

Office of Research & Sponsored Programs

Research Ethics & Compliance

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Main Campus
Research Compliance Coordinator



Don't Let This Happen to You

Recent Cases

- (2007) Dr. J. Reece Roth, emeritus professor of electrical engineering at the University of Tennessee in Knoxville recently was sentenced to four years in prison for deemed export violations.
- Dr. Ryan Wolfort, a graduate student at Louisiana State University, was proven guilty of falsifying and fabricating data in his doctoral dissertation and three publications. For this, his degree was revoked and he has been banned from receiving federal funding for two years.

OFFICE OF RESEARCH INTEGRITY

- **Data Management**
- **Mentor/Trainee Relationships**
- **Publication Practices**
- **Peer Review**
- **Collaborative Science**
- **Human Subjects**
- **Animal Welfare**
- **Research Misconduct**
- **Conflict of Interest and Commitment**

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Research Ethics

RESPONSIBLE CONDUCT OF RESEARCH TRAINING

- **STRONGLY RECOMMENDED FOR ALL GRADUATE STUDENTS!**
- **New regulatory (2010) requirement for:**
 - **Faculty, post-docs and students on NIH Training Awards**
 - **Post-docs and students supported by NSF grants**
- **[www. citiprogram.org](http://www.citiprogram.org) (see Office of Research website for more information)**



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- **Research Misconduct**
- **Conflict of Interest and Commitment**
- ***Environmental Safety (chemical, radiation & biosafety)***
- ***Export Control Laws***



RESEARCH PROTOCOLS

Students MUST be Named Participants on Approved Protocols for Research Involving:

- **Human Subjects**
- **Animals**
- **Environmental Safety**
 - **Chemical, radiation & biohazards**

GRAD Approval & Assurance Form



RETURN TO: College of Graduate Studies
(Office for Respective Campus)

Main Campus Health Science Campus
University Hall Room 3240 Mulford Library Room 117
Mail Stop 933 Mail Stop 1042

Graduate Research Advisory (GRAD) Committee Approval & Assurances Form

This form replaces the Notice of Project, Notice of Thesis, and Assurances of Compliance Forms for Main Campus and replaces the Academic Advisory Committee and the Ph.D./MSBS Research Track Major Advisor/Departmental Responsibility Forms for the Health Science Campus.

Instructions: Students must complete this form and receive the required approvals prior to beginning any research for a project, thesis, or dissertation involving humans, animals, radiation, or biohazardous substances. Federal regulations do not allow retroactive approval.

For the purposes of this document, the term "investigator" includes both the **Principal Investigator or Faculty Advisor and the Student Investigator**. The completion of this form indicates that a student's committee has approved both a topic and an approach for the research, and is aware of federal requirements for institutional review of research methods.

This form, signed by the Student, Advisor, Committee Members, and Department Chairman (Health Science Campus) should be routed to the individuals noted in the approval section of this form. (Please note Advisor on this form denotes "Major Advisor" on the Health Science Campus and "Research Advisor" on the Main Campus.)

The respective College of Graduate Studies Office will record receipt of the form, signifying that institutional review requirements have been met. The Policy Information and Forms cited below are available on the following Research & Sponsored Programs Web-site: <http://utoledo.edu/research/RCMMain.html>

Student's Name:	Student ID #:	Date:
Degree:	Concentration or Track (if applicable):	
Term and Year Matriculated (check one):	<input type="checkbox"/> Fall <input type="checkbox"/> Spring <input type="checkbox"/> Summer	Year:
Research (check one):	<input type="checkbox"/> Scholarly Project <input type="checkbox"/> Thesis <input type="checkbox"/> Dissertation	
Advisor:		
Proposed Title:		

I. Are HUMAN SUBJECTS involved in the research? (check one) Yes No

A project meets the definition of **Human Subjects Research** if it involves living individuals about whom an investigator conducting research obtains:

(1) **data through intervention or interaction with the individual;** or
(2) **identifiable private information**

This includes direct data collection, such as through interview or questionnaire or indirect data collection or interaction such as observing subjects through one-way glass, or reviewing records, or identifiable private

information. For additional information or if you have questions about whether or not IRB review and approval is required, please contact the **Department for Human Research Protections** at 419.383.6796.

If you answer **YES** to Question I, you must file an application for review with a UT Institutional Review Board (IRB). The application can be submitted to either office of the **Department for Human Research Protections (DHRP)** and it will be forwarded to the appropriate IRB. The office on Main Campus is located in Room #2300 in University Hall and the office on the Health Science Campus is located in the CCE Building, Room 0106.

Researchers must complete the required research training and submit the following items with this GRAD Form prior to beginning the research:

- 1) your Training Verification Form and
- 2) a copy of the IRB Approval Notice

Research utilizing UT Medical Center patients or patient records may require additional approvals and/or training to comply with the Health Insurance Portability and Accountability Act (HIPAA).

