Lessons Learned

Responsible Conduct of Research Education in the U.S.

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University of California, San Diego
September 5th, 2014
JSPS and NSF Workshop

Morning agenda

9-10:15

- A brief history of RCR in the US:
  - ✓what is RCR education?
  - ✓why and how have federal requirements evolved?
  - ✓what resources are there to meet the requirements?
  - ✓how is it working?

Structure of morning format from
Michael Kalichman
A Brief History of RCR Education
In Accountability in Research: Policies and Quality Assurance
20:5-6, 380-394.

Morning agenda

10:45 – noon

- Goals of RCR education
- Possible content for RCR education
- Possible approaches for teaching RCR
  - ✓integrate with other courses
  - ✓integrate into the research context
  - ✓ethics across the curriculum
  - ✓on-line courses
  - ✓seminars/workshops
  - ✓courses

What is RCR?

- Responsible conduct of research
- Research ethics
- Scientific integrity

Research ethics addresses…

the ethical issues of

being a scientist,

rather than the ethical questions

raised by science

“Responsible conduct of research is more reminiscent of teaching good practice in science rather than teaching someone not to commit research misconduct.”

Michael Kalichman

A Brief History of RCR Education

In Accountability in Research: Policies and Quality Assurance

20:5-6, 380-394.

NIH

NOTICES

REQUIREMENT FOR PROGRAMS ON THE RESPONSIBLE CONDUCT OF RESEARCH IN NATIONAL RESEARCH SERVICE AWARD INSTITUTIONAL TRAINING PROGRAMS

A fundamental aspect of research is that it be conducted in an ethical and scientifically responsible manner. National Institutes of Health (NIH) … supported research training programs are notable for producing high quality researchers in the various fields of biomedical and behavioral science. Within this framework of excellence and relevance, it is important that attention be directed towards scientific integrity in the conduct of research.

NIH

Most universities and academic institutions have practices and procedures to ensure the responsible conduct of research. These may include informal seminars and presentations on conflict of interest, data recording and retention, professional standards and codes of conduct, responsible authorship, institutional policies and procedures for handling allegations of misconduct, policies regarding the use of human and animal subjects, etc. or formal courses on bioethics, research conduct, the ideals of science, etc.

NIH

To address this aspect of research training, the NIH [is] revising the administrative guidelines for all National Research Service Award institutional training grants to require that a program in the principles of scientific integrity be an integral part of the proposed research training effort.

Effective July **1, 1990,** all competing National Research Service Award institutional training grant applications must include a description of the formal or informal activities related to the instruction about the responsible conduct of research that will be incorporated into the proposed research training program.

Vol. **18,** No. ***45,*** December 22, 1989

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"With this simple, largely unheralded half-page requirement, the era of formal RCR education was essentially born."

Steneck and Bulger

The History, Purpose and Future of Instruction in the Responsible Conduct of Research

Academic Medicine, 82(9), September 2007

Why were those regulations established?

1989 Institution of Medicine (IOM) Report

The Responsible Conduct of Research in the Health Sciences

1995 Commission on Research Integrity

Integrity and Misconduct in Research

1989 IOM Report

The Responsible Conduct of Research in the Health Sciences

The primary task of the committee was the development of principles and proposals to guide both national and local institutions in strengthening the professional standards of academic research.

Our concern was the … professional climate of the research environment, which influences everyday practice and sets the tone for future generations of researchers. By improving the integrity and quality of the institutional environment of research, we sought to foster professional research standards of individual researchers and to discourage future incidents of scientific misconduct.

1989 IOM Report

The Responsible Conduct of Research in the Health Sciences

The communication of the ideals of science, its values and methods, traditionally occurred through individual discussions between senior investigators and students. Given the increased size, complexity, and heterogeneity of the research training process, the committee believes that reliance on these discussions alone is not sufficient to provide effective instruments of professionalization and education.

1989 IOM Report

The Responsible Conduct of Research in the Health Sciences

The lack of formal discussion about responsible research practice and the ethics of research is a serious flaw in the professional training of young scientists and clinicians. The committee believes that instruction in the standards and ethics of research is essential to the proper education of scientists.

1989 IOM Report

The Responsible Conduct of Research in the Health Sciences

Universities should provide formal instruction in good research practices. This instruction should not be limited to formal courses but should be incorporated into various places in the undergraduate and graduate curricula for all science students.

NIH

REMINDER AND UPDATE: REQUIREMENT FOR INSTRUCTION IN THE RESPONSIBLECONDUCT OF RESEARCH IN NATIONAL RESEARCH SERVICE AWARD INSTITUTIONAL TRAINING GRANTS

NIH GUIDE, Volume 21, Number 43, November 27, 1992

NIH

With this notice, the NIH updates and reinforces the commitment to ensure that all NRSA supported trainees are provided an opportunity for training in the responsible conduct of research. Plans for instruction in the responsible conduct of research will continue to be required in all applications for institutional NRSA research training grants.

1995 Commission on Research Integrity

Integrity and Misconduct in Research

Promoting research integrity and attempting to prevent research misconduct

- Research integrity is best fostered by developing and disseminating clear standards of behavior in science (whether by professional organizations or by research institutions or both), and by reinforcing those standards through education and example at all stages of scientific development, and at all levels of research administration.

1995 Commission on Research Integrity

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1995 Commission on Research Integrity

Integrity and Misconduct in Research

The Commission believes that a positive ethical example set by a research supervisor or mentor in a laboratory or other research setting provides a powerful learning experience.

However, given the size, complexity, and at times impersonality of many training environments, other mechanisms are also needed to ensure that high ethical standards and exemplary scientific practices are clearly and credibly communicated and fostered.

1995 Commission on Research Integrity

Integrity and Misconduct in Research

The Commission believes that [the] required [PHS] educational activity is essential and should be more broadly implemented to ensure that, through such training, all individuals who perform research in institutional settings are sensitized to the ethical issues inherent in research.

1995 Commission on Research Integrity

Integrity and Misconduct in Research

At present, the training is required only of recipients of institutional training grants, and does not reach all graduate, professional, and postdoctoral students or more senior researchers and other members of research groups, such as technicians.

1995 Commission on Research Integrity

Integrity and Misconduct in Research

The Commission strongly believes that all of these individuals would benefit from participation. Providing such training is an important step toward creating a positive research environment that stresses the achievement of research integrity more than the avoidance of research misconduct

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2000 NIH Policy

- "through ORI, the Department will require research institutions to provide training in the responsible conduct of research to ***all staff*** engaged in research or research training with PHS funds."

- Suspended in 2001

NSF

- 1997
- Integrative Graduate Education and Research Traineeship (IGERT) Program

“Discuss plans for how students will be recruited and mentored as well as career development opportunities, provisions for developing professional and personal skills, fostering an international perspective and ability to work in diverse teams, and integrating instruction in ethics and the responsible conduct of research."

NSF

- 2009

"The Director shall require that each institution that applies for financial assistance from the Foundation for science and engineering research or education describe in its grant proposal a plan to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduate students, graduate students, and postdoctoral researchers participating in the proposed research project."

NSF

"… 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 specific needs for RCR training in all areas at that institution for which NSF provides support. Furthermore, each institution must decide if development of content or pedagogical method is required, or if appropriate content and training can be provided from some existing sources or capabilities, and take appropriate action to implement their decisions."

NIH 2009 update

The purpose of this Notice is to update NIH policy on instruction in the responsible conduct of research, convey some of the consensus best practices that have evolved in the research training community over the past two decades, and to provide access to additional information that may be useful to institutions and individuals in meeting their obligations under NIH policy.

