chemical safety, and polices regarding the use of radioisotopes and radiation sources and controlled substances in research.

(5) The responsibilities and relationships of mentors and mentees.

(6) Collaborative research.

(7) The peer review process.

(8) Data acquisition and laboratory tools; management, sharing and ownership of data and research tools.

(9) Research misconduct and policies for handling research misconduct.

(10) Authorship and publication.

(11) Science and engineering in society which may include: responsibilities to the community and society; ethical issues in research; and the environmental and societal impacts of scientific research.

(12) Export control.

(13) Compliance with terms and conditions contained within agreements related to research activity such as federal awards, sponsored project agreements, material transfer agreements, and confidentiality agreements.

(E) University Responsibilities

(1) The responsibilities of the University in research activities include, but are not limited to:

(a) Ensuring compliance with the terms of sponsored project agreements;

(b) Monitoring and regulating the appropriate use of animals, human subjects, recombinant DNA, biological agents, radioactive materials, and the like;

(c) 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;

(d) Securing the intellectual property rights of the University; and

(e) Facilitating the investigation of charges, such as scientific misconduct or conflict of interest.

(F) Research Data

(1) Ownership

University ownership and stewardship of Research Data for projects conducted by University faculty, staff, and students through the use of University facilities and resources, is based on state law (ORC §3345.14), federal regulation (OMB Circular, part 215.53), and sound management principles.

(2) Collection and Retention

(a) 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, regulations and sponsor requirements governing the conduct of the research.

(b) The RD is responsible for the collection, management, and retention of Research Data. The RD 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 projects, the RD should prepare for preservation of Research Data in the case of fire, natural disaster, or any other emergency.

(c) Research Data should be archived for a minimum of five years after the final project closeout, with original primary data retained wherever possible. In addition, any of the following circumstances may justify longer periods of retention:

(i.) Terms and conditions of a sponsored project agreement;

(ii.) As long as may be necessary to protect intellectual property resulting from the work. Research 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 Office of Research & Sponsored Programs (ORSP);

(iii.) 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, until such charges are fully resolved, or as required by applicable University policy 3364-70-21; and

(iv.) If a student is participating in the research, Research Data must be retained until the degree is awarded, or until it is clear that the student has abandoned the work.

(d) Beyond the period of retention specified here, the destruction of research records is at the discretion of the RD. Records will normally be retained in the unit where they are produced. Research records must be retained in University facilities unless pursuant to procedure (F)(5)(d) below. For additional information regarding specific records retention procedures see the University of Toledo's General Records Retention Schedule (managed by the University Archives).

(3) Data Security

(a) The collection, retention, and sharing of Research Data that incorporates individually-identifiable protected health information (PHI) must comply with all applicable Health Insurance Portability and Accountability Act (HIPAA) policies and processes, including security standards.

(b) 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". It is the responsibility of the RD to properly identify the classification of the 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 or data use agreement (such those in the Federal Information Security Management Act or the Food and Drug Administration's electronic records regulations).

(c) It is the responsibility of the RD to immediately report any suspected or proven disclosure or exposure of personal information or other restricted data in the custody of the RD, 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. (Technology incident response policy, 3364-65-10).

(d) The RD 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.

(4) Access

(a) Trainees or other research contributors or collaborators (referred to as researchers) may be granted access to Research Data by a RD for academic or research purposes in connection with a course of study or degree program or in their capacity as employees.

(i.) 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 Research Data.

(ii.) Research Directors who give researchers access to Research Data must inform them in writing, where appropriate, of any limitations or restrictions, including but not limited to export controls, on the use or dissemination of the data.

(iii.) Researchers must retain access to Research Data resulting from research projects they themselves have initiated, and to data acquired by processes for which they were primarily responsible.

(iv.) 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 RD or other responsible University official for reasonable cause.

(v.) Concerns or disputes concerning access to Research Data will be handled according to the procedures described below.

(a) If a dispute arises concerning a researcher's access to data, an initial effort to resolve the dispute will be made by the student's director or department chair (in the case of students) or the unit head (for other researchers) of the relevant unit(s) involved, following stated grievance procedures for the program or academic unit(s).

(b) 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 first; and the Office of Research & Sponsored Programs under the direction of the Vice President for Research. Appeals for students will be referred to the College of Graduate Studies.

(b) 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 and electronic communication (e.g. emails) in a manner specified in University policy 3364-70-21.

(5) Transfer of data from the University

(a) In general, when the RD or co-investigators involved in research projects at The University of Toledo 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 RD, or as may be formally agreed-upon beforehand by the RD and other co-investigators in a data use agreement.

(c) In all cases, the RD must retain the primary Research Data at the University unless specifically authorized pursuant to procedure (F)(5)(d) below.

