

Conference Abstract

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Title: **Social value and benefit sharing in international biomedical research**

Abstract text: Value of research for society plays a pivotal role in justifying the exposition of human subjects to research risks. Recently, the CIOMS Working Group on the Revision of CIOMS 2002 International Ethical Guidelines for Biomedical Research Involving Human Subjects has made a proposal to consider social value a threshold requirement for ethical acceptability of all health-related research involving humans (see: project of a revised version of Guideline 1: *Social value*). Yet, both in regulatory sources and bioethical literature, there is little discussion on how social value should be understood, assessed, or balanced against research risks. A notable exception in this respect are papers by Freedman (1987), Karlawish (1999), Grady (2002), Casarett et al. (2002), Kimmelman (2009), Habets et al. (2014), Wertheimer (2015). However, none of these authors analyzes the concept of social value in a broader context of different direct and indirect benefits a research may bring to communities, nor through the lenses of the Fair Benefit Sharing framework developed by the participants of the 2001 Conference on Ethical Aspects of Research in Developing Countries [2002, 2004]. Thus, their understanding of social value of research is narrow and difficult to apply, especially to international research practice.

In this paper I will present a multidimensional model of social value of biomedical research involving four dimensions, namely *scientific value* (being dependent but different from scientific validity), *health value*, *clinical value* and *community value*. I will show that this model is able to accommodate different kinds of benefits to population during and after the research, in particular those mentioned in the Fair Benefit Sharing framework (collateral health services unnecessary for research study, employment and economic activity, reasonable availability of effective intervention, research and medical care capacity development, public health measures, long-term research collaboration, sharing of financial rewards from research results). And as such, it is able to support the view expressed by numerous ethicists and researchers involved in international research that „**benefit sharing is ... one of the means for promoting the social value of international collaborative health research**” [Lairumbi et al. 2012: 22; Emanuel et al. 2004].

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