Reviewer's report

Title: Experiences with community engagement and informed consent in a genetic cohort study of severe childhood diseases in Kenya

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Reviewer: Shimon Tashiro

Reviewer's report:

This paper addresses some of the key issues in contemporary research ethics: community engagement in international health research, general or blanket consent for the future research, and therapeutic misconception. In my opinion, the study methodology is interesting and generally valid. While action research method is frequently used in other fields, few studies in this field have employed the methodology. The paper shows the method is also useful in this field. I believe the authors demonstrate that a thick description of “doing ethics” by using action research methods can contribute to a better understanding of the reality in biomedical research than one-shot questionnaire survey.

As for this paper, I don't find any serious flaws either in its content or in its methods. This means that I don’t think that the paper requires a major compulsory revision. The paper is worth publishing for the journal. At the same time, I also believe that the paper will become more readable as well as persuasive if the authors revise it on some relatively minor points. I hope that the following comments will be helpful for the authors to make such revisions.

1. The relationship between the KGBC and the action research

The authors write that “the Kilifi Genetic Birth Cohort (KGBC) is an example of a study in which action research informed ongoing community engagement....” (BACKGROUND, second paragraph) and also suggest that the “community engagement at the centre …draws on action research principles of continuous evaluations and adaption” (BACKGROUND, fifth paragraph). However it is still unclear for me how the researchers conducted the action research. While the authors give a rich description of the KGBC itself, very little is explained about the action research (BACKGROUND, second and sixth paragraph). For instance, it is not clear if those who are involved in the KGBS, including field workers and chiefs, are informed of the action research. Do they understand that what they talk with the authors in the meetings will be analyzed and published?

2. Ethical review process in Kenya

The authors' description of the ethical review process of the KGBC seems too sketchy and quick, given that the most readers (including myself) are not familiar with the situation in Kenya. For example, the authors say that the KGBC was reviewed by “local, national and international scientific and ethical review bodies” (BACKGROUND, sixth paragraph). However I don't know how these review
bodies are related with each other, or what their roles are. This point is related to the later description of field workers: “the revised information sheet and consent form were subsequently submitted to and approved by the national ethics review committee” (FINDINGS, fourth paragraph and DISCUSSION, sixth paragraph). Why was the revised information sheet submitted only to the national review committee? I surmise that each committee has its own role and responsibility. But I recommend the authors to add one or two sentences to explain a little more about the whole review process of the KGBC, or the ethical review system in Kenya in general, and also to provide references (if any).

3. Empirical ethics based on social science research for community engagement
The authors’ view about empirical ethics (i.e., that “empirical ethics based on social science research” has the possibility of making contributions to community engagement practice) may well be correct (DISCUSSION, last paragraph). However I don’t think that the authors should propose it in this paper. In my view, any conclusions must be given based only on relevant data, especially in the case of social science studies. I don’t see any data the authors provided to support their proposal. A proposal on empirical ethics for community engagement seems to be beyond the scope of this paper.

4. Explicit references to the authors’ previous research
It will be better for the authors to explain explicitly how the paper is related to their previous research. I know that they have already published some articles in this topic. However there are no clear indications as to in what respect this paper adds new findings to the authors’ previous research.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**
I declare that I have no competing interests