### 21-24 July 20109, Singapore the 2 nd World Congress on Research Integrity

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

Biomedical research

Autonomy Informed consent Research ethics committee

Privacy protection

Research ethics guidelines

#### Inverse order of the regulatory frame

**Guidelines on** 

Responsible Ministries

Genome research: Mar 2001 **MEXT** 

**MHLW** 

**METI** 

Epidemiological research: Jun 2003 **MEXT** 

**MHLW** 

Clinical studies: Jul 2003 **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, Flexbility 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

No one gets the final say.
 No one has personal authority.
 Jonathan Rauch

Think the opposite: "It is true, because I said so."

#### **Helsinki Declaration 2008**

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。