


<p>Name of Policy: <u>Responsible conduct of scholarship and research.</u></p> <p>Policy Number: 3364-70-02</p> <p>Approving Officer: President</p> <p>Responsible Agent: Vice President for Research Administration</p> <p>Scope: All University of Toledo Campuses</p>	 <p>Effective date: March 25, 2008</p>
<p><input type="checkbox"/> New policy proposal</p> <p><input type="checkbox"/> Major revision of existing policy</p>	<p><input checked="" type="checkbox"/> Minor/technical revision of existing policy</p> <p><input type="checkbox"/> Reaffirmation of existing policy</p>

(A) Policy statement/preamble

This policy describes the standards of practice required for the conduct of scholarship and research at The University of Toledo (hereinafter, “University”). 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 scientific misconduct. The University complies with all applicable laws and regulations governing aspects of the conduct of research and other scholarly activities. The present policy is based on three important principles:

- (1) The University is obligated to protect and foster the academic freedom and intellectual integrity of all members of the university community in their pursuit of knowledge;
- (2) The University is accountable to outside funding and regulatory entities that support and/or regulate the research and scholarship of its faculty, staff, and Trainees; and
- (3) Each Scholar has ultimate responsibility for the accuracy and validity of his/her own work and that of junior colleagues, fellows, and Trainees working under his/her mentorship. Each Scholar shares this responsibility with colleagues with whom she/he establishes collaborative relationships.

(B) Definitions

Research Director is used as a generic term to mean any individual who is a dissertation advisor, laboratory director or research program director. The principal investigator on any grant/contract is the Research Director for the research program(s) supported by that grant/contract.

Scholar is used as a generic term to mean any individual who is engaged in communicating/teaching or learning existing knowledge, or in the creation or discovery of new knowledge

Trainee is used as a generic term to mean any individual in training. Trainees may include, but may not be limited to, undergraduate and graduate students, postdoctoral fellows, residents, and junior colleagues.

Unit Head is used as a generic term to mean the immediate responsible administrator, generally a department chair, program director, center director, or a dean.

(C) Areas of applicability

This policy applies to research in all areas of intellectual inquiry. A separate section (section E) addresses issues specific to scientific research. This policy is intended to heighten awareness of potential ethical issues and to instruct individuals regarding appropriate procedures for resolving and documenting ethics-related matters. The focus is on the individual Scholar; the purpose is to emphasize that his/her responsibility includes a duty to maintain high scholarly and ethical standards, and a commitment to instill those standards in junior colleagues, co-investigators, and Trainees.

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 scholarly activity within the University community. Scholarly responsibility, quality of scholarly activity, accuracy of scholarly contributions and their sources, responsible authorship, and provision for training in ethics of each discipline are issues inherent to all areas. The implications of this policy apply as fully to the Scholar who co-authors a textbook in his/her discipline as to the laboratory scientist who reports a biological discovery, or the clinician who publishes the results of a prospective study of a patient-oriented research problem.

This policy addresses the following concerns:

- (1) The Scholar's authority and responsibility for research activities;
- (2) The establishment of the quality of research;
- (3) Authorship of publications, including multi-author publications and requisites for authorship;
- (4) The supervision of Trainees;
- (5) The education of Trainees in research ethics and integrity;
- (6) Documentation of, access to, and retention of scientific research protocols and data; and
- (7) The social responsibility of the Scholar.

(D) The conduct of research and scholarship

(1) Authority and responsibility for research activities

Each Unit Head is responsible for assuring that each Trainee has a specific faculty Research Director. This responsibility should not be construed as carrying rights of authorship, consultation, or approval of manuscripts prior to publication.

