Reviewer’s report

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

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Reviewer: Henry J. Silverman

Reviewer's report:

The authors report their findings are an important subject involving the consent process in Vietnam. The study design involved a mixed method approach: surveys and semi-structured interviews that were obtained simultaneously rather than in a sequential manner.

My general comments are as follows:

1. I encourage the investigators to provide further characteristics of the setting and of the participants and the relatives of child participants who gave informed consent. Regarding the setting, the authors mentioned that the study was conducted in "referral hospitals", it might be useful to know whether these hospitals were public or private hospitals. Regarding the 4 study participants and the 11 family/relatives of child participants, what were their educational levels, severity the health status and the economic status.

2. Adult study participants might hold different perspectives and attitudes from parents/relatives of child participants. The literature has reported on certain of these characteristics, for example, it has been reported that parents of children expect benefits from participation and are very concerned with risks. As such, it might be helpful to know whether there were appreciable differences in their perspectives/attitudes on the interview responses.

3. Why did the authors conduct the study with "relatives" of child participants and not the parents?

4. Information regarding the type of study to which study participants gave consent to participate in might be helpful in understanding their responses in the interviews. For example, studies have shown that responses of study participants differed according to the perceived risk associated with the study: for example, perceived risks differed between between survey/interviews, blood sampling, and experimental drugs and as such, responses differed accordingly.
5. The authors use the following terms interchangeably and somewhat inconsistently: perspectives, attitudes, opinions, experiences, and values. For example, the title states "perspectives", but there are many places in the text where the authors refer to the responses as "attitudes", "opinions", and "experiences". In general "perspectives" refer to as to what individuals "see" in the world, whereas "attitudes" refer to how individuals "evaluate" their perceptions. It appears that the authors obtained both perspectives and attitudes and I encourage the authors to clarify which of the responses represented either of these two categories.

6. How did the authors determine the sample size for the surveys? Also, regarding the interviews, was they the sample size determined by when the point at which "saturation was reached?"

7. I suggest several ways in which the organization of the manuscript can be improved, thus enhancing clarity. For example, results regarding recruitment are reported in the methods section rather than the results section. Also, the authors tend to interpret some of their findings in the results section rather than the discussion section (e.g., their discussion regarding the existence of choice in lines 247-256.

8. In several places in the manuscript, authors make reference to how medical care and research can be blurred and gave examples of when the interview responses reflected such "blurriness". Did the authors find the therapeutic misconception to be a prominent theme? For example, on page 9, the authors mentioned "The delineation of clinical care and nghien was not clear for this patient".

9. The authors discuss in the results section the use of the word nghien to build trust, but at the end of this section on page 9 the authors comment on how research in "trusted institutions" is a starting point for increased trust in the research process. As such, the authors intermingle two distinct points: use of the word nghien to build trust and the presence of trust a priori to enhance the acceptance of research.

10. One of the survey questions regarding the importance of the elements of informed consent asked about the "inclusion of the word research". Did survey used the word nghien for this question?

11. The results of the survey showed that 73.3% of the study participants thought that the use of the word "research" was essential, but it appeared that many of these participants expressed negative attitudes of the use of this word. It would be helpful if the authors can discuss more about this discrepancy. This would also be important in understanding why study participants held such negative attitudes of the word research, especially since these participants had given consent for participation in research.
12. In lines 240-242, the authors state that the use of the work neghien cicu would ensure that the study participants would realize that the participants had a choice. I am not sure of the basis of this conclusion.

13. Beginning on line 200, the authors state that it was difficult to determine from the interview data whether providing limited information was a strategy to provide sufficient information to a population that had limited understanding or was a strategy to hide information that might be scary. I am wondering why this issue was not unpacked during the interview process itself.

Other comments:

1. In the results section, the author would use the word "many" and "other" when referring to the responses. It might be helpful to provide the exact number of these responses.

2. The authors refer to researchers, members of research ethics committees and study coordinators as "stakeholders" and the individuals who gave consent for research participation as "participants". To reflect the current thinking that both groups of individuals are equal partners in the research enterprise, I suggest that individuals who participate in the research should also be considered as stakeholders.

3. On line 246, where the authors refer to the setting of the interviews, the word "privacy" is probably a more appropriate word than "confidentiality", which refers to the obligations of researchers "after" data are obtained.

4. The authors mention they obtained "written" informed consent. Several research regulations mention that when the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality, then waiving documentation of the signature would be appropriate. The authors should explain why written consent was obtained instead of verbal consent, which is ethically preferable.

**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.

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

No

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