原　著

# 医薬品・医療機器・再生医療等製品の企業主導・医師主導治験における被験者健康被害補償：共通点・相違点と医法研ガイドライン適用性

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# Compensation for clinical trial-related injury in sponsor-initiated or investigator-initiated trials of drugs, medical devices, and regenerative medical products: Commonalities and differences in the applicability of JPILA guidelines

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## Abstract

**Background**：The ethical obligation to provide compensation for research-related harm has become a matter of common sense since the revision of the Declaration of Helsinki in 2013. The Japan Pharmaceutical Industry Legal Affairs Association (JPILA) provides detailed guidelines for compensation focusing particularly on sponsor-initiated clinical trials of drugs. Most of the guidelines are applicable in the cases of trials involving medical devices and regenerative medical products, as well as investigator-initiated trials. However, some aspects are specific to each category.

**Objective**：To clarify commonalities and differences in the applicability of JPILA guidelines to each category of clinical trials.

**Method**：A comparative study of clinical trial regulations and discussions among stakeholders engaged in different categories of clinical trials.

**Findings**：Most of the JPILA guidelines can be applied to different categories of clinical trials. Notable differences among them, though, are as follows: (1) In the case of medical devices, the 'Relief System for Adverse Health Effects' for approved products is not applied; compensation for injured staff may be needed; and special consideration for implantable devices is required; (2) In the case of regenerative medicine, compensation for a cell or tissue donor should be considered; (3) In the case of an investigator-initiated trial, institutional policy development for trial-related injury is necessary.

**Conclusion**：The findings of this study will contribute by enabling improvement in the compensation offered in each category of clinical trials, and will also help ensure equitable and fair compensation for injured trial participants regardless of the categories of clinical trial.

## Key words

compensation for research-related harm, medical device, regenerative medical product, investigator-initiated clinical trial, good clinical practice (GCP)

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