Reviewer's report

Title: Informed consent in Sri Lanka: a survey among ethics committee members

Version: 4  Date: 26 November 2007

Reviewer: Dominique Sprumont

Reviewer's report:

General

Globally, both the topic and the article are interesting. As such the paper can be published with minor revisions.

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

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

One problem concerns the sampling of the participants in the study. First, in the background (back ground?) section, it is mentioned that there are 5 Research Ethics Committees (RECs) in Sri Lanka plus 5 other ethics committees, while in the strategy for data collection section there are 8 RECs identified while in the results section, there are 9 RECs with a 10th ethics committee mentioned as not being a REC. At the end, it is unclear how many RECs there are finally in Sri Lanka: 5, 8, or 9? Second, the sampling size was supposed to be originally 20 out of the 60 members of all RECs in Sri Lanka. The final number of participants is 29. How was the sampling done? Did all RECs were invited to participate in the study, respectively were all RECs members contacted as mentioned on p. 6 (point 4 of the strategy for data collection)? It would be important to specify how this number of 29 participants was reached: are the 29 the only ones who answered the questionnaire or were they actually selected? This issue should at least be addressed in the discussion section, especially if the questionnaire was send to more than 29 participants it would be useful to explain why some did not answer and give the percentage. Third, to what extend the sampling is representative of the RECs composition in Sri Lanka. Unless this last point is clarified, the conclusion can not pretend to present the opinion of all RECs members in Sri Lanka.

Another problem is linked to the presentation of the results. It should be harmonized. For instance on page 8, in the need for ethical approval section, figures are first mentioned as followed: 20 (69 %), and then three lines under (10; 48.7%). Sometimes, numbers are in letter (again page 9 in the same section) or not. The presentation of the tables could as well be improved and simplified. This
is also the case for the list of abbreviation which should separate more clearly the abbreviations from their definitions. Some notes should also be revised, for instance there seems to be a problem with the note 11.

The discussion and conclusion only reflect part of the results. The limits of the study are not presented, neither the bias in the selection of the participants (see comments above) and in their answers (do they answer what they know or what the interviewer wants to hear?). Some questions in the interview guide (Q2 – Q5) are open and their answers should therefore be more varied than the ones discussed in the paper.

Discretionary Revisions (which the author can choose to ignore)

If the study remains mostly descriptive, we would have found interesting to have a discussion on the difference between the answers of the participants and the ethical requirements on informed consent as recognized in the main international documents of references in research ethics. For instance, when some participants consider that illiterate, debilitated or mentally handicapped need not provide written consent. Of course, this is based on the fact the subjects are deemed incompetent, but it does not solve the issue of who should consent for them, normally their legal representatives. There is the same problem with the issue on verbal consent and the need to keep a written proof that the consent was obtained.

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, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

We declare that we have no competing interests.

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