論　説

米国IND制度の生成と発展 ― 規制範囲及びその対象

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The generation and development of the system of Investigational New Drug in the US ― Its regulatory scope

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Abstract

In the United States, the system of Investigational New Drug Application (IND) has been developed since its establishment in 1962, incorporating the contemporary development of human subject protection rule, which ultimately resulted in the Federal Policy for the Protection of Human Subjects (Common Rule). At the same time, FDA's jurisdiction over the clinical trials using drugs under IND has been interpreted broadly; additionally, FDA considers as its purpose, protection of public health from the risk caused by the use of drugs in clinical trial. As a result, the system of IND has become an integrated rule for human subject protection for clinical trials involving use of medical products in general. In Japan, in the face of the implementation of the Act on Clinical Research in 2018, as we still maintain the dual regulations of clinical trials for drug application under the Pharmaceutical and Medical Device Act and those not for drug application, it is worth learning from the development of IND rule in the US to manage the new act.

Key words

Investigational New Drug (IND), human subject protection, U.S. Food and Drug Administration (FDA), Federal Food, Drug, and Cosmetic Act, Common Rule

Rinsho Hyoka (*Clinical Evaluation*). 2018；46：321-34.