Research Ethics Program Model Using the Concept of Values-sharing

Ethical issues in science

Many Scientific misconducts in Japan

- Taira/Kawasaki Data Fabrication at the University of Tokyo (2005-2007)
- Data Fabrication at Osaka University (2005-2006)
- RIKEN (The Institute of Physical and Chemical Research) Data Falsification (1999-2004)
- And many others

Abroad

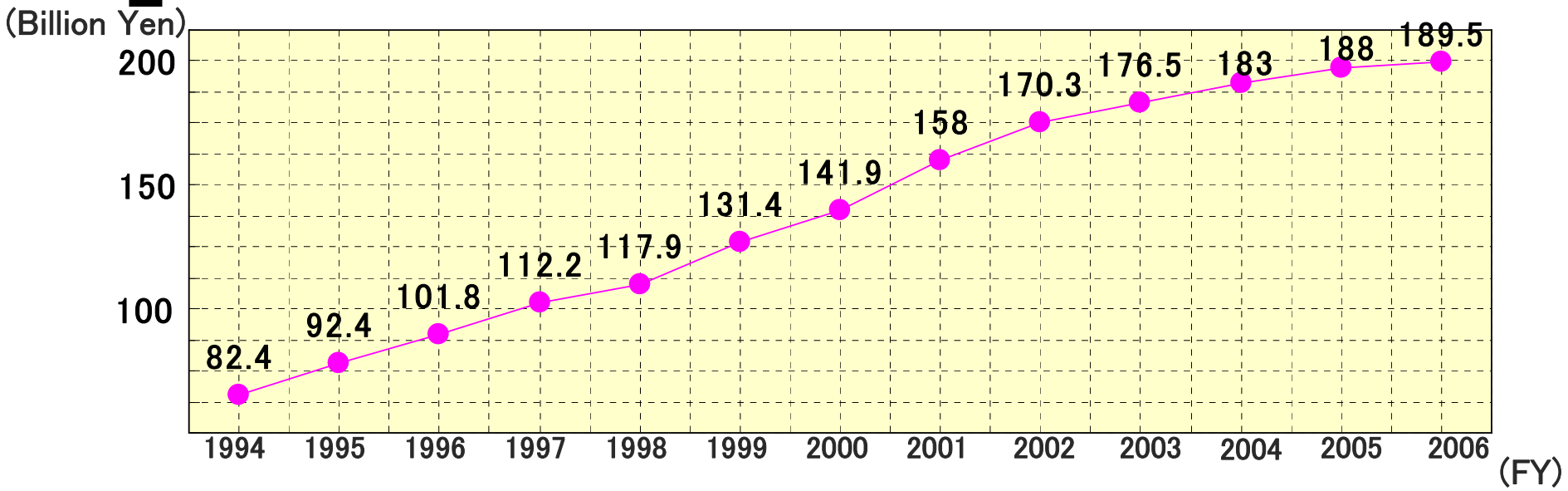
- Embryonic Stem Cell Scandals in Korea (2002(?)-2006)
- Schön at the Bell Laboratories (1998-2002)
- Cold Fusion (1989-91)
- Baltimore/Imanishi-Kari (1986-96)

Misconduct Cases happened and recognized by academic societies from 1999 to 2004 (SCJ)

- Duplicate publications （67：83 cases～）
- Plagiarism （23：26 cases）
- Violation of privacy （5：14 cases）
- Fabrication of data （2：2 cases～）
- Falsification of data （2：2 cases）
- Misuse of fund （2：2 cases）
- Others （43 cases）

And increasing

Expanding Grant-in-aid for scientific research (KAKENHI)



FY	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006
Budget (billion Yen)	82.4	92.4	101.8	112.2	117.9	131.4	141.9	158.0	170.3	176.5	183.0	188.0	189.5
compared with the previous fiscal year (%)	12.0	12.1	10.2	10.2	5.1	11.5	8.0	11.3	7.8	3.6	3.7	2.7	0.8
*index	—	—	—	—	—	—	1.00	1.11	1.20	1.24	1.29	1.32	1.34

(*) 1.00 in the index is as same rate as 1990 fiscal year's (2nd S&T Basic Plans were established in 1991 fiscal year)

“Do Scientists Behave Badly?”(2005)

- How many researchers in the US and funded by NIH were involved in 2001-2004?

