原　著

米国における臨床試験規制と研究対象者保護規制

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Regulations for clinical trial and human subject protection in the United States

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Abstract
Background：In the United States (U.S.), human subject protection regulations, called “Common Rule”, were fully revised in January, 2017. Meanwhile, as for the clinical trial regulations under the Food, Drug and Cosmetic Act, a new regulation to require clinical trial information including its results information to be submitted to publicly available database was implemented on January 18, 2017. In Japan, a new law for clinical research was established in April 2017 and will be implemented in a year.
Objective：To overview U.S. research regulations to identify key information for the Japanese research community to find the way how to manage the new law for clinical research.
Method：Narrative, non-systematic literature review.
Results：U.S. regulations for clinical trial were established in the 1960s responding to the Thalidomide drug disaster and established since this era with the framework now internationally known to be Good Clinical Practice, along with the investigational new drug (IND) application system. Additionally, new regulations requiring clinical trial registration are prominent as they make detailed results open to the public. U.S. regulations for human subject protection were established in the 1970s for governing federally funded research. Most important changes are (1) to define “broad consent” which makes possible secondary use of bio-specimen and information of humans; (2) to make informed consent document of clinical trial open to the public; (3) to make it mandatory to rely on a single IRB (institutional review board) for multi-center study.
Conclusion：It is useful to learn U.S. research regulations from the above-mentioned points to find the best way to manage the new Japanese law for clinical research.

Key words
Good Clinical Practice (GCP), investigational new drug (IND), human subject protection, U.S. Food and Drug Administration (FDA), Office for Human Research Protections (OHRP)

Rinsho Hyoka（*Clinical Evaluation*）. 2017；45：455-80.