

[13] Health Science

Technology Policies of MHLW

Overview

Summary of Technology Policies of MHLW

Basic ideas of technology study promotion

Security of health safety
 (1) Security of medical care safety, etc.
 (2) Security of food safety
 (3) Enhancement of health crisis control measures

Realization of advanced medical care
 (1) Development of basic technologies for advanced medical care
 (2) Promotion of the development of clinical study (clinical trial) foundations

Promotion of health safety (extension of healthy life expectancy)
 (1) Promotion of nursing care, implementation of comprehensive dementia control measures, and improved and Quality Of Life (QOL) for persons with disabilities
 (2) Improvement health of females throughout life and next generation development
 (3) Development of cancer prevention, diagnosis, and treatment methods
 (4) Life style disease control measures, conquest of immune/allergic diseases, improved QOL for intractable diseases
 (5) Enhanced new/reemerging infectious disease measures
 (6) Mental health promotion

Social situation

Progress of an aging society with a declining birthrate

Public worries, anxieties, and desires

- Life after retirement
- Health
- Medical care/social security system reform

Emphasis on life science study

Status of technologies

1. Advancement of life science
 - Arrival of full-scale post-genome era
 - Progress in human stem cell studies
2. Progress in administrative measures
 - Third Phase of the Science and Technology Basic Plan
 - Comprehensive 10-year Strategy for Cancer Control, Basic Plan for Persons with disabilities
 - Healthy Japan 21, Health Promotion Act

Realization of safe and quality healthy life

Promotional measures

1. Study system

- Introduction of result-oriented business systems (strategy type studies), development of efficient/efficient study techniques
- Security of study systems through applications open to the public and appropriate study evaluation
- Cooperation with public/private medical institutions/doctors, etc. via policy medical care network

2. Establishment of research organizations and effective management

- Establishment of core institutions for the utilization of large-scale experiment facilities, etc., promotion of cooperation among research institutions (large-scale genome/protein analysis, establishment of embryonic stem cells, security of research resources, clinical study data management, etc.)

3. Human resource development

- Human resources required for research, field of medicine-engineering cooperation, clinical study coordinators, experts in life ethics
- Development of experts that can support experts in epidemiology and statistics, etc.
- Persons to engage in research evaluation, young researchers, study leaders

4. Industry-government-academia cooperation and technology transfer

- Establishment of Technology Licensing Offices (TLO)
- Transition to institutional-ownership of research products and development of reward provisions
- Development of research results database

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 (MECSST), 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 for the purpose of responding to the smooth implementation of the Act on Protection of Personal Information (Act No. 57 of 2003) and progress made in research, the MHLW in cooperation with MECSST and METI revised the Guidelines in December 2004 from the point of view of protecting personal information by ensuring all the personal information protection measures prescribed for in the said Act, in principle, were included (MECSST/MHLW/METI Notification No. 1 of 2004).

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 establish an Ethical Review Committee and ensure that the Committee reviews the research plan in advance and approves it, protection of personal information, including genetic information, shall be strictly implemented through on-site inspections by external experts, etc., and consideration shall be given to genetic diseases through implementing genetic consultations, etc.