Status of IRB Establishment and Operation in Japan

Shinichi Kobayashi, M.D., Ph.D.

Chairman and Professor, Department of Pharmacology, St. Marinna University School of Medicine, Japan

After the Japanese GCP(Good Clinical Practices for trial on drugs) and GCP manual(explanation of GCP) were enforced by the Ministry of Health and Welfare in 1990, clinical trials in Japan have been much improved in pharmaceutical companies and medical institutions. However, there are still many problems on clinical trials. Today, I'd like to present you the ethical aspect of clinical trials, especially the status of IRB in Japan as follows ;

1) The background and the regulation on IRB

The GCP was prepared with enough and careful consideration on the Declaration of Helsinki and was expected to form a firm ground for ethically and scientifically sound clinical studies. After the GCP was enhanced, almost all the big medical institutions had established IRB to carry out clinical trials. I'll introduce the Japanese GCP and the GCP manual which mention the organization and duties of IRB.

2) The activity of IRB

Since the IRB in the medical institutions(University hospitals, National hospitals, etc.) usually has to review too many protocols in a meeting, sometimes we can't have enough time to review them. This is one of the big problems for operation in the busy IRB.

3) The problems on operation of IRB

The operation of IRB has been much improved in these years. However, we have still many problems to enforce the duties of IRB. One of the reasons I think is that there are very few specialists, clinical pharmacologists, in the IRB.

4) Informed Consent

In the present Japanese situation between physician and patients, it seems still difficult to get the written informed consent. Then, I'd like to show furthermore the results of the questionnaire on clinical trials for physicians.

From this presentation, I'd like to introduce the status of IRB and ethical situation on clinical trials in Japan.