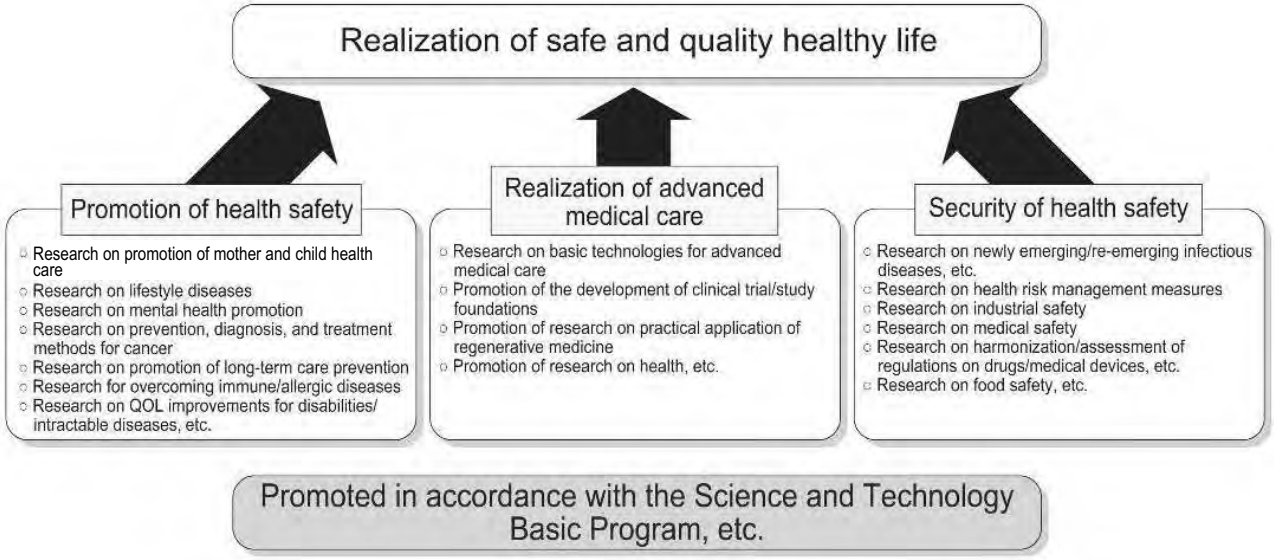
[13] Health Science

Technology Policies of MHLW

Overview **Basic Ideas of Technology Study Promotion**



Appropriate Implementation of Clinical Research

Overview **Outline of Various Guidelines**

In the field of medical research, we established various guidelines such as “Ethical Guidelines for Medical and Health Research involving Human Subjects”, “Ethical Guidelines for Human Genome and Gene Analysis Research“ and “Ethical Guidelines for Clinical Trials on Gene Therapy” to ensure researchers carry out their researches appropriately, including how to protect subjects’ personal information.

i) Ethical Guidelines for Medical and Health Research involving Human Subjects

Medical and health research involving human subjects has greatly contributed to the maintenance and promotion of the health of the people and the improvement of recovery from illness and quality of life through the development of medicine, health science and medical technology. On the other hand, it may impact significantly on bodies and minds of the research subjects, and our society. Therefore, in order to promote these researches, the Ministry of Health, Labor and Welfare (MHLW) established the “Ethical Guidelines for Epidemiologic Studies” (Ministry of Education, Culture, Sports, Science and Technology (MEXT) / MHLW Notification No. 2, 2002) and “Ethical Guidelines for Clinical Trials” (MHLW Notification No. 255, 2003).

Due to the diversification of research in recent years, the scopes of application of these two guidelines have become unclear, and some kinds of research misconducts have occurred. Considering this situation, we reviewed them and established “Ethical Guidelines for Medical and Health Research Involving Human Subjects” (MEXT/ MHLW Notification No. 3, 2014; hereinafter referred to as “Medical Guideline”).

ii) Ethical Guidelines for Human Genome/Genetic Analysis Research

In medical studies involving analysis of the genetic information of humans, the genetic information managed in such studies can reveal the genetic predisposition of the providers and their blood relatives. Therefore, depending on how to manage these information, various ethical, legal or social problems can be caused. The MHLW, in collaboration with the MEXT and the Ministry of Economy, Trade and Industry (METI), established “Ethical Guidelines for Human Genome and Gene Analysis Research” (MEXT; MHLW; METI Notification No. 1, 2001; hereinafter referred to as “Genomic Guideline”), in order to promote researches appropriately taking into account human dignity and human rights.

iii) Ethical Guidelines for Clinical Trials on Gene Therapy, etc.

Gene therapy is a new medical technology, to administer genes or cells to which specific genes have been introduced into the human body in order to treat or prevent diseases, and it is expected to be an innovative treatment for diseases without established treatments, such as serious hereditary diseases.

The MHLW has established the “Ethical Guidelines for Clinical Trials on Gene Therapy” (MHLW, Notification No. 23, 1994), and has the Committee on Science technology, Health Science Council with the aim of evaluating from the viewpoints of clinical usefulness and ethical validity.

From November 2014, the evaluation of these researches has been carried out in the Evaluation Committee on Regenerative Medicine, and the clinical research that gene-introduced cells are administered into the human body has been examined based on the Act to Endure the Safety of Regenerative Medicine (Act No. 85 of 2013) instead of the old guidelines.

Furthermore, in order to ensure the medical effectiveness and ethical validity of clinical research using genome editing technology, which has been rapidly advancing in recent years, and to manage the gene therapy clinical research where genes are administered into the human body properly under the Clinical Trials Act , we established “ Guidelines on Clinical Research on Gene Therapy, etc. “ (MHLW Notification No. 48, 2019) in order to clarify the required procedures.

Overview **Integration of Medical Guidelines and Genomic Guidelines**

Medical guidelines stipulate the basic matters to be observed when conducting medical and health research involving human subjects, and Genomic Guidelines stipulate the especial matters to be adhered to when revealing information on genomes or genes that can be passed on to offspring.

In recent years, with the progress of human genome and gene analysis technology, it is sometimes expected that genome and gene analysis is performed in medical research, and researchers should observe both Medical Guideline and Genomic Guideline in such cases.

Because there are some differences between the provisions defined commonly in both guidelines such as the informed consent procedures, we set up the joint meeting to review the ethical guidelines related to medical researches in August 2018, and examined the consistency of items commonly stipulated between the two guidelines and how to revise them.

In the meeting, we reached the result that we could ensure the same procedures as Medical Guidelines to be followed in implementation of human genome and gene analysis research by unifying the description of the provisions defined commonly in both guidelines, while following the Medical Guidelines and retaining the concepts of the Genomic Guidelines. As a result, both guidelines were supposed to be integrated, and now we are going to integrate Medical Guidelines with Genomic Guidelines.

On the other hand, Ethical Guidelines for Clinical Trials on Gene Therapy stipulate procedures differed from Medical Guidelines, such as submission of an implementation plan to the minister, in order to ensure the safety and scientific validity of the trials on gene therapy. Therefore we aggregate new findings to the examination committee of the national government and maintained a system that enables to examine the research more technically and carefully.

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.