

Responsible Conduct of Research (RCR) Instruction: What, Why, How

Susan H. Frey, MAT, JD
Assistant Provost
Office of Research Compliance

January 18, 2012

Learning objectives

- To outline the content of instruction in Responsible Conduct of Research (“RCR”).
- To consider why RCR instruction is timely and relevant to clinical research, as described by NIH, National Academies (NAS, NAE, IOM) and ACCME.
- To learn about resources for RCR instruction and to experience a small group discussion of an RCR case study.

1. What is RCR Instruction?

RCR Foundation Texts

- *On Being a Scientist* (hereafter “OBS), National Academy of Sciences. Washington D.C.: The National Academies Press, 2009. Print
- *Introduction to the Responsible Conduct of Research*, Steneck, Nicholas H. Washington D.C.: U.S. Government Printing Office, 2007. Print
- Responsible Conduct of Research [CITI]...
 - www.citiprogram.org
 - <https://www.citiprogram.org/rcrpage.asp?language=english&affiliation=100> (public access for RCR)

Professional Standards of Science

“Over many centuries, researchers have developed **professional standards** designed to enhance the progress of science and to avoid or minimize difficulties in research.”

- “Rarely expressed in formal codes”
- Yet, “widely accepted ways of doing research and interacting with others.”

OBS, 2009, 2-3.

Motivations to be ethical

“Researchers have three sets of obligations to motivate their adherence to professional standards.”

- Honor the trust of your colleagues
- Build the integrity of your research career
- Act in ways that serve the public.

Topics Covered in *OBS*

- Advising and Mentoring
- The Treatment of Data
- Mistakes and Negligence
- Research Misconduct
- Responding to Suspected Violations of Professional Standards
- Sharing of Research Results
- Authorship and the Allocation of credit
- Intellectual Property
- Competing Interests Commitments and Values
- The Researcher in Society

Note: Human subject, animal research and safety are also covered in *OBS*, but training in these areas is often separated from generic RCR training.

NIH RCR Topics

- Data acquisition and laboratory tools; management, sharing and ownership
- Mentor/mentee responsibilities and relationships
- Responsible authorship and publication
- Peer review
- Collaborative research including collaborations with industry
- Conflict of interest
- Research misconduct and policies for handling misconduct
- The scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

Note: Human subject, animal research and safety are also covered by NIH, but training in these areas may be separate from generic RCR training.

NOT-OD-10-019, November 2009 **NIH's Update on the Requirement for Instruction in the Responsible Conduct of Research**

In sum, what is RCR

- RCR consists of *understanding* and *applying* all of the professional standards designed to ensure integrity in science and the advancement of human knowledge, in such a way as to uphold your own integrity as a scientists, the trust of other scientists and serve the best interests of society.

2. Why Attend Now to RCR Instruction?

National Academies state:

- “the assimilation of professional standards through [research] experience remains vitally important”
- “[h]owever, many beginning researchers are not learning enough about the standards of science through research experience”
- “experienced researchers often do not have the time or opportunity to explain”
- “beginning researchers do not always get the best advice or witness exemplary behavior”
- “changes within science have complicated efforts to ensure that every researcher has a solid grounding in the professional codes of science”

OBS, 2009, x-xi

National academies are concerned that:

PIs have less time to discuss research standards
due to:

- Increased competition for insufficient resources and funding
- More interdisciplinary and international research
- The rapid advance of technology, especially digital communications
- Increased community involvement in research
- Students may not be sufficiently prepared in the core curriculum.

OBS, 2009, x-xi

NIH notes that research groups include Individuals not trained as scientists:

Institutional members Include but are not limited to
“officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents, and contractors, subcontractors, and subawardees, and their employees.” 50 CFR 93.100

All “institutional members”
have an “affirmative duty to protect [federal] funds from misuse by ensuring the integrity of all [federal] supported work, and primary responsibility for responding to and reporting allegations of research misconduct...” 50 CFR 93.214

ACCME requires assurance of conformity to standards of responsible research:

“All scientific research referred to, reported or used in CME in support or justification of a *patient care recommendation* must conform to the generally accepted standards of experimental design, data collection and analysis.”

