The History, Impact and Future of Responsible Conduct of Research (RCR) Education in the US

Symposium on Education in Research Ethics
Helsinki, Finland
October 11, 2006

Nicholas H. Steneck, PhD
University of Michigan
nsteneck@umich.edu

nsteneck@umich.edu

1

Definitions: Integrity vs. Ethics

☛ **Research Integrity**
…the use of honest and verifiable methods in proposing, performing and evaluating research and in reporting research results, with particular attention to adherence to rules, regulations, guidelines and commonly accepted professional codes or norms.

Should !

☛ **Research ethics**
…the critical study of the moral problems associated with biomedical and behavioral research and its application to health care decision-making.

Should ?

nsteneck@umich.edu

2

RCR

Responsible Conduct of Research

Government Regulations   *Professional Codes*

Plan → Conduct → Report

R C R

Commonly accepted practices   *Personal Ethics*

Practices that deviate from RCR:

✓ Questionable research practices (QRP)

✓ Research Misconduct (FFP)

nsteneck@umich.edu

3

How should researchers behave?

Good scientific practice …

Hyvä tieteellinen käytäntö ja sen loukkausten käsitteleminen

1. follow modes of action endorsed by the research community, that is, integrity, meticulousness and accuracy …
2. apply ethically sustainable data-collection, research and evaluation methods…
3. take due account of other researchers' work and achievements…
4. [plan, conduct and report] in detail and according to the standards set for scientific knowledge;
5. [determine and record]questions relating to the status, rights, co-authorship, liabilities and obligations … in a manner acceptable to all parties before the research project starts or a researcher is recruited to the team;
6. [report] the sources of financing and other associations relevant to the conduct of research …
7. [observe] good administrative practice and good personnel and financial management practices

nsteneck@umich.edu

4

Standards for responsible science?

European Science Foundation Policy Briefing

Good scientific practice in research and scholarship

Foreword

At a time when the need to build trust between science and society is becoming ever more important, it is vital that the conduct of science itself is based on the highest ethical considerations and that misconduct within science itself can be identified and dealt with in an open and transparent manner.
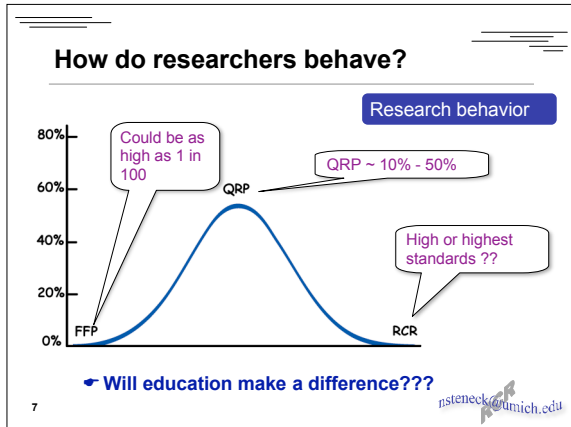
nsteneck@umich.edu

5

Need for high standards widely accepted

The Wellcome Trust

Guidelines on good research practice

The Wellcome Trust expects the highest standards of integrity to be adhered to by the researchers whom it funds. To facilitate this it has drawn up these 'Guidelines on Good Research Practice'.

nsteneck@umich.edu

6

How do researchers behave?

Research behavior

Could be as high as 1 in 100

QRP ~ 10% - 50%

High or highest standards ??

80%
60%
40%
20%
0%

FFP   QRP   RCR

☞ Will education make a difference???

7

nsteneck@umich.edu

Origin of RCR Education

☞ **1980s, assumed, no special training needed**
☞ **1989, two key developments:**
  ✓ IOM, *RCR in the Health Sciences*
  ✓ **NIH/ADAMHA Training Grant Requirement**
    ▪ **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.
  ✓ **Recommended include six key areas (1994)**
    1. **Conflict of Interest**   4. **Data Management**
    2. **Responsible authorship**   5 & 6. **Human & animal subjects**
    3. **Policies for handling misconduct**

8

nsteneck@umich.edu

1990s, shift to formal RCR education

☞ **On Being a Scientist (2nd edition)**
  ✓ **In the past, young scientists learned the ethics of research largely through informal means–by working with senior scientists and watching how they dealt with ethical questions. That tradition is still vitally important. But science has become so complex and so closely intertwined with society's needs that a more formal introduction to research ethics and the responsibilities that these commitments imply is also needed-an introduction that can supplement the informal lessons provided by research supervisors and mentors. (Preface)**
☞ **Impact**
  ✓ **Increase in number of courses and web programs**
  ✓ **Development of an "RCR community"**
  ✓ **Increase in resources: textbooks, course outlines…**