II. Are ANIMALS involved in the research? (check one) Yes No

If yes, you must file an application for approval from the Institutional Animal Care and Use Committee (IACUC) and attach a copy of the approval notice to this form. For additional information, contact Jeff Busch, Ph.D. Main Campus 419.530.2844 or Susan Watterson, Health Science Campus 419.383.4252. http://utoledo.edu/research/RC/AnimalCare_Menu.html

III. Are SOURCES OF IONIZING RADIATION involved in the research? (check one) Yes No

If yes, you must file an application for usage and it must be approved by the Radiation Safety Committee (a copy of the approval notice must be attached to this form); required training must be completed through the University's Radiation Safety Officer. For additional information, contact Ed Brentlinger 419.383.4301. http://utoledo.edu/research/RC/Radiation_Menu.html

IV. Are BIOHAZARDOUS SUBSTANCES involved in the research? (check one) Yes No

If yes, you must file an application for approval from the Biosafety Committee and attach a copy of the approval notice to this form. For additional information contact Jeff Busch, Ph.D. Main Campus 419.530.2416 or Susan Watterson, Health Science Campus 419.383.4252. http://utoledo.edu/research/RC/Biosafety_Menu.html

V. Please check the applicable box(es):

- There are no restrictions on the publication or other public disclosure of the project/thesis/dissertation research. If any are placed on the research, the student and the College of Graduate Studies will be notified in writing with a copy of the restrictions.
- There are restrictions on the publication or other public disclosure of the project/thesis/dissertation research. The advisor has discussed these restrictions with the student and has provided in writing to the student, a copy of which is attached.
- The terms of the grant(s)/contract(s) supporting this student's research have the potential to direct the research of this student for primarily commercial purposes that may adversely affect the student's degree goals.
- The terms of the grant(s)/contract(s) supporting this student's research have the potential to restrict public disclosure or publication of the research results, or restrict the evaluation of the results.



HUMAN SUBJECTS RESEARCH

DEFINITION OF “HUMAN SUBJECTS”:

- **HUMAN SUBJECTS** refers to living individuals about whom an investigator conducting research obtains:
 - Data through **INTERVENTION** or **INTERACTION** with the individual, OR
 - **IDENTIFIABLE PRIVATE INFORMATION**
- **Research needs to be reviewed & approved by IRB.**

ANIMAL SUBJECTS RESEARCH

- Use of LIVE, VERTEBRATE Animals for RESEARCH, RESEARCH TRAINING, or BIOLOGICAL TESTING
 - Includes:
 - Lab Testing
 - Behavioral Testing
 - Field Collection
 - Field Observation
- Review & Approval by IACUC.

ENVIRONMENTAL SAFETY

Radiation Safety

- Radioisotopes
- Radiation Generating Devices
 - Irradiators, Electron Microscopes, Particle Accelerators
- Review & Approval by Radiation Safety Committee

Chemical Safety

- Toxic, Carcinogenic, Caustic or Flammable Materials
- Review & Approval by Safety & Health Department

Bio-Safety

- Recombinant DNA Research
- Other Biohazardous Microorganisms
- Review & Approval by IBC



Responsible Conduct of Research

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Export Control Laws

Exports: The shipment or transfer of *items*, *information*, or *software* outside the U.S. or; the release or sharing of restricted technology or data

- ***Items*** – Tangible things, equipment or hardware
- ***Information*** = “Technical Data” such as models, formulae, engineering designs or technical assistance such as training or instruction.
- ***Software*** – Computer programs in either “Source Code” (programming statements) or “Object Code” (machine-readable instructions).

Prohibited Countries

Commerce Sanctioned Countries

Afghanistan	Liberia
Armenia	North Korea
Azerbaijan	Syria
Belarus	Tajikistan
Cuba	Ukraine
Iran	Vietnam
Iraq	

Arms Embargoed Countries

Burma
China
Fed. Rep. of Yugoslavia
Haiti
Liberia
Somalia
Sudan
Zaire

Subject to U.S. Trade Embargoes

Burma
Cuba
Iran
Syria
North Korea
Sudan

State Sanctioned Countries

Balkans
Cote D'Ivoire
Iraq
Liberia
Libya
Palestinian Authority
Zimbabwe

Export Control Laws

Violations of trade sanctions and export controls can result in criminal penalties:

- **Heavy Institutional Fines** (up to \$1 M per violation)
- **Individual Prison Terms** (up to 20 years per violation)

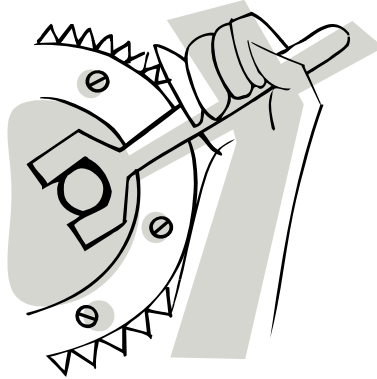
What is a Financial Conflict of Interest?

Any financial relationship that could potentially compromise the impartiality of a researcher.

- **Formal Disclosures**
 - **Financial disclosure form needed for every grant or protocol submission by all researchers.**
- **Conflict of Interest Management Plans**

Summary

Practice Everything You Learned in Kindergarten



Work Hard and Do Things Right

Be Aware of Rules and Regulations That Effect You



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Office of Research & Sponsored Programs

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