Adopted by ACCME July 2002

Federal sponsors worry about “research misconduct”:

- Intentional or reckless FPP
 - Falsification
 - Fabrication
 - Plagiarism

Sample Research Misconduct Cases

http://ori.hhs.gov/case_summary

2011

- Jayant Jagannathan, M.D., University of Virginia Medical Center, 2011
 - “former Resident Physician at UVA Medical Center”
 - “ORI found that the Respondent engaged in research misconduct by including, in five publications, large amounts of text and an illustration that he plagiarized”
 - Voluntary Agreement for four years:
 - prior to his participation in any capacity on PHS-supported research, the institution employing him must submit a plan for supervision of his duties
 - any institution employing him must submit...certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported
 - He must submit a retraction letter admitting plagiarism
 - He may not serve in any advisory capacity to PHS.

Sample Research Misconduct Cases

http://ori.hhs.gov/case_summary

2009

- Jennifer Wanchick, MetroHealth System:
 - “former Research Assistant, MetroHealth System (an affiliated hospital of Case Western Reserve University)”
 - “by her own admission, Ms. Wanchick engaged in research misconduct by fabricating information in the electronic database purportedly collected from 150 individuals about their willingness to sign up to be an organ donor at the time they obtained a driver's license. Ms. Wanchick also admitted to fabricating the information on several survey instruments. The study at issue was entitled "Community Based Intervention to Enhance Signing of Organ Donor Cards."

Voluntary Agreement for three years:

- Institutional supervisory plan on any proposal for her to participate in research/

Needed Response to these concerns:
Sufficient attention to professional
ethics in a variety of venues and spread
over time

- Orientation seminars
- Classroom curriculum
- PI's research team meetings
- Mentoring relationships
- Institutional RCR programs

3. RCR Instruction Resources and Methods

RCR Methods

- “should include active researchers who bring their practical experience to the discussion and demonstrate by their presence that they recognize the critical importance of responsible conduct.”
- “case studies...can be valuable to the group discussions by introducing different scenarios and then fostering debate.”
- “there are better and worse ways to approach particular problems.”
- “[at] the same time, [cases will be seen in different ways] “depending on [each person’s] level of experience and convictions.”

OBS, 2009, xvi

RCR Resources available for use in your research group

- *Advisor, Teacher, Role Model Friend*, NAS, NAE, IOM, 1997.
 - http://www.nap.edu/openbook.php?record_id=5789
- *On Being a Scientist* National Academy of Sciences. Washington D.C.: The National Academies Press, 2009. Print
- *Introduction to the Responsible Conduct of Research*, Steneck, Nicholas H. Washington D.C.: U.S. Government Printing Office, 2007. Print
- Responsible Conduct of Research [CITI]
 - www.citiprogram.org
 - <https://www.citiprogram.org/rcrpage.asp?language=english&affiliation=100> (public access for RCR)

RCR Resources available for use in your research group continued

- BU online Blackboard courses
<http://blackboard.bu.edu>
- BU RCR Resource Page
<http://www.bu.edu/orc/rcr/resources/>
- Association of American Medical Colleges, Teaching the Responsible Conduct of Research through a Case Study Approach: A Handbook for Instructors. Washington D.C.: Association of American Medical Colleges, 1994.

Contact BU Office of Research Compliance for assistance with local RCR discussions. rcr@bu.edu

BU Advanced Core RCR Program

- For doctoral candidates and postdoctoral researchers (meets requirements of NIH training grants and NSF research grants)
- A one-hour online introduction
- 4 two-hour workshops (to be completed in 2 years)
 - Addressing all RCR Topics
 - Using case studies
 - Discussed in small facilitated groups.

200 certificates of completion anticipated 2011-12
Some 127 facilitators participating in 2011-12.