Conference Abstract

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Although the language slightly varies, all international and European ethical guidelines and regulations on biomedical research involving humans state that research risks are acceptable only if they are necessary, proportionate to potential benefits (both to society and science, and to the health of the subjects, if expected), and minimized [Levine 1986; Emanuel et al. 2000; King & Churchill 2008]. Where the research has no potential to produce results of direct clinical benefit for subjects, proportionality requirement is strengthened by additional preconditions setting a more stringent level of admissible risk. There is a regulatory consensus that in case of "non-beneficial" biomedical research involving persons unable to give consent (or deemed to be vulnerable for other reasons), the risk should not exceed a certain minimal risk threshold [Kopelman 2004; Rid 2014a]. However, different definitions and methods of setting this threshold have been developed both in regulatory documents and bioethical literature [Ackerman 1980; Barnbaum 2002; Freedman et al. 1993; Kopelman 2000, 2004; Resnik 2005; Wendler 2005; Wendler & Glantz 2007; Westra et al. 2011; Binik 2014; Rid 2014].

In this paper, I will critically analyze three approaches to setting minimal risk threshold, namely: [i] *a process approach* adopted by the WMA Declaration of Helsinki (1964-2013) which leaves determination of the risk permissibility to the REC/IRB judgment; [ii] *a comparative approach* endorsed by the US federal regulations (1991) and the CIOMS Guidelines (2002); the approach defines minimal risks as no greater than those associated with "routine medical and psychological examinations" or those "ordinarily encountered in daily life"; and [iii] *a non-comparative no-serious-harm standard* adopted by the Council of Europe Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (2005). I will provide overview of the theoretical and practical problems posed by each of the approaches. **I will argue that a non-comparative approach is the most promising one, however not exactly in the form adopted by the Additional Protocol. I will propose a new version of a non-comparative standard of minimal risk.**

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