PHS EDUCATION PROGRAM IN THE RESPONSIBLE CONDUCT OF RESEARCH (RCR)

- Purpose: to increase knowledge of, and appreciation for, responsible research practices for research staff working on PHS-supported research projects.

- Status: Policy suspended February 21, 2001, pending further review. Education program ongoing.

CASE 1

Dr. Freeze is a well-established PI with over 5 years of successful PHS funding for his lab. He recently learned that one of his colleagues in his field of research at another institution had a misconduct complaint filed against a lab member. Although his colleague has not been implicated directly, the lab member was found

guilty of misconduct and dismissed by the institution, two other members left the lab, everyone in the lab was distracted for over a year while the case was ongoing, and laboratory morale is in disarray. Dr. Freeze is in a panic that something like that could happen to him.

What should he do?

A. Win the lottery and retire to Florida.

B. File his own misconduct complaint against his lab so he can get the trauma over with.

C. Make sure he has clear, well-established procedures for recording and monitoring data.

D. Hold regular lab meetings to present research findings and review the data.

E. Provide adequate mentoring by himself or other senior staff to new researchers and trainees.

BACKGROUND AND RATIONALE

- 1989 (IOM)
- 1990 (NIH)
- 1992 (NAS)
- 1995 (Commission Report)
- 1999 (HHS Announcement)

RCR POLICY REVIEW

- Further review process over several months.
- Other RCR requirements still in effect: clinical research education, animal welfare training, IRB education, NIH research training grants.
- Review will consider other options, including formal regulation.
- In meantime, ORI will continue RCR education program.

RCR EDUCATION PROGRAM
(CORE AREAS FOR RCR INSTRUCTION)

- Data acquisition, management, sharing, and ownership

- Mentor/trainee responsibilities

- Publication practices and responsible authorship

- Peer review

RCR EDUCATION PROGRAM
(CONT'D)

- Collaborative science

- Human subjects

- Research involving animals

- Research misconduct

- Conflict of interest and commitment

RCR EDUCATION PROGRAM
(CONT'D)

Self-instruction Booklet

- Covers each of the core instructional areas listed in the RCR policy

- Currently under development with support from ORI and expected completion in 2001

- Provides immediate assistance to small and mid-sized institutions in providing RCR education.

RCR EDUCATION PROGRAM
(CONT'D)

- A comprehensive RCR web site linked to ORI's homepage: <rcr.ucsd.edu>

- Contains instructional resources, cases, useful links, instructional tools, and other useful information for instruction in RCR

RCR EDUCATION PROGRAM
(CONT'D)

SBIR/STTR funds for educational resources

- PHS funds for support of development of educational resources in the responsible conduct of research

- Program announced in January 2001.

RCR EDUCATION PROGRAM
(CONT'D)

- Watch the ORI web site for more information http://ori.dhhs.gov (listed as "RCR education" under "programs")
- RCR workshops planned for 2001:
  - American Speech-Language-Hearing Association (May 3-4)
  - PRIM&R (May 17-19)

CASE 2

Harry Hope is a new Ph.D. in Dr. Mean's lab and has been assigned to an ongoing research project. Dr. Hope read an earlier publication of Dr. Mean related to the ongoing research and did not understand it. When he asked Dr. Mean for an explanation, she rebuffed him.

Following further review of the publication, Dr. Hope believes the research may have been misreported but is afraid to ask Dr. Mean about it again. What should he do?

A. Transfer to another lab.

B. File a misconduct complaint.

C. Call the local newspaper to report the incident.

D. Seek advice from a trusted colleague or senior scientist outside the lab.

E. Contact the institutional ombudsperson, if available.

WHY IS RCR IMPORTANT?

- Need to educate next generation of scientists.

- Increasing complexity of research integrity/medical ethics issues: e.g., new financial incentives and financial arrangements; gene therapy; xenotransplantation; stem cell research; organ donation; collaborative research; international collaboration.

WHY IS RCR IMPORTANT? (con't)

- Improve laboratory management
- Avoid or reduce research misconduct and questionable research practices
- Improve collaborations
- Reduce conflicts over responsible research practices (e.g., authorship/credit disputes)

Research Integrity Continuum

F,F,P* and	Questionable	Responsible
Other Institutional	Research	Research
Misconduct	Practices	Practices

=_____<

LESS   MORE

INTEGRITY   INTEGRITY

*Fabrication, falsification, and plagiarism

QUESTIONABLE RESEARCH PRACTICES (NAS: 1992)

- Concept: actions by scientists that violate traditional values of the research community but fall short of research misconduct.

- These practices "erode confidence in the integrity of the research process, violate traditions associated with science, affect scientific conclusions, and weaken the education of new scientists."

Examples are:

1. Failure to retain research data;
2. Maintaining inadequate research records;
3. Authorship without a significant research contribution;
4. Refusing reasonable access to unique research materials or data;
5. Using inappropriate statistics to enhance significance of research findings;
6. Inadequate supervision or exploitation of subordinates; and
7. Misrepresenting speculations as fact or releasing preliminary research results, without sufficient data to allow critical review.

