Reviewer’s report

Title: The ethics of using placebo in randomised controlled trials: a case study of a Plasmodium vivax antirelapse trial

Version: 0 Date: 20 Mar 2017

Reviewer: Larry R. Churchill

Reviewer's report:

The essay presents 6 criteria that, if fulfilled, would justify the use of placebos in human subjects research. While a range of proposals and objections to the use of placebos in clinical trials have been argued over the past several years, I have not seen a paper that lays out criteria in such a concise and practical way. The arguments about avoidance of a double standard, and that use of a placebo is no more harmful than not being in the trial are particularly well done, although I thought just a bit more could be said about the claim that there is no increased burden from being in the trial and being randomized to the placebo arm. This would assume that there are no additional burdens incurred from simply being a subject in the trial under discussion, such as ancillary risks. I assume this is correct, but I think it would be helpful if the authors said just a bit more about that possibility, and also comment on the way the possibility of ancillary risks could affect the generalizability of their conclusion. In some trials, simply being in a study, in whatever arm, provides benefits from more careful monitoring of a disease. This might be true in the study under discussion, and also in these sorts of studies more generally.

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
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Acceptable

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