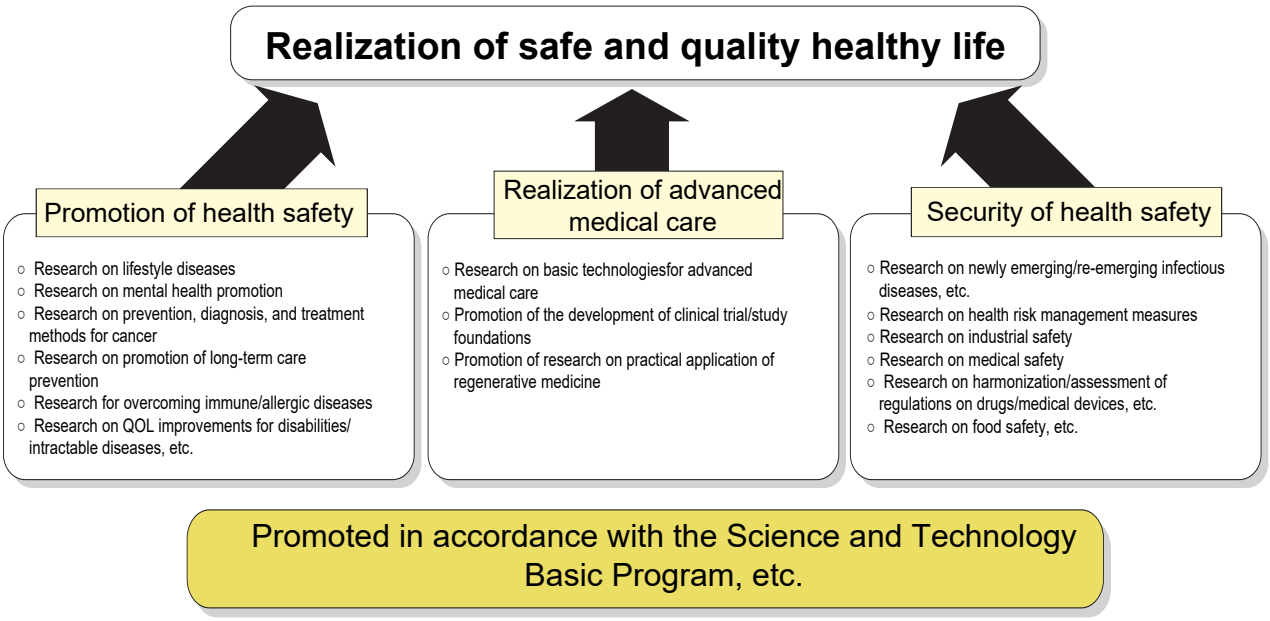
[13] Health Science

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” 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 Biological Research Involving Human Subjects

“Ethical Guidelines for Medical and Health Research Involving Human Subjects” (Public Notice of the MEXT and MHLW No. 3 of 2014, hereinafter called the “Medical Guidelines”) stipulate the basic mattered to be observed when humans are subject to medical research, and “Ethical Guidelines for Human Genome/Gene Analysis Research” (Public Notice of the MEXT, MHLW and METI No. 1 of 2001, hereinafter called the “Genomic Guidelines”) set out specific requirements to be observed in research that reveals information about the genome or genes that can be passed on to offspring.

In recent years, with the progress of human genome/gene analysis technology, genome analysis is expected to be performed in medical research, and both Medical and Genomic Guidelines have been applied to this type of research. Because there are some differences in common items specified in both guidelines, a joint meeting was set up in August 2018 to review the ethical guidelines related to medical research, etc., where the consistency of common items in both guidelines and the way to provide revision guidelines were examined.

With regard to the common items specified in both guidelines, it was concluded that the two guidelines are to be integrated in a way that is in line with the provisions of the Medical Guidelines while retaining the concept of the Genomic Guidelines, and in March 23, 2021, new guidelines, “Ethical Guidelines for Medical and Health Research Involving Human Subjects” (Public Notice of the MEXT, MHLW and METI No. 1 of 2021) was formulated.

In addition, based on the fact that some provisions of the Act on the Arrangement of Related Laws for the Formation of a Digital Society (Act No. 37 of 2021) were enforced on April 1, 2023, the guidelines were reviewed, and “Partially Revising Ethical Guidelines for Medical and Health Research Involving Human Subjects” (the Ministry of Education, Culture, Sports, Science and Technology [MEXT], the Ministry of Health, Labour and Welfare [MHLW], and the Ministry of Economy, Trade and Industry [METI] Notification No. 1 of 2023) was announced on March 27, 2023 (and enforced on July 1 of the same year).

ii) 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.

In addition, based on the fact that some provisions of the Act on the Arrangement of Related Laws for the Formation of a Digital Society (Act No. 37 of 2021) were enforced, the guidelines were reviewed, in light of the provisions of the Act on the Protection of Personal Information (Act No. 57 of May 30, 2003), and revised pursuant to this Act, and “Partially Reviewing the Guidelines for Clinical Research Such as Gene Therapy” (MHLW Notification No. 103 of 2023) was announced on March 27, 2023 (and enforced on July 1 of the same year).

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.