

# 研究対象者の権利と補償の正義：倫理的考察

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## Right of human research subject and compensatory justice: Ethical considerations

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### Abstract

**Background** : The 2013 revision of the Declaration of Helsinki by the World Medical Association (WMA) defined that “Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.” The Japanese Good Clinical Practice regulations require the sponsor or investigator to prepare for compensation for trial-related injuries regardless of negligence, and not to burden the injured subject to prove causality between the trial and injury. The Japanese Ethical Guidelines for Research Involving Human Subjects in 2015 require the research institution to provide compensation for the injured research subject. Hence, we have reached a consensus on the ethical obligation of compensation for research subjects. Meanwhile, the implication of human rights of research subjects related to compensation and its ethical foundation have not yet been clearly identified in Japan.

**Objective** : To clarify the implication of the right of injured human research subject for compensation and its ethical foundation.

**Method** : Narrative, non-systematic review of the literature.

**Findings** : From ethical view point, fundamental right of human research subjects could be protected when their dignity and autonomy is respected without monetary inducement for participation in research; and with provision of compensation for research-related injury because they participate in research not for their own sake but for the benefit of society. Ethical foundation of this theoretical thesis could be “compensatory justice” and “distributive justice”, which can be derived from “Nicomachean ethics” by Aristotle.

### Key words

compensation for research-related harm, human dignity, compensatory justice, distributive justice, Nicomachean ethics

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