9

nsteneck@umich.edu

Effort peaked in 2000

Core Areas
1. Data acquisition, management, sharing, and ownership
2. Mentor/trainee responsibilities
3. Publication practices and responsible authorship
4. Peer review
5. Collaborative science
6. Human subjects
7. Research involving animals
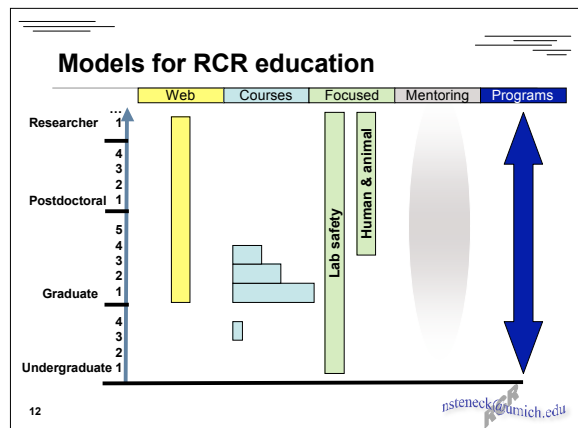8. Research misconduct
9. Conflict of interest and commitment

☞ **NIH, *Required Education in the Protection of Human Research Participants (2000)***
☞ **PHS, *Policy on Instruction in the Responsible Conduct of Research (2000)***
  ✓ **All PHS-funded research**
  ✓ **All research staff**
  ✓ **9 core areas**

RCR suspended

☞ **NSF requires RCR on IGERT awards**
  ✓ **Must include: " instruction in ethics and the responsible conduct of research"**

10

nsteneck@umich.edu

Current Situation in US

☞ **Driven by human subjects and training grants**
☞ **Approaches (in order of importance)**
  ✓ **Courses, seminar & special programs**
  ✓ **Web-based training (1st for human subject)**
  ✓ **Mentoring seldom formalized but important**
☞ **Shortcomings**
  ✓ **No standards or model curricula**
  ✓ **Weak coordination (institutional / fields)**
  ✓ **Minimum assessment**
☞ **Evaluation**
  ✓ **Quality of training varies considerably**
  ✓ **Effectiveness has not been demonstrated**

11

nsteneck@umich.edu

Models for RCR education

| | Web | Courses | Focused | Mentoring | Programs |

Researcher
4
3
2
Postdoctoral 1
5
4
3
2
Graduate 1
4
3
2
Undergraduate 1

Lab safety

Human & animal

12

nsteneck@umich.edu

Web

University of New Hampshire
http://www.unh.edu/rcr/

UNIVERSITY of NEW HAMPSHIRE
Responsible Conduct of Research — Online Study Guide

HomePage
- **Introduction**
- **Human Subjects**
- **Animal Subjects**
- **Authorship**
- **Misconduct**
- **Data Management**
- **Conflict of Interest**
- **Hazardous Materials**
- **Mentoring**
- **Peer Review**
- **Collaborative Research**

13
- **Quit**
- **Bibliography**

edu

Web

University of Alaska, Fairbanks
http://www.uaf.edu/ori/RCR_Course/about.html

UNIVERSITY OF ALASKA **FAIRBANKS** — A 360+ Million-Acre Classroom

ABOUT US | CONTACT STAFF
Office of Research Integrity

About the ORI
UAF Blackboard
RCR Course Content
Instructor Resources
RCR Contact Information

University of Alaska Fairbanks :: Center for Research Services :: Office of Research Integrity :: RCR Course :: About the Course

Research Misconduct
Data Management
Use of Animal Subjects
Use of Human Subjects
Conflicts of Interest
Authorship
Publication & Peer Review
Collaboration & Mentoring
UAF Proposal Submission & Grant Management

ased RCR Course

ersity's research community, this self-directed tutorial program or both responsible conduct of research and for maintaining the gaged in research activities, irrespective of discipline, is g of these topics. This includes administrators and research tudents, and technicians. Some sponsors require formal search team have received this training. This course is intended to meet most training grant requirements; however, it is up to the individual Program Director and his/her funding agency to determine whether this form of instruction is sufficient.

