

Excepting this title page, only slides with notes are included in this file.

Teaching research ethics

An overview

(of the topic, not the workshop)

Kenneth D. Pimple, Ph.D.

Presented at the Nineteenth Annual
Teaching Research Ethics Workshop
Indiana University Bloomington
May 2012

Copyright © 2012 by Kenneth D. Pimple; all rights reserved.

Poynter Center for the Study of Ethics and American Institutions
Indiana University Bloomington
618 East Third Street
Bloomington IN 47405-3602
<http://poynter.indiana.edu>

1. What is research ethics?

- a. Compliance
- b. Responsible conduct of research
- c. Research integrity
 - integrity of the research process
 - integrity of the research record
 - scientific integrity
- d. Research ethics

More terminology can be found in Appendix A of Pimple 2002 (“Six Domains of Research Ethics”)

a. RCR – The preferred term by NIH; NSF uses “the ethical and responsible conduct of research.”

“[T]hink of irresponsible conduct of research, which would be any behavior that tends to lead to unreliable research, such as the use of inappropriate statistical methods; or to be dangerous, such as using harmful chemicals without adequate safeguards; or fails to be in compliance with pertinent regulations or policies. Responsible conduct, in short, is nearly synonymous with professional competence. Taken this way, it’s somewhat alarming that NIH and NSF feel the need to compel universities to provide training in RCR; it should clearly be part-and-parcel of research training.” (Pimple 2012a – “Fundamentals of scholarly and research integrity”)

RCR as basic competence.

Responsibly changing a car’s tire requires tightening the lug nuts enough, but not too much. I don’t think of this as an ethical requirement even though under-tightened nuts can pose a serious hazard (there goes your tire, rolling

down the highway without you). Carelessness about human safety is an ethical issue, but tightening lug nuts? I don't know. ...

RCR, to me, means adhering to high standards of accuracy and rigor in collecting and recording data; using appropriate statistical models, and using them appropriately; reporting research results honestly, completely, and transparently; in short, doing good research.

(Pimple in
<https://nationalethicscenter.org/groups/whatwecallwhatwedo/forum?task=topic&topic=102>)

integrity of the research process is defined in Responsible Science (NAS 1992) as “the adherence by scientists and their institutions to honest and verifiable methods in proposing, performing, evaluating, and reporting research activities.”

integrity of the research record (OSTP 1999)

scientific integrity

2. Why teach research ethics?

- Because most graduate students, postdocs, faculty, technicians, staff, and administrators are unethical without special training
- Not a good way to establish rapport
- Misconduct is rare (Pimple 2011)

Teaching research ethics can play a part in preventing misconduct and other bad behavior, but it can't – and shouldn't be expected to – carry the entire burden.

Research misconduct

Source	Number	Rate
Reported to ORI	~24/yr	~ 0.01%
Swazey est.	~300/yr	~ 0.13%
Titus et al. est.	~2,300/yr	~ 1.5%
Fanelli meta-analysis	~3,800 to ~32,500/yr	~ 1.97% to ~14.12%

Fanelli – Meta-analysis of 18 surveys, FF only.

~ 1.97% self-reported

~14.12% observed

Why ... (continued)

- Because NIH and NSF say so
 - Historical forces (Pimple 2008)
 - Mandates (Pimple 2012b)
- To make it easier for researchers to be responsible

“The 1970s and 1980s also saw a number of cases in which scientists falsified or fabricated data or plagiarized the work of other scientists (four major cases in the summer of 1980 alone – see Chapter 7). The scientific community responded to reports of ‘scientific fraud’ (as it was often called) by asserting that such cases are rare and that neither errors nor deception can be hidden for long because of science’s self-correcting nature – between peer review, replication of published experiments and the process of building on earlier work, the argument goes, bad science will be discovered eventually.” (Pimple 2008:xviii)

“The growing publicity around cheating in science and the clear need for improved standards led the United States Public Health Service (PHS, 1989) and the National Science Foundation (NSF, 1991) to adopt and publish similar definitions of misconduct in science. The core of both definitions was fabrication, falsification, plagiarism or other practices that seriously deviate from those that are commonly accepted in the scientific community. By this time, the phrase ‘misconduct in science’ or ‘scientific misconduct’ had replaced ‘scientific fraud’ because ‘most legal interpretations of the term ‘fraud’ require evidence not only of intentional deception but also of injury or damage to victims, ... [and] this evidentiary standard seemed poorly suited to the methods of scientific research’ (COSEPUP, 1992, p. 25). These definitions, especially the ‘other deviations’ clauses, evoked immediate and ongoing resistance from the research community.” (Pimple 2008:xix)

NIH announced the first “Requirement for Programs on the Responsible Conduct of Research” in 1989 (Pimple 2012b:2).

