解　説

韓国における「臨床試験と対象者保護プログラム（HRPP）運営ガイドライン」について

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On the Korean Guideline for Clinical Trial and the Human Research Protection Program

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Abstract

In 2014 March, the Korean Ministry of Food and Drug Safety issued a Guideline for Clinical Trial and the Human Research Protection Program (HRPP). In Korea, six organizations have obtained accreditation from the Association for the Accreditation of Human Research Protection Program (AAHRPP), which is an accreditation organization in the United States (U.S.). Korean Guideline for HRPP is not a mandatory requirement but a governmental recommendation for organizations to develop HRPP and establish a Human Research Protection Center voluntarily, for the purpose to assure the safety, rights and welfare of clinical trial subjects. The scope of this guideline is clinical trials under the Pharmaceutical Affairs Act, not limited to clinical trials aiming at new drug application.

This guideline is composed of six parts: self-check; helpdesk management; conflict of interest management; formation and revision of institutional regulations; compliance; and education. One of the important points is to set up a helpdesk at the office of HRPP for the purpose of responding to inquiries concerning human rights of trial participants. This would be done independently from and additionally to other helpdesks at the offices of the principal investigator (PI) and clinical research coordinator (CRC), for responding to inquiries concerning a trial's procedures. This guideline could be a useful example for an organization whose resources are insufficient and/or whose status is in the process of obtaining accreditation from the AAHRPP to establish and manage a HRPP appropriate to its own status and situation.

Key words

Human Research Protection Program (HRPP), Association for the Accreditation of Human Research Protection Program (AAHRPP), clinical trial, helpdesk, Korean Ministry of Food and Drug Safety

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