Top Ten Behaviors (1)

1. Falsifying or ‘cooking’ research data (0.3)
2. Ignoring major aspects of human-subject requirements (0.3)
3. Not properly disclosing involvement in firms whose products are based on one’s own research (0.3)
4. Relationships with students, research subjects or clients that may be interpreted as questionable (1.4)

Top Ten Behaviors (2)

5. Using another's ideas without obtaining permission or giving due credit (1.4)
6. Unauthorized use of confidential information in connection with one's own research (1.7)
7. Failing to present data that contradict one's own previous research (6.0)

Top Ten Behaviors (3)

8. Circumventing certain minor aspects of human-subject requirements (7.6)
9. Overlooking others' use of flawed data or questionable interpretation of data (12.5)
10. Changing the design, methodology or results of a study in response to pressure from a funding source (15.5)

And the ratio is

33% !

N=3,409, response rate 43%(1,479)

B. C. Martinson et al., “Scientists Behaving Badly,” *Nature*, 435 (9 June, 2005), 737-738

Other misconducts

11. Publishing the same data or results in two or more publications (4.7)
12. Inappropriately assigning authorship credit (10.0)
13. Withholding details of methodology or results in papers or proposals (10.8)
14. Using inadequate or inappropriate research design (13.5)
15. Dropping observations or data points from analyses based on a gut feeling that they were inaccurate (15.3)
16. Inadequate record keeping related to research projects (27.5)

N. Steneck's conclusion

"What Do We Know? : Two Decades of Research on Research Integrity"

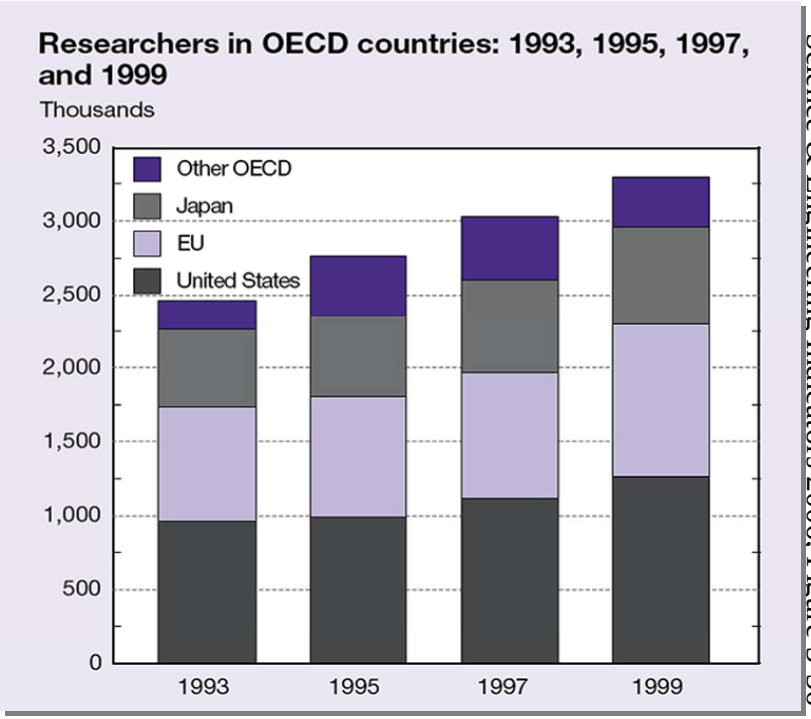
Presented at the World Conference on RESEARCH INTEGRITY

Lisbon, Portugal, 16-19 September 2007

www.esf.org/conferences/researchintegrity

Conclusions?

