

The appropriate enforcement of the gene therapy clinical study

Gene therapy is a new medical technology that administers cells into the body of a person for treatment of an illness, a serious hereditary disease, cancer, terminal disease or a disease that fails a physical function, it is hoped that it will become the epoch-making cure for illnesses that have no established cure even though many clinical studies have already been performed by many foreign countries.

For this reason, the Ministry of Health, Labour and Welfare devised "an indicator about the gene therapy clinical study" in February 1994, and evaluated utilities in the medical care of the plan and ethicality in a technology sectional meeting of the public welfare science council about the gene therapy clinical study of disease to surprise life or the disease to lose general physical functionality. After that, it revised the indicator limit to study plans with the new regulations to evaluate studies, for example, having been accumulated, the sectional meeting (2002 Ministry of Education, Culture, Sports, Science and Technology / the first Ministry of Health, Labour and Welfare notification) and plans the acceleration of the procedure.

The first gene therapy clinical study in Japan was related to adenosinedeaminase deficiency by staff at Hokkaido University, till now around 20 enforcement plan organizations had applied for confirmation of the clinical study enforcement plan. That is accomplished and confirmed by the Minister of Health, Labour and Welfare, when past by the examination process of the technology sectional meeting.

In addition, to enforce the "Act on protection of the personal information", in December 2004, the Ministry of Health, Labour and Welfare cooperated with the Ministry of Education, Culture, Sports, Science and Technology and made an amendment to incorporate the measure for protection of prescribed personal information in the law by the personal information protection (2004 Ministry of Education, Culture, Sports, Science and Technology / the second Ministry of Health, Labour and Welfare notification) .