

人を対象とした研究にかかる米国連邦規則の改定： コモンルール改定の経緯と新規則

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Federal Policy for the Protection of Human Subjects (Common Rule), revised: Revision of Code of Federal Regulations, Title 45, Part 46, Subpart A (Basic HHS Policy for Protection of Human Research Subjects)

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Abstract

In the United States, the Federal Policy for the Protection of Human Subjects (Code of Federal Regulations, Title 45, Part 46), generally known as “Common Rule”, has been a basic set of principles and regulations applicable to clinical (biomedical and behavioral) research since its promulgation in 1991. It has also been widely recognized as one of the international guiding standards on research governance for human protection. This rule was revised in January 2017, after a long discussion, to better protect human subjects involved in research, and at the same time, to facilitate valuable research. This paper aims to present a succinct overview of this rule, the processes of its revision since 2009, and the points of changes therein incorporated.

Key words

clinical research, Protection of Human Subjects, Common Rule, the United States, Code of Federal Regulations

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