NIH 2009 update

- Specifically this Notice: 1) develops principles based on 20 years' experience of providing instruction in responsible conduct of research by the scientific research community; 2) is more specific about who should participate, how often instruction should occur, and the form that instruction should take; 3) addresses issues that have arisen as the practice of biomedical, behavioral and clinical science has evolved; and 4) provides guidance to applicants, peer reviewers and NIH staff in determining how well specific plans for instruction in responsible conduct of research compare with the best practices accumulated over the past two decades by the research training community.

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NIH 2009 update

Definition

For the purpose of this Notice, **responsible conduct of research is defined as the practice of scientific investigation with integrity. It involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research.**

NIH 2009 update

Basic Principles

The following principles are based on several key concepts about responsible conduct of research and best practices that have evolved over the past two decades' experiences:

NIH 2009 update

1. Responsible conduct of research is an essential component of research training. Therefore, instruction in responsible conduct of research is an integral part of all research training programs, and its evaluation will impact funding decisions.

NIH 2009 update

2. Active involvement in the issues of responsible conduct of research should occur throughout a scientist's career. Instruction in responsible conduct of research should therefore be appropriate to the career stage of the individuals receiving training.

NIH 2009 update

3. Individuals supported by individual funding opportunities such as fellowships and career development awards are encouraged to assume individual and personal responsibility for their instruction in responsible conduct of research.

NIH 2009 update

4. Research faculty of the institution should participate in instruction in responsible conduct of research in ways that allow them to serve as effective role models for their trainees, fellows, and scholars.

NIH 2009 update

5. Instruction should include face-to-face discussions by course participants and faculty; i.e., on-line instruction may be a component of instruction in responsible conduct of research but is not sufficient to meet the NIH requirement for such instruction, except in special or unusual circumstances.

NIH 2009 update

NIH recognizes that instruction in responsible conduct of research occurs formally and informally in educational settings and that informal instruction occurs throughout the research training experience. The guidance provided below is directed at *formal instruction in responsible conduct of research*. It reflects the accumulated experiences and the best practices of the scientific community over the past two decades. These practices have been incorporated into many of the best regarded programs of instruction in responsible conduct of research.

How have these guidelines evolved?

NIH (1989)
conflict of interest
data recording and retention
responsible authorship
institutional policies and procedures for handling allegations of misconduct
policies regarding the use of human and animal subjects
professional standards and codes of conduct, bioethics, research conduct, the ideals of science

NIH (1989)	NIH (1992)
conflict of interest	conflict of interest
data recording and retention	data management
responsible authorship	responsible authorship
institutional policies and procedures for handling allegations of misconduct	policies for handling misconduct
policies regarding the use of human and animal subjects	policies regarding the use of human and animal subjects
professional standards and codes of conduct, bioethics, research conduct, the ideals of science	not addressed

NIH (1989)	NIH (1992)	NIH (2000)
conflict of interest	conflict of interest	conflict of interest and commitment
data recording and retention	data management	data acquisition, management, sharing, and ownership
responsible authorship	responsible authorship	publication practices and responsible authorship
institutional policies and procedures for handling allegations of misconduct	policies for handling misconduct	research misconduct
policies regarding the use of human and animal subjects	policies regarding the use of human and animal subjects	human subjects; research involving animals
not addressed	not addressed	mentor/trainee responsibilities
not addressed	not addressed	collaborative science
not addressed	not addressed	peer review
professional standards and codes of conduct, bioethics, research conduct, the ideals of science	not addressed	not addressed

NIH (1992)	NIH (2000)	NIH (2009)
conflict of interest	conflict of interest and commitment	conflict of interest – personal, professional, and financial
data management	data acquisition, management, sharing, and ownership	data acquisition and laboratory tools; management, sharing and ownership
responsible authorship	publication practices and responsible authorship	responsible authorship and publication
policies for handling misconduct	research misconduct	research misconduct and policies for handling misconduct
policies regarding the use of human and animal subjects	human subjects; research involving animals	policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
not addressed	mentor/trainee responsibilities	mentor/mentee responsibilities and relationships
not addressed	collaborative science	collaborative research including collaborations with industry
not addressed	peer review	peer review
not addressed	not addressed	the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

conflict of interest	conflict of interest and commitment	conflict of interest – personal, professional, and financial
data management	data acquisition, management, sharing, and ownership	data acquisition and laboratory tools; management, sharing and ownership
responsible authorship	publication practices and responsible authorship	responsible authorship and publication
policies for handling misconduct	research misconduct	research misconduct and policies for handling misconduct
policies regarding the use of human and animal subjects	human subjects; research involving animals	policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices

Material on current and 4 preceding slides from Kalichman, M. (2013) A Brief History of RCR Education in Accountability in Research: Policies and Quality Assurance, 20:5-6, 380-394

1) what, exactly, should we teach about these topics? And
2) what formats should we use to teach about these topics?

Responsible authorship

Meaning of authorship, within and across disciplines?

Meaning of authorship order?

Institutional authorship guidelines?

Journal guidelines?

Who decides who will be an author? Who decides authorship order?

Managing authorship conflicts?

1) what, exactly, should we teach about these topics? And
2) what formats should we use to teach about these topics?

Formats: NIH

… in person, face-to-face discussions (not solely on-line training)

… faculty involvement

… at least 8 hours in duration

… no less frequently than once every four years and at each career stage

Formats: NSF

"… 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 specific needs for RCR training in all areas at that institution for which NSF provides support. Furthermore, each institution must decide if development of content or pedagogical method is required, or if appropriate content and training can be provided from some existing sources or capabilities, and take appropriate action to implement their decisions."

Resources

- Office of Research Integrity (ORI)
  - http://ori.hhs.gov
- Ethics CORE (Collaborative Online Resource Environment), University of Illinois Urbana-Champaign
  - http://nationalethicscenter.org
- Online Ethics Center for Engineering and Research, National Academy of Engineering
  - http://www.onlineethics.org

Resources

- Fostering Integrity in Research, Scholarship and Teaching (FIRST), Univ of Minnesota
  - http://www.research.umn.edu/ethics
- Project for Scholarly Integrity, Council of Graduate Schools
  http://www.scholarlyintegrity.org

Resources

- Responsible Conduct of Research for Postdocs, National Postdoctoral Association
  - http://www.nationalpostdoc.org/publications/rcr

Resources

Materials coupled with questions (typically multiple choice) to assess completion and understanding	*Course in the Responsible Conduct of Research*, CITI https://www.citiprogram.org/rcrpage.asp *Responsible Conduct of Research*, CMDITR http://nationalethicscenter.org/index.php?option=com_rcrtutorial *Responsible Conduct of Research*, Columbia University http://ccnmtl.columbia.edu/projects/rcr *Program for Education and Evaluation in Responsible Research and Scholarship*, University of Michigan http://my.research.umich.edu/peerrs

Resources

Syllabus and other resources to supplement an on-line learning environment to interact with other students and/or the instructor by discussion boards, e-mail conversations, instant messaging, etc.	*Research Ethics*, U Nebraska Medical Center (1999-2005) (Mann, 1999) *Scientists and Subjects*, Indiana University (1999-2006) (Pimple, 2005) Scientific Integrity, UC San Diego (1999-present): http://ethics.ucsd.edu/courses/integrity

Resources

- ✓ Ken Pimple's *Teaching Research Ethics* at Indiana University in 1993
- ✓ Michael Zigmond and Beth Fischer's *Survival Skills and Ethics* at the University of Pittsburgh in 1995 (Taubes, 1995b)
- ✓ Francis Macrina (Virginia Commonwealth University) and Michael Kalichman (UCSD) taught the first of many *RCR101* train-the-trainer research ethics workshops under the auspices of PRIM&R (Public Responsibility in Medicine & Research)
- ✓ Kalichman and Plemmons (2012-) teach three train the trainer workshops: new courses, integrating ethics into existing courses, and integrating ethics into the research context.

