

# Responsible Conduct of Research

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**Janis T. Eells**

University of Wisconsin-Milwaukee

**William Sharp**

University of Kansas

**Kari E. Whittenberger-Keith**

University of Wisconsin-Milwaukee

## Topics addressed today

- What is “the responsible conduct of research” (RCR)?
- “Flow-down” principle of RCR regulations
- Professional standards and accrediting agencies
- “Responsible conduct of research” as historical Public Health Service (PHS) and National Science Foundation (NSF) requirements
- RCR programs at the University of Kansas
- RCR programs at the University of Wisconsin-Milwaukee
- Questions/Discussion

## Ways of Looking at “RCR”

- Ethics. Right conduct.
- Rules (federal, organizational, institutional)
- Community standards (of the disciplines and professional organizations)
- Principle of “flow-down” ethics and rules
- RCR as a specific historical initiatives (e.g., PHS and NSF)

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# RCR

## What are the responsibilities of the researcher to...

- human participants?
- animal subjects?
- conduct research ethically?
- students, peers, and the public at large?
- external agencies sponsoring research?

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# “Flow-Down” Principle

Example: Research Misconduct\*

Office of Science and Technology Policy

[http://ori.hhs.gov/policies/fed\\_research\\_misconduct.shtml](http://ori.hhs.gov/policies/fed_research_misconduct.shtml)

\*aka “Scientific Misconduct”  
(not to be confused with “academic misconduct”)

The screenshot shows a Microsoft Internet Explorer browser window with the address bar displaying [http://www.ostp.gov/html/001207\\_3.html](http://www.ostp.gov/html/001207_3.html). The page content is titled "FEDERAL POLICY ON RESEARCH MISCONDUCT<sup>11</sup>".

**I. Research<sup>12</sup> Misconduct Defined**  
*Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.*

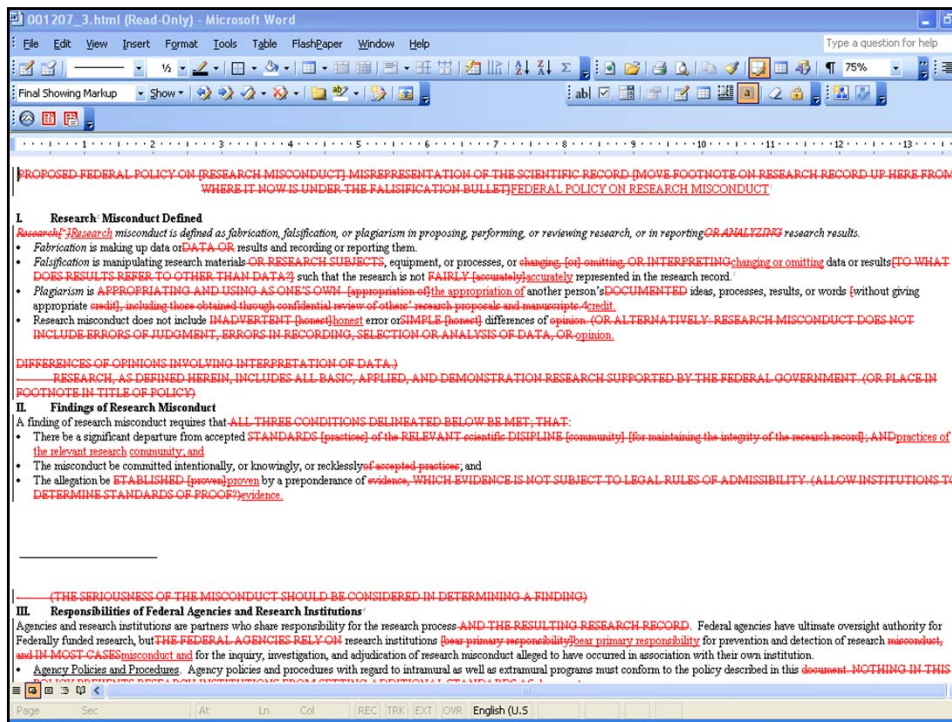
- *Fabrication* is making up data or results and recording or reporting them.
- *Falsification* is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.<sup>3</sup>
- *Plagiarism* is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- Research misconduct does not include honest error or differences of opinion.