NSF was charged by Congress to promote RCR training in 2007; the implementation plan was published in 2009 (Pimple 2012b:1).

Why ... NIH 2009

- Definition
- Basic principles
- Instructional components
 1. Format
 2. Subject matter (9 areas)
 3. Faculty participation
 4. Duration (at least 8 hours)
 5. Frequency

Overview / Pimple

11

Definition – See earlier slide

Principles

1. RCR and RCR instruction are “essential” and “integral” aspects of research training
2. RCR is a career-spanning endeavor and RCR instruction should “be appropriate to the career stage” of trainees;
3. individuals “supported by individual funding opportunities” (in contrast to institutional grants) “are encouraged to assume individual and personal responsibility” for their own RCR instruction;
4. research faculty should be involved in RCR instruction and serve as “effective role models;”
5. RCR instruction should include “face-to-face discussions by course participants and faculty” (online training is inadequate); and
6. RCR instruction “must be carefully evaluated” in NIH grant applications.

Instructional Components

RCR instruction “occurs formally and informally.” Formal instruction should include the following five instructional components that “have been incorporated

into many of the best regarded programs of instruction in responsible conduct of research.”

1. The **format** should emphasize “substantial face-to-face discussions among the participating trainees/fellows/scholars/participants; a combination of didactic and small-group discussions (e.g. case studies); and participation of research training faculty members in instruction in responsible conduct of research.” Online instruction can be used, but it is not sufficient.
2. “Most acceptable plans” have included the following **subject matter** (quoted verbatim):
 - a. conflict of interest – personal, professional, and financial
 - b. policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
 - c. mentor/mentee responsibilities and relationships
 - d. collaborative research including collaborations with industry
 - e. peer review
 - f. data acquisition and laboratory tools; management, sharing and ownership
 - g. research misconduct and policies for handling misconduct
 - h. responsible authorship and publication
 - i. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

Courses related to “professional ethics, ethical issues in clinical research,” and the like are usually “not sufficient to cover all of the above topics.” Summary of NSF and NIH RCR Instruction Requirements 4

3. There should be substantial **faculty participation**: “Training faculty and sponsors/mentors are highly encouraged to contribute both to formal and informal instruction in responsible conduct of research.”

4. The **duration of instruction** “should involve substantive contact hours between the trainees/fellows/scholars/participants and the participating faculty. Acceptable programs generally involve **at least eight contact hours**” (my emphasis). A series of short seminars, workshops, etc., over time are preferred to a single one-day event.

5. The **frequency of instruction** should span the stages of “a scientist’s career: at the undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels. ... Instruction must be undertaken at least once during each career stage, and at a frequency of

no less than **once every four years**” (my emphasis). Predoctoral training should occur “as early as possible in graduate school.”

4. What can be taught? – NIH

- a. conflict of interest
- b. human and non-human subjects, safe laboratory practices
- c. mentor/mentee responsibilities and relationships
- d. collaborative research, including with industry
- e. peer review
- f. data acquisition, management, sharing, ownership
- g. research misconduct and policies
- h. responsible authorship and publication
- i. science and society, contemporary issues, etc.

Overview / Pimple

13

This list can be found on the back of the handout.

- a. conflict of interest – personal, professional, and financial
- b. policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
- c. mentor/mentee responsibilities and relationships
- d. collaborative research including collaborations with industry
- e. peer review
- f. data acquisition and laboratory tools; management, sharing and ownership
- g. research misconduct and policies for handling misconduct
- h. responsible authorship and publication
- i. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

4. What ... G601 compared to NIH

1. Introduction to the course and moral theory
2. Research regulation, self-regulation, and research ethics **(g)**
3. Honesty, candor, compromise, and integrity
4. Authorship **(h)**, plagiarism **(g)**, and peer review **(e)**
5. Data ownership and stewardship **(f)**, conflicts of interest **(a)**, and collaboration **(c, d)**
6. Non-human animal subjects **(b)**
7. Human subjects **(b)**
8. Research and researchers in society **(i)**

Overview / Pimple

14

This comparison can be found on the handout. It's just meant to show that the NIH categorization does not – or does not have to – dictate the organization of the training. There's a strong tendency to dedicate one session to each of the 9 subject areas even though some merit more time than others.

When and where ... (continued)

- As an annual half-day or full-day meeting sponsored by the Vice President for Research (Provost, Chancellor)
 - Collaborate with OHRP or ORI
- As a session or forum at a professional meeting
- As an Internet-based module, tutorial, or seminar

OHRP Research Community Forums – <http://www.hhs.gov/ohrp/education/>
ORI conferences – <http://ori.hhs.gov/conference>