Reviewer’s report

Title: The case for conducting First-in-Human (Phase 0 and Phase 1) clinical trials in Low and Middle income countries.

Version: 2 Date: 5 September 2011

Reviewer: Robert Levine

Reviewer’s report:

Discretionary revision

You have given satisfactory responses to all of my suggestions for revision with one exception. My first "compulsory revision" has not been addressed directly. I think it would be helpful to point out that your recommendations are at odds with the leading international research ethics documents—namely, Helsinki, CIOMS and ICH. I think this would be a good idea but no longer consider this revision compulsory.

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.