Reviewer’s report

Title: Exempting Low-Risk Health and Medical Research from Ethics Reviews: comparing Australia, United Kingdom, United States and The Netherlands

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Reviewer: Charlotte Ullrich

Reviewer's report:

This paper analyses documents providing national guidance on research ethics in four countries. As a starting point, the current situation in health and medical research is described as highly regulated. Thus, according to the authors, exempting low-risk research from ethic reviews is required. The authors offer a good and precise description of methods used for analyzing the documents. Comparing four countries, the analysis offers interesting insights that can stimulate discussion as well as (inter) national guidance.

The question how to regulate research ethics in health and medical research is of great and current importance. Both are increasing and - more and more so - interdisciplinary fields of research, where different rationales and cultures of research ethics meet. The article is well written.

However, all in all the paper tends to give the impression that the authors view ethic reviews as an unnecessary burden to research (e.g. wording "hyper-regulation", "research waste"). It would be helpful to recognize rationale and history of ethic reviews and characterize the specifics regarding medical research (ethics) shortly. Against this background one could discuss whether or not these concerns are applicable for "low risk research". In fact, "low risk" as a category itself might be worth a bit more attention (similarly "hyper-regulation").

Suggestions for focusing the paper:

a. Elaboration research waste/the problem at hand
   - It would be helpful to know a bit more about the problem at hand: E.g. to describe the rationale and benefits of ethic review: Why and when are they important?
   - What is "research waste"? The authors offer some concrete aspects in paragraph 2. How do these relate to exempting low-risk research? What might be lost by this exemption?
   - What are (general) alternatives to avoid "hyper-regulation"?
   - The background is quite short, some important context information is only included in the discussion
   - Conclusion: Could there be any disadvantages of international regulation (e.g. leading to even more "hyper-regulation")?

b. Elaboration of rationale/use of ethic review in general and context regarding each country
   - Is this paper limited to ethics review clinical research? It might be helpful to differentiated between
clinical research and research more on the social science side (behavior change, organization change, interviews, questionnaires etc.) as there are quite different needs and formal requirements as well as academic discussions. However, both approaches are relevant in the field of health and medical research.

– What are missions and mandate of the research ethic institutions investigated? Besides the ethical aspect, there might e.g. be legal ones.

c. Consider literature on method/methodology and research ethics


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Please indicate how interesting you found the manuscript:

An article of importance in its field

**Quality of written English**
Please indicate the quality of language in the manuscript:

Acceptable

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