ETHICS GUIDELINES AND PRINCIPLES FOR GENETIC RESEARCH IN JAPAN

Eiji Maruyama, Kobe University
Faculty of Law, Kobe, Japan

Several Sets of Ethics Guidelines and Principles for Genetic Diagnosis/Testing and Research in Japan

- “Guidelines on Genetic Testing” of Japanese Society of Human Genetics (February 2000).
- “Guidelines for Research and Clinical Application of Genetic Diagnosis of Familial Tumors” of Japanese Society for Familial Tumor (June 2000).
- “Guidelines on Ethical Issues Surrounding Genetic Analysis Research” of Ministry of Health and Welfare (MHW) (May 2000)
- “Fundamental Principles of Research on the Human Genome” of the Bioethics Committee of Council for Science and Technology (CST) (June 2000).

MHW's GUIDELINES

- October 1999: Japanese Ministry of Health and Welfare (MHW) announced a large 5 year human genome analysis project which starts in April 2000.
- November 1999: MHW created an ad hoc working group to draw up draft ethics guidelines for the project.
- February 2000: The draft guidelines were published for public comment.
- April 2000 (actually May 2000): MHW's Frontier Medical Technology Assessment Committee adopted the Guidelines after considering public comments and making some modifications.

MHW's GUIDELINES

"Guidelines on Ethical Issues Surrounding Genetic Analysis Research"

- They apply only to the research plans that are included in the MHW's 5 year Genetic Analysis Project.

Features of MHW's Guidelines: Ethics Review Committee

- The director of the institute, in deciding whether to approve the research, must consult its ethics review committee.
- The director is prohibited from making a decision to the subject's detriment contrary to the opinion of the committee.
- Individuals not connected with the institution must consist half or more of the members of the committee and half or more of the outside members must be nonscientists.

Features of MHW's Guidelines: Informed Consent

- Voluntary consent must be obtained after detailed explanation has been given.

Features of MHW's Guidelines: Informed Consent: Minors

- Only when the research cannot be pursued without using samples from minors, the use of their samples is permitted. In that case, the consent of the parents must be obtained.
- If the subject is 16 years old or over, the subject's consent must also be obtained.
- Even if the subject is less than 16 years old, the effort to obtain the subject's assent must be made.

Features of MHW's Guidelines: Existing Samples

A. Samples obtained with the consent to their use for genetic research.

- The samples can be used according to the terms of consent.

Features of MHW's Guidelines: Existing Samples

B. Samples obtained with the consent to their use for medical research.

- As a rule, new consent must be obtained to their use for genetic research. However, they can be used where

(1) they have been made unlinked samples, or

(2) in the case of coded samples, the ethics review committee finds that the risk to the subjects and their families is minimal, the research is highly valuable, and it is impracticable to conduct it otherwise.

Features of MHW's Guidelines: Existing Samples

C. Samples obtained without the consent to their use for research.

- As a rule, new consent must be obtained to their use for genetic research. However, they can be used where

(1) they have been made unlinked samples, or

(2) in the case of coded samples, the ethics review committee finds all of the followings requirements:

(a) the risk to the subjects and their families is minimal,

(b) the research will contribute greatly to the society's interest,

(c) it is impracticable to conduct it otherwise, and

(d) the effort to publicize the research has been made, and the scheme for the objection to be filed has been established.

Features of MHW's Guidelines: Disclosure of the Genetic Information

- The wish of the subject to be informed or not to be informed must be respected.
- Even where the subject has not expressed his desire to be informed of his own genetic information, if it comes to be known that the genetic information will seriously affect his life and there exists a valid means of treatment, the director of the research institute must, following the opinion of the ethics review committee with respect to the disclosure, consult with researcher, physician attending the subject and the director of the facility to which the attending physician belongs. The same rule shall be applied with respect to the disclosure to the subject's relatives.

CST's PRINCIPLES

- December 1999: The Bioethics Committee of the Council for Science and Technology [advising body to the Prime Minister] created a subcommittee on the research on the human genome.
- April 2000:The subcommittee published the draft of the "Fundamental Principles of Research on the Human Genome" for public comment.
- June 2000: The Bioethics Committee adopted the "Fundamental Principles of Research on the Human Genome."

CST's PRINCIPLES

- They apply generally to any research on the human genome as a so-called constitutional document of genome research.
- Only basic principles are laid down.
- In August 2000, MHW and other departments and agency created an ad hoc working group to draw up guidelines that will provide for more specific rules based upon this Principles.

Features of CST's Principles: Ethics Committee

- Any research plan should undergo a prior review by an independent, multidisciplinary and pluralist ethics committee.
- The ethics committee should examine a submitted plan mainly from the ethical, legal and social points of view in addition to its scientific merit, and comprehensively evaluate whether the execution of the project should be approved or not.
- The ethics committee should ensure its transparency in its organization and deliberations.

Features of CST's Principles: Informed Consent

- A sample may be collected from a subject only after sufficient explanation has been given to him/her, and he/she has given his/her voluntary consent to its collection.
- The consent should be expressed in writing.
- An individual who is requested to provide a research sample but does not consent should not be treated disadvantageously for his/her refusal.

Features of CST's Principles: Informed Consent: Incompetent Persons

- Where research is to involve individuals who do not have the capacity to consent, the necessity must be shown of conducting research using their samples.
- Informed consent should be obtained from their representatives.
- With respect to minors of a certain years old or over, it is desirable that their consent is also secured.

Features of CST's Principles: Existing Samples

- Existing samples, collected prior to the implementation of the Principles and for which informed consent has not been obtained, may be used only after consent is obtained anew.
- Existing samples, collected prior to the implementation of the Principles and for which informed consent has been obtained, may be used only within its terms.

Features of CST's Principles: Existing Samples: Exceptions

- Where it is necessary to conduct research using existing samples for which informed consent has not been obtained or beyond the terms of the original consent, the samples may be used only after the ethics committee has approved their use.
- The ethics committee should determine the conditions for their use, including the necessity of obtaining new consent, by considering the factors which include their anonymity and linkage possibility, their characteristics, the plan and nature of the research, possible impact on subjects, protection of personal information.

Features of CST's Principles: Disclosure of the Genetic Information

- A subject has the right to be informed of his/her genetic information obtained from the research.
- A subject has the right not to be informed of his/her genetic information obtained from the research. The findings of the research may not be made known to him/her against his/her will.

Features of CST's Principles: Disclosure of the Genetic Information

- Genetic information of a subject may not be disclosed to his/her relatives or family members against his/her will.
- Notwithstanding the principle described above, where the genetic information obtained from the research leads to a determination that his/her relatives carries a genetic factor pertaining to a disease, and its prevention or treatment is considered possible, the determination may be disclosed to his/her relatives following the review by the ethics committee.