

Reviewer's report

Title: Ethical approval and informed consent: analysis of biomedical publications originating from Sri Lanka

Version: 1 **Date:** 21 October 2007

Reviewer: Adnan Hyder

Reviewer's report:

General

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

This paper is on an issue of great importance to international health research and comes from a part of the world which is of critical relevance to integrations of good practices in the developing world. The major issue relates to the organization of the paper, and an inconsistent use of key terms which makes the paper somewhat confusing.

In the first instance, the authors assert the basis of the paper is to assess current trends in adherence to guidelines regarding ethical approval of research in Sri Lanka. They assert that there are two essential elements of the approval process: rigorous scientific evaluation of protocols, and informed consent. The authors inconsistently lump these two things together and sometimes call it "ethical approval", while at other times in the paper referencing the two things – review of protocols and informed consent – separately. The authors reference international guidelines for their claim but do not specifically state how they narrowed down human subject protection to just these 2 activities? The references do not do this for sure and so the authors have to defend their claim.

A second source of confusion - in the paper, the authors evaluate three separate sources of research: graduate theses from PGIM, scientific articles in the Ceylon Medical Journal, and articles by Sri Lankan authors in international medical journals. However – the methods section specifically mentions only review of PGIM thesis and generally mentions a Medline search. The METHODS section should be expanded to specify each specific area of the work (thesis, CMJ, international journals) and how it was done for the reader to understand issues such as selection bias.

A third source of confusion – the authors review three sources of research, and in describing this use different phrases and terms to explain the results of their review. For instance, in the RESULTS section the authors describe reviewing PGIM theses and calculating the % of those mentioning or providing evidence of "ethical approval". There is no mention of informed consent. Then when CMJ

articles are discussed, the authors reference both ethical approval and informed consent. The analysis of results needs to be consistent across sources and if there are differences, then they need to be explained.

Importantly, only in the discussion of the Sri Lankan articles in International journals do the authors, prior to discussing the issue of consent, first define the number of articles that involved human subjects – in the discussion of the other sources of research papers the authors are silent on this point, leading to the inference that ALL papers from those sources (PGIM and CJM) involved human subjects --- possible but not likely and in any event this issue needs to be specifically described --- 'X of the 305 theses involved human subjects', for example.

This last comment is a weakness throughout the paper – the lack of distinction between the number of total research pieces (theses, CMJ articles, international articles) vs. the subset of those involving human subject research. So, first, this distinction (% of research involving human subjects) should always be made and presented – otherwise the denominators may be incorrect and it is generally confusing, and second in each area of analysis both key components of ethical review (as these authors identify them – scientific review of protocols and informed consent) should be addressed. Again, see RESULTS section.

The authors have not indicated the basis of their “proxy indicator” as “good enough” except for their ‘opinion’? Moreover, it is unclear what the proxy is a proxy for. What if any is the empirical basis? Are there other opinions that support this choice? It is important to understand the underlying basis of this decision.

Of 367 you downloaded only 131 – why – you did not explain? What does this create in scientific terms? Does this not affect the validity of your result? You need to refer to methods for bibliometric analysis and then present your findings.

There needs to be a full discussion of your limitations and threats to validity based on your methods and results. There is both selection and non-sample bias in your methods and thus the nature of your recommendations has to be affected (and frankly made more humble and toned down).

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

What were the rules for student theses in academia in Sri Lanka for 1999-2005? Have they changed during this time? Was ethical approval essentially required or by choice of advisor? Also, over the course of this time period there was a sharp increase in the number of theses – even if this sharp increase is utterly irrelevant to this paper, it is striking and the authors may want to provide a brief comment.

The discussion section actually reads in large part like a series of recommendations, not a discussion of the findings of this study. The authors need to first discuss their findings, especially their limitations, and then make

recommendations.

The authors need to include some comparison with other types of empirical work from South Asia or the developing world on this issue. The papers lacks a good review of the literature of this type. Review papers by the following authors to see if you can use any: Kumar N et al; Jafarey A et al; Raja A et al; Moazam F et al; Hyder AA et al; Ahmad A et al; Indian Council for Medical Research; etc.

Discretionary Revisions (which the author can choose to ignore)

The tables can be reduced – for example table 4 is not needed as it can be described in text. The language and headings used in the table can also be improved.

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.