(2) Establishing the quality of research

- (a) Primary assurance of the quality of research stems from the scholarly qualifications of individual faculty members. All faculty members are ultimately responsible for the scholarly character, accuracy, and reliability of their own research and for that conducted under their supervision. Each Scholar is also responsible for the integrity and originality of his/her own research. The most effective single process for ensuring research of high quality is peer review, formal and informal, and internal as well as external. Informal peer review occurs through departmental and interest-group seminars and research discussion groups. Each college, department, or program should encourage such informal peer review procedures. Formal peer review will be accomplished by existing internal and external review committees that are charged with the task of evaluation of the merit and relevance of research and other scholarly activities. (An example of an internal peer review committee is the promotions and tenure committee. An example of an external peer review committee is a NIH study section.)
- (b) Faculty should establish an intellectual atmosphere that promotes high academic and moral standards and in which issues of social responsibility and professional ethics are addressed.
- (c) The University's formal policy governing investigations of misconduct in research should be followed when allegations of research improprieties have been made. That document, which is incorporated herein by reference, should be on file in the office of each Research Director and faculty member and should be distributed to all members of the research team.

(3) Authorship of publications

- (a) By virtue of the multiplicity of sources of concepts and information upon which any piece of scholarship is based, it is essential that proper attribution be emphasized in the presentation of ideas and the publication of manuscripts.

- (b) Authorship should be granted to, and only to, those persons who have made appropriate contributions to the conceptualization, design, execution, or interpretation of the work reported. Individuals who have made lesser contributions such as providing advice, analysis, subject material, or who may have supported the research in other ways, should be acknowledged. The principal author should determine whether such individuals should be listed as authors. Acquisitions of funding, collection of data, or general supervision of the research group, by themselves, do not justify authorship. In some fields, written permission may be required for acknowledgments. In factual or scientific reports, authors should take care to cite relevant data including those which do not support the hypothesis being presented. It is an authors' responsibility to be familiar with and to cite other publications relevant to his/her work. It is unethical, and harmful to the scholarly endeavor, to submit the work of others, in whole or in part, as one's own, to fabricate research results, or to suppress or alter information. (Modified from "Ethical Guidelines for Publication of Research", *Endocrine Reviews*, 10:1, 1989 and "Authorship and Other Credits", N. Fotion and C.C. Conrad, *Annals of Internal Medicine*, 100:592, 1984.) Authors who wish to cite information learned personally from others or from unpublished materials of others should obtain written permission from the source(s).
- (c) It is inappropriate to submit simultaneously manuscripts, abstracts, or reports of the same research to more than one publisher unless the action is authorized by the editors of each publication or multiple submission is the accepted standard of practice in a discipline/field. Preliminary reports or abstracts of work already published should be referenced in any complete report of that work.
- (d) Multiple authorship raises issues such as criteria for inclusion as an author, ability of each author to evaluate all aspects of a study, and sequence of listing of authors. Authors should discuss these issues openly before initiating a multi-author project and repeatedly during the course of such work. The corresponding or primary author has responsibility for coordinating the completion and submission of the work, and for assuring that the contributions of all collaborators are appropriately recognized. All authors should approve the final version of a manuscript and should be prepared to take public responsibility for the work.
- (e) Each author or co-author is responsible for composing, reviewing, and verifying those portions of a manuscript, publication, or presentation that represent his/her contribution. A good practice would be for each author to sign a statement of verification attesting to the authenticity of the manuscript(s). The signatures should be appended to the final manuscript. All co-authors are

entitled to make appropriate copies of a manuscript, including figures and appended documents.

- (4) Supervision of Trainee scholarship
 - (a) An academic institution's responsibility to educate and prepare Trainees to enter society and to practice their disciplines with high ethical standards does not cease with formal course work. The University and its faculty have an obligation to the academic community, the public, and the Trainee to ensure that all Trainees engage responsibly in scholarship and research, using the highest professional standards.
 - (b) Research Directors and Unit Heads share responsibility for guaranteeing an open and equitable research environment that protects the interests of Trainees, assistants and other vulnerable research personnel. They should ensure that Trainees are given due recognition for original work, that demands made upon Trainees are reasonable, and that they are treated with the same professional courtesy granted peer colleagues. Avenues must be available for Trainees who feel their supervision or training is inadequate to bring this to the attention of the Research Director or, if necessary, to the appropriate Unit Head.
 - (c) Research Directors should meet regularly with Trainees and other collaborators to review their work and progress.
 - (d) Research Directors should serve as role models and maintain the highest standards in performance of research. They should encourage Trainees to be open and to share ideas and information with other members of the scholarly community. They should ensure that the experience of their Trainees serves to prepare them to become independent Scholar and researchers.
 - (e) The number of Trainees each Research Director is responsible for should be small enough that close interaction is possible for scientific exchange as well as oversight of research at all stages.

