Researcher's integrity: acquiring reactivity and losing responsibility

Tohru Masui, Ph.D., Director
Department of Disease Bioresources Research
Office of Policy and Ethics Research,
National Institute of Biomedical Innovation, Japan
Research Integrity and culture

- Research Integrity
- International Recognition of Research Integrity
- Culture of Nation or/and Society
- **Culture of Research Community**
- Culture of an Institution
- Culture of Research Group
- Behavior of a Researcher
Japanese Research Ethics System

- Autonomy
- Informed consent
- Research ethics committee
- Privacy protection

Biomedical research

Research ethics guidelines
Inverse order of the regulatory frame

**Guidelines on**

**Genome research:**
Mar 2001

**Epidemiological research:**
Jun 2003

**Clinical studies:**
Jul 2003

**Responsible Ministries**

- MEXT
- MHLW
- METI

- MEXT
- MHLW
Effects of Ethical Guidelines on Biomedical Research

• They set the outside frame of the research
• Researchers have become passive to the research guidelines
• Researchers complain on guidelines
At the Establishment of Data Protection Act

• Late 1990 discussion had started in the government
• 2000-2002 Prototype Bill was presented and discussed
• That time, Academic Researchers discussed actively on the issues of Data Protection.
• They also appealed their opinion on the use of Data in academic research
• Late 2002 Bill incorporated Exemption of academic use of Data.
• After this, Researchers Stop the discussion and appeal almost immediately.
What did it mean?

• Researchers were satisfied by the exemption
• The exemption was incorporated, since the act appreciated “freedom of expression”.
• **Freedom should make academic researchers responsible**
• However, they did not discuss or establish their own self-regulatory code on the use of Data in academic research
What does “Exemption” mean?

- The Act appreciates the freedom of expression in Academic Research.
- Self-regulation of Academic researchers is essential in protection of Data.
- It was the responsibility of the researchers to **work on their self-regulation system**.
- It did not happen.
- They were satisfied by the incorporation of exemption.
Researchers became “Reactive”

- The guidelines said researchers should be obedient to them.
- In the course of establishing research ethics guidelines;
  - Researchers: Obedient, Rigidity, and Reactive

- Research integration requires
  - Researchers: Freedom, Flexibility and Responsibility

- Governmental guidelines incubated totally opposite culture of researchers
Why did it happen?

- “Ethics” is translated into a word “Rinri (倫理)”
- **Authoritative**: some other person knows the right thing.
- At the discussion on the ethical guidelines:
  - Legal academics and scientists of high position led discussion and decision
  - **Lack of understanding on the nature of science**
  - **Formal discussion** made by high position scientists
- These situations made lay researchers reactive.
One Nature of Science

1) No one gets the final say.
2) No one has personal authority.

Jonathan Rauch

Think the opposite:

“It is true, because I said so.”
30. ••• Negative and inconclusive as well as positive results should be published or otherwise made publicly available.

30. ••• 消極的結果および結論に達しない結果も積極的結果と同様に、公刊または他の方法で一般に公表されるべきである。刊行物の中には、資金源、組織との関わりおよび利益相反が明示される必要がある。