**II. Findings of Research Misconduct**  
A finding of research misconduct requires that:

- There be a significant departure from accepted practices of the relevant research community, and
- The misconduct be committed intentionally, or knowingly, or recklessly, and
- The allegation be proven by a preponderance of evidence.

**III. Responsibilities of Federal Agencies and Research Institutions<sup>4</sup>**  
Agencies and research institutions are partners who share responsibility for the research process. Federal agencies have ultimate oversight authority for Federally funded research, but research institutions bear primary responsibility for prevention and detection of research misconduct and for the inquiry, investigation, and adjudication of research misconduct alleged to have occurred in association with their own institution.

- **Agency Policies and Procedures.** Agency policies and procedures with regard to intramural as well as extramural programs must conform to the policy described in this document.
- **Agency Referral to Research Institution.** In most cases, agencies will rely on the researcher's home institution to make the initial response to allegations of research misconduct. Agencies will usually refer allegations of research misconduct made directly to them to the appropriate research institution. However, at



## Federal (OSTP) Definition of Research Misconduct

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- *Research misconduct does not include honest error or differences of opinion.*

## HHS Definition of Research Misconduct

- Sec. 93.103 Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
- (a) Fabrication is making up data or results and recording or reporting them.
- (b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- (c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- (d) Research misconduct does not include honest error or differences of opinion.

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## University of Kansas Definition of Scholarly Misconduct

**Scholarly misconduct** includes fabrication, falsification, or plagiarism or other practices that seriously deviate from those commonly accepted in the scholarly community, when such misconduct occurs in the context of scholarly activities as set forth in section 9.1.2.

- (a) Fabrication is making up data or results and recording or reporting them.
- (b) Falsification is manipulating materials, equipment, or processes, or changing or omitting information, data or results such that the scholarship is not accurately represented in the record, or misrepresenting facts in grant applications, submissions, or other documents provided to agencies which fund grants or sponsor scholarly activities.
- (c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- (d) Scholarly misconduct does not include honest error or differences of opinion.

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Professional Organizations:

## Example

### **Modern Language Association: Statement of Professional Ethics**

- [http://www.mla.org/repview\\_profethics](http://www.mla.org/repview_profethics)
- In this statement we adopt the definition of plagiarism given in Joseph Gibaldi's *MLA Style Manual*: "Using another person's ideas or expressions in your writing without acknowledging the source constitutes plagiarism.... [T]o plagiarize is to give the impression that you wrote or thought something that you in fact borrowed from someone, and to do so is a violation of professional ethics.... Forms of plagiarism include the failure to give appropriate acknowledgment when repeating another's wording or particularly apt phrase, paraphrasing another's argument, and presenting another's line of thinking" (6.1; see also Gibaldi, *MLA Handbook*, ch. 2). It is important to note that this definition does not distinguish between published and unpublished sources, between ideas derived from colleagues and those offered by students, or between written and oral presentations.

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Accrediting Organizations:

## Example

### **Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC)**

- <http://www.aaalac.org/>
- AAALAC International is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs.

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## What is RCR?

### The PHS/ORI perspective:

- Public Health Service (PHS), Office of Research Integrity (ORI) policy promoting responsible research practices
- Nine core instructional areas
- Mandated instruction to all “research staff”

## INSTRUCTIONAL CORES

- Conflict of interest and commitment
- Research misconduct
- Human subjects
- Research involving animals
- Collaborative science
- Peer review
- Publication practices and responsible authorship
- Mentor/trainee responsibilities
- Data acquisition, management, sharing, and ownership

## Sample Areas Not Included:

- Fiscal oversight of sponsored projects
  - » Cost sharing
  - » Effort reporting
  - » Subrecipient monitoring
  - » Etc.
- Export controls

## PHS ALSO RECOMMENDS...

### RCR Training for:

- Non PHS-supported research staff
- Departmental, administrative and other support staff (with instruction relevant to their jobs)
- Best practice also to include graduate students




## Who Would the ORI RCR Requirements Affect?

- All institutions receiving PHS funds
- Staff who have direct and substantive involvement in
  - » Proposing
  - » Performing
  - » Reviewing or
  - » Reporting research

**Or who receive research training supported by PHS funds.**

## HISTORY OF RCR

- Oct. 1, 2000: PHS requirement for education in the protection of human subjects goes into effect

