Topics addressed today

- “Flow-down” principle of RCR regulations
- Scientific misconduct
- Professional standards and accrediting agencies
- “Responsible conduct of research” as a historical Public Health Service (PHS) initiative
- Financial conflicts of interest
- Human subjects in research
- “Rules of the Road” – RCR and research ethics
- 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 initiative (Public Health Service)
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?
“Flow-Down” Principle

Example: Research Misconduct*

Office of Science and Technology Policy

http://ori.hhs.gov/policies/fed_research_misconduct.shtml

*aka “Scientific Misconduct”

(Not to be confused with “academic misconduct”)
I. Research 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.
- 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

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
PROPOSED FEDERAL POLICY ON RESEARCH MISCONDUCT
MISREPRESENTATION OF THE SCIENTIFIC RECORD [MOVE FOOTNOTE ON RESEARCH RECORD UP HERE FROM WHERE IT NOW IS UNDER THE FALSIFICATION BULLET] FEDERAL POLICY ON RESEARCH MISCONDUCT

I. Research Misconduct Defined

Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting OR ANALYZING research results.

- Fabrication is making up data or DATA OR results and recording or reporting them.
- Falsification is manipulating research materials OR RESEARCH SUBJECTS, equipment, or processes, or changing, [or] omitting, OR INTERPRETING changing or omitting data or results [TO WHAT DOES RESULTS REFER TO OTHER THAN DATA?] such that the research is not FAIRLY [accurately] accurately represented in the research record.
- Plagiarism is APPROPRIATING AND USING AS ONE'S OWN [appropriation of the appropriation of another person's DOCUMENTED ideas, processes, results, or words [without giving appropriate credit], including those obtained through confidential review of others’ research proposals and manuscripts. 4credit.
- Research misconduct does not include INADVERTENT honest error or SIMPLE [honest] differences of opinion. (OR ALTERNATIVELY, RESEARCH MISCONDUCT DOES NOT INCLUDE ERRORS OF JUDGMENT, ERRORS IN RECORDING, SELECTION OR ANALYSIS OF DATA, OR OPINION.

DIFFERENCES OR OPINIONS INVOLVING INTERPRETATION OF DATA.

Research, as defined herein, includes all basic, applied, and demonstration research supported by the federal government. (OR PLACE IN FOOTNOTE IN TITLE OF POLICY)

II. Findings of Research Misconduct

A finding of research misconduct requires that ALL THREE CONDITIONS DELINENATED BELOW BE MET; THAT:

- There be a significant departure from accepted STANDARDS [practices] of the RELEVANT scientific DISCIPLINE [community] [for maintaining the integrity of the research record], AND practices of the relevant research community; and
- The misconduct be committed intentionally, or knowingly, or recklessly of accepted practices; and
- The allegation be EMBRACED [proven] [proven] by a preponderance of evidence, WHICH EVIDENCE IS NOT SUBJECT TO LEGAL RULES OF ADMISSIBILITY. (ALLOW INSTITUTIONS TO DETERMINE STANDARDS OF PROOF?

(The seriousness of the misconduct should be considered in determining a finding)

III. Responsibilities of Federal Agencies and Research Institutions

Agencies and research institutions are partners who share responsibility for the research process AND THE RESULTING RESEARCH RECORD. Federal agencies have ultimate oversight authority for Federally funded research, but THE FEDERAL AGENCIES RELY ON research institutions [bear primary responsibility] primary responsibility for prevention and detection of research misconduct, and in most cases, conduct 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. NOTHING IN THIS PANHINCTS RESEARCH INSTITUTIONS FROM SETTING ADDITIONAL STANDARDS AS LONG AS THEY ARE CONSISTENT WITH THE FEDERAL POLICY ON RESEARCH MISCONDUCT.
Federal Definition of Research Misconduct

- 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.
- 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.
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.
Emporia State University Definition of Scientific Misconduct

Scientific misconduct or misconduct in science means fabrication, falsification, plagiarism, or other practices that seriously deviated from those that are commonly accepted with the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

http://www.emporia.edu/dotAsset/abf69774-a557-4d1d-9c7c-2d8d6cc22a48.pdf
...is it Scientific Misconduct?

1. Hazardous materials in your lab are handled improperly, resulting in exposure of several people to toxic substances.

2. Your colleague did not properly cite sources of text in a research proposal.

3. Your research assistant forgot to feed the research animals over the weekend.

4. You publish research that shows a company’s product in a favorable light, but neglect to disclose that you received $80,000 in speaking fees from the company last year.
Fabrication

- Making up data or results and recording or reporting them
Falsification

• 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.
Plagiarism

• 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.
…is it Scientific Misconduct?

1. Hazardous materials in your lab are handled improperly, resulting in exposure of several people to toxic substances. **Probably not**

2. Your colleague did not properly cite sources of text in a research proposal. **Probably so**

3. Your research assistant forgot to feed the research animals over the weekend. **Probably not**

4. You publish research that shows a company’s product in a favorable light, but neglect to disclose that you received $80,000 in speaking fees from the company last year. **…what do you think?**
Modern Language Association: Statement of Professional Ethics

• 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.
Accrediting Organizations:

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

- [http://www.aaalac.org/](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.
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
INSTRUCTIONAL CORES

- Peer review
- Publication practices and responsible authorship
- Mentor/trainee responsibilities
- Data acquisition, management, sharing, and ownership
Some Sample Areas Not Included:

- Fiscal oversight of sponsored projects
- Cost sharing
- Subrecipient monitoring
- Export controls
PHS ALSO RECOMMENDS…

- 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 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.
• Oct. 1, 2000 Requirement for education in the protection of human subjects goes into effect
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.

