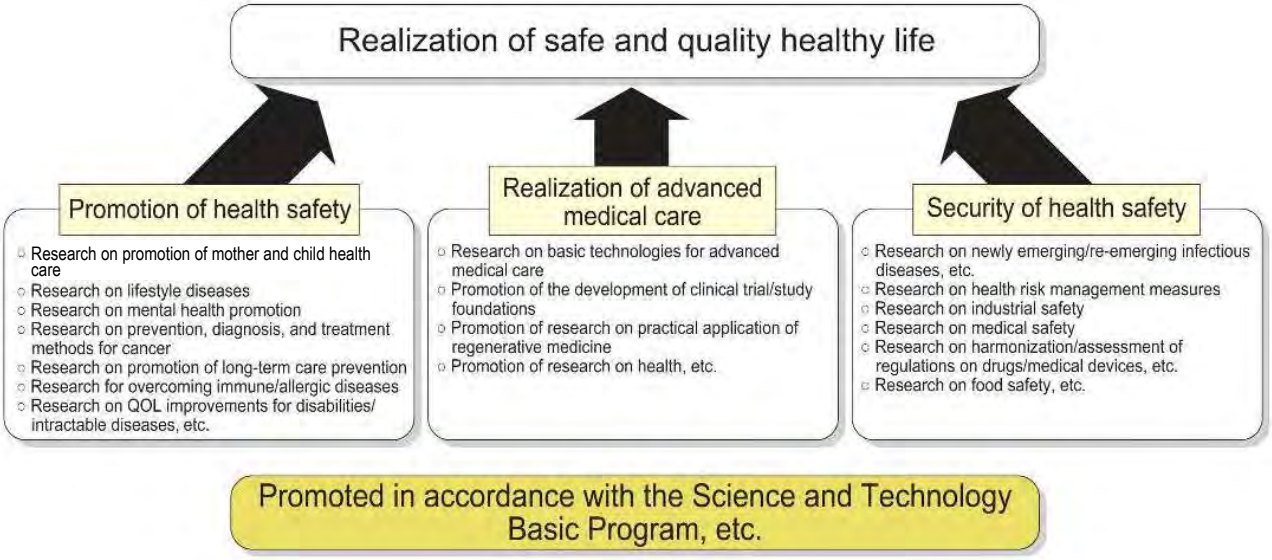
[13] Health Science

Technology Policies of MHLW

Overview **Basic Ideas of Technology Study Promotion**



Appropriate Implementation of Human Genome/Genetic Analysis Studies

Overview **Appropriate Implementation of Human Genome/Genetic Analysis Studies**

Medical studies involving analysis of the genetic information of humans can be expected to contribute to the identification of the causes of diseases and disease mechanisms, diagnosis/treatment/prevention that reflects the differences in individual physical constitutions (so-called tailor-made treatment), and the development of pharmaceuticals based on genomic information (so-called genomic drug discoveries). However, the genetic information obtained in the course of any such study can reveal the genetic predispositions of the providers and their blood relatives and thus lead to various ethical, legislative, or social problems if inappropriately handled. It is therefore necessary to ensure that any such studies are appropriately implemented with human dignity and human rights fully respected.

In order to promote the appropriate implementation of human genome/genetic analysis studies, therefore, the Ministry of Health, Labour and Welfare (MHLW), the Ministry of Education, Culture, Sports, Science and Technology (MEXT), and the Ministry of Economy, Trade and Industry (METI) jointly formulated and enforced “Ethical Guidelines for Human Genome and Genetic Analysis Research” in April 2001 as guidelines for researchers to observe. In addition, and to respond to the smooth implementation of the Act on Protection of Personal Information (Act No. 57 of 2003) and research progress made, the MHLW revised the Guidelines (MEXT/MHLW/METI Notification No. 1 of 2004) in December 2004 from the perspective of protecting personal information, and again in February 2013 (MEXT/MHLW/METI Notification No. 1 of 2013), reflecting how genomic information can now be analyzed more swiftly and easily and genome research styles are becoming more diverse amid recent progress made in human genome/genetic analysis technologies.

The Guidelines prescribe and request researchers and other relevant parties involved in human genome/genetic analysis studies to observe that informed consent shall be obtained, in principle, when conducting studies, any institutions involved in studies shall review the research plan and obtain approval in advance at the Ethical Review Committee, protection of personal information, including genetic information, shall be strictly implemented through on-site inspections by external experts, etc., and consideration shall be given for genetic diseases by implementing genetic consultations, etc.