(d) If a RD 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 RD, the Vice President for Research, and with written agreement from the new institution. At a minimum, such written agreement must include:

(i.) 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;

(ii.) Formal recognition by the new institution of the University of Toledo's continued ownership of the data; and

(iii.) Guaranteed access by the University of Toledo to the primary data, should such access become necessary.

(G) Publication and Authorship

(1) Publication and Presentation of Research

The RD should ensure that procedures for resolving detailed concerns, such as the timing of presentations or publications, order of authorship, and privilege of presenting results at meetings, be discussed with research team members to the extent feasible at the beginning and throughout the research activities as needed and as part of on-boarding new members to the research group or project.

The RD (or Corresponding Author) 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 the initial publication or presentation of Research Data and results, including poster or conference presentations.

(a) Authorship disputes should be addressed through the relevant academic units and through procedures established by the Provost's Office.

(b) In the event that an allegation of fabrication, falsification, plagiarism, or a deliberate violation of regulations exists in addition to the authorship dispute, the chair, dean, provost, or their designees must immediately consult with the Vice President for Research or the University Research Integrity Officer regarding the allegation(s). Allegations of research misconduct will be reviewed under the University policy 3364-70-21.

Approved by: /s/ Gregory C. Postel, M.D. Interim President November 18, 2020 Date *Review/Revision Completed by: Senior Leadership Team*	**Policies Superseded by This Policy:** *03-012 Responsible conduct of scholarship and research (former Health Science Campus Policy, revision date 07/01/03)* Initial Effective Date: March 25, 2008 Review/Revision Date: August 19, 2011, November 18, 2020 **Next review date: November 18, 2023**

Resources

University Policies

Integrity in research and scholarship, 3364-70-21

Protection of human subjects in research, 3364-70-05

Use of biohazardous materials, recombinant and synthetic nucleic acids, stem cells, and toxins in research, 3364-70-06

The Use of Controlled Substances in Animal and in vitro research, 3364-70-27

Laboratory animal welfare, care and use, 3364-70-10

Facilities and administration policy, 3364-70-23

Technology incident response policy, 3364-65-10

University of Toledo General Records Retention Schedule

Patent Policy, 3364-70-04

Laws and Regulations

Ohio Revised Code §3345.14 http://codes.ohio.gov/orc/3345.14 and §ORC 149.43 http://codes.ohio.gov/orc/149.43

Office of Management and Budget - Uniform administrative requirements for grants and agreements with institutions of higher education, hospitals, and other non-profit organizations (OMB Circular A–110), Part 215, section 53, https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A110/2cfr215-0.pdf

Health Insurance Portability and Accountability Act (HIPAA), https://aspe.hhs.gov/report/health-insurance-portability-and-accountability-act-1996

International Traffic in Arms Regulations (ITAR) - 22 CFR sections 120-130, https://ecfr.gov/cgi-

bin/retrieveECFR?gp=&SID=2b696098de1ff50ea0b25e7959b4b0bb&r=PART&n=22y1.0.1.13.57

Export Administration Regulations (EAR)- 15 CFR sections 730-774, https://www.govinfo.gov/content/pkg/CFR-2020-title15-vol2/xml/CFR-2020-title15-vol2-part730.xml

NIH Requirement for Instruction in the Responsible Conduct of Research, NOT-OD-10-019

Other Resources

National Academies of Sciences, Engineering, and Medicine. 2017. Fostering Integrity in Research. Washington, DC: The National Academies Press. https://doi.org/10.17226/21896

National Academies of Sciences, Engineering, and Medicine. 2019. Reproducibility and Replicability in Science. Washington, DC: The National Academies Press. https://doi.org/10.17226/25303

Committee on Publication Ethics (COPE) Authorship Resources, https://publicationethics.org/authorship

CRediT (Contributor Roles Taxonomy), https://casrai.org/credit/

The GDPR and its Impact on the Clinical Research Community (including non-EU Researchers), https://www.advarra.com/the-gdpr-and-its-impact-on-the-clinical-research-community-including-non-eu-researchers/

How GDPR Changes the Rules for Research, https://iapp.org/news/a/how-gdpr-changes-the-rules-for-research/

International Committee of Medical Journal Editors (ICMJE), Defining the Role of Authors and Contributors, http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

Council of Science Editors, Authorship and Authorship Responsibilities, https://www.councilscienceeditors.org/resource-library/editorial-policies/white-paper-on-publication-ethics/2-2-authorship-and-authorship-responsibilities/

Questionable Research Practices, https://replicationindex.com/2015/01/24/questionable-research-practices-definition-detect-and-recommendations-for-better-practices/