- Findings:
  - ✓ Frequency range: ~ 0.1 –> 1.0%
  - ✓ over 10 years: ~.01 –> 0.1%
- Implications, cases/year:
  - ✓ US ~ 150 -> 1,500
  - ✓ EU ~ 100 -> 1,000
  - ✓ Japan ~ 60 -> 600
  - ✓ Other OECD ~ 40 -> 400
- Cases reported/year: US ~20/year; EU ~ 10/year
- Conclusions:
  - ✓ Evidence does not support view that misconduct is "rare"
  - ✓ Most research misconduct is not detected, reported and investigated



Science & Engineering Indicators 2006, Figure 3-36

nsteneck@umich.edu

Code of Ethics for Science in Japan

- “Charter for Scientific Researchers” (1980) by the Science Council, Japan <Reaction to the 1974 UNESCO Recommendation>, but very limited influence in Japan
- The SCJ has established committees on scientific misconducts since 2003

Continued

- A number of academic societies have established their codes of ethics since the late 1990s.
- In early 2000s, scientific misconduct became a hot issue and a number of organizations started working on this issue

Continued

- SCJ, Ad-hoc committee on the code of conduct for Scientists was created in Dec. 2005
- MEXT, the Council of Science and Technology, Special Committee, Feb. 2006
- the CSTP (Council for Science and Technology Policy) , an official response to scientific misconduct.

The CSTP Response

- “The decision, recognizing that the robust self-discipline of the scientific community is the keystone to cope with issues concerning misconduct, acknowledges the deliberation in the Science Council of Japan in developing an ethical code for scientists, and asks universities and research institutes to set up rules and procedures to manage misconduct cases. Moreover, funding ministries must establish their policies regarding the handling of research funds related to cases of misconduct.”

Creation of a Code of Conduct

- Descriptive study as well as normative study are necessary
- Identify appropriate stakeholders
- Reflect values which are significant in Asia
- Various issues in terms of the relationship of international and national standards
- Consultation process can be very political

Values in Science?

- Internal Values
- External Values

Responsible Conduct of Research: RCR

- honesty
- accuracy
- efficiency
- objectivity

N. H. Steneck, *ORI Introduction to the Responsible Conduct of Research* (2005)

QRP: Questionable Research Practices (Steneck)

RCR QRP Misconduct

Integrity
- Honesty
-Accuracy
-Efficiency
-Objectivity

Misrepresentation
Inaccuracy
Bias
Etc.

Fabrication
Falsification
Plagiarism

Study done by UNESCO on Existing Codes

- 67 codes were examined

Africa	Arab States	Asia and the Pacific	Europe and North America	Latin America and the Caribbean
South Africa Zimbabwe (4)		Australia (5) China (2) Fiji India (2) Japan (2) New Zealand (5) Republic of Korea (2) Singapore Sri Lanka	Belgium Bulgaria Canada (4) Germany (2) Latvia Netherlands Norway Sweden (4) United Kingdom (2) United States (8)	Argentina

Expressed Internal Values

- Confidentiality of information
- Maintain/upgrade professional competence
- Avoid and report conflicts of interest
- Honesty
- Cooperation with co-workers
- Integrity
- Follow policies, regulations, laws
- Work only in area of competence
- Informed consent
- Objectivity
- Respect property rights
- Prevent and report unethical conduct

(Source : UNESCO)

Internal Values（ORI）

RCR QRP Misconduct

- Integrity
  - honesty
  - Accuracy
  - efficiency
  - objectivity

Expressed External Values

- Environmental responsibility
- Public safety and welfare
- Respect for human dignity
- Social responsibility
- Enhance/maintain prestige of the profession
- Human rights
- Enhance public understanding of the profession/discipline

（Source：UNESCO）

The SCJ Suggestions (Draft was approved in April, 2006)

- Each organization (academic societies, associations, universities, research institutes, etc.) should write its own code of conduct
- Each organization to design and implement an ethics program to encourage scientific integrity and reduce misconducts

From the results of survey

- The committee sent a questionnaire to all Japanese institutions of higher education and scientific research, and also to Japanese academic societies and associations.
- By August 2006, 1,323 responses (a response rate of 46.9%)
- The code of conduct (Universities)
  - Yes 14.3% (78 universities/colleges)
  - Drafting 3.6%
  - Planning 41.4%
- 48 out of 79 were after 2004

Statement: Code of Conduct for Scientists/SCJ/Oct. 3, 2006

- **Introduction**
- **The Code of Conduct for Scientists**
- **“Toward Autonomous Implementation of the Code of Conduct for Scientists”**

http://www.scj.go.jp/ja/info/kohyo/pdf/kohyo-20-s3.pdf

“Science for Society”

- World Science Conference in 1999 (Budapest, Hungary)
- In the preface of the SCJ code, there is a very clear statement that “Science and scientific research exist both with and for society”.

