

## **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.