Reviewer’s report

Title: Research Ethics Committees in South Africa 10 years into democracy

Version: 1 Date: 6 April 2006

Reviewer: Joses M Kirigia

Reviewer’s report:

General
In the Sub-Saharan Africa not much research has been done on the health research ethics committees. Thus, this research makes an important contribution to the existing limited body of literature from Africa on the subject. The paper is well written. Thus, the few suggestions made below are to enhance the already good quality of the manuscript.

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

TITLE:
Given that in the last sentence under Methods section, the authors seem to have limited themselves to RECs in health sciences faculties, I suggest that the authors restrict the title to health research ethics committees. If that is acceptable to the authors, then the title would read as “Health Research Ethics Committees in South Africa 10 Years into Democracy”.

BACKGROUND:
In paragraph 1, first sentence, at the end add the words “..dignity, integrity, health and safety”. This would help to clarify aspects of protection we are referring to. In the last sentence of the same paragraph, the authors give [M Joffe unpublished data], we would advise that the authors provide the full reference, even though unpublished.

In paragraph 4, the first sentence should read as “In 2001, the World Health Organization Regional Committee for Africa expressed….”. In the following sentence, the authors assert that “While the practise of ethical review by health RECs is firmly entrenched in South Africa,…”. If there is published evidence to that effect, the authors should provide a reference or references.

METHODS:
In paragraph two of the Background section, the authors mention that there are 34 REC in South Africa. In the first paragraph of Methods section, they mention that there are 22 REC, one wonders where the remaining 12 went to. In the second paragraph, fourth sentence, authors mention “All 12 REC chairpersons agreed to participate…”. Again out of the 22 REC mentioned in paragraph one of this section, one wonders what happened to the remaining 10? Or are they the ones said to be too small. I suggest that the authors should state upfront that out of the estimated population of X number of health research REC in the country, Y number was included in the current study and provide the criteria for selection.

It is mentioned in paragraph 1 that “The remaining 10 academic REC are smaller…” were excluded from the study. The smallness in size is not an adequate justification for exclusion. Thus, this should be mentioned as a limitation of the study. In the last sentence of the same paragraph authors say that “Where REC were attached to universities, only those in the Health Sciences faculties were included in the sample as this is where clinical trials are reviewed”. From the title, the study is looking at all the REC, and REC functions are not restricted to clinical trials but includes all health research. Once again this is another limitation of the current study that should come out clearly
In the second paragraph, at the end of the second sentence, authors should insert a reference for the Declaration of Helsinki.

RESULTS:

General:
No comments.

Diversity:
In paragraph one, third sentence authors say “In 83% of RECs in SA,…”. Isn’t this 83% of the 12 RECs instead of 34 RECs in the country? If that is the case then we need to correct that.

Training and development of REC members in research ethics:
In the Discussion section, the authors could speculate a bit about the potential implications of charging for research protocol review on the submission of protocols especially from the formerly disenfranchised communities/populations, i.e. equity issues. In other words, might this be contributing the existing racial gap in health research capacities in the country?

Workload:
In the first paragraph, third sentence, the use of the word “latter” is a bit confusing. It does not logically follow from the preceding sentence. Authors are encouraged to give it another look.

Efficiency of protocol review time:
In the Discussion section, the authors should give explanation of why there are variations in the charges for protocol review? Doesn’t the national ethical review guidelines give an indication of how much a REC should charge? In the opinion of the authors, should these charges continue, even the equity concerns notwithstanding or should the government explore other mechanisms of financing the work of the RECs?

Infrastructure and administrative staff:
No comments.

DISCUSSION:

In paragraph four, the authors should provide the potential ethical implication of the last sentence.

In paragraph 8, would the community participation in RECs be enhanced if the national ethical guidelines were translated into various local languages and if conscious effort was made to raise their awareness? The authors might give their own opinion about that aspect.

In paragraph 11, in the last sentence, insert the words “of interest” after the word “conflict”.

I strongly recommend that the authors should consider inserting two paragraphs (or subsections) at the end of the Discussion. (i) One paragraph on limitations of this study. (ii) Another paragraph on suggestions for further research. Reading the authors text, possible suggestions for further research may include:

§ An assessment of health research ethics training needs among REC members. This should explore evaluate the exposure to and familiarity with various key international ethical standards and guidelines.
§ Assessment of the impact of research protocol review charges on the total number of protocols received and approved from formerly disenfranchised populations in South Africa.
§ Sustainable and equitable mechanisms of financing the work of RECs.
§ Ways of increasing the representation of the people of colour on the membership of RECs. § Assessment of the extent to which affiliation of REC members to the institutions they are reviewing protocols for influences their decision to accept or reject a protocol.

MINOR ESSENTIAL REVISIONS (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

DISCRETIONARY REVISIONS (which the author can choose to ignore)

NONE.

What next?: Accept after minor essential revisions

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No

Declaration of competing interests:

I DECLARE NO COMPETING INTERESTS.