SCJ's definition of "Scientists": Engineers included

- … Here, the word "scientists" refers to researchers and specialists engaged in activities that create new knowledge, or in the use and application of scientific knowledge, in all academic fields ranging from humanities and social sciences to natural sciences, regardless of which institution they belong to …

The Code of Conduct

- Preface (“Science for society”)
- 11 provisions under the following headings:
  - Responsibilities of Scientists, Conduct of Scientists, Effort to Improve Ability, Explanation and Disclosure, Research Activities, Establishing Research Environments, Observance of Laws and Regulations, Consideration to Research Subjects, Relations with Others, Elimination of Discrimination, and Conflict of Interest.

SCIENCE WITH HONOR: THE SCIENCE COUNCIL OF JAPAN'S CODE OF CONDUCT

"However, the Code goes even a step further. It charges scientists to strive in understanding the relationships between science and society and to evaluate the potential implications of their work."

AAAS, *Professional Ethics Report*, Vol. XX, No. 2 (Spring 2007)

“Toward Autonomous Implementation of the Code of Conduct for Scientists” 1

- The document describes specific elements for effective implementation of the Code, which should be included in the ethics programs for research adopted by individual institutions. All scientific organizations are requested to introduce their own research ethics programs to meet to their purposes and needs, and to promote honest and autonomous activities of scientists.

“Toward Autonomous Implementation of the Code of Conduct for Scientists” 2

- The document consists of eight articles covering such issues as the responsibility of directors and managers of institutions, the need for ethics education programs, the mutual observation within a research group, the precautions in research process, the countermeasures against misconduct, and the establishment of a self-monitoring system.

Elements of Research Ethics Program Suggested in the Document 1

1. A code of ethics/conduct should be formulated and circulated among all members of the organization
2. Implementation of an effective research ethics program/Commitment and leadership of the top management
3. Research ethics education
4. Healthy research environment

Elements of Research Ethics Program Suggested in the Document 2

5. The need to observe the Code of Conduct for Scientists
6. Proper complaint/investigation system
7. Rules/regulation for the conflicts of interest
8. Self-monitoring system

Research Ethics Programs at Leading Institutions

- National Institute of Advanced Industrial Science and Technology
- RIKEN
- The University of Tokyo
- Nagoya University

- Toshiba/Hitachi
- Tokyo Electric Power Company

Value-based program?

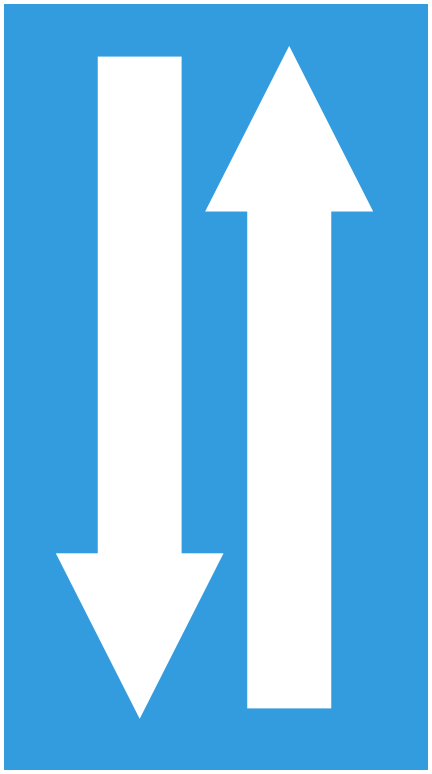
- WHO is already using this approach

Presented by Guitelle Baghdadi-Sabeti at the World Conference on RESEARCH INTEGRITY

