

"Responsible Conduct of Research Training: Federal Regulations and the UT Response"

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Background

Increasing pressures for obtaining extramural research funds increases the potential for research misconduct behavior.

NSF observed a doubling of allegations of research misconduct between 1998-2005 and an increasing number of serious cases.¹

In a recent survey of 2,500 scientists by the Pew Research Center, 11% of those polled indicated that the possibility of making a lot of money leads many in their specialty to violate ethical principles, while 26% reported that it leads their colleagues to cut corners on quality.²

In a survey of over 1700 scientists more than one third admitted to questionable research practices.³

¹Fischer.PL, OIG, NSF; SRA International Webinar November 19 2009

²“Public Praises Science; Scientists Fault Public, Media”, Pew Research Center for the People and the Press, July 2009

³ Martinson et al *Nature* 435, 737-738 (9 June 2005)

New National Science Foundation Requirement

“Effective January 4, 2010, NSF will require that, at the time of proposal submission to NSF, a proposing institution's Authorized Organizational Representative certify that the institution has a plan to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduates, graduate students, and postdoctoral researchers who will be supported by NSF to conduct research.”

Section 7009 of the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Act (42 U.S.C.1862o-1)



New National Science Foundation Requirement (cont.)

- While training plans are not required to be included in proposals submitted to NSF, institutions are advised that they are subject to review upon request.
- An institution must designate one or more persons to oversee compliance with the RCR training requirement.
- Institutions are responsible for verifying that undergraduate students, graduate students, and postdoctoral researchers supported by NSF to conduct research have received training in the responsible and ethical conduct of research.

NSF and NIH Core Focus Areas

1. Introduction to RCR
2. Authorship and Publication
3. Collaborative Research
4. Data Acquisition and Management
5. Conflict of Interest
6. Mentoring
7. Research Misconduct
8. Peer Review
9. Research Involving Human Subjects
10. Research Involving Animal Subjects

NSF RCR Committee

- Karen Bjorkman, Arts and Sciences
- Samir Hefzy, Engineering
- Walt Edinger, Medicine
- Patsy Komuniecki, Graduate Studies
- Elsa Nadler, Off. Res. and Dev.
- Jeff Busch, Res. Spon. Prog.
- Jim Trempe, Res. Spon. Prog.

NSF RCR Committee

Discussions:

1. Develop our own training curriculum on RCR
2. Online training via Collaborative Institutional Training Initiative (CITI)
 - Univ. of Miami, federally funded
 - RCR, IRB, IACUC, HIPAA, etc.

NSF RCR Committee

Develop our own training curriculum on RCR

Advantages:

- Control over curriculum
 - Foundation lectures
 - Student projects
 - Etc.
 - Case studies
 - Small group discussions
- Fully engage students

Disadvantages:

- Requires long-term planning
- Resources: faculty and administrative commitments,

NSF RCR Committee

Online training via Collaborative Institutional Training Initiative (CITI)

Advantages:

- Rapid response - ready to go
- Widely used, >800 institutions
- Favorable comments from prior users
- Low cost \$1750/yr.

Disadvantages:

- Little control over curriculum
- Students are not fully engaged

NSF RCR Committee

Recommendations:

Long-term

- UT should establish its own RCR curriculum comprised of lecture, small group discussion, case studies and video vignettes.
- All graduate students, postdoctoral fellows and graduate faculty should take the training.

Short-term

Use the online CITI programs for RCR training.

CITI Collaborative Institutional Training Initiative

[Home](#)[Human Subjects Research](#)[Become a Member](#)[HIPS Course](#)[RCR Course](#)[International Course Site](#)[Lab Animal Course](#)[FAQ](#)[Language](#)

Welcome

CITI Login and Registration Page

i The CITI Program is a subscription service providing research ethics education to all members of the research community. To participate fully, learners must be affiliated with a CITI participating organization.

The CITI course is a protected site. If you are a new learner at a participating organization you must register to create your own username and password and gain access to the site.

i New Users [Register Here](#)

i Already Registered? [Login Below](#)

Username

Password

[Forgot login information](#)

To ensure that all users enjoy rapid response times, access is temporarily limited to 2500 concurrent users. As

CR# 4150627: Biomedical Responsible Conduct of Research Gradebook

To pass this course you must complete all the elective modules with a combined score of **80**. Your current score is **97**.

