“Cooperative IRB” issues in Japan, United States, Europe, and Asia

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Abstract
Background: In Japan, GCP Ordinance was revised in 2008 to make research institutes which have an IRB (Institutional Review Board) possible to commit their review to an external IRB. The United States (US) Food and Drug Administration (FDA) issued in 2006 a guidance to facilitate Central IRB review. The European Union (EU) issued in 2001 a Clinical Trial Directive to mandate member states to establish regulations by which multinational clinical trials can be initiated based on authorizations of one Ethics Committee (EC) and one regulatory authority in one member state.
Objectives: To find information on regulatory reformation and the actual situation towards facilitating utilization of cooperative or central IRB/EC after 2008.
Method: Literature survey and interview survey.
Findings: The US government has proposed regulatory reformation to mandate one IRB review for one multi-central clinical research. The EU has proposed regulatory reformation to make possible one EC review in EU for multi-national clinical trials. In Korea and Taiwan, a cooperative review system has been facilitated and quality improvement of IRB review and human subject protection system has been simultaneously facilitated. In Japan, there is a finding of a survey that shows the utilization rate of cooperative IRB is approximately 30%. Actual utilization of cooperative/central IRB in the world has been steadily increasing but not dramatically, and the above mentioned international situation is worth noting.

Key words
cooperative review, central IRB, Ethics Committee (EC), clinical trial, Human Research Protection Program