Reviewer’s report

Title: Researcher and study participants’ perspectives of consent in clinical studies in four referral hospitals in Vietnam

Version: 0 Date: 19 Feb 2019

Reviewer: Johannes Van Delden

Reviewer's report:

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This is an article on the consent process for research in four hospitals in Vietnam. It describes the results of surveys and interviews with 41 individuals, both participants (4), family members (11), doctors (14), EC members (11) and one nurse. Data were collected in 2013-14, so rather old.

I would suggest to the authors to include descriptive data about the respondents in a table. Also, at present all answers of the research stakeholders are lumped together. This is understandable because it concerns a small number of respondents, but in case of some results it might be good to know who held which opinion. For instance who were the 11 individuals who thought that it is not essential to inform about changes in the protocol? It seems to me that there is also a gap between the current and desired level of knowledge of these stakeholders. In general the statistical testing doesn't help much with such small numbers.

As such, this is a small descriptive study on an ethically relevant subject matter in a heterogenous group in a local context. There is some room for such studies in the academic literature, although this room is limited because it is often unclear what others who operate outside this context can learn from it. This is precisely the weak point of this manuscript: in its current version it isn't clear what we can really learn from it. This problem already starts in the introduction where the research question is formulated as ‘accounting for the broader context of a study and the participants' lives...’. It would perhaps help if the gap that the authors mention in the next sentence is elaborated on. In the discussion the reader is told that he needs to understand the broader social and and economic constraints of the participants. Sure! But please explain what you learned from the data, and what others can learn from it too.
My other problem with the manuscript is that the findings are not critically discussed. It is alright to search for a better translation of the word research into Vietnamese but it is not at all alright to 'provide just enough information so that participants feel comfortable and safe but not too much so that they become scared of the research' as EC members and study doctors apparently said. Instead of concluding that these stakeholders were wrong, the authors state in the conclusion that in a hospital patients may suffer from the therapeutic misconception. I would say that this is precisely why it is so important to make it absolutely clear that the patient is invited to participate in research. The fact that research stakeholders 'argued that the word for research should be modified to increase acceptance of joining research studies' goes uncriticized as well, where it should have been. This goes for a lot of the quantitative findings.

**Are the methods appropriate and well described?**
If not, please specify what is required in your comments to the authors.

Yes

**Does the work include the necessary controls?**
If not, please specify which controls are required in your comments to the authors.

No

**Are the conclusions drawn adequately supported by the data shown?**
If not, please explain in your comments to the authors.

Yes

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If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

Not relevant to this manuscript

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Acceptable
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