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Ten Subjects Gathered Under "Kenkyu Rinri (Research Ethics)" In Japan

Takashi TSUCHIYA

Department of Philosophy

Osaka City University

Five Spheres of Medical Law and Ethics

Medical law and ethics has at least five spheres of tasks, namely in:

1. treatment of patient
2. research
3. education
4. management of institutions
5. public health policy

Among them, law and ethics of medical research invite special interests.

Ten Subjects Gathered under "Research Ethics" in Japan

However, in Japan today, many subjects of other concerns have been gathered under the same title of "Kenkyu Rinri (Research Ethics)." This gathering has made in a hurry, without principle and reflection. Some of them are of scientific research in general, not specific to medical research. As a professor teaching research ethics course, I feel embarrassed.

Each subject has distinct problems and needs different treatment. I discriminate ten subjects as follows:

Ten Subjects Gathered under "Research Ethics" in Japan

1. management of interests in research
2. protection of human subjects
3. securing researchers' safety
4. minimization of suffering of animal subjects
5. prevention of pollution of environment, biological and chemical hazards

Ten Subjects Gathered under "Research Ethics" in Japan

6. prevention of misconducts in research procedure
7. prevention of misapplication of research grants
8. prevention of misconducts in publication of research results
9. protection of consumers of the products
10. responsibility for application of research results

1. Management of Interests in Research

- Conflict of Interests (COI)
 - Guidelines for Management of Conflict of Interests in Health and Labor Research (2008~, MHLW [Ministry of Health, Labor and Welfare])
 - conflict of commitments: between obligations from different businesses
 - financial conflicts of interests: of researchers, of institutions
- Interference of Political Powers
 - National Security Technology Research Promotion (2015~, ATLA [Acquisition, Technology & Logistics Agency, of Ministry of Defense]) raises concern that Japanese sciences will be mobilized for military forces again.
 - of national and local politicians

2. Protection of Human Subjects

Japan performed deadly human experiments mainly in China from 1932 to 1945 (in Unit 731 and other facilities). But, unlike Nazi Germany, the atrocities were hidden with collaboration of U.S. The story has become taboo in Japanese medical academe. So in Japan ethics of medical research had called little attention until the end of 1990's.

In the beginning of 2nd millennium, Japan took the national policy "BioTech Strategy" to get top rank of bio- medicine and technologies in the world. Government began promoting research, but it is clear that research review is a necessary procedure.

2. Protection of Human Subjects

So Japanese government promulgated many "ethical" guidelines for biomedical researches, for example:

- Guidelines for Treating Ethical Issues in Genetic Analysis Research (2000, then Ministry of Health)
→ Ethical Guidelines for Human Genome and Genetic Analysis Research (2001~, MHLW/MEXT [Ministry of Education, Culture, Sports, Science and Technology]/METI [Ministry of Economy, Trade and Industry])
- Ethical Guidelines for Epidemiologic Studies (2002~, MEXT/MHLW)
- Ethical Guidelines for Clinical Research (2003~, MHLW)
→ Ethical Guidelines for Medical and Health Research Involving Human Subjects” (MEXT/MHLW, 2014~)

They established standards of informed consent and research review in Japan.

3. Securing Researchers' Safety

- prevent hazards in laboratory
 - poison chemicals
 - radioactive materials
 - radiation devices
 - pathogens, viruses
- proper maintenance of experimental devices
- proper care for animals used for experimentation
- keep laws and guidelines

4. Minimization of Suffering of Animal Subjects

In western countries, animal welfare and liberation movements have been protesting against cruel animal experimentation since 19th century.

→ the "three 'R's" principle:

- Replace: Instead of higher mammals, using computer simulations, cultivated cells, microbes, lower animals
- Reduce: using fewer animals and avoiding animal death as possible
- Refine: preventing unnecessary sufferings

In Japan,

- Animal Welfare and Care Act (1973~, revised 2005)
- Standards of Experimental Animal Care and Reduction of Sufferings (2006, ME [Ministry for the Environment])

→ fundamental guidelines for animal experimentation (2006, MEXT, MHLW, MAFF [Ministry of Agriculture, Forestry and Fisheries] each)

Presidents of research institutions administer according to the review of Animal Experiments Committee.

5. Prevention of Environmental, Biological and Chemical Hazards

- prevent hazards outside laboratory
 - poison chemicals
 - radioactive materials
 - pathogens, viruses

ex. genetically modified organisms

- concerns for release experiment to environment
- concerns for accidental release
 - Lawsuit against relocation of the National Institute of Public Health to Shinjuku (next to Waseda Univ, 1989~2005)
- concerns over the spread of easier and more efficient technology (genome editing, etc.) in society

6. Prevention of Misconducts in Research Procedure

- prevent "specific research misconducts" (Fabrication, Falsification, Plagiarism)
- avoid Questionable Research Practice (inappropriate data management, insufficient research training, exploitation of students, etc.)
- to keep authenticity of science
- "On Proper Treatment of Research Misconduct" (2006, then CST [Council for Science and Technology] of Cabinet Office)
 - Guidelines by MEXT (2006), by MHLW (2007), by METI (2007)
- called "Research Ethics Education"
- but these policies were insufficient
 - Kato affair (Tokyo Univ., 2012)
 - Stimulus Triggered Acquisition of Pluripotency (STAP) cell affair (2014)
- revised and reinforced (2014~)

7. Prevention of Misapplication of Research Grants

misapplication of

- public grants ← tax = sponsored by citizens
 - governmental administration (ex. ORI of U.S.)
 - duties to citizens
- private grants ← foundations, companies
 - duties to the sponsors
- "On Prevention of Misapplication of Public Grants (Common Guideline)" (CST, 2006)
 - Guidelines by MEXT (2007), by METI (2008), by MHLW (2014)
 - return money, disqualification, reprimand, criminalization
- called "compliance education"

8. Prevention of Misconducts in Publication of Research Results

misconducts not in research itself, but in its publication

- improper authorship
 - gift authorship
 - ghost authorship
- improper presentation methods
 - duplicate posting/publication
 - “salami (bologna) slicing” in publishing
- improper referencing of prior research
- infringement of copyright

9. Protection of Consumers

Research misconduct can bring consumer's damage when research results are developed into commodities.

- drug and medical devices
- food (ex. Genetically Modified food)
- cosmetics
- electronic/gas devices
- transportation vehicles (automobile, railway, airplane, ship, etc.)
- regulations of commodities
 - safety: food, cosmetics, "specified products" (Product Safety Consumer mark system, METI), electronic/gas devices, etc.
 - efficiency: drug, medical devices, "Food for Specified Health Uses"
- Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act (2013~)
- Good Clinical Practice

10. Responsibility for Application of Research Results

two meanings of "dual use"

- military and non-military use: results of non-military research (with non-military fund) are used for military purpose (and vice versa)
- good and evil use: results of research for human happiness are used for terror and massacre (...and vice versa?)
 - "Security Export Control" (METI) based on Foreign Exchange and Foreign Trade Act (revised in 2017)

Conclusion

In Japan, most research administrations of governments, institutions, and universities do not notice these different characters between ten subjects. Research administration is in a mess.

Now every research administrator must observe differences among them, and reconstruct policy based on clear recognition.