Lisbon, Portugal, 16-19 September 2007

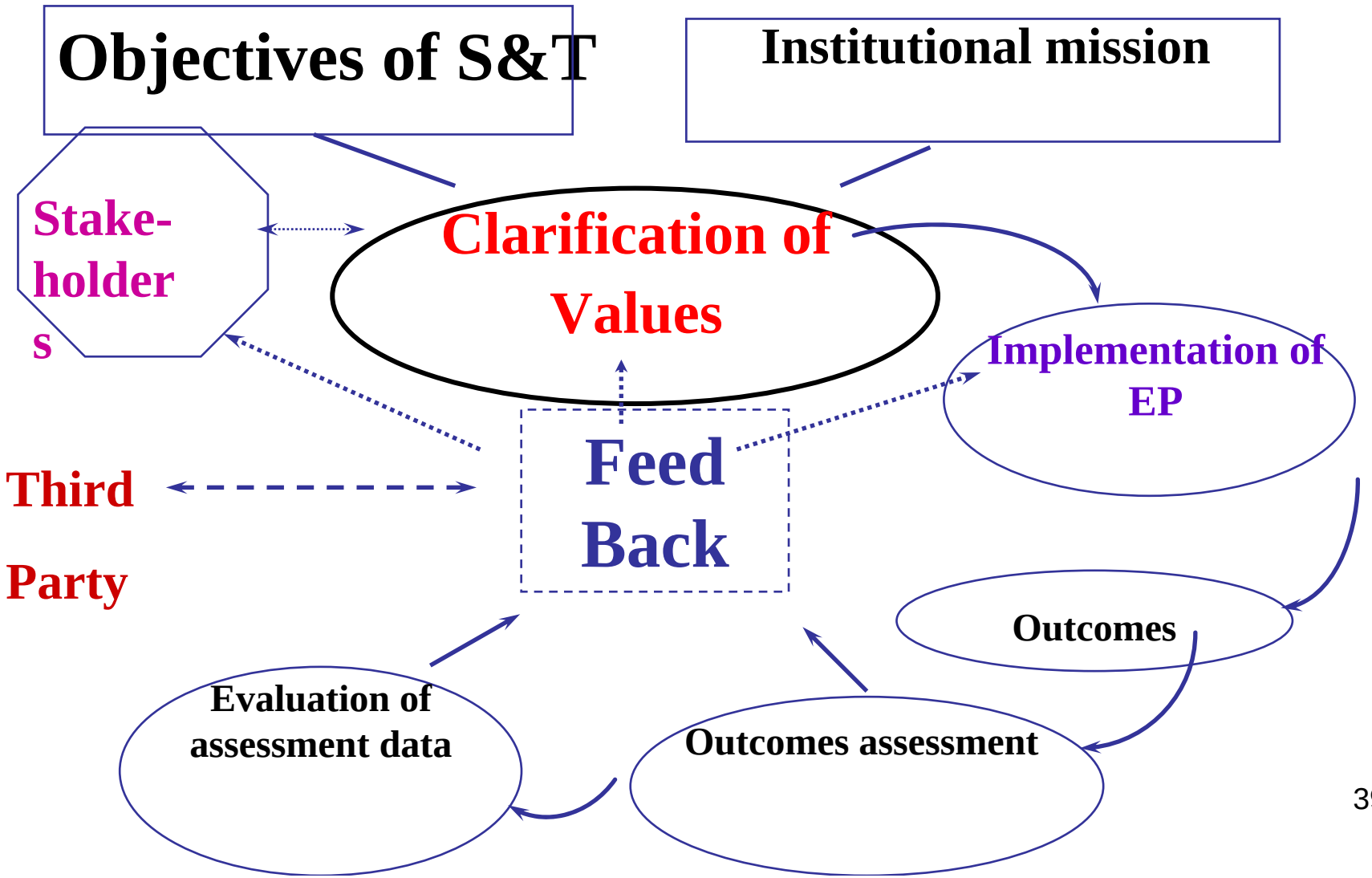
www.esf.org/conferences/researchintegrity