- (5) Education of Trainees in research ethics and integrity
 - (a) Ethical issues and questions in the conduct of scholarship should be made an integral part of the education of all Trainees. Research directors are responsible for establishing a training environment in which value-related issues are discussed freely. The research director should expect and foster a familiarity with ethics as related to scholarship. The goals should be to teach Trainees how to identify ethical issues and how to address the common ethics-related questions that arise in the course of investigation and publication.

- (b) Unit Heads, division chiefs, and program directors are responsible for fostering the teaching of ethics within their academic units. An ethics component of the curriculum should provide Trainees and faculty with the intellectual tools and interactional skills to apply ethical thinking to everyday problems encountered in their research and other scholarly pursuits. Ethical issues, concepts and theoretical grounding should be introduced as part of the orientation of all Trainees.

(6) The social responsibility of the Scholar

Scholars have an obligation to ensure that scholarship is not misused and that it does not become a tool for abuse. Scholars are more likely than others to know the limits and conditions of current knowledge in their own fields, and the problematic aspects of using this knowledge to make public policy. Scholars have a right and a responsibility to make their voices heard when their scholarship and their contribution to society are being misquoted, misunderstood, or misapplied. Scholars are also responsible for being familiar with all University policies related to research.

(7) Peer review and privileged information

Peer review, as used in this policy, is defined as expert critique of a scholarly treatise, such as a manuscript, a grant/contract proposal, a research protocol, or of an entire research program, (e.g., as in a site visit). Peer review is an essential component of the conduct of scientific research and other scholarly activity. Decisions made in the peer review process must be based on thorough, fair, and objective evaluations by recognized experts. Therefore, although it is often difficult and time-consuming, scientists have an obligation to participate in the peer review process and, in doing so they make an important contribution to science.

Peer review must be objective. It should thus be based solely on scholarly evaluation of the material under review within the context of published information and should not be influenced by scientific information not publicly available.

All material reviewed must be considered to be privileged information. It should not be used to the benefit of the reviewer unless it previously was made public. It should not be shared with anyone unless necessary to the review process, in which case the names of those with whom the information was shared should be made known to those managing the review process. Material under review should not be copied and retained or used in any manner by the reviewer unless specifically permitted by the journal or reviewing organization and the author of the material.

Privileged or confidential information may also be obtained by an individual as a result of a collaboration with other investigators, both within the University and outside of the University, or when involved in research projects sponsored by corporate entities that share some of their confidential information or trade secrets in order to facilitate the research project. This information obtained from corporate entities generally is protected by a written confidentiality agreement between the company and the investigator and, at times, the University. All parties to such an agreement are expected to adhere strictly to the responsibilities imposed by the agreement. Even when information exchanged between collaborators or between investigators and research sponsors is not protected by a written confidentiality agreement, investigators should consider that information to be privileged, unless they know that the information has been previously published, or the owner of the information makes it clear that the information is not privileged or confidential.

(E) The conduct of scientific research

The following paragraphs refer specifically to scientific research and serve as an addendum to the broader guidelines described above.

(1) Authorship and responsibility for scientific research activities

Each Unit Head or program director is responsible for assuring that:

- (a) Every laboratory or research unit has a designated Research Director, and
- (b) Each Trainee has a specific faculty research preceptor, usually a full-time University faculty member.

(2) Establishing the quality of scientific research

- (a) The Research Director is responsible for assuring close personal supervision of the research of Trainees including the design of research protocols, approval by appropriate committees, data gathering and recording, statistical analysis, interpretation of results, preparation of manuscripts, submission and revision of manuscripts for publication, and presentations at scholarly meetings.
- (b) The Research Director is also responsible for informing each new staff person, Trainee, or junior investigator of applicable federal, state and institutional regulations for conduct of studies involving human subjects, animal subjects, radioactive and other hazardous materials, including biohazards and recombinant DNA. The Research Director is responsible for informing personnel in their laboratories about applicable University policies, including this one. The Research Director is also responsible for explaining and

discussing the relevant requirements for the responsible conduct of research with Trainees and visiting scientists in the laboratory, and to ensure that such requirements are met.

