Conference Abstract

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Title: **The Concept of Risk in International Biomedical Research**

Abstract text:

Research ethics committees (RECs) - in the US referred to as Institutional Review Boards (IRBs) – are tasked to assess risks-benefit profile of biomedical research involving human subjects. Although RECs/IRBs are expected to do "systematic, nonarbitrary analysis of risks and benefits" [Belmont Report 1979], there are no clear criteria how the risk-benefit assessment should be performed. Many factors contribute to this situation: metaphorical language of regulatory documents (research risks must be "outweighed" by, "reasonably balanced" against, "proportional", or "not disproportionate" to potential benefits); diversity, heterogeneity, and incommensurability of research risks and potential benefit [Martin et al. 1995]; lack of objective scientific methods for evaluating probability and magnitude of research related harms and benefits [Rid et al. 2010b; Rid et al. 2011b]; complexity and value-ladenness of the concept of risk. In this talk I will discuss the last problem in the context of international biomedical research. First, I will argue that both in ethics and law on biomedical research, risk is understood in "technical mono-causal terms" as a function of the magnitude and probability of a harm occurring in a result of a research procedure. Second, I will present arguments against this narrow view and argue for a rich conception of research risks that takes into account various psychological, social, cultural, and normative factors and contexts [Kimmelman 2004; Cranor 2009; Hansson 2013]. Finally, I will discuss the difficulties RECs/IRBs may face when using the rich concept of risks in making risk-benefits assessment in international research.

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