Reviewer's report

Title: When is informed consent required in cluster randomized trials in health research?

Version: 1 Date: 26 June 2011

Reviewer: Valentino Manase Lema

Reviewer's report:

The article is of great importance to health research especially in the developing world. Ethical issues remain thorny and of major concern. The article raises very pertinent issues especially for the developing world where most such studies will be conducted.

I have issues with any study being conducted in the developing world without proper informed consent process. As a researcher and some one who has served on ethics committee I do not agree that informed consent can be done away with for CRT. All efforts should be made to get informed consent of all participants, otherwise a study involving human subjects should not be carried out.

I do not buy the assertion that providing complete information in CRT may lead to bias of study results/findings! The same can be said with regards to reliability of authenticity of study findings in cases where informed consent was not obtained in advance.

It is important to appreciate the fact that such studies will be carried out in developing countries and funded by multinationals from the developed world. For whose interest are the studies being conducted? Why should the researchers not invest in obtaining informed consent at all times? Would such processes be acceptable in the developed world? I guess NOT! as in-fact shown by the reference to the USA where it is stated in the article that each state may vary what has been recommended. This to me is a another way of saying that it is okay for other countries but not the USA!

All the examples given in the article are on studies carried out in developing countries and by non-developing country researchers I guess. It therefore supports the above assertion.

The article opens a pandora box on a critical issue - research in developing world funded by the developing world!

The comments notwithstanding, I feel the article is worth publishing if only to stimulate further discussion on the subject!

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.