Author’s response to reviews

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

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2nd Responses to Editors and Reviewers (3.7.17)

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Assessing informed consent in malaria research proposals submitted to a research ethics committee in Thailand: a retrospective qualitative review.

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BMC Medical Ethics

Editor Comments:

Two places in particular can use some clarification:
P. 12 -- you mentioned the importance of confidentiality, and since your study is about ICP, and that later on p. 22, you mentioned that confidentiality wasn't a major issue in your study, it would be helpful to tie briefly the issue of confidentiality to the ICP (eg., that participants need to be informed about confidentiality provision).

Thank you for the comment. We would like to use your wording for the revision. We wish to clarify the issue on page 22, as follows:

(d) Confidentiality and contact

Researchers appeared to be well aware that study participants need to be informed about confidentiality provision. Almost all proposals contained such confidentiality information, so that the FTM-EC seldom needed to raise the issue of confidentiality in proposals. This ICP element appears to be well understood among researchers. Proposals to use existing linked data often generated concerns about who could access and/or extract data for use (i.e., the relevant or authorized person). Proposals requesting the archiving of specimens/data for future use also raised confidentiality issues. A few proposals had problems with furnishing contact details for untoward or unethical incidents. FTM-EC generally requested clarification and revision in such matters (see Table 3(d)).

P. 16: In the section regarding ICP elements, the word "comments" was used. Are these REC comments to the researchers regarding the procedures as discussed in the consent documents? Does this mean that the REC was requiring the researchers to revise their wordings, or raised concerns about these issues? "Comments" is a very broad term. Since you mention later that there are four categories regarding revisions, it would be helpful to clarify this a bit from the outset.

Thank you for pointing out this important key word. We have now changed the wording as highlighted below.

ICP elements by study type

Of the 63 studies requiring a new ICP, about 67% required comments raised concerns among FTM-EC committee members about procedures (study activities or specimen/data collection process), about 40% for risk and discomfort, vulnerable status and compensation, and about 15–20% for most other ICP issues (see Table 2(a)).