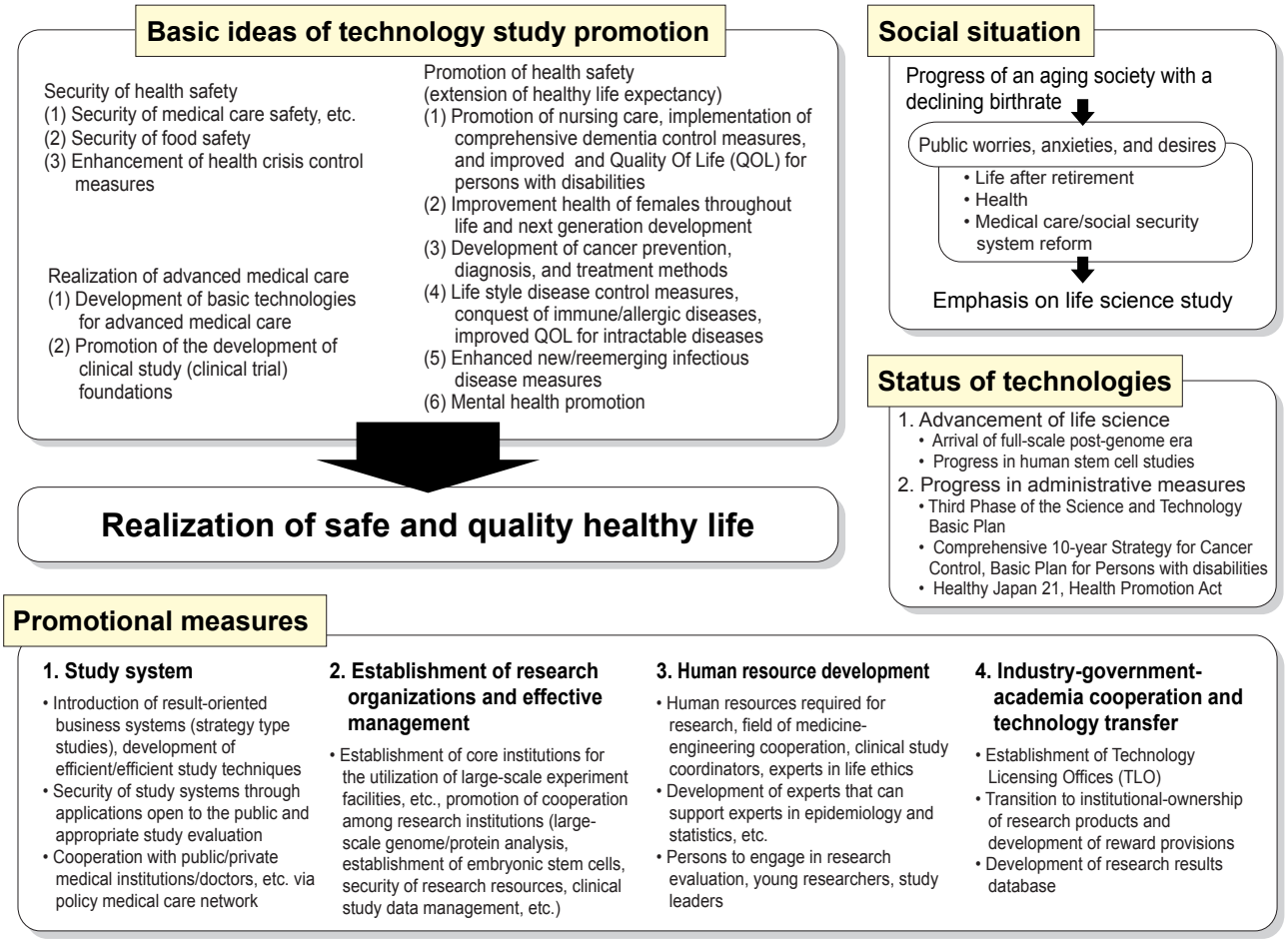
[13] Health Science

Technology Policies of MHLW

Overview **Summary of Technology Policies of MHLW**



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.