

Conference Abstract

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„INDIVIDUALS, PUBLIC INTERESTS AND PUBLIC GOODS:
WHAT IS THE CONTRIBUTION OF BIOETHICS?“
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Title: **What makes clinical research socially valuable?**

Abstract text: (Maximum 250 words. Please include Research Problem and Findings, Methodology, Originality, and Conclusion)

[Research Problem and Findings] It is often claimed that value of research for society plays a critical role in justifying the exposition of human subjects to research risks. Yet, international guidelines use various terminology to refer to what is called the social value of research. With the notable exception of papers by Freedman (1987), Karlawish (1999), Grady (2002), Casarett et al. (2002), Kimmelman (2009), Habets et al. (2014), Wertheimer (2015), the bioethics literature has little in-depth discussion on how the concept should be understood, assessed, and weighted against risks.

[Methodology] This is a conceptual analysis, drawing on literature and regulatory sources (incl. draft of the revised version of the CIOMS Guidelines).

[Originality] I will propose a new multidimensional model of social value in clinical research.

[Conclusion] I will argue that, if social value is to be considered as a threshold requirement (in addition to *scientific validity*), it should be understood as a multidimensional concept involving four dimensions: (a) *scientific value* (novelty of knowledge to be gained and its power to stimulate further studies); (b) *health value* (severity and extent of a target health problem; nature and magnitude of a health improvement the tested intervention is expected to bring); (c) *clinical value* (likelihood of immediate clinical application of the tested intervention and of its broad accessibility for patients, in particular the subject population); and (d) *community value* (research potential to advance broader societal needs/goals of the host community). I will briefly discuss how the model could be used in ethical review process.

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