The content of this course (except for the UAF specific sections and some modifications) is offered through this institution's membership in the RCR Education Committee, a special interest project administratively housed with the Association for Practical and Professional Ethics (APPE). Content is derived from courses taught by Dr. Michael Kalichman at the University of California, San Diego (UCSD) and Dr. Francis Macrina at Virginia Commonwealth University.

The format of this course has been designed to take advantage of the strengths of the Internet while de-emphasizing methods better adapted for a classroom setting. In practice, this means that participants in the course must spend more time reading than would otherwise be the case for a lecture course.

14

nsteneck@umich.edu

Web

University of Pittsburgh
https://cme.hs.pitt.edu/servlet/IteachControllerServlet?actiontotake=displaymainpage

INTERNET-BASED STUDIES IN EDUCATION AND RESEARCH
University of Pittsburgh Health Sciences eLearning Environment

Module List | Contact Us | My Account | Help | Search | Site Map

News & Announcements
- Modules are now categorized for your convenience. Modules required for researchers can be found under "Responsible Conduct of Research". A full list of modules is still available or try the search function

Modules Listings
- **All Modules**
- **Angiogenesis**
- **FY07 Physician Services Division Safety Training**
- **HIPAA**
- **Patient Safety/Risk Management**
- **Responsible Conduct of Research**

START HERE
Login
Email Address
Password
🔒 Log In
- Create Account
- Retrieve Password
- Having problems retrieving your username/password?
- Help with login

Common Questions

15

nsteneck@umich.edu

Courses

University of Pittsburgh
http://www.survival.pitt.edu/

Survival Skills & Ethics Program
events | calendar | about | resources | contact | home

Saturday Series
At the University of Pittsburgh

This series of workshops provides you with training in professional development and ethics. The workshops are geared toward the needs of graduate and professional students, postdoctoral fellows, residents, junior faculty, and mentors. However, anyone who is interested is welcome to attend. Each workshop is designed as an independent unit, thus you may choose to attend only the workshops of interest to you.

Review the Fall 2004 Schedule
Review the Spring 2005 Schedule
Register for a Workshop

Schedule: Fall 2004

16

nsteneck@umich.edu

Courses / **Web**

NIH
http://researchethics.od.nih.gov/index_confirm_browse.htm

NIH RESEARCH ETHICS

Introduction
Scientific Integrity
Data Acquisition and Management
Publication and Authorship
Peer Review
Mentor/Trainee Relationships
Collaborative Science
Human and Animal Subjects
Conflict of Interest and Commitment
Conclusion

MENU

☛ **Must also attend case study discussion**

17

nsteneck@umich.edu

Programs

OLD DOMINION UNIVERSITY

Office of Research: Responsible Conduct of Research
Home | News | Faculty and Staff | Students | Visitors

☛ **Administrative approach**
- ✓ Campus atmosphere survey
- ✓ Advisory committee
- ✓ Faculty training
- ✓ Rewards to incorporate in courses

http://www.odu.edu/ao/research/services/responsible%20conduct%20of%20research.html

What are the core elements of RCR?
- Data acquisition, management, sharing, and ownership
- Mentor/trainee responsibilities
- Publication practices and responsible authorship
- Peer review
- Collaborative science
- Human subjects
- Research involving animals
- Research misconduct
- Conflict of interest and commitment

What types of skills help promote responsible conduct of research?
- Ethical Decision Making
- Critical Thinking
- Moral Reasoning
- Analytical
- Communication
- Methodological

Slide 19

Programs

University of Rhode Island
http://www.uri.edu/research/compliance/educandtrain.htm

RESEARCH ETHICS FELLOWS PROGRAM

☞ **Training sessions**
- ✓ series of bi-weekly, semester-long workshops,
- ✓ equip participants with the conceptual tools necessary for ethical decision-making
- ✓ discuss and generate case studies relevant to their respective fields
- ✓ develop training materials that can be used when they return to their home departments to facilitate training in research ethics

