Conference Abstract

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Title: Limiting risk in research on healthy volunteers

Abstact text:

In a recent paper, David Shaw argues that competent individuals should have a right to participate in high-risk research. Research ethics committees (REC) "should never reject a study because it poses too high a risk to participants, and that their role should be confined to ensuring that risks and any potential benefits are fully explained to potential participants"[1]. By refusing to accept research protocol, because it is too risky, REC not only paternalistically interferes with the autonomy of those who would like to participate in it, but also slows down the development of scientific knowledge and the emergence of new drugs.

I do not agree with this view. I believe that there are two features of research in general, and „non-therapeutic" research on healthy volunteers in particular, which justify imposition of limits on permissible research risks, namely [a] the social mission and complex collaborative nature of research enterprise, and [b] the inequity of power between researchers/sponsors and subjects due to asymmetries in information allocation and control, risk allocation and control, and economic position. In my recent paper I argue that setting upper limit on risks that healthy volunteers may face in „non-therapeutic" research is justified by the need to protect research enterprise from the potential loss of public trust in result of research tragedies, and the obligation to protect the weaker party – research subjects – against unwanted/excessive risks and exploitation[2].

Having established that we should set upper limit on research risks, in this presentation I will try to decide who and how should set the limit. I will critically analyze four approaches to setting research risk ceiling that have been developed in the literature: [i] non grievous injury standard adopted by the Nuremberg Code (1947); [ii] a pragmatic-oriented 'numerical strategy' aimed at indicating a precise risk threshold defended by David Resnik[3] and Sigmund Simonsen[4] [iii] a comparative approach based on a principle proposed by Alex London that the risk of "non-therapeutic" research should not be greater than the risks of 'other socially sanctioned activities that are similar in structure to the research enterprise'[5]; and [iv] a process approach adopted by the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research (2005) that leaves the judgment of risk acceptability to REC/IRB discretion. I will discuss strengths and weakness of each of the approaches. I will claim that the last approach is the best strategy to set boundaries of risk in "non-therapeutic" research.

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[1] D. Shaw. The Right to Participate in High-Risk Research. *Lancet* 2014; 383: 1009
[2] J. Rozynska. On the Alleged Right to Participate in High-Risk Research. *Bioethics* 2015. doi: 10.1111/bioe.12146
[3] D.B. Resnik. Limits on Risks for Healthy Volunteers in Biomedical Research. *Theor Med Bioeth* 2012; 33(2
[4] S. Simonsen. *Acceptable Risk in Biomedical Research. European Perspective*. Dordrecht Heidelberg London New York: Springer Science+Business Media B.V. 2012.
[5] AJ. London Reasonable Risks in Clinical Research: a Critique and a Proposal for the Integrative Approach. *Stat Med* 2006;25:2869–85.