| Elective Modules Required: 12 Completed: 8 | Date Complete | Score |
|--|--------------------|---------------|
| Complete The Integrity Assurance Statement before beginning the course. | | |
| Introduction to the Responsible Conduct of Research | Completed 10/07/09 | no quiz |
| Research Misconduct <small>1-1215</small> | Completed 10/08/09 | 6/6 (100%) |
| Data Acquisition, Management, Sharing and Ownership <small>1-1308</small> | Completed 12/01/09 | 5/5 (100%) |
| Publication Practices and Responsible Authorship <small>1-1380</small> | Completed 02/01/10 | 5/5 (100%) |
| Peer Review <small>1-1368</small> | Completed 12/03/09 | 8/8 (100%) |
| Mentor and Trainee Responsibilities <small>01234 1250</small> | Completed 02/02/10 | 6/6 (100%) |
| Animal Welfare <small>13301</small> | Incomplete | |
| Conflicts of Interest and Commitment <small>1-1622</small> | Incomplete | |
| Collaborative Research <small>1-1450</small> | Completed 02/07/10 | 5/6 (83%) |
| Human Subjects <small>13566</small> | Incomplete | |
| The CITI RCR Course Completion Page. | Completed 02/05/10 | no quiz |
| University of Toledo | Incomplete | |

Research Misconduct

"The public will support science only if it can trust the scientists and institutions that conduct research."

- *Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct*, Institute of Medicine 2002.

Introductory Video Case

Please review this 3 minute video case study before you begin reading the foundation text. The video may permit you to identify with the issues and provide some personal relevance to the topic.

The Case

An investigator at **Big Time University** is jammed up against a submission deadline and needs conclusive data for a grant application in a highly competitive field. Unfortunately, the data are filled with inconsistencies and do not seem to support his working hypothesis. Frustrated, the investigator aggressively pushes his non-U.S. graduate student and third-year post-doc to find the problem, get it fixed and get him the data in time to meet the submission deadline. **How should they go forward?**

Watch the video to see how the student and post-doc resolve the issues. **What would YOU do?**

This video was funded in part by a grant to the University of Nebraska at Lincoln from The Council of Graduate Schools and the National Science Foundation. Used with permission.- 10-2007.



Click on the image to view the video

This streaming video is best viewed with MS Media Player. It is also available in the [QuickTime format](#). Download [QuickTime Video Player](#) or [Real Player](#) for this video.

Introduction

For the vast majority of those people engaged in the research enterprise, doing the right thing is the operative principle. Scientists want to conduct carefully designed experiments, take into consideration the ethics of human and animal subject protection, record data properly, and report results in the literature and at conferences as accurately as possible in order to advance knowledge.

Someone who would knowingly lie about research data or steal someone else's ideas, according to the bioethicist Arthur Caplan, suffers from lapsed morals. All the information in the world about research misconduct and the responsible conduct of research probably wouldn't change his or her behavior, Caplan says. In fact, a scoundrel taking part in training programs dedicated to these issues might actually get better ideas about performing misdeeds.

The goal of this educational module is to provide information to researchers about what constitutes misconduct, how to report it, how institutions can deal with it, and identify some practices that might reduce the risk of both unintentional and deliberate research misconduct.

What is Research Misconduct?

Office of Science and Technology Policy Definition

"Advances in science, engineering and all fields of research depend on the reliability of the research record, as do benefits associated with them in areas such as health and national security," begins the December 6, 2000, Notice of Final Policy in the Federal Record from the Office of Science and Technology Policy (OSTP). It continues, "Sustained public trust in the research enterprise requires confidence in the research record and in the processes involved in its ongoing development."

- ▶ Listen to Dr. Dana Fisher discuss "[Upholding Standards](#)".

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Time commitment: ~10-12 hrs

New NIH Requirements

- NIH requires that all trainees, fellows, participants, and scholars receiving support through any NIH **training, career development award (individual or institutional), research education grant, and dissertation research grant** must receive instruction in responsible conduct of research.
- January 24, 2010
- UT currently has three such awards
–(F31, K99/R00).

New NIH Requirements

NIH also dictates format:

“While on-line courses can be a valuable supplement to instruction in responsible conduct of research, online instruction is not considered adequate as the sole means of instruction. A plan that employs only online coursework for instruction in responsible conduct of research will not be considered acceptable, except in special instances of short-term training programs, or unusual and well-justified circumstances. “

On Being a Scientist (602/802)

Offered Fall and Spring semesters

Randy Ruch, Course Director

| <u>Week</u> | <u>Topic</u> | <u>Instructor</u> |
|-------------|--|---------------------|
| 1 | Intro. to RCR: History of Science and Scientific Ethics | Edinger |
| 2 | Research Misconduct | Edinger |
| 3 | Research Ethics | Nadler |
| 4 | Data Acquisition & Management; Authorship & Publication | Edinger |
| 5 | Conflict of Interest | DeVries |
| 6 | Collaborative Res. Commercialization, Intellectual Prop. | Fox |
| 7 | Use of Human Subjects in Research | Pinkston/Wisniewski |
| 8 | Use of Animals in Research – IACUC | Chiaia |
| 9 | Research Funding: NIH, NSF and more | Ratnam |
| 10 | Biohazard and Biosafety Policies | Valigosky |
| 11 | Preparation of a Professional CV | Tietz |
| 12 | Mentoring/Trainee Relationship & Case Studies | Ruch |

