

ETHICS DAY: ENGAGING LIBRARIANS IN THE RESPONSIBLE CONDUCT OF RESEARCH (RCR) OCTOBER 8, 2010

Funder Requirements for Ethics Training

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“In general terms, responsible conduct of research is simply
good citizenship applied to professional life.”

Nicholas H. Steneck
Introduction to the Responsible Conduct of Research
DHHS Office of Research Integrity (ORI)



SETTING OFF ON THE ROAD TO RESPONSIBLE CONDUCT OF RESEARCH

INTRODUCTION TO THE RESPONSIBLE CONDUCT OF RESEARCH, N.H. STENECK

ILLUSTRATIONS BY DAVID ZINN

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FEDERAL AGENCIES WITH FORMAL RCR TRAINING REQUIREMENTS:

- National Institutes of Health (NIH)
 - Since 1989
 - National Science Foundation (NSF)
 - Since January 2010
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Mandates for RCR Training Requirements Established by:

- ✘ U. S. Department of Health & Human Services (DHHS), Office of Research Integrity
 - + 1985 Health Research Extension Act
- ✘ National Science Foundation (NSF)
 - + The 2007 America COMPETES Act, Section 7009

Current RCR/ethics requirements grew out of early regulations & requirements for:

- Human subject protection (1974 National Research Act)
- Animal care & use requirements (1966 Animal Welfare Act)
- Misconduct in research (1985 Health Research Extension Act)

RCR IS BASED ON SEVERAL CORE VALUES:

- × Honesty – conveying information truthfully & honoring commitments
- × Accuracy – reporting findings precisely & taking care to avoid errors
- × Efficiency – using resources wisely & avoiding waste
- × Objectivity – letting the facts speak for themselves & avoiding improper bias

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Comparing Federal agency requirements for RCR/ethics training:

- ✘ **US Dept of Health & Human Services/National Institutes of Health**
 - + Policy codified in NIH NOT-OD-10-019
 - + Longer standing than NSF's policy – requires affirmative description in proposals addressing RCR training
 - + Much more detailed in its training requirements – outlines specific format, subject matter, faculty participation, duration, frequency, etc.
 - + Establishes “Basic Principles” and definitions
- ✘ **National Science Foundation**
 - + Policy effective January 2010
 - + Requires AOR to certify at the time of proposal submission that the institution has a plan to provide appropriate training/oversight in RCR to undergraduates, graduate students and postdoctoral researchers
 - + Little specific guidance on curriculum content, delivery format, etc – “It is the responsibility of each institution to determine both the content and the delivery method for the training that will meet the institution’s particular needs for RCR training...”
 - + Concern for “administrative burden” on investigators

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NIH policy defines RCR as:

“The practice of scientific investigation with integrity. [RCR] involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research.”

NOT-OD-10-019

November 24, 2009

Basic Principles from NIH Policy

- ✘ Responsible conduct of research is an essential component of research training.
- ✘ Active involvement in the issues of responsible conduct of research should occur throughout a scientist's career.
- ✘ Individuals supported by individual funding opportunities such as fellowships and career instruction awards are encouraged to assume individual and personal responsibility for their instruction in RCR

Basic Principles from NIH Policy (cont'd)

- ✘ Research faculty of the institution should participate in instruction in RCR in ways that allow them to serve as effective role models.
- ✘ Instruction should include face-to-face discussions by course participants and faculty (ie, online instruction only is not sufficient).
- ✘ Instruction in RCR must be carefully evaluated in all NIH grant applications for which it is a required component.

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ORI-identified core areas of RCR

- ✘ Research misconduct
- ✘ Protection of human subjects
- ✘ Animal use & welfare
- ✘ Conflicts of interest
- ✘ Data management practices
- ✘ Mentor & trainee responsibilities
- ✘ Collaborative research
- ✘ Authorship & publication
- ✘ Peer review

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Research Misconduct

Uniform Federal definition says:

Research misconduct is “fabrication, falsification and plagiarism in proposing, performing or reviewing research, or in reporting research results”.

