

原著

# 抗肥満薬リモナバント治験訴訟で 医法研21年ガイドラインは何故持ち出されたのか — ヘルシンキ宣言2013年フォルタレザ改訂 補償責任の明記を踏まえて —

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The issue of compensation of clinical trial subjects in Japan:  
The rimonabant lawsuit  
and the Ihoken Clinical Trial Compensation Guideline 2009

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## Abstract

On August 9, 2012, the Tokyo District Court handed down its decision on the lawsuit involving the clinical trial of the anti-obesity drug rimonabant. This clinical trial was conducted in Japan before the publication of the Revised Ihoken Clinical Trial Compensation Guideline in 2009 (“Revised Guideline”). Therefore, compensation of patients in this trial was assured in accordance with the original guideline, i.e. the Ihoken Clinical Trial Compensation Guideline 1999. Yet the Revised Guideline was brought up during the trial of the Rimonabant lawsuit. Why is this so? In this paper, the author explains the background of this lawsuit and what we can learn from it. It was found that the Revised Guideline has several critical flaws. Some of its contents conflicts with the GCP Ordinance, according to the Evaluation and Licensing Division of the Pharmaceutical and Food Safety Bureau in the Ministry of Health, Labour and Welfare. The Revised Guideline also fails to provide contingencies in case of unforeseen or other peculiar events. Therefore, the author proposes the J&T Guideline as an alternative to overcome such critical flaws.

In October 2013, the Declaration of Helsinki-Ethical Principles for Medical Research Involving Human Subjects was revised at the 64<sup>th</sup> WMA (World Medical Association) General Assembly in Fortaleza, Brazil. The revised Declaration added a new provision for compensation and treatment of subjects who are harmed as a result of participating in research. From viewpoint of the Declaration, the author explains why it is necessary to include compensation in the guideline, and also presents current trends overseas in this area.

## Key words

compensation, WMA Declaration of Helsinki-Ethical Principles for Medical Research Involving Human Subjects, Ihoken Clinical Trial Compensation Guideline, J&T Clinical Trial Compensation Guideline, GCP Ordinance

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