- (c) The distinction between intellectually-driven inquiry and commercially-targeted research is sometimes vague. Many respected faculty are committed to developing and studying tools, techniques and processes whose primary purpose is to promote the health or welfare of society in areas having potential commercial value. The Research Director is responsible for assuring that such investigations meet the same standards of quality and reproducibility as investigations of a more basic nature. Furthermore, any faculty member that has financial interests in a company sponsoring his/her research should disclose such financial interests to his/her Unit Head, in accordance with the University conflict of interest policy to avoid the potential for conflicts-of-interest, or the appearance thereof. When there is a possibility that Trainees may be involved in research sponsored by a commercial entity, special care must be taken to ensure that the academic welfare and freedom of the Trainees is protected. Frequently, research contracts with commercial sponsors contain confidentiality and/or publication provisions that limit the ability of laboratory personnel, including Trainees, to communicate freely the results of their research. Student participation in projects with such restrictions has a potential to affect timely dissemination of results of a student's research in the form of a dissertation or other publications. Prior to student participation in such projects, the Research Director should consult with the Dean of the College of Graduate Studies.
- (d) In keeping with the principle of fostering reproducibility in science, and in the absence of intellectual property considerations, novel compounds and reagents used for experiments should be made available, or appropriately described means for obtaining these should be given, to other competent members of the research community upon request. In some cases, execution of a Material Transfer Agreement (MTA) may be required prior to exchange of such materials. Investigators should have the latitude to make a fair and balanced response to requests for all research substances, including novel compounds and reagents.
- (e) Clinical research requires special attention to issues of informed consent and confidentiality. Because patients have a right to assume that decisions about their treatment are made in their best interests, the physician-investigator should disclose all significant alternatives and risks to patients who are potential research subjects so that they can make an informed judgment about participation in a research study. Signed copies of informed consent must be provided to study subjects and placed in the

subject's/patient's clinical records as well as being maintained with research records. Clinical research records generally remain the property of the University, and the Unit Head of each principal investigator conducting clinical trials is responsible for ensuring the maintenance of the records associated with those trials. Faculty members, as well as the company which sponsors the clinical trials, may make copies of the records upon departure of the faculty member from the University, but the original records must remain at the University under the custodial care of the principal investigator, or in his/her absence, his/her Unit Head.

- (3) Access to and retention of scientific research protocols and data (also see Appendix)
 - (a) Both the Research Director and the University have rights and responsibilities concerning access to, and use and maintenance of original research data. In general, since grant/contract agreements are between the University and the sponsoring agency, not between the principal investigator and the sponsoring agency, research data are owned by the University, not the principal investigator or the researcher producing the data. Consistent with the precepts of academic freedom and intellectual integrity, data management, including the decision to publish, is the responsibility of the Research Director.
 - (b) Each Research Director is ultimately responsible for the maintenance and proper retention of research records. These records should include sufficient detail for the following: (i) to permit examination for the purposes of replicating the research; (ii) responding to questions that may result from unintentional errors; (iii) responding to allegations of misinterpretation of research results; (iv) responding to allegations of scientific misconduct; (v) establishing data authenticity, and (vi) confirming the validity of the conclusions. In the absence of unambiguous, easily retrievable primary experimental data, honest errors may be mistaken for misconduct.
 - (c) Each Research Director should maintain a laboratory manual, either in paper or electronic format, which describes all experimental procedures and results. Correspondence with institutional review committees and records of the use of controlled substances and radioactive materials should be maintained as part of the research record in accordance with the law and with governmental regulations, and University policies.
 - (d) A standardized system of data organization should be adopted and should be communicated to all members of a research group and to appropriate administrative person(s). The appropriate administrative person(s) should be determined by the research director.

