**Reviewer’s report**

**Title:** Ethical issues of informed consent in malaria research proposals submitted to a research ethics committee in Thailand: a retrospective document review

**Version:** 0  **Date:** 02 Mar 2017

**Reviewer:** Manasse Bambonye

**Reviewer's report:**

P.1. Line 1 &2: I do find that the title should reflect the limitations expressed in this research. I agree with the statement that "this study is based on information on malaria research proposals submitted to only one institutional REC, the IRB of the Faculty of Tropical Medicine, Mahidol University, Thailand. It may therefore not be representative of RECs elsewhere in Thailand or around t". That is why for me, the title of this research should reflect this reality. Moreover, this research does not study informed consent as specific variable, but is about decisions rendered by a specific REC in one specific faculty of one university (Mahidol). Then the title as it is seems to be misleading. In reality, the purpose of this study is to summarize issues raised by a REC in one faculty at the Mahidol University as rendered about informed consent and not study about completeness of the consent form compared to those stated in a specific guideline. Additional to that the authors do not justify their choice with regard to retained criteria used in reviewing rendered decisions about consent information provided. I would like to see these issues commented and the title reviewed to reflect their limitation and the real object of study.

Purpose of this study:

The objective of this study is somehow not clear. In fact, it is not clearly stated that there are any problems in conducting research in received complaints or in variations of informed consent formulation that need improvements. We understand that there are lot of studies conducted by faculty is involved or is carrying. It is not enough to state the amount of studies carried out, it has to be an existing large research conducted by the faculty to justify the need to know how the informed consent is respected. If this is one of the purposes, this should clearly mention. Clarification on these issues could be helpful for readers.

**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.

Yes

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

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

Declaration of competing interests
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?

If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

I declare that I have no competing interests.
I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal.