

原著

治験／臨床研究に起因する健康被害の治療に対する 公的医療保険制度の適用について

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Application of public healthcare insurance system for the treatment of research-related injury

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Abstract

Background : The relevant regulatory authority has clarified that the public healthcare insurance system can be applied for the treatment cost of the injury of patient volunteers resulting from clinical trials under the Good Clinical Practice (GCP) Ordinance, meanwhile, they have not clarified explicitly both in the case of injury of healthy volunteers and in the case of injury resulting from clinical research under the Ethical Guidelines for Medical and Health Research involving Human Subjects.

Objectives : To show the range of regulatory framework of clinical trial where it has been already clarified that we can make use of the public healthcare insurance system for the treatment of injured study volunteers; and to show the points for which the public healthcare insurance coverage policy for treatment of injury of study volunteers should be more clarified.

Method : Narrative, non-systematic review of related legal documents and literatures.

Findings : Based on reviewing the texts of the Health Insurance Act and related documents, we can conclude that it is possible and desirable in terms of equitable protection of human subjects to make use of the public healthcare insurance system for the treatment cost of the injury of both in the cases of patient and healthy volunteers, notwithstanding regulatory frameworks. This should be clarified by relevant regulatory authority as the policy of our public healthcare insurance system, because the regulator's explicit perspective has been provided only in the case of patient volunteers' injury resulting from clinical trials under the GCP Ordinance.

Key words

compensation for research-related injury, medical cost, public healthcare insurance, claim for third party's indemnity, human subject protection

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