Efforts to address corruption need coordinated application of two basic strategies

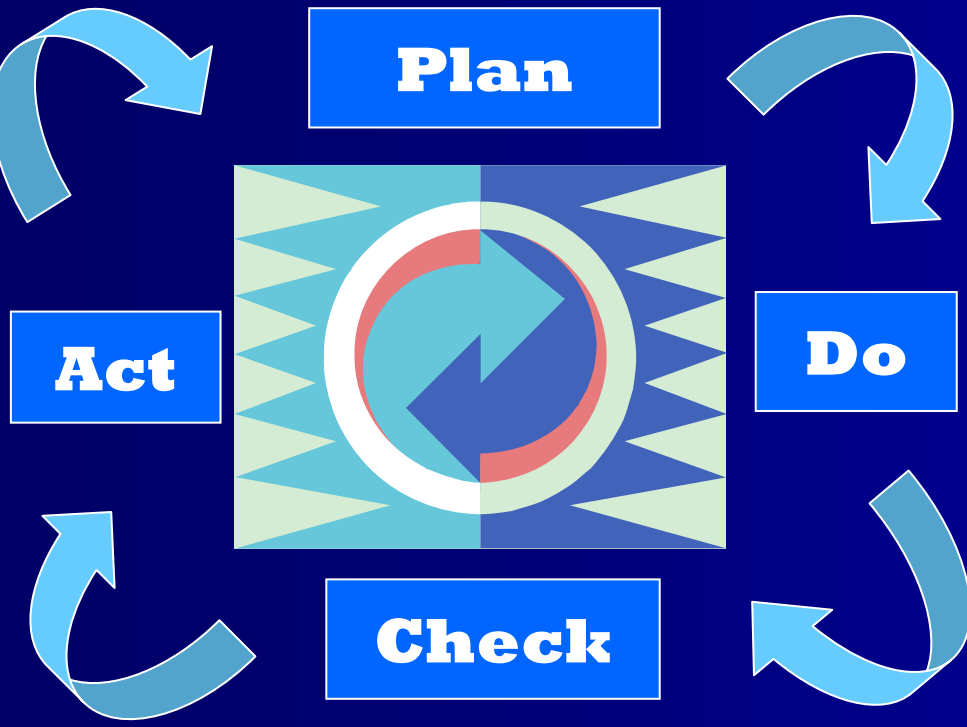


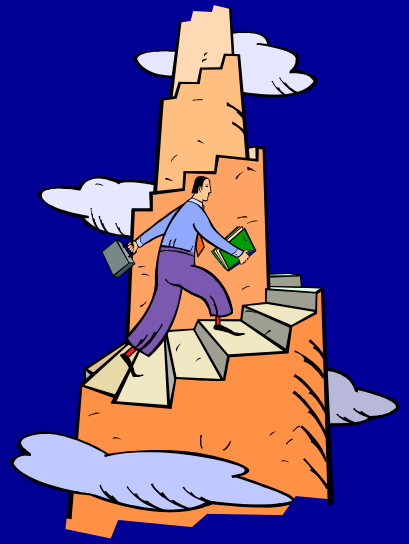
- "Discipline-based approach" (top-down)
  - Laws, policies and procedures against corruption and for pharmacy practice with adequate punitive consequence for violation
  - Attempts to prevent corrupt practices through fear of punishment
- "Values-based approach" (bottom-up)
  - Promotes institutional integrity through promotion moral values and ethical principles
  - Attempts to motivate ethical conduct of public servant

PDCA cycle of REP



Continuous Improvement for Values-sharing





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Examples (Graduate Schools)

1. A code of ethics/conduct should be formulated and circulated among all members of the organization

- Establishment of a code of conduct using both top-down and bottom-up approaches
- Required at the entrance exams/interview
- Familiarized students with various orientations and session (Require to sigh a written oath)
- ID card

