Ethics:
An Introduction

Michael Kalichman, Ph.D.
Pathology
Director, UCSD Research Ethics Program

CSE 190

April 4, 2002

WHY SHOULD WE TEACH ETHICS?

WHAT IS RESPONSIBLE CONDUCT OF RESEARCH?

QUESTIONS FOR DISCUSSION

WHY SHOULD WE TEACH ETHICS?

WHAT IS RESPONSIBLE CONDUCT OF RESEARCH?

QUESTIONS FOR DISCUSSION

WHY SHOULD WE TEACH ETHICS?

- History
- Requirements for Training
- Integrity of Research
- Public Obligation
- Avoiding Problems

WHY SHOULD WE TEACH ETHICS?

- History

History

Experimental Science: 17th century

Millikan: 20th century

World War II

Beecher, New England Journal of Medicine, 1966

Tuskegee: 1932-1973

- 412 African American males
- untreated syphilis

History: Misconduct Cases

- Summerlin
- Slutsky
- Imanishi-Kari

Misconduct Cases: William Summerlin

1971-1974

- worked with Robert Good, an immunologist

Sloan-Kettering Institute for Cancer Research

- Observation: tissue maintained in organ culture for 4-6 wks transplantable without rejection

By 3/74:

- Data not being reproduced
- Good prepared to publish failure to replicate

Used black felt-tip pen to paint backs of mice

Misconduct Cases: Robert Slutsky

Radiology Resident and Associate Clinical Professor of Radiology, UCSD

1983-1985

- One paper every 10 days over a period of 2 years.

1985

- Department ad hoc committee
- Apparent duplication of data in two publications

Misconduct Cases: Robert Slutsky

Formal ad hoc committee assigned to case

Reports found to include:

- experiments that were not performed
- measurements that were not made
- statistical analyses that were not performed.

Analysis of 137 articles:

- 77 (including reviews) were valid
- 48 were questionable
- 12 were fraudulent

Misconduct Cases: Thereza Imanishi-Kari

Principals:

- Thereza Imanishi-Kari (Principal Investigator)
- Margot O'Toole (Postdoc)
- David Baltimore (Collaborator)

Weaver et al. (Cell 45:247-259, 1986)

1985-1998

- Tufts, MIT
- NIH, OSI, Congress, ORI, DHHS appeals board

WHY SHOULD WE TEACH ETHICS?

- History
- Requirements for Training

Requirements to Teach Responsible Conduct of Research

- **NIH Training Grant Requirement**
  - Trainees
- **PHS Human Subjects Training Requirement**
  - Key personnel
- **PHS Policy for all Researchers**
  - Trainees, Staff, Faculty

Requirements to Teach Responsible Conduct of Research

- NIH TRAINING GRANTS

- "Since July 1990, the National Institutes of Health (NIH) has required all applications for Institutional National Research Service Award (NRSA) Research Training Grants (T32, T34) to include a description of a program to provide instruction in the responsible conduct of research."

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

Requirements to Teach Responsible Conduct of Research

- HUMAN SUBJECTS RESEARCH

- “Beginning on October 1, 2000, the NIH will require education on the protection of human research participants for all investigators submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects.”

- **NIH Notice, OD-00-039, June 5, 2000**

Requirements to Teach Responsible Conduct of Research

- ALL PHS RESEARCH STAFF

- "It is the policy of the PHS that all staff engaged in research or research training with PHS support shall successfully complete a program of instruction in the responsible conduct of research..."

- **PHS Policy, December 2000; suspended, February 2001**

WHY SHOULD WE TEACH ETHICS?

- History
- Requirements for Training
- Integrity of Research

Integrity of Research

- Obligation to trainees
- Trust in what we read
- Integrity of science

WHY SHOULD WE TEACH ETHICS?

- History
- Requirements for Training
- Integrity of Research
- Public Obligation

Public Perception

Ethical responsibility

- Public servants
- Obligation

Practical consideration

- The privilege to do research … is granted by the public

WHY SHOULD WE TEACH ETHICS?

- History
- Requirements for Training
- Integrity of Research
- Public Obligation
- Avoiding Problems

Avoiding Problems

1. Desire to do the right thing
2. Desire to not get caught
3. Meet federal regulations
4. Integrity of science
5. Obligation to public
6. Perception as bad as a mistake

WHY SHOULD WE TEACH ETHICS?

WHAT IS RESPONSIBLE CONDUCT OF RESEARCH?

QUESTIONS FOR DISCUSSION

WHAT IS "Responsible Conduct of Research?"

Responsible Conduct

Irresponsible Conduct

Responsible Conduct

What you do

- Rules, guidelines, standards
- Promote responsible conduct
- Discourage irresponsible conduct

What you don't do

- Break the law
- Violate accepted standards of conduct

Irresponsible Conduct?

- Violations of law
  - Placing others at risk of physical harm
  - Theft
  - Fabrication, Falsification, Plagiarism
- Grey areas
  - Failure to share data
  - Withholding publication for personal advantage
  - Gift authorship
  - Denial of authorship
  - Failure to give sufficient credit
  - Bias in research or review

WHY SHOULD WE TEACH ETHICS?

WHAT IS RESPONSIBLE CONDUCT OF RESEARCH?

QUESTIONS FOR DISCUSSION

QUESTIONS FOR DISCUSSION

Cheating

- What is it?
- Why does it occur?
- When is it OK?

QUESTIONS FOR DISCUSSION

Confidentiality

- What is it?
- Does it matter?
- Is it at risk?
- How can it be protected?

QUESTIONS FOR DISCUSSION

Credit

- What is it?
- Why does it matter?
- Who deserves it? Who doesn't?

QUESTIONS FOR DISCUSSION

Conflicts of interest and bias

- What are they?
- Why is it a problem?
- What is the solution?

QUESTIONS FOR DISCUSSION

???

UCSD Research Ethics Program

http://ethics.ucsd.edu

- Michael Kalichman, Ph.D.
- 858-822-2027
- kalichman@ucsd.edu

Integrity of Research

If you have integrity, nothing else matters.
If you don't have integrity, nothing else matters.

Alan Simpson (former Senator)