Issues in Research and Scholarship (ARS2980)

Summer Seminar Series

Tom Kvale, Course Director

| <u>Week</u> | <u>Topic</u> | |
|-------------|---------------------------------------|----------------------|
| 1 | Welcome Reception | Provost |
| 2 | Laboratory Safety | Safety & Health |
| 3 | Research Ethics and Compliance | RSP |
| 4 | Plagiarism and Compliance | Acad.Writ.Ctr. |
| 5 | Ethics and Commitment in Research | Honors Prog. |
| 6 | Doing Advance Research in the Library | Library Admin. |
| 7 | Business Prospects and Patents | Off. Res.&Dev. |
| 8 | Diversity Issues in Research | Inst. Diversity |
| 9 | Summer Recap & Miscellaneous | Off. Undergrad. Res. |
| 10 | Research Presentation | Student Researchers |



Tuesday, February 23, 2010

Welcome to The University of Toledo Research Enterprise



Research at UT

- | | | |
|---|---|---|
| Research News and Reports Forms | Jacobson Center for Clinical & Translational Research | NSF PFI Workshop Outstanding Faculty Researcher Award |
| Staff Contacts | UT Research Policies | FAQ |
| Collaborative Research and Grants | RSP Calendar | Economic Development |

Funding . . . with **NEW Stimulus Info Page!**

- | | | |
|---|---|---|
| Sponsors and Programs | Institutional Data | Cost-Share Request Form |
| Undergraduate Research | Limited Submissions | Proposal Preparation |
| Internal UT Funding Opportunities | Stimulus Funding (ARRA) Information | Useful Links |

Technology Transfer

- | | | |
|--|------------------------------|------------------------------------|
| Technology Licensing | New Ventures | Inventor Resources |
| Available Technologies | News | Industry Resources |
| Template Agreements | Contact | Material Transfer |

Business Incubation

- | | | |
|--|--|-------------------------|
| Business Incubation Services | Minority Business Incubator | Press |
| Clean and Alternative Energy Incubator | Community Business Resources | Apply |
| IT Incubator | | Contact |

Responsible Conduct of Research

- | | | |
|---|--|--|
| IRB - Institutional Review Boards | Radiation Safety Biosafety | Financial Conflict of Interest |
| Animal Care and Use in Research | Responsible Conduct of Research Training | More... |

Limited Submissions: Campus Deadline : next 90 days

- › [Robert Noyce Teacher Scholarship Program](#)
February 24, 2010
- › [NSF MRI Campus Deadline](#)
March 01, 2010
- › [Presidential Awards for Excellence in Sci, Math, Engin mento](#)
March 02, 2010
- › [Robert Noyce Teacher Scholarship Program](#)
March 10, 2010
- › [Integrative Grad. Ed and Research Trainee Prog.](#)
March 12, 2010
- › [Opportunities for Enhancing Diversity in the Geosciences](#)
March 15, 2010
- › [NSF Graduate STEM Fellows in K-12 Education](#)
April 20, 2010
- › [Opportunities for Enhancing Diversity in the Geosciences](#)
May 01, 2010
- › [Research Coordination Networks in Biological Sciences](#)
May 24, 2010
- › [Improvements to Biological Research Collections](#)
May 24, 2010

Complete RSP Calendar

Sponsor Deadline : next 90 days

- › [ADVANCE: Increasing Participation, Advancement of Women](#)
February 24, 2010
- › [Ethics Education in Science and Engineering \(EERE\)](#)
March 01, 2010
- › [Industry/University Cooperative Research Centers Program](#)
March 06, 2010
- › [NSF 05-550, FSML: Improvements in Facilities, Communications](#)
March 10, 2010
- › [Centers of Biomedical Research Excellence ... P20](#)
March 28, 2010
- › [Emerging Frontiers in Research and Innovation 2010, 09-606](#)
March 31, 2010

Research at The University of Toledo

Responsible Conduct of Research

- ▶ [Human Subjects in Research](#)
- ▶ [Animal Care and Use in Research](#)
- ▶ [Biosafety](#)
- ▶ [Radiation Safety](#)

Quick Links

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- ▶ [Technology Transfer](#)
- ▶ [Business Incubation Services](#)
- ▶ [Research Funding](#)

Training for Responsible Conduct of Research

Responsible Conduct of Research (RCR)

The University of Toledo is committed to fostering an environment of responsible conduct of research. Integrity in research and scholarship is a fundamental value upon which the University is founded. Without integrity, we could not justify the privilege of the academic freedom that is intrinsic to research, other forms of scholarship and education nor could we provide to society the advancements of knowledge that derive from free and open inquiry.

New National Science Foundation Requirements

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