☞ **Fellows nominated by program directors**

☞ **Certificates of Completion**

19

nsteneck@umich.edu

Slide 20

Programs

University of Kansas

RCR KU
The Graduate School
Responsible Conduct of Research Awareness Week 2006

3/6 MONDAY	2:00–3:00 p.m.	Jayhawk Room, Kansas Union
	Professor Emeritus Richard Schowen, Department of Pharmaceutical Chemistry "Responsible Conduct of Research: Some Practicalities"	
3/7 TUESDAY	11:30 a.m.–1:00 p.m.	Lied Auditorium, KU Medical Center
	Luncheon: Professors Don Marquis, Department of Philosophy, and Jerry Menikoff, History & Philosophy of Medicine "The Moral Dilemmas of Medical Research: A Case Study of Treatment of Ovarian Cancer"	
3/8 WEDNESDAY	5:30–6:30 p.m.	Room 250, Regnier Hall, Edwards Campus
	Professor Ben Eggleston, Department of Philosophy "Ethical Issues in Responsible Conduct of Research"	
3/9 THURSDAY	7:30 p.m.	Alderson Auditorium, Kansas Union
	Keynote speaker: Professor Michael Kalichman, Director, Research Ethics Program, University of California, San Diego "Research Ethics: Are We Meeting Our Goals?"	

☞ **Began with RCR Awareness week**

☞ **Offered incentives to faculty to add RCR to existing courses**
- ✓ Reduced teaching
- ✓ Travel funds
- ✓ Research funds
- ✓ Part of annual merit reviews

Ethical research is paramount to success for all academics, from first year graduate students to tenured professors. Responsible Conduct of Research (RCR) Awareness Week explores the ethical issues you will encounter in your research fields. Please join the Graduate School, the Office of the Vice Provost for Research, KU Medical Center (KUMC), academic deans, faculty and staff as we explore and develop a basis for ethical research based on the KU RCR Program.

The Graduate School   (785) 864-6161   www.graduate.ku.edu

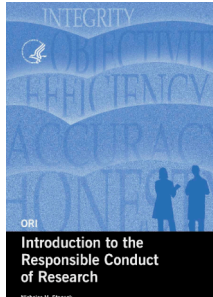Sponsored by the Graduate School, the Office of the Vice Provost for Research, and the KU Medical Center

20

Slide 21

Useful sites:

☞ **Office of Research Integrity – http://ori.dhhs.gov/**
- ✓ Click: Education - RCR Educational Resource Products

☞ **Poynter Center, Teaching Research Ethics**
- ✓ http://poynter.indiana.edu/tre/

☞ **Online Ethics Center, Case Western**
- ✓ http://onlineethics.org/

☞ **RCR Education Consortium**
- ✓ http://rcrec.org/

☞ **100s of RCR program in the US, from single courses to campus-wide programs**

21

nsteneck@umich.edu

Slide 22

ORI Resources and Programs

INTEGRITY
OBJECTIVITY
EFFICIENCY
ACCURACY
HONESTY

ORI
Introduction to the Responsible Conduct of Research
Nicholas H. Steneck
Illustrations by David Zinn

☞ **Basic RCR textbook**
- ✓ $14.95 thru GPO
- ✓ PDF free on the web
- ✓ Web-based version available

☞ **Other resources on line**
- ✓ RCR bibliography
- ✓ On-line instruction modules
- ✓ Links & resources

☞ **Programs**
- ✓ RCR Expo
- ✓ RCR resource program
- ✓ RCR professional societies
- ✓ CGS project

22

nsteneck@umich.edu

Slide 23

National Institutes of Health

Bioethics Resources on the Web

Directory
- Search this Site
- Bioethics and the NIH
- Other Federal Resources
- General Resources
- Specific Topics
- Organizations of Interest

National Institutes of Health

Welcome to the NIH's Bioethics Resources on the Web! The Internet is replete with resources available to those with an interest in bioethics including education, research involving human participants and animals, medical and health care ethics, and the implications of applied genetics and biotechnology. This website contains a broad collage of annotated web links, and while this list is comprehensive, it is not totally inclusive. The listed resources provide background information and various positions on issues in bioethics. Where possible, we have linked directly to those positions. Click here for more information on this site.

NEWS FLASHES!!!
- Revised Federalwide Assurance forms and institutional review board/independent ethics committee Registration form from The Office for Human Research Protections (02/05).
- Updated Human Subject Regulation Decision Charts from the Office of Human Research Protections (10/04)

NEWS Archives

http://www.nih.gov/sigs/bioethics/index.html

23

nsteneck@umich.edu

Slide 24

How to establish an RCR Program?

First, begin with four basic questions:

❶ **Reasons ~ why establish a program?**

❷ **Audience ~ who are you trying to reach?**

❸ **Objectives ~ what are you trying to accomplish?**

❹ **Resources ~ what funds and people are available?**

Second, assess what you can and want to do.

Third, implement!!