Commonly known as “FFP”

Researchers & research institutions bear primary responsibility for reporting & investigating allegations of misconduct

Every institution receiving PHS funding must have procedures for receiving & investigating reports of alleged misconduct

See UMass Amherst procedures at:

<http://www.umass.edu/research/ora/ResearchMisconductProceduresNov2009.pdf>

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Protection of Human Subjects

DHHS rules codified after 1974 Congressional directive (45 CFR 46)

FDA rules codified at 21 CFR 50 & 46

“Common Rule” (45 CFR 46) adopted by most Federal agencies in 1991

Oversight by Office for Human Research Protections (OHRP)

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Animal Use and Welfare

1966 Animal Welfare Act (7 USC, 2131-156)

1985 Health Research Extension Act, Sec. 495

Adherence to the regulations is an institutional responsibility via the Institutional Animal Use and Care Committee (IACUC)

Oversight & voluntary accreditation by

- ✘ Office of Laboratory Animal Welfare (OLAW)
- ✘ USDA
- ✘ Assoc. for Assessment and Accreditation of Laboratory Animal Care (AAALAC)

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Conflicts of Interest

Mid-1990s – financial conflict of interest policies promulgated by PHS and NSF

Policies require *significant* conflicts to be disclosed

- ✘ Reporting of *significant* conflicts before research begins
- ✘ Managing, reducing or eliminating *significant* financial conflicts of interest
- ✘ Documenting how conflicts were handled (“managed”)

State and other local conflicts policies also come into play (ie, MGL 268A)

Conflicts of commitment

Organizational conflicts of interest

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Data Management Practices

Procedures to address:

- ✘ Ownership – who owns it?
- ✘ Collection – appropriate methods; attention to detail; authorized use; recording
- ✘ Storage – protect from accidental damage, theft or loss; centralized? National security interests (ie, export controls)
- ✘ Sharing – when & with whom?

Tidbits:

Rights to publish (*sacrosanct* in academia!)

Funders interests in broadly sharing data for the public good
(interests differ among public, private & non-profit funders)

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Mentor & Trainee Responsibilities

Guidance provided by NIH, NAS, professional organizations, etc.

Encompasses formal & informal RCR training – “face time”

Proper supervision of a trainee takes time!

Transition of trainee to independent researcher is the ultimate goal

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Collaborative Research

Develop a clear understanding of roles & responsibilities

Develop a management plan addressing:

- ✘ Financial issues – reasonable, allowable, allocable (OMB Circular A-21)
- ✘ Training & supervision
- ✘ Formal agreements – who owns materials, how can they be used, proper acknowledgement of sources
- ✘ Compliance – must be throughout the project and across project sites

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Authorship & Publication

Responsible publication includes:

- ✘ A full & fair description of the work
- ✘ An accurate report of the results
- ✘ An honest and open assessment of findings

Authors listed should accurately reflect the person or persons responsible for the work

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Peer Review

An essential component of research, but it must be:

- ✘ Timely
- ✘ Thorough
- ✘ Constructive
- ✘ Free from personal bias
- ✘ Respectful of the need for confidentiality

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BASIC RESOURCES FOR MEETING RCR/ETHICS REQUIREMENTS

- ✘ Professional codes of conduct
- ✘ Government regulations
- ✘ Institutional policies
- ✘ Personal convictions

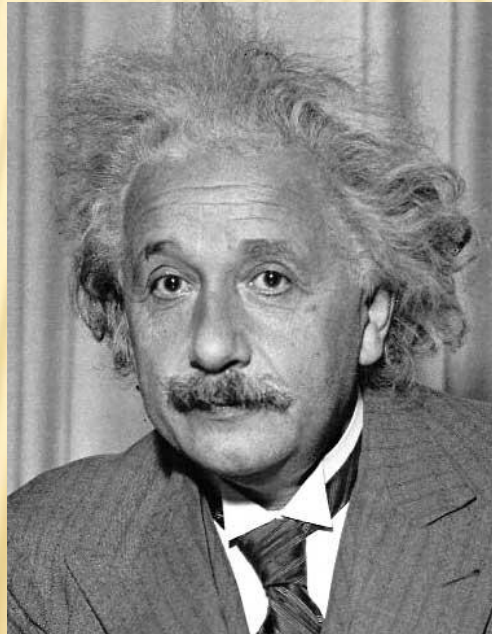
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Other Resources for RCR/Ethics Training & Compliance

- ✘ NSF – <http://www.nsf.gov/bfa/dias/policy/rcr.jsp>
- ✘ DHHS Office of Research Integrity – <http://ori.hhs.gov/policies/statutes.shtml> and http://ori.hhs.gov/education/products/rcr_general.shtml
- ✘ ESENCE - <http://www.ethicslibrary.org/about.html>
- ✘ National Academy of Sciences- <http://www.nas.edu/>
- ✘ Council of Graduate Schools - <http://www.cgsnet.org/>
- ✘ National Postdoctoral Association – <http://www.nationalpostdoc.org>
- ✘ NSF RCR Frequently Asked Questions (FAQs) (August 16, 2010) – <http://www.nsf.gov/pubs/policydocs/rcr/rcrfaqs.jsp>

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“Most people say that it is the intellect which makes a great scientist. They are wrong: it is character.”



Albert Einstein

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- ✘ NSF
- ✘ NIH
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