2. Commitment and leadership of the top management

- Committee headed by president
- Review of Ethical Principles at the Beginning of Important Meetings
- Orientation conducted by the top administration
- Establishment of Devoted Ofiices
- Train specialists for IRB

3. Ethics Education

- Required course on research ethics
- Ethics across the Curriculum
- Bottom-up formulation of a code of conduct for each lab（active learning）
- Require a Certain Level of Consideration of social implications of research in proposing and conducting a research project

4. Open Communication

- Bottom-up formulation of a code of conduct for each lab（active learning）

Others

8 Establishing self-monitoring system

→

Adoption of Engineering Accreditation Model

Be Cautious

- Negative emphasis on Stronger compliance system
- Positive program to encourage RCR

The Central Role of Education (clamed by many including *Nature*)

- Leading by examples（Editorial: *Nature*, Vol. 445, No. 7125 (18 January 2007), p. 229）

Objectives

PHS Policy, 2000

1. 研究の責任ある遂行に関連する諸問題に関する知識、および感受性の育成
2. 科学研究に伴う対立や相反に直面した際、倫理的で合法的な選択ができる能力の向上
3. 研究を遂行する上で受け入れられている科学的方法・手段の範囲について正しい認識力の育成
4. PHSの助成による研究の遂行を管理する規則、ポリシー、法令、ガイドラインに関する情報の提供
5. 研究の責任ある遂行について生涯学び続けることに対する積極的態度の涵養

ORI's Core Instructional Areas in RCR (2000)

1. Data management
2. Mentor/trainee responsibilities
3. Publication and authorship
4. Peer review
5. Research with human beings
6. Research involving animals
7. Research misconduct
8. Conflict of interest and commitment
9. Collaborative science

Instructional Methods

- Research ethics in daily activities
- Courses
- Case method

  (such as materials created by Poynter Center)
- e-learning
  - CITI Program
  - LANGURE (Land Grant University Research Ethics)

What is CITI?

- Collaborative Institutional Training Initiative
- CITI is a volunteer organization whose goal is to develop and distribute high quality, peer reviewed educational resources designed to raise awareness to the Responsible Conduct of Research for all members of the research team.