- (e) Where feasible, all original primary data are to be retained by the Research Director or by his or her designee. Accepted practices for retaining data vary among disciplines and depend on the perishability, nature, and logistics of retaining each type of data. Each investigator should treat data properly to ensure authenticity, reproducibility, and validity and to meet the requirements of relevant grants/contracts and other agreements concerning the retention of data. Primary data should be retained for a reasonable duration to ensure that any questions raised by the researcher, colleagues, or readers of any published results can be answered. It is recommended that, where feasible, data be retained for seven years; in circumstances where there are no federal or other requirements such as those referred to in the Appendix, requiring a longer retention period. Sub-units of the University may wish to establish uniform standards and procedures for retention and destruction of data. Data should not be destroyed without proper notification of and approval by an appropriate administrative person, generally University legal counsel. Data associated with potentially patentable inventions or discoveries should be signed and dated by the investigator at the time they are entered into notebooks or maintained by other methods of retention in the event the results are questioned. Departing investigators or Trainees may take copies of notebooks or other data for further work, but the originals must be kept at the University by the Research Director or Unit Head.
- (f) In the event the Research Director leaves the University, an agreement of disposition of research data (see sample agreement at end of this policy) may be negotiated by the Scholar and his or her Unit Head or Dean to allow the departing Scholar's data, notebooks, and other data retention materials (other than clinical research records) to be transferred to the Scholar's new institution. Consistent with the same precepts, and to fulfill its obligations to funding sources and others, the University will ensure in such agreements its own access to the transferred data for purposes of review. In unusual cases (e.g., data used for a patent application filed by or on behalf of the University) it may be necessary for original data to be kept at the University. In such cases an individual written agreement shall be signed which preserves the Scholar's right to access and copy (where practical) such data. In cases of multi-institutional studies, the institution of the primary study director is ultimately responsible for guaranteeing appropriate access to, use of, and retention of original data.

(4) Collaborations

Research collaborations frequently facilitate progress and should be encouraged. It is advisable that the ground rules for collaborations, including data access and management and eventual authorship issues be

discussed openly among all collaborators from the beginning. Whenever collaborations involve the exchange of materials between University investigators and investigators outside of the University, a Material Transfer Agreement (MTA) or other formal written agreement(s) may be necessary. Information regarding such formal agreements may be obtained from the University Office of Research Development.

(This policy was adapted with permission from similar policies of Emory University and the NIH.)

<p>Approved by:</p> <p><u> /s/ laj </u> Lloyd A. Jacobs, M.D. President</p> <p><u> May 20, 2008 </u> Date</p> <p><i>Review/Revision Completed by:</i> <i>Senior Leadership Team</i></p>	<p>Policies Superseded by This Policy: <i>03-012 Responsible conduct of scholarship and research (former Health Science Campus Policy, revision date 07/01/03)</i></p> <p>Initial Effective Date: March 25, 2008 Review/Revision Date: Next review date: 12/1/2010</p>
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APPENDIX

RECORDS RETENTION Grants and Other Types Of Agreements

[NOTE: Retention of any specific record is controlled by the applicable requirement with the LONGEST retention requirement]

General Regulation:

See UT Policy on Records Retention and Management for general information regarding records retention.

Specific requirements for records retention of certain types of records related to extramural Grants and Contracts are outlined below.

Federal Requirements

OMB (Office of Management and Budget) Circular A-110 (Uniform Administrative Requirements for Grants and Agreements of Higher Education, Hospitals and Other Non-Profit Organizations). This regulation applies to all federally funded grants and other types of agreements.

Records must be retained for at least three (3) years from the date of the submission of the final expenditure report.

Specific Agencies (for example):

1. Health and Human Services: 45 C.F.R (Code of Federal Regulations) 74(D): Records must be retained for at least three (3) years from submission of last expenditure report.
2. US Department of Education: 34 C.F.R 74(A): Records must be retained for at least three (3) years from submission of last expenditure report.

State of Ohio Requirements

1. Records relating to awarded grants must be kept for the active year plus the previous five (5) years
2. Records relating to patents must be kept for the active year plus the previous six (6) years
3. Recruitment/search committee files for contract employees (including faculty) must be kept for three (3) years

Records and Reports: Clinical Trial Agreements

1. Food and Drug Administration: 21 C.F.R. 312.62: In general, records must be retained for at least two (2) years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, until two (2) years after the investigation is discontinued and FDA is notified, OR as agreed to in the contract with the sponsor governing the clinical trial.
2. Food and Drug Administration: 21 C.F.R. 56.115: Regarding IRB records: Records required by this regulation shall be retained for at least three (3) years after completion of the research.

