

Office of Research & Sponsored Programs

Research Ethics & Compliance

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Vice President for Research



<http://www.utoledo.edu/research/>



The Sounds of Music

Coming from a singing family where music was an elemental part of her life from a young age, Denise Ritter Bernardini says it was only natural that she would choose singing as a lifetime effort. After teaching in public schools for three years, she decided to enter the master's program at Texas Christian University, which had a partnership with Fort Worth Opera. "To my shock, I won the audition," she says. And the rest, as they say, is history.

[Read More](#)

GETTING STARTED WITH A PROPOSAL

HSC

MAIN CAMPUS

THE GRANT PROPOSAL

- Where do I start?
- HSC data for grants
- Main Campus data for grants
- Tips
- Samples
- Boilerplates and Templates
- Forms

THE AWARD

- What now?
- Grants Accounting
- Human Resources

RELATED LINKS

Research Centers and Institutes



Bioweapon in the lettuce patch

The common cottontail rabbit — ubiquitous in forests, suburban woods and backyard gardens — seems an unlikely agent of bioterrorism.

[Read more](#)



Dance of life and death

Plants, insects and fungi in every sort of ecosystem have over time developed complex, mutually beneficial interactions that allow delicate coexistence.

[Read more](#)



Too few fish in the sea?

Fish feces seem an unlikely tool to help preserve the world's much-stressed coral reefs. John W. Turner Jr. in the Department of Physiology and Pharmacology knows better ...

[Read more](#)

INTERNAL FUNDING

EXTERNAL FUNDING

COMPLIANCE ISSUES

CORE LABS

THE AWARD

[URAF Programs Undergraduate Research](#)
Kohler *Temporarily suspended

[Program for Academic Excellence Center for Teaching and Learning Fellowships](#)

[Graduate Student Assoc. Funds Translational Research Stimulation Award](#)

Office of Research & Sponsored Programs

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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.
- (2009) 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 For this, his degree was revoked and he has been banned from receiving federal funding for two years.

RESEARCH ETHICS AND COMPLIANCE

- **Research Ethics**

- **Data Management**
- **Mentor/Trainee Relationships**
- **Publication Practices**
- **Peer Review**
- **Collaborative Science**

- **Research Compliance**

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

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 (OBAS-HSC)**
 - **Post-docs and students supported by NSF grants (CITI)**
- **www.citiprogram.org (see Office of Research website for more information)**

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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 protocols must be reviewed & approved by the Institutional Review Board (IRB).**
- **Human subjects research training at:**
www.citiprogram.org

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



Original Submission
 Amended Date _____

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

Main Campus University Hall Room 3240 Mail Stop 933
 Health Science Campus Mulford Library Room 117 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/RCMain.html>

Date: _____

Student's Name: _____ Rocket ID: _____

Degree Program: _____

Concentration or Track (if applicable): _____

Research (check one): Scholarly Project Thesis Dissertation Field Experience

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 provide the IRB Approval Number _____ prior to beginning the research.

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? (check one) Yes No

If yes, you must file an application for approval from the Institutional Animal Care and Use Committee (IACUC) and provide the **Approval Number _____**. For additional information, contact Monica DeGregorio, Research Compliance Coordinator. 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 (**Approval Number _____**); 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 provide the **Approval Number _____**. For additional information contact Monika DeGregorio 419.383.4252. http://utoledo.edu/research/RC/Biosafety_Menu.html

V. Are **CADAVERIC TISSUES** involved in the research? (check one) Yes No

If yes, you must file an application for approval from the UT Cadaveric Tissues Research Committee and provide the **Approval Number _____**. For additional information contact Mark Hankin, Ph.D., Department of Neurosciences 419.383.4129.

ANIMAL SUBJECTS RESEARCH

- Use of LIVE, VERTEBRATE Animals for RESEARCH, RESEARCH TRAINING, or BIOLOGICAL TESTING
 - Includes:
 - Lab Testing
 - Behavioral Testing
 - Field Collection
 - Field Observation
- **Protocols Reviewed & Approved by the Institutional Animal Care and Use Committee (IACUC).**
- **Animal subjects research training at:**
www.citiprogram.org

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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.
 - <http://coi.toledo.edu>
- **Conflict of Interest Management Plans**
 - To eliminate the conflict

ENVIRONMENTAL SAFETY

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

Radiation Safety

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

Research Protocols

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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. **“Deemed Export”**
- ***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

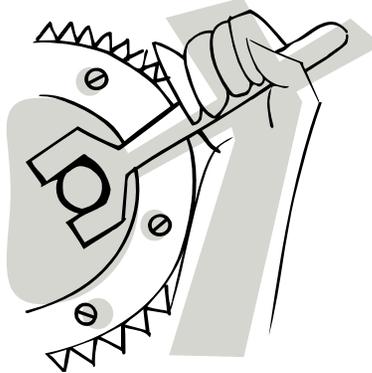
Export Control Laws

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)

Summary

**Practice Everything You
Learned in Kindergarten**



**Work Hard and Do
Things Right**

**Be Aware of Rules and
Regulations That Effect You**



Responsible Conduct of Research

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