CITI – Startup Organizations 9-2000

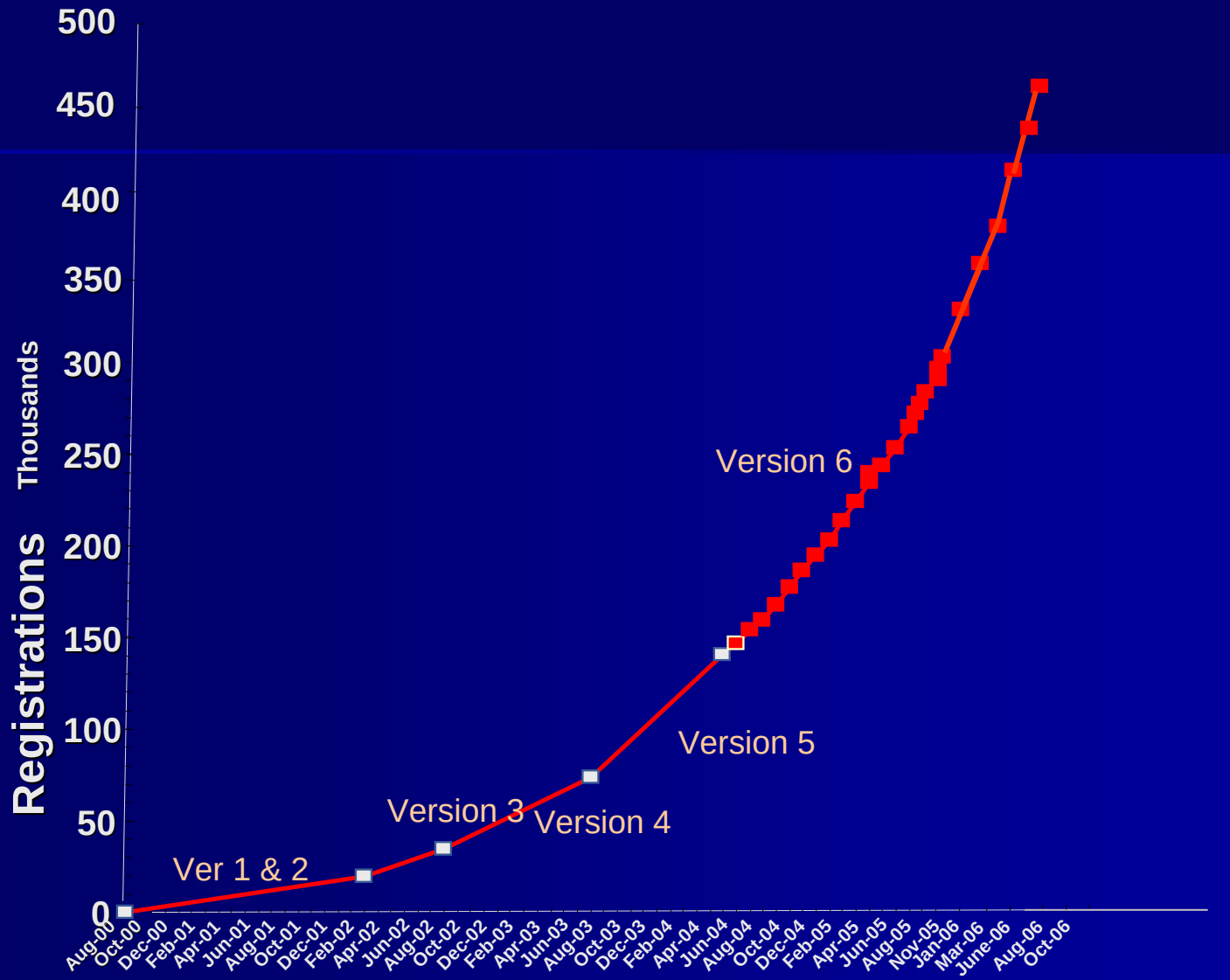
- **University of Miami**
  - Paul Braunschweiger,Ph.D., Ken Goodman, Ph.D.
- **Fred Hutchinson Cancer Research Center**
  - Karen Hansen, BA
- **Albany Medical Center**
  - Jeff Cooper, MD
- **Children's Hospital-Boston**
  - Susan Kornetsky, MPH
- **Dartmouth College**
  - Liz Bankert, MA
- **University of Kentucky**
  - Ada Sue Selwitz, MA, Norma Epley, MS
- **The National Comprehensive Cancer Network**
  - Diane Paul, MS
- **University of Nebraska**
  - Bruce Gordon, MD, Ernie Prentice, Ph.D.
- **Group Health Cooperative**
  - Barbara Young, Ph.D., Janelle Erickson, MPH
- **University of Washington**
  - Helen McGough, MS

CITI Course Materials

- Basic course human subjects protection
  - 12 modules for biomedical research investigators.
  - 11 modules for social & behavioral research investigators
  - 5 general interest modules.
- Human Subjects Refresher courses
  - 2 Biomedical
  - 2 Social & Behavioral
- Good Clinical Practice (GCP)
  - 14 modules for investigators
- Responsible Conduct of Research
  - >25 modules
- HIPS
  - 18 modules on privacy and security
- Animal Welfare (January 2007)
  - Course to meet the basic instruction requirements of the NIH and USDA.

Monthly Usage

CITI Cumulative Registrations



From “Science Education” to “the Formation of Scientist”

Office of Research Integrity:

Introduction to the Responsible Conduct of Research (2003)

National Academy of Sciences:

On Being a Scientist: Responsible Conduct of Research (1995)

Roles of Other Stakeholders

- Learned/Academic/Professional Societies
- Academic Journals
- Funding Agencies
- Others

Concluding Remarks

1. The values-sharing approach can be used in research ethics
2. Business ethics models can be used
3. The Science Council, Japan has already established the code of conduct for scientists and requested each institution to establish and implement a research ethics program
4. Research ethics education has a central role in RER
5. Engineering ethics education model (such as EAC) is also useful