- NAS added:

  "Scientists and their institutions should act to discourage questionable research practices through a broad range of formal and informal methods in the research environment."

- ORI recommends RCR education to discourage questionable research practices.

TABLE 2 – SELF-REPORTED ATTITUDES TOWARD MISCONDUCT

Action	1992 Kalichman	1996 Eastwood
Past misconduct (yes/no?)	15.1%	12%
Future misconduct (yes/no?)	14.8%	
…modify data for paper	7.3%	15%
…fabricate data for a paper or grant application	1.3%	<2%
…select or omit data for paper or grant application	14.2%	27%
…list an undeserving author	-	41%

Table 3 - Misrepresentation in medical resident training program applications

Author	1995 Sekas	1996 Gurudevan	1997 Panicek	1998 Bilge	1999 Dale
Specialty	Gstro-Enterology	Emergency Medicine	Radiology	Pediatrics	Orthopaedic
Total Applications	236	350	201	404	213
…with citations	53 (22%)	113 (32%)	87 (43%)	147 (36%)	64 (30%)
…misrepresented	16 (30%)	23 (20%)	14 (15%)	29 (20%)	11 (17%)

Table 4 – Duplicate Publication

Study	Journal	Articles	Duplicate %
Waldron (1992)	BMJ	354 published	6-12%
Bernard (1993)	NTvG	172 published	11%
Koen (1994)	NTvG	108 rejected	4%
Blancett (1995)	INJS	642 published	9%
Bloemenkamp (1999)	NTvG	148 published	7%

Several studies suggest that duplicate publication occurs 5-10% of the time.

RCR QUIZ

- What is an inadequate program of RCR instruction?

A. Memorizing the full text of over 4,000 articles on research integrity published in the past 20 years.

B. Writing "research integrity" on the blackboard 500 times.

C. Flying a plane over campus for 10 minutes with a research integrity banner.

D. All of the above.

RCR QUIZ

- What happens to your institution if you have an inadequate RCR program?

A. ORI will go into a funk.

B. ORI will try to assist you in improving your program.

C. Your research staff will suffer because of inadequate education.

D. B and C.

RCR QUIZ

- What is the appropriate role of the PI in RCR instruction?

A.   A silent bystander.

B.   A recipient of RCR instruction.

C.   An active teacher in RCR issues.

D.   Any role jointly agreed to by the institution and the PI.

E.   B, C, and D.

RCR QUIZ

- What is the definition of "core area" in the RCR program?

A. The center of an apple.

B. The white, pasty goop in an Oreo cookie.

C. One of the nine required elements in the RCR program, such as human subjects, conflict of interest, and responsible authorship.

How Would
You Improve
The RCR Policy?

MAJOR FEATURES OF POLICY

- Requires a basic level of instruction.

- Covers nine core areas of RCR education.

- Applies to all "research staff" at institution defined as staff "who have direct and substantive involvement in proposing, performing, reviewing, or reporting research, or who receive research training, supported by PHS funds or who otherwise work on the PHS-supported research project."

MAJOR FEATURES OF POLICY
(con't)

- Provides institutional flexibility to:

  – determine the exact content, length, level, and method of instruction.

  – determine whether a demonstration of competency is required by recipients of instruction.

MAJOR FEATURES OF POLICY
(con't)

– determine which "research staff" reasonably fall within the scope of the policy.

– determine which core areas are reasonably applicable to its research staff.

– determine the method of documenting that instruction has occurred.

MAJOR COMMENTS RECEIVED
ON POLICY

- Imposed significant fiscal and resource burdens.

- Coverage of research staff too broad.

- Policy too prescriptive.

- Phase-in too short.

- Unfunded mandate

- Education should be left to discretion of research community.

- What would you do to improve the policy?

COMMITMENT TO RCR

Responsible conduct of research is a basic tenet of the research enterprise and a goal that every research institution and individual scientist should strive for. Education in the principles of responsible research is just a starting point. Personal, institutional, and governmental commitment is also needed. We invite you to join PHS in making this commitment a reality.

ORI: Who To Call

Division of Education and Integrity   **301-443-5300**

    Policies and publications

    Workshops and conferences

    Research Agenda/Studies

Division of Investigative Oversight   **301-443-5330**

    Allegations

    Oversight of inquiries and investigations

    Technical assistance

Research Integrity Branch, Office of   **301-443-3466**

General Counsel

    Legal issues and litigation

ORI home page: <http://ori.dhhs.gov>

REFERENCES

1. "The Responsible Conduct of Research in the Health Sciences" (IOM 1989).

2. "Responsible Science: Ensuring the Integrity of the Research Process" (National Academy of Sciences, 1992).

3. "Report of the Commission on Research Integrity: Integrity and Misconduct in Research" (Office of Research Integrity, 1995).

4. October 22, 1999, HHS News.

5. "ORI Report: Assessing the Integrity of Publicly Funded Research" (November 2000).