 <h2 style="display: inline;">Human Subjects Protection Training</h2>	
<a href="#">KU Home</a>   <a href="#">About KU</a>   <a href="#">KU Sites A-Z</a>   <a href="#">People Search</a>	
<ul style="list-style-type: none"> <li>• <a href="#">Back</a></li> <li>• <a href="#">Home</a></li> <li>• <a href="#">Next</a></li> </ul>	<p>This computer-based training program was designed by the NIH for investigators in their intramural programs. The NIH allows institutions to modify this training for their own use.</p> <p>This NIH program was modified by the University of Wisconsin-Madison so that it could be edited to fit the needs of individual institutions. The University of Kansas Center for Research has customized the University of Wisconsin-Madison adaptation for use by KU researchers.</p> <p>Effective October 1, 2000, the National Institutes of Health (NIH) required that all investigators conducting research that involves human participants be trained in the protection of human research participants.</p> <p><a href="#">A detailed description of the NIH Mandate can be found here.</a></p> <p>This requirement applies to all persons identified as "key personnel" according to NIH's definition, namely "all individuals responsible for the design and conduct of the study."</p> <p>This computer-based training program is designed to fulfill the NIH requirement.</p>

### RCR Federal Requirements - Highlights

- **July 1990** - NIH requires all NRSA grant applications to include a description of a program to provide instruction in the responsible conduct of research.
- **Dec 2000** – PHS ORI policy promoting responsible research practices. Training for “all research staff” proposed.
- **Feb 2001** – PHS ORI proposed training requirements tabled.
- **Jan 2010**, America Competes Act - NSF requires that institutions certify that appropriate training in the responsible and ethical conduct of research will be given to undergraduates, graduate students, and postdoctoral researchers who will be supported by NSF to conduct research.
- **August 2012** – PHS implements new My requirements for “Responsibility of Applicants for Promoting Objectivity in Research,” which includes new conflict of interest training requirements.

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# How are Institutions Addressing These Requirements?

Examples from:  
The University of Kansas  
The University of Wisconsin-Milwaukee

## RCR at the University of Kansas

Persons conducting research involving humans:

- » Online tutorial required, administered by the Collaborative Institutional Training Initiative (CITI).

- Persons conducting research involving vertebrate animals (non-human):

- » Required training (required reading, in-person training) tailored to the nature of the research proposed.

## RCR at the University of Kansas

### Conflict of interest training:

- » As of 8/24/12, all “investigators” on PHS-compliant projects must complete an online tutorial (~45 minutes) before funds may be expended under the project.



## RCR at the University of Kansas

### Academic courses focusing specifically on RCR/ethics:

- » “Issues in Scientific Integrity” (pharmacy and pre-nursing)
- » “The Ethics of Scientific Research” (biology/philosophy)



## RCR at the University of Kansas

Integration of RCR instruction within introductory graduate disciplinary courses:

- » Ethics Education in Science and Engineering initiative (NSF grant to enhance ethics instruction in STEM disciplines)
  
- » Introduction to graduate study in \_\_\_\_\_.

## RCR at the University of Kansas

Research Skills and Responsible Scholarship Requirement Plan:

- » Every doctoral student is required to have training in responsible scholarship pertinent to the field of research
- » Every doctoral student is required to obtain research skills pertinent to the doctoral level of research in their field(s)
- » A “Research Skills and Responsible Scholarship Plan” is a prerequisite to receiving a doctorate.
- » The plan for each student must be approved by the department and school/college.

## RCR at the University of Kansas

### NSF RCR Requirement:

- » As of January 4, 2010, every undergraduate and graduate student supported under an NSF project must complete an online RCR tutorial (in addition to the Research Skills and Responsible Scholarship Plan required of doctoral students).
- » The RCR tutorial was developed at KU, but is modeled heavily upon ORI's "Introduction to the Responsible Conduct of Research" (Nicholas Steneck).
- » The RCR tutorial is currently administered online via BlackBoard.
- » KU is considering migrating this requirement to CITI.



## RCR:

### The Trials and Tribulations of the Research Administrator

# Office of Research Integrity – Introduction to RCR

<http://ori.hhs.gov/documents/rcrintro.pdf>

**ORI**  
Introduction  
to RCR

## 1. Rules of the Road

### Introduction

Introduction

Professional self-regulation

Government regulation

Institutional policies

Personal responsibility

Questions

Resources

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Table of Contents

How should you conduct your research? What practices should you follow? The public and their professional colleagues expect researchers to follow many rules and commonly accepted practices as they go about their work advancing knowledge and putting knowledge to work. Responsible conduct in research is conduct that meets this expectation.

