

フランス「人対象研究法」の現在

— 研究管理の理念と、実務および EUの規制との調整の結果として —

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The current state of the French Law
on Research involving Human Being:
As a result of the adjustment of doctrine
and practice under the EU regulation

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Abstract

In France, all research involving human subjects are regulated by law since 1988. The 30 years history of the French law on research involving human being (hereafter “the Law”) shows how to balance the protection of human dignity and rights of the research subject and the promotion of biomedical research.

In this article, first, the characteristics and the doctrine of the Law are elucidated. Second, the development of the Law through the 1988 enactment and a series of revisions up to 2021 is sketched. Third, the current contents of the Law are reviewed. Finally, in the light of the French Law, crucial problems in the regulation of research involving human subjects in Japan are indicated.

Key words

legal regulation on research, human rights, integrity of person, interventional/non-interventional research, ethics review committee, clinical trial on medicinal product

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