Reviewer’s report

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

Version: 4 Date: 26 November 2007

Reviewer: Samia Hurst

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General
This is an interview study of ethics review committee (ERC) members in Sri Lanka, regarding requirements for informed consent in human subjects research. The authors present data based on 29 interviews in a context where little data exists. This makes their contribution valuable. However, there are currently several points in the manuscript that require strengthening.

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

1. It was not clear to me what the interest of this study’s results were. On second reading, it does seem clear that this is an interesting project, but the authors could clarify their purpose to a greater degree. Is the primary goal to contribute to shared experience of ERC members? To contribute to critique/local adaptation/validation of the WHO check-list? To provide a perspective on adaptations necessary in a context such as Sri Lanka? The goals should be clearer both in the introduction and in the discussion.

2. This study seems to use a mixed quantitative-qualitative methodology. This is fine, but does merit greater clarification of methodology. Was a random sample selected, or was recruitment based on methods of qualitative research, such as snowball sampling? How were open-ended responses coded?

3. The question of what research subjects have understood prior to enrollment is indeed important, but it is not specific to developing countries. Study after study in industrialized countries have found similar gaps in information and understanding.(1-6) This should be clarified as part of the context.

4. Discussion of ERC members’ views on the requirement of written consent for illiterate, debilitated, or mentally handicapped research subjects does seem to merit discussion. This is currently short enough that the authors’ intentions are not clear. Do they believe that the ERC members who would exempt illiterate subjects from the requirement of written consent are correct? Are misguided, perhaps even showing how capacity building in bioethics is needed? Are signalling a logistical problem with a requirement of consent (rather than written consent) that they do not question fundamentally even in cases where they believe that such consent cannot be in written form? I am outlining these different
possible interpretations simply to highlight the need for greater clarity as to what
the authors make of this result.

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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)

5. On page 7, it is not clear whether “leaflets” refers to information leaflets written
by investigators, or to the standard format offered by the ERC. Though it
becomes clearer later in the paragraph, it is still not clear how respondents
answered this question. Did they give an opinion on a range of different
information leaflets? Or did they choose a “representative” one, or a recent one?

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Discretionary Revisions (which the author can choose to ignore)

6. Were respondents who agreed that there should be a uniform format members
of the ERCs that provided them?

7. Page 8: what does “studies where the participants are at the same level as
researchers” mean?

8. Results include the view among respondents that “constraints on reviewing all
studies would be, human resources and time available” (p8). The discussion then
mentions the importance of “capacity building on bioethics” (p10), but no longer
the need for more material resources. As the strength of results regarding
capacity building in bioethics and regarding the need for resources seem equally
strong, it is strange to see only one reflected in the discussion.

References:

1. Williams CJ, Zwitter M. Informed consent in European multicentre randomised

Strategic physician communication and oncology clinical trials. J Clin Oncol.

3. Hietanen P, Aro AR, Holli K, Absetz P. Information and communication in the


5. Howard JM, DeMets D. How informed is informed consent? The BHAT

6. Flory J, Emanuel E. Interventions to improve research participants'
understanding in informed consent for research: a systematic review. Jama.
What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory 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:
I declare that I have no competing interests