原　著

臨床試験・研究対象者保護法制の国際比較
― 国際規範，日本，米国，欧州，韓国，台湾，南アフリカ ―

栗原千絵子
国立研究開発法人量子科学技術研究開発機構放射線医学総合研究所　信頼性保証・監査室

International comparative study on clinical trial and human subject protection regulations
― International norms, Japan, United States, South Korea, Taiwan, and South Africa ―

Chieko Kurihara
Quality Assurance and Audit Office, National Institute of Radiological Sciences,
National Institute for Quantum and Radiological Science and Technology

Abstract
Background：Japanese Clinical Research Act was enacted in April 2017 and this Act covers clinical trial of drug, device, and regenerative medicine product, except the trials aiming at marketing authorization under the Pharmaceuticals and Medical Devices Act (PMD Act). The trigger of this Act was a substantial number of misconducts of industry-sponsored clinical research.
Objectives：To clarify commonalities and differences among Japanese regulations for clinical trials and research involving human subjects in comparison with international standards and other countries' regulations, to identify future directions to go ahead, concerning this new Act in Japan.
Method：Literature review and comparative analysis of regulations and/or standards of clinical trial and research of international organizations; Japan; the United States; Europe; South Korea; Taiwan; and South Africa.
Findings：In Japan, GCP (good clinical practice) Ordinance under the PMD Act covers only clinical trials aiming at new product/indication authorization. On the other hand, in other countries, GCP under pharmaceutical laws covers a wider range of clinical trials. International organizations and other countries have developed a wider range of laws and standards for human research not only in medical but also in social or behavioral research, as well as for the use or retention of human samples or information, some of which are referred to as biobank and health database.
Conclusion：Product promotion-oriented commercial sponsoring research by industries should be changed to aim at "global health" for the people who need the results of medical development. To pursue this idea, the Japanese new Clinical Research Act and related regulations and policies should be reformed to establish legal protection of the rights of human subjects, and on this basis clinical trials of medical products should be covered by GCP under the PMD Act, following the international standard.

Key words
good clinical practice (GCP), human subject protection, human right, biobank, clinical trial

Rinsho Hyoka（*Clinical Evaluation*）. 2017；45：649-65.