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.

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.

A detailed description of the NIH Mandate can be found here.

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."

This computer-based training program is designed to fulfill the NIH requirement.
History of RCR

- **July 1990** - NIH requires all for 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** - Training requirement 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.

(NIH) National Institutes of Health  
(NRSA) National Research Service Award (T32, T34)Training Grants  
(ORI) Office of Research Integrity  
(PHS) Public Health Service  
(NSF) National Science Foundation
Financial Conflicts of Interest
A Conflict of Interest is...

...the possibility, from the perspective of an independent observer, that an individual’s private financial interests or his/her families’ interests, may influence the individual’s professional actions, decisions or judgments.
Appearance, Reality and COI

- The existence of a COI does not mean that unethical behavior has occurred
- The existence of a COI can cast doubt on integrity
- An undisclosed COI has great potential for damage
Consider...

New York Times Health Section, Sept. 28, 2009

Probiotics: Looking under the Yogurt Label

...After gathering at a Yale workshop to review the available evidence, a panel of 12 experts concluded that there was strong evidence that several probiotic strains could reduce diarrhea, including that associated with antibiotic use. Several studies have also suggested that certain probiotics may be useful for irritable bowel syndrome, with the strongest recommendation for Bifidobacterium infantis 35624, the probiotic in the Procter & Gamble supplement Align.

(Two members of the panel had ties to Procter & Gamble; three others had ties to other companies that sell probiotics.)
COI in the Headlines


Tough-Talking Journal Editor Faces Accusations of Leniency

By DONALD G. McNEIL Jr.

“…In one case, the authors of a study on the use of antidepressants during pregnancy, published in JAMA in February, neglected to disclose fees and research money from drug makers. The study found that pregnant women who stopped taking antidepressants risked renewed depression.

In another case at JAMA, the authors of a study saying that women with migraines were more likely to get heart disease did not mention they had received money from companies that make painkillers. The authors of a study linking some arthritis drugs to cancer omitted mention of speaking fees. …”
Conflicts of interest pose risks to...

- Direction and Control of Research
- Publication and Dissemination of Research
- Mentoring Students
- Protection of Human Subjects
- Appointments and Promotions
- Service on University Committees
- Use of University Facilities and Resources
- Commitment to the University
Declaration Form A

Form A has 6 yes/no questions. Only one has a correct answer.

Question B.1.

Have you read the Regents COI Policy?

Yes
Each section in Form B corresponds to a question on Form A.

If you answer YES to a question on Form A, then you must disclose details on Form B.
New HHS Conflict of Interest Regulations

- Effective August 2012
  - Lower reporting threshold ($5000)
  - Mandatory training
  - Management plans must be available to the public
Human Subjects in Research
On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, thereby creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
RIGHTS of RESEARCH PARTICIPANTS


• Three principles guide research involving human subjects.
• Respect for Persons

» Participants understand and voluntarily agree to take part in a research project
BELMONT REPORT Second Principle

• Beneficence

» Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being.
• Justice

» Those who bear the burdens of research should share its benefits, for example, sharing research findings with participants.
Institutional Review Board (IRB) Approval

- Involves consideration of the proposed research within the context of the three guiding principles of the Belmont Report.
HOW TO GET IRB APPROVAL

• See http://www.emporia.edu/research/irb.html
Rules of the Road
Introduction

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 professional codes and institutional guidelines. It is important for you to incorporate these guidelines into your own practice.
1. There is an acknowledged need for a permanent, officially recognized “steering committee” or “advisory committee,” to advance RCR proposals through the curriculum process, to plan RCR educational interventions, to serve as ethics committees (in the manner, for example, of hospital ethics committees), to promote campus-wide awareness of RCR, etc. Without a structural change of this sort, an RCR initiative may prove more difficult to sustain. The role of the advisory committee should be clearly stated and worked out in collaboration with the chief research officer on campus, to avoid the perception that it is aimed at compliance with federal regulations or at policing of research.
“It is important that such a committee’s proposals and suggestions not be confused with ‘policing’ efforts to achieve compliance with federal regulations....the committee’s charge can be clearly and explicitly stated as educational in nature, and it can be prominently announced as entirely unconnected with compliance processes.” (p. 21)
## A False Dichotomy?

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Ethics

Compliance
Responsible Conduct of Research

- In the curriculum
- In the extra-curriculum
RCR Resources

• KU Responsible Scholarship Resource Page
  » www.rgs.ku.edu/responsible_scholarship
  » Contains links to free resources in all of the core RCR areas

• ORI Introduction to the Responsible Conduct of Research
  » 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
  » 82-page PDF from the National Academies Press (also available in hard copy for a price)
RCR Resources

• C ITI Online Training
  » www.citiprogram.org
  » Includes modules on:
    • Research misconduct
    • Data management
    • Conflict of interest
    • Collaborative science
    • Responsible authorship
    • Mentoring
    • Peer review
    • Lab animals
    • Human subjects

» www.responsibleresearch.org
  • Emporia State University uses this site for online training
Questions?

Discussion?

Topics of particular interest to you?