Appropriate Implementation of Clinical Trials on Gene Therapy

Overview **Appropriate Implementation of Clinical Trials on Gene Therapy**

Gene therapy is a new medical technology that administers gene or gene-introduced cells into the human body to treat an illness and can be expected to be an innovative treatment method for serious hereditary diseases, cancer, other terminal diseases, and diseases that severely impair bodily functions. So far many clinical trials on gene therapy have taken place in a number of foreign countries.

Therefore, in February 1994, MHLW formulated the “Ethical Guideline for Clinical Trials on Gene Therapy” and evaluated comprehensively the medical effectiveness and ethnicity on the scheme regarding clinical trials on gene therapy at the Committee on Science and Technology of the Health Sciences Council. So far we have received 55 applications of clinical trials’ implementation schemes from institutions which plan to implement. As a result of the examination of those applications at the Committee on Science and Technology, we have concluded that 53 applications are eligible for clinical trials.

In November 2014, due to the enforcement of the “Act on the Safety of Regenerative Medicine” (Act No. 85 of 2013), it was decided to evaluate clinical trials on gene therapy studies at the Evaluation Committee on Regenerative Medicine. As for clinical trials on gene therapy that administer gene-introduced cells into the human body to treat illness, the decision was made to move from a guideline-based examination to an examination based on the Act on the Safety of Regenerative Medicine.

Given the changing circumstances of recent clinical trials on regenerative medicine such as other countries’ trends, an Expert Committee was established under the Committee on Science and Technology, which reviewed the contents of the Guidelines, and formulated the "Guidelines on Clinical Research on Gene Therapy, etc." (MHLW Notification No. 344 of 2015) in August 2015.

Appropriate implementation of medical and health research involving human subjects

Overview Appropriate implementation of medical and health research involving human subjects

Epidemiologic studies investigate the frequency and the distribution of health phenomenon, including the morbidity of diseases, and clarifies the factors associated with it. The Ministry of Health, Labour and Welfare (MHLW), in cooperation with the Minister of Education, Culture, Sports, Science and Technology (MEXT), formulated the “Ethical Guidelines for Epidemiologic Studies” (MEXT/ MHLW notification No. 2 of 2002) in June 2002 and appropriate implementation of epidemiologic studies was conducted.

On the other hand, clinical trials are conducted on humans for the purpose of preventing diseases, improving diagnostic/treatment methods, improving understanding of the causes and pathologies of diseases, and improving the quality of life of patients. MHLW formulated the “Ethical Guidelines for Clinical Trials” (MHLW Notification No. 255 in 2003) in July 2003 and appropriate implementation of clinical trials studies was conducted.

Along with diversification of recent studies, based on the fact that the boundary between epidemiologic studies and ethical studies has become unclear and inappropriate incidents related to studies have occurred, a review of both of the guidelines was made. As a result, both guidelines were integrated under “Ethical Guidelines for Medical and Health Research Involving Human Subjects” (MEXT/ MHLW Notification No. 3 of 2014) in December 2014. Under this new Guideline, for the purpose of protecting participants engaged in studies and ensuring reliability of the study results, clarifying responsibilities for researchers, managing conflicts of interest and formulating new regulations for monitoring/auditing the research were established. The new Guideline was enforced as of April 2015. (The enforcement of implementation of monitoring/auditing was enforced as of October 1, 2015.)

Appropriate implementation of Regenerative Medicine

Overview Appropriate implementation of Regenerative Medicine

Regenerative medicine is to regenerate dysfunctional parts and systems due to illness, injury etc. through utilization of iPS cells, somatic stem cells etc. To secure efficacy/safety of regenerative medicine, MHLW formulated the “Guidelines on clinical research using human stem cells” (MHLW Notification No. 425 in 2006) and under these guidelines, the items that personnel engaged in clinical researches must comply with were regulated in order to secure both safety and efficacy as well as informed consent.

In May 2013, an Act related to comprehensive promotion of measures which enable the nation’s smooth understanding and acceptance of regenerative medicine (MHLW Notification No. 13 in 2013) was promulgated and enforced. Under this act, the basic concept was clearly described, which enables the nation’s smooth understanding and acceptance of regenerative medicine. In addition, the measures related to the Act, which the government shall take, were clearly described. Based on this Act, the “Act on the Safety of Regenerative Medicine” (Act No. 85 of 2013) was established in November of the same year and enforced on November 25, 2014.

Under the Act on the Safety of Regenerative Medicine, offering criteria in accordance with risks for regenerative medicine etc., procedures for notification of a plan etc. were regulated in both clinical research and private practice. Accordingly, these regulations enabled medical institutions to outsource the cell culture processing to the private companies. Furthermore, the Guidelines on clinical research using human stem cells were abolished when the Act on the Safety of Regenerative Medicine came into effect.