Reviewer's report

Title: Health Research Ethics Committees in South Africa 12 years into democracy

Version: 2 Date: 11 May 2006

Reviewer: Udo Schuklenk

Reviewer's report:

General

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

I am afraid, my central concern has not been dealt with in any satisfactory manner. The analysis of community representation is not of a publishable standard. It repeats South African mantras in a chant like fashion, but there is no substance to the analysis. Let me illustrate. You write 'The primary duty of a REC is participant protection.' You then go on to argue for community representation in such a way as to ignore this crucial requirement. You say in your analysis pertaining to this point, 'participant protection must be entrusted to a demographically representative REC in order for participants to believe [sic!] that their rights are being fairly protected.' So it's not even about matters of fact (ie the stated primary duty being met by a given committee, but about participants' beliefs, which isn't exactly the same)... - You make matters worse by adding to this a concluding line, stating that 'Hence in SA it is important that protection of the rights of the study participants is entrusted to a representative group of people.' This is not only begging the question that concerned my specific comment (despite the 'hence'), but it's also begging your own question, as it simply repeats what the sentence prior to the 'hence' already asserts. It's a classical petitio principii. My initial point was that there could easily be conflicts between representativeness (if there can be such a thing, which incidentally I doubt, of course) and maximisation of participant protection (which is measurable). You have not dealt with this in your revisions as far as I can ascertain.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

You also introduce on various occasions a new concept, namely that of 'vulnerable' people. This concept is hotly contested within research ethics, something you seem to be oblivious to. You seem to have an intuitive understanding of who is and who isn't vulnerable, but in an academic paper this must be explicated and defended.

The last sentence on pg 16 (revision beginning on top of the page) is seriously muddled and should be translated into proper English.

Discretionary Revisions (which the author can choose to ignore)

You decided to add - presumably in response to another reviewer's comments - 'dignity' related content. I should declare that I consider this phrase meaningless, but even if you disagree, surely you would have to explain what you mean when you are concerned about participants' dignity (after all, in your argument above you do not seem to think leading participants on to believing something about their committee by making it representative in certain senses, without investigating whether there is a factual basis for such beliefs, is dignity violating -). In your own wording you distinguish between 'dignity, integrity, health and safety of study participants (p. 3). So, from my vintage point it would be useful to know what else can be protected after patients health, safety and integrity has been protected, namely something distinctly different that you call 'dignity'.

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article of limited interest

Quality of written English: Needs some language corrections before being published
Statistical review: No

Declaration of competing interests:
I still do not have a conflict of interest.