

Human genome and the reasonable enforcement of the gene analysis study

Medical studies on the analysis of the genetic information of humans that expects such things that connect the development (so-called genome drug development) of medical supplies based on a diagnosis, treatment, prevention (so-called tailor-made treatment) and the genome medical information that reflects the elucidation of the disease origin and illness mechanism. On the other hand, the genetic information provided by the process of such a study clarifies a provider and the gene factor of the blood relative, depending on the handling, it may cause a law, ethic or social problem, it is necessary for a study to be carried out appropriately while respecting human dignity and human rights.

Therefore to plan human genome research, the reasonable enforcement of the gene analysis study, as the indicator that a researcher should observe, in April 2001, 3 ministries, the Ministry of Health, Labour and Welfare / Ministry of Education, Culture, Sports, Science and Technology / Ministry of Economy, Trade and Industry are devised "ethic indicator (2001 Ministry of Education, Culture, Sports, Science and Technology, Ministry of Health, Labour and Welfare, the first Ministry of Economy, Trade and Industry notification) about human genome, the gene analysis study" jointly and enforced. In addition, correspondent development of enforcement and the study of "Act on the Protection of Personal Information" (The 57th law of 2003), the Ministry of Health, Labour and Welfare co-operates with Ministry of Education, Culture, Sports, Science and Technology and Ministry of Economy, Trade and Industry in December, 2004 and, it includes a step for the protection of prescribed personal information in the law entirely as a general rule, it revised an indicator from the viewpoint of personal information protection (2004 Ministry of Education, Culture, Sports, Science and Technology, Ministry of Health, Labour and Welfare, the first Ministry of Economy, Trade and Industry notification).

Getting principle informed consent at the enforcement of the study, the organization studying will set up an ethics screening committee, perform the prejudging of the study plan and approval in the committee, carry out thorough protection of the personal information including the genetic information such as the principle anonymity, samples or the setting of the personal information manager, Secure the transparency of the study by enforcement investigation with experts, enforcement of the counseling of the heredity prescribes that we consider a hereditary disease, we demand the observance from the people concerned such as all researchers engaged in human genome / a gene analysis study.