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: 27 Mar 2017

Reviewer: Patricia Marshall

Reviewer's report:

The process of informed consent and its review and assessment in study protocols by Research Ethics Committees (RECs) or IRBs in low- and middle-income countries continues to be an important issue for investigators and members of review committees. In this manuscript, the authors examine concerns associated with the informed consent process raised by RECs reviewing malaria protocols in Thailand. The authors conducted a granular analysis of the protocols and have succeeded in shedding light on the review process and outcomes. The paper is well written. The methods are clearly described. I recommend publication with minor revisions.

1. Page 2, line 9: Delete "or communication."

2. Page 2, lines 14-15: Delete the sentence that begins "The Faculty of Tropical Medicine's…." It is not needed here.

3. Page 2, line 20: Change "…during 2010…” to "from 2010…"

4. Page 7, line 19: Do you mean "…proposals submitted to Research Ethics Committees from 2010-2015"?

5. Page 8, line 21 through page 10, Elements of the ICP: This is a very long paragraph (one and a half pages). I suggest breaking this up into several paragraphs. You might consider beginning a new paragraph on page 9, line 11, and beginning with "The US FDA guideline…” You could also begin a new paragraph on page 9, line 18, beginning with "The Royal College of Nursing…” Another paragraph could begin on page 10, line 1, "The literature suggests…"

6. Page 11, line 17: the phrase "at times it could be controversial" is not clear in this sentence. Either delete the phrase but keep the reference (#29) or create a new sentence that clarifies what you mean.

7. Page 15, line 17: Begin a new sentence with "Half of the studies…"

8. Page 21, line 11: Start a new paragraph beginning with "Although the collection…”
9. Page 24, line 14: What do you mean by "border areas"? Please clarify.

10. Page 25, line 9: What guideline are you referring to?

11. Page 28, line 14: Begin a new sentence with "The researchers must ensure…"

12. Page 40, line 48, Table 3: This table is extremely long. Is there any way to shorten it, for example, by cutting back on how many words are used in the "Purpose" column?

**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

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