Is it working?

Diverse goals, content, approaches

Not taken seriously

Requirements unclear, inconsistent

Nominal evidence of effectiveness

Morning agenda

10:45 – noon

- Goals of RCR education
- Possible content for RCR education
- Possible approaches for teaching RCR
  - ✓integrate with other courses
  - ✓integrate into the research context
  - ✓ethics across the curriculum
  - ✓on-line courses
  - ✓seminars/workshops
  - ✓courses

Goals for RCR education

"to decrease the amount of unethical behavior going on in the world."

"[teach students to] demonstrate commitment, responsibility, and respect for all aspects of research, including subjects of research, whether they're animal models or human models, as well as those that would be affected by the results of the research."

Kalichman M and Plemmons D (2007)
Reported Goals for Responsible Conduct of Research Courses
Academic Medicine: September 2007 - Volume 82 - Issue 9 - pp 846-852

“[teach students] to recognize what research misconduct is and to avoid it.”

“keep them out of trouble.”

Kalichman M and Plemmons D (2007)
Reported Goals for Responsible Conduct of Research Courses
Academic Medicine: September 2007 - Volume 82 - Issue 9 - pp 846-852

"Graduate students think they understand research ethics based on egregious examples; however, most issues are in the gray area. [We] need to teach them to recognize that it is the small things that can make an enormous difference—especially in regards to impacting the community."

Plemmons D and Kalichman M (2007)

Reported Goals For Knowledge to be Learned in Responsible Conduct of Research Courses

Journal of Empirical Research on Human Research Ethics: An International Journal

Vol. 2, No. 2 (June 2007) (pp. 57-66)

"[I want to] encourage a sense that part of doing good science is through fulfilling ethical principles, that those two things go hand in hand, as opposed to being in opposition."

Kalichman M and Plemmons D (2007)
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Academic Medicine: September 2007 - Volume 82 - Issue 9 - pp 846-852

Goals for RCR education

- Knowledge
- Skills
- Attitudes
- Behaviour

Goals for RCR education: Knowledge

Trainees should have information about

- ✓ data management, animal subjects, human subjects, conflicts of interest, authorship, publication, peer review, collaboration, mentoring, research misconduct, and whistleblowing
- ✓ uneven power situations, vulnerable populations
- ✓ copyrights, patents (esp. in terms of life forms and genetics)
- ✓ where to find help

Goals for RCR education: Skills

Trainees should know how to

- ✓ make ethical decisions
- ✓ think critically
- ✓ manage stress
- ✓ work in a multidisciplinary research team
- ✓ resolve conflicts

Goals for RCR education: Attitudes

Researchers will recognize that

- ✓ research is often characterized by ethical dilemmas that are not simple but are amenable to mitigation or resolution
- ✓ open communication with others is a part of RCR
- ✓ regulations were developed in response to real problems

Goals for RCR education: Behaviour

Researchers will

- ✓ model the highest standards of scientific conduct
- ✓ engage in more effective communication with others

Possible goals/outcomes

- Goal: Engage in conversations with peers and mentors about ethical challenges of research

- Measurable Outcome: amount of time spent in conversations about the ethical challenges to the responsible conduct of science

Possible goals/outcomes

- Goal: Know rules, issues, options, and resources for RCR

- Measurable Outcome: Ability to identify places, people, and/or other resources to help in addressing ethical challenges to conduct of science

Possible goals/outcomes

- Goal: Understand the purpose and value of ethical decision making
- Goal: Have a positive disposition (or at least not a negative disposition) toward lifelong learning about RCR
- Measurable Outcome: Self-reported disposition to research ethics

Research Ethics Topics

Examples of General Topics

- Data Management
- Conflict of Interest and Commitment
- Authorship
- Publication
- Peer Review
- Collaboration
- Mentoring
- Social Responsibility
- Research Misconduct
- Raising Questions, Addressing Problems
- Dispute Resolution
- Whistleblowing

