

## Overview

### 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 25 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) .

## Overview

### The proper enforcement of the epidemiologic study

The epidemiologic study investigates frequency and the distribution of the phenomenon about the health including affection of illnesses, and the scientific research to clarify the factors associated with it. To investigate the origin of the illnesses and the epidemiologic study serves to be great for medical development and the health maintenance and a relation with the health not to be able to lack, and in recent years, become important to explain and obtain concurrence from people subjected to research, in addition to improvements of the consciousness about the right of privacy and in the trend of public opinion of the protection, of personal information which demands standards to be clarified.

For these reasons, the Ministry of Health, Labour and Welfare in cooperation with Ministry of Education, Culture, Sports, Science and Technology is setting up a "ethic indicator about the epidemiologic study" (in 2002 the Ministry of Education, Culture, Sports, Science and Technology / the second Ministry of Health, Labour and Welfare notification) in June 2002. In the principle, the research enforcement decided that they should receive an informed consent from people subject to research, taking the examination of an ethic screening committee set up by the research organization and the personal information structure protection system is determined, so that demand for an observance for those involved in epidemiologic studies, make an effort to proper research operation.

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

Moreover, in August 2007, research organization leader's duty, the personal information structure protection system is determined (in 2007 the Ministry of Education, Culture, Sports, Science and Technology / the first Ministry of Health, Labour and Welfare notification) .

## Overview

### The proper enforcement of the clinical study

The clinical study is medical science for preventing disease, diagnosis and improvement of treatment plans, cause of disease and understanding of morbid states also improve patients quality of life, this subject of investigation for humans, with development of the recent science and technology, the importance increases remarkably.

Repeatedly, improvement of medical treatment is that in the end a lot of cases cannot but depend on a clinical study, respect for the dignity of people and human rights, obtain understanding and cooperation of society, it is essential to advance clinical studies.

For these reasons, the Ministry of Health, Labour and Welfare provides for proper clinical studies that they set upon an "ethical indicator about the clinical study" (the 255th of the Ministry of Health, Labour and Welfare notification in 2003) in July, 2003.

In principle, when researchers are doing clinical studies they should explain about research details and obtain concurrence from examinees, consideration of the protection of the personal information of examinees, and it established carried out the propriety of the clinical study and examination of the continuation by an ethic screening committee established in the clinical study organization. In addition, made amendment to the main principle in December 2004 and, added a necessary rule for the appropriate handling of the personal information in the clinical study. Moreover, an attempted reworking of study ethics and improvement of the subject protection in July, 2008. And then, the demand for observance for those involved in clinical studies were to make efforts for proper research operations.