

The Legal Implication of Biobanking: Ethical and Legal Framework and Aspects of Biobanks in Japan

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Introduction

In this presentation, I would like to show the present stage of Biobank Japan and J-MICC study, together with governmental ethical guidelines for biomedical research and the impact of the recently enacted Personal Information Protection laws.

Personalized Medicine and Biobank Japan Project (Only patient blood and data is collected.)

J-MICC Study Project (Cohort study involving both patients and non-patients.)

Both projects protect subjects through Informed consent and anonymization of specimens and data.

Guidelines for Biomedical Research

April 2000: “Guidelines on Ethical Issues Surrounding Genome Analysis Research” applicable only to genomic research conducted under the Millennium Genome Project (“Millennium Guidelines”, MHW).

October 1999: MHW announcement of a large 5 year human genome analysis research project (Millennium Genome Project) as a part of Millennium Project which was to start in April 2000.

March 2001: “Ethics Guidelines for Human Genome/ Gene Analysis Research” applicable to every kind of genomic research (“Genome Guidelines”, MEXT , MHLW, METI).

Guidelines for Biomedical Research

Guidelines for Derivation and Utilization of Human Embryonic Stem Cells (MEXT, September 2001)

Guidelines for Handling of Specified Embryos (MEXT, December 2001)

Ethical Guidelines for Epidemiological Research (MHLW, June 2002)

Ethical Guidelines for Clinical Research (MHLW, July 2003)

Guidelines for Clinical Study of Gene Therapy (MEXT & MHLW, March 2002. The original gene therapy guidelines were enacted in June 1994)

Features of Ethical Guidelines

- The requirements of voluntarily given informed consent
- Protection of personal information
- Review and approval by research ethics committees that is composed of members of multiple disciplines and both sexes.

Personal Information Protection legislation in May 2003

Largely follows the model of OECD Guidelines on the Protection of Privacy and Transborder Flows of Personal Data.

- Specification of purposes for which data are collected.
- Limitation of Use of data to the purposes.
- Nondisclosure to third parties without the consent of the subject or the authority of law.
- Protection by reasonable security safeguards.
- Subject's right to disclosure and correction.

Personal Information Laws and Ethical Guidelines

- Personal Information Protection legislation (taking full effect in April 2005) explicitly exempts researchers of academic institutions from specific obligations regarding personal information processing for the purpose of academic research.
- However, most obligations thus exempted have been incorporated in the guidelines revised in December 2004.

Biobank and Genome Guidelines

- As biobanks and researchers who use their specimens are supposed to make genome/gene analysis research, the Genome Guidelines govern their operation and researches.
- Genomic/genetic information, which is unique to each individual, will not change for life, and may indicate the future onset of or susceptibility to particular diseases. These characteristics of genomic/genetic information justify an individual's control of it and special protection against the violation of its confidentiality.

Requirement of Informed Consent

Guideline 10(3) provides that before receiving a specimen and clinical data from a donor, the principal investigator must obtain a written consent based on his/her free will (informed consent), after providing him/her with an adequate explanation of such matters as the significance, objectives, methods and expected results of the research, disadvantages that he/she might suffer, and the method of preservation and use of a human specimen and clinical data.

Guideline 10(9) provides that the donor or his/her proxy may withdraw at any time in writing his/her informed consent without suffering any disadvantage.

Personal Information Security Measures and Anonymization

Guideline 6(3) provides that the head of research institution must take the organizationally, personally, physically and technologically effective measures to secure the protection of personal information.

Guidelines make it a rule to anonymize specimens and data before they are used in research.

Guidelines 14(2) provide that where the specimens are deposited to a human cell/gene/tissue bank, it must be ensured that they will be anonymized in an unlinkable manner when distributed to researchers.

Personalized Medicine Project and Biobank Japan

Spring of 2003: A five year governmentally funded \$180 million project led by Professor Yusuke Nakamura of the Institute of Medical Science of the University of Tokyo was launched.

The project, named “Personalized Medicine Project,” was first conceived as a research and development project to revitalize the Japanese economy, and, in a sense, is a successor to the Millennium Genome Project.

ELSI Committee of the Personalized Medicine Project

Summer of 2003: ELSI Working Group was established under the Project's Steering Committee (Working Group's first meeting was held in August 2003).

It was not independent of the Steering Committee and lacked its own secretary office, it could not work efficiently.

Sept. 2004: ELSI committee replaced ELSI-WG.

ELSI committee stands parallel with the Steering Committee and can perform its duty more efficiently.

The ELSI Committee

The committee now consists of 9 members.

- a medical scientist

- a sociologist

- a journalist

- a genetic counselor

- two representatives of patient groups

- a bioethicist

- a practicing lawyer

- a law teacher

(4 are female and 5 are male.)

It meets once a month.

The ELSI Committee

The committee's activities includes

- (1) visiting collaborating hospitals to make on-site checking of the informed consent procedures and personal information protection system;
- (2) inspection of the records of the research ethics committees of the participating institutions regarding the ethical review of this project;
- (3) checking the project's system for distributing specimens to outside researchers;
- (4) ensuring the project's conformity to the revised Genome Guidelines.

ELSI committee's report for 2004

July 2005: ELSI committee submitted the report covering its activities during the fiscal year 2004.

We concluded that by and large the project had been carried out properly.

At the same time, we indicated several points that we thought should be improved.

- (1) Protection of personal privacy in the medical coordinator's room
- (2) Provideing information to the subjects and collaborating hospitals, e.g. by newsletters
- (3) Enhancement of knowledge of medical coordinators with respect to intelligent property rights and the significances of each entry of clinical information

Committee for Social Affairs of the J-MICC study

The Committee for Social Affairs of the J-MICC study started its activities in June 2005.

Now, we are reviewing the protocols of the J-MICC study and those of the individual study by the participating study group.

Like the ELSI Committee, we are planning to make site visits to check the informed consent process and protection of personal information.

Personal Experiences

The subjects' ability to understand the genomic research and biobank.

Researchers' ability to project the every detail of their study plan.

The difficulty of striking an ideal balance between ensuring the voluntariness of subjects and efficient implementation of the research.

The rule of no returning of personally useful information to participants.

The ways control samples should be collected and its collection explained.

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