Examples of Specific Topics

- Human Subjects
- Animal Subjects
- Stem Cells
- Environmental Protection
- Agriculture
- Engineering
- Computers and Information Technology
- Nanotechnology
- Dual Use Technology
- Intellectual Property

Approaches

- Stand alone courses
- Integrated with existing courses [for example, methods courses, data / statistics courses]
- Integrated into the research context
- On-line courses and on-line modules
- Ethics across the curriculum approaches
- seminars/workshops
- Combinations of the above

From the journal *Science*

"At the advanced level, research training occurs mainly via apprenticeships. And probably the best way to learn scientific integrity is by example, from principled mentors who model scientific virtues: meticulous attention to detail, an intensely critical approach (including, especially, to their own work), a commitment to truth above reputation -- or to the idea that reputation is intrinsically linked to truth -- and so on. Of course, not everyone has a principled mentor who is a master scientist who recognizes the importance of passing on the unspoken substance of what we do as scientists."

“…there's value in conscious analysis, in the careful consideration of what integrity is, globally and in the context of particular fields and decisions, and what it means to have it and use it.”

By Jim Austin

November 05, 2010

Accessed at http://sciencecareers.sciencemag.org/career_magazine/previous_issues/articles/2010_11_05/caredit.a1000108

“Ethical behaviour is not an inherent human quality. There is nothing natural about internalizing a collective framework for how people should operate within a culture. It’s learned behaviour.”

Chuck Klosterman
The Ethicist
October 20, 2013

From *Academic Duty*

"Future researchers, like other professionals in the making, need to become acquainted with the kinds of challenges they are likely to face. Without some thoughtful consideration of what their own responsibilities are to be, and an examination of ethical issues researchers regularly confront, is it reasonable to expect that they will get it right the first time? Surely that places too much faith in instinct, or in the general kind of moral guidance that is part of an average upbringing."

Donald Kennedy, Academic Duty, page 19

It’s not just about misconduct…

“Research integrity is an active, positive pursuit, and not merely the absence of scientific wrongdoing. It's the sum total of all the little decisions scientists make in the course of their scientific work: the way they handle data, treat trainees and peers, deal with regulatory requirements, keep the books, and so on. It's the foundation of everything we do as scientists…”

By Jim Austin

November 05, 2010

Accessed at http://sciencecareers.sciencemag.org/career_magazine/previous_issues/articles/2010_11_05/caredit.a1000108

It’s not just about misconduct…

Misconduct is not, however, the first or even the most important test of integrity in scientific practice. More significant by far are the dozens of routine decisions scientists make every day. The relevance to integrity of these small choices may not be apparent. As small decisions, their consequences are not obvious, which makes it easier to justify bending rules and cutting corners: What difference would it make if you described essentially the same research results in more than one publication without proper notification, added a few references in your notes that may or may not actually support your research, or used a few sentences from someone else's methods section to describe what you have done? When the active consideration of integrity is put off to another day, it becomes easier to take the first compromising steps toward irresponsible research practices.

Career Advice
Perspective: Put Integrity High on Your To-Do List
By Nicholas H. Steneck
November 05, 2010
Accessed at http://sciencecareers.sciencemag.org/career_magazine/previous_issues/articles/2010_11_05/caredit.a1000106

Hello Dr. Plemmons,

I was a part of your class on research ethics in Spring 2013. I found the course fascinating, illuminating, and very useful in the time that has passed since.

I definitely agree that preemptive awareness is the way to go. That's one of the ways the class material has been useful to me, making it something interesting that's automatically part of the conversation rather than some taboo topic of unwritten laws that nobody really effectively communicates about. I think of active awareness of these issues as a serious part of being a professional as opposed to a technician.

Regards,

Rory Klinger

PhD Student / Teaching Associate

Environmental Engineering, SDSU-UCSD Joint Doctoral Program