Reviewer's report

Title: Seeking consent to genetic and genomic research in a rural Ghanaian setting: the MalariaGEN experience

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Reviewer: Miguel Ruiz-Canela

Reviewer's report:

This manuscript deals with an interesting topic and it provides interesting insights for those issues related to informed consent from genomic studies. However, some revisions are also needed.

1. The authors have made some comments at the results section that should be included at the methods or the discussion sections:
   - The first subsection (the consent process) describes different ways used at the MalariaGEN study to provide the information. This should be described at the Method section.
   - Please clarify whether blood samples were collected for research purposes or were first just taken for clinical purposes.
   - The subsection “Knowledge and understandings of genetic and genomic research” begins with an interpretation of a result (differences at the level of understanding between research staff). Any interpretation of the results should be included at the discussion to make a clear distinction between the results and the possible reasons for these findings.
   - The subsection “Sample use and data sharing” refers to the results from a study carried out in Uganda. Again the comparison of the results from other studies should be included as part of the discussion of this research.
   - Concerning the results on the boundaries between research and therapy, this is an observational study and therefore it does not include any experimental drug. However, I believe that the main issue has to do with the data collected as part of the MalariaGEN study. These data, as it generally occurs in observational studies, will not have any direct benefit for the children included at this observational study. I guess that this idea is difficult to understand in this specific clinical environment. I find it hard to believe that that this issue was clearly understood by mothers of cases and even less by mothers of controls.

2. The first paragraph at the Discussion describes some general points related to informed consent’s issues in genomic research, mainly at developing countries. This idea should be more properly detailed at the introduction. At this section a brief reference to this idea could be made but connecting it more clearly with the results of the study.

3. The limitations of this qualitative study (limitations usually found at this type of
research) should be more clearly stated at the discussion. Some of them are:
- The number of researchers, research assistants and research staff is low and any comment would be appreciated.
- There are many factors that can be related to the level of understanding and that cannot be shown with this study (such as literacy level and other social and economic factors).

4. This study suggests that, in this context (a developing country), the importance of written information is lower than it may be in developed countries. In general, some requirements from international guidelines (influenced by developed countries) are not easily applied at developing countries. At the same time there are other needs that must be fulfilled. I would encourage authors to develop this idea a little bit more.

**Level of interest:** An article of importance in its field

**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