Society's expectations for the responsible conduct of research are complex and not always well defined. Becoming a responsible researcher is not like becoming a responsible driver. Responsible driving is clearly defined through laws and written down in drivers' manuals. Before individuals are allowed to drive, they are tested on both their knowledge of the rules of the road and their skills. Then, licensed drivers are constantly reminded of their responsibilities by signs, traffic signals, and road markings. They also know that their behavior as drivers is monitored and that there are specific penalties for improper behavior.

Guidance for the responsible conduct of research is not this well organized. Some responsible practices are defined through law and institutional policies that must be followed. Others are set out in



Setting off on the road to the responsible conduct of research  
(enlarge)

Short Case

## A False Dichotomy?

Ethics

Academics

Philosophical

Education

Compliance

Administration

That's us!

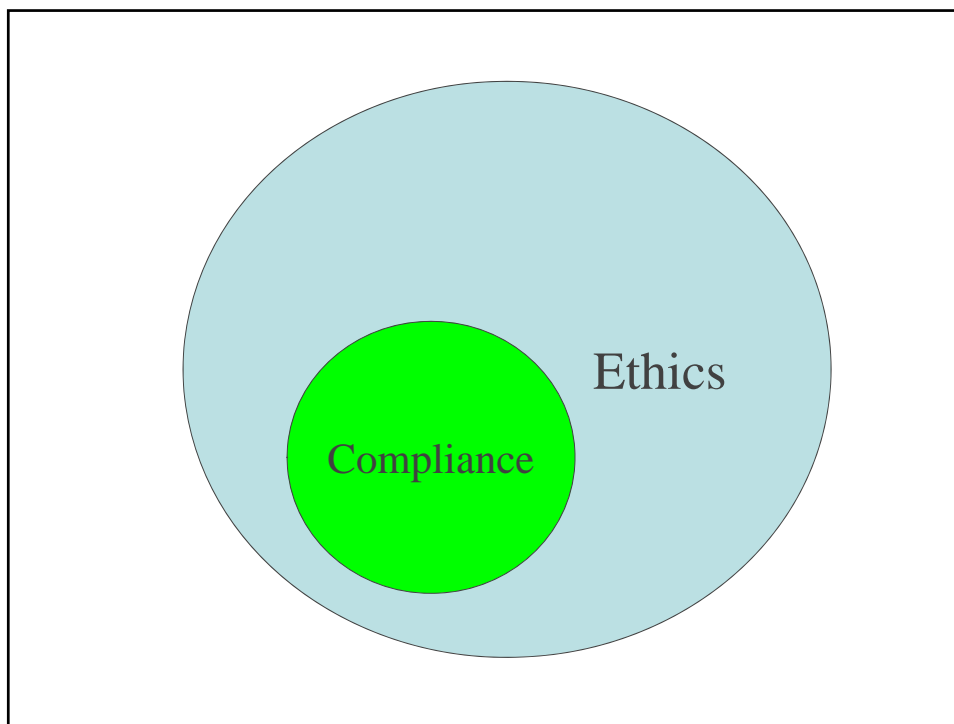
Regulatory

Police

Bad cop

Internal Affairs

**KU**  
THE UNIVERSITY OF  
KANSAS



## RCR Resources

- ORI Introduction to the Responsible Conduct of Research
  - » [ori.dhhs.gov/documents/rcrintro.pdf](http://ori.dhhs.gov/documents/rcrintro.pdf)
  - » 164-page PDF book covering the core RCR areas (HHS) (also available in hard copy for a price)
- On Being a Scientist: A Guide to Responsible Conduct in Research
  - » [http://www.nap.edu/catalog.php?record\\_id=12192](http://www.nap.edu/catalog.php?record_id=12192)
  - » 82-page PDF from the National Academies Press (also available in hard copy for a price)
- KU Responsible Scholarship Page
  - » [http://research.ku.edu/responsible\\_scholarship](http://research.ku.edu/responsible_scholarship)
  - » Contains links to free resources in all of the core RCR areas
- CITI Online Training
  - » [www.citiprogram.org](http://www.citiprogram.org)





The University of Wisconsin-Milwaukee  
[THESE SLIDES YET TO BE ADDED]