24

nsteneck@umich.edu

Q1. Reasons for RCR instruction?

- ☞ **Required**
  - ✓ Currently only trainees and human-subject researchers in US
- ☞ **Good publicity**
- ☞ **Awareness**
  - ✓ Know regulations governing research
- ☞ **Foster integrity**
  - ✓ Encourage researchers to adopt higher standards
- ☞ **Prevent misconduct**
  - ✓ Stop researchers from engaging in FFP

25

nsteneck@umich.edu

Q2. Target audience?

- ☞ **Graduate students and post docs**
  - ✓ Defined & controllable audience
  - ✓ Key point in career development
- ☞ **PIs**
  - ✓ Directly responsible for research projects
  - ✓ May be resistant to required instruction
- ☞ **All research staff and administrators**
  - ✓ Play important roles in research, should be trained
  - ✓ Significant increase in instructional effort
- ☞ **Larger community???**

26

nsteneck@umich.edu

Q3. General objectives?

Options?

- ☞ **Impart information**
  - ✓ Policies & regulations
  - ✓ Codes of ethics
  - ✓ Best practices

Research Integrity   Research Ethics

- ☞ **Develop critical reasoning skills**
  - ✓ Principle-based reasoning
  - ✓ Ways to recognize and resolve ethical dilemmas
- ☞ **Change behavior/enhance integrity**
  - ✓ Recognize and change unprofessional behavior
  - ✓ Avoid practices that could lead to misconduct

27

nsteneck@umich.edu

Q4. Resources?

- ☞ **Commonly staffed by unpaid volunteers**
  - ✓ Seed funds for organization are helpful
  - ✓ Meals and other rewards provide incentives
- ☞ **Additional resources**
  - ✓ RCR coordinators becoming more common
  - ✓ Web designer if web-based
- ☞ **Budgets vary widely**
  - ✓ Major efforts, $5M -10m investment
  - ✓ Small programs, $5-10k/year

28

nsteneck@umich.edu

Individual Researchers

- ☞ **Essential elements**
  - ✓ Written research policies (data, authorship, ….)
  - ✓ Clear understanding of responsibilities
  - ✓ Conscientious supervision and mentoring
  - ✓ Proactive commitment to responsible practice
- ☞ **Laboratory/Clinical RCR program**
  - ✓ Regular discussion of responsibilities in team meetings
  - ✓ Special discussions of cases and articles that raise questions about research integrity
  - ✓ Regular review of research findings and publications
  - ✓ Empower others to raise questions, present cases, a lead discussions

29

nsteneck@umich.edu

Research institutions

- ☞ **Essential elements**
  - ✓ Written research policies (misconduct, data, authorship, conflict of interest….)
  - ✓ Clear statements about responsibilities
  - ✓ Review committees, administrative and audit offices
  - ✓ Proactive commitment to responsible practice
- ☞ **Institutional RCR program**
  - ✓ Required basic training researchers using humans, animals, hazardous substances …
  - ✓ Training for research oversight committees
  - ✓ Training for mentors, backed by review of mentoring
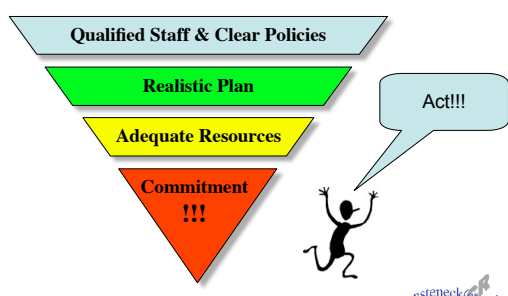 - ✓ Special programs (lectures, courses) to draw attention to the importance of RCR

30

nsteneck@umich.edu

Professional societies

☞ **Essential elements**
- ✓ Written policies and guidelines (authorship, peer review, consulting …)
- ✓ Clear statements about responsibilities ~ Code
- ✓ Proactive commitment to responsible practice

☞ **RCR program for professional societies**
- ✓ Special sessions at annual meetings
- ✓ Committees to develop field-specific research guidelines
- ✓ Committees to develop field-specific RCR training programs
- ✓ Space for the discussion of responsible practices in newsletters and journals

31

nsteneck@umich.edu

Assembling the pieces

Qualified Staff & Clear Policies

Realistic Plan

Adequate Resources

Commitment !!!

Act!!!

32

nsteneck@umich.edu

ORI.HHS.GOV

for help

nsteneck@umich.edu

33

nsteneck@umich.edu