Reviewer’s report

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

Version: 1 Date: 29 Aug 2019

Reviewer: Henry J. Silverman

Reviewer's report:

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I appreciate the additional information provided by the authors.

I have several additional comments.

The authors state in their introduction the following: "The data from this study will inform future consent research and guide the revisions of policies that inform the consent processes for specific studies within our research context, as well as pointing to several larger issues surrounding researcher-participant expectations, communication, and trust."

I recommend that in their discussion section the authors should suggest what changes in consent policies are in order. This is key as it appears that many researchers do not consider that several of the basic elements of informed consent are necessary (survey results) and many provided limited amount of information "so that the participants feel 'comfortable' and 'safe' but not too much so that they become scared of the research".

1. In their conclusion section, the authors state "To maximize the development of valid consent, it is important to engage the hospital-based communities…". The authors should explain more how this conclusion emanated from their results.
2. On page 17, the authors mention that "participants relied on the physicians to help them make the decision, which is not a unique finding to Vietnam....." and then provide several questions that deserve further exploration. As the authors' intent was to investigate the practice of consent in the context of the hospital setting in Vietnam, I need to ask why this contextual issue was not pursued in the present study?

3. On page 14, the authors mentioned "However, in practice.....the line between care and research was easily blurred.". From where did the authors obtain this insight about "practice"?

4. On page 10, the authors state that the survey results showed that a large majority of participants believed that the idea of voluntariness is essential in the consent process. However, the survey asked about the concept of voluntariness in the consent "form" rather than practice. It appears from the results of their interviews there are many questions about researchers' practice of informed consent.

5. In the authors' response to my comments, they state that the sample size was dependent on timeline/budget, "as well as the point at which saturation occurred" (during interviews). However, they mentioned later on that the "interviews were analyzed after the data were collected...". If the latter is true, then how did the authors determine when there was data saturation?

6. In the authors’ discussion of their limitations they should also mention that the interviews were analyzed after the data were collected and as such, as stated by the authors, the interviewer "missed some of the probing opportunities". The authors stated that they would mention this limitation in their discussion.

7. The authors state on page 6 that they coded all interviews "with a predefined codebook based on the specific areas we wanted to investigate". Did the interviews reveal other 'codes' that were unexpected?

Thank you for this opportunity to re-review this manuscript.

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

No

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

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

No  

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?  
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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