

Reviewer's report

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

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Reviewer: Lisa S. S Parker

Reviewer's report:

General

This is an interesting initial attempt to document an issue of interest to researchers and institutions in Sri Lanka, as well as the broader research and regulatory communities concerned with research conducted in the developing world and across cultural boundaries. The literature cited is appropriate. The prose is readable, clear, and engaging.

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

page 6, Methodology, Protocol development process -- I recommend relabeling this section and adding a paragraph that actually describes the protocol that is developed. Some of that description seems to follow in the "Data collection" section on page 8 and might be moved here. The reason for this recommended change is that the sentence "During these meetings, it was agreed that a proxy indicator reporting ..." does not make sense when the following information has not been provided:

- * what is the research question that the study sought to answer?
- * what was the initial protocol that underwent subsequent discussion, review, and revision?

The use of a proxy indicator should be explained more fully; what is the proxy a proxy for?

Moreover, the second line in this current paragraph ("A consultation meeting ...") is a mere sentence fragment, and the following sentence ("Revised protocol") should begin "The revised protocol"

page 10 -- Here the authors claim "recent candidates are more conscious of the informed consent process as indicated in table 3," however, they lack evidence for this claim. (a) They cannot justifiably make a claim about the state of mind of candidates (their conscious awareness of informed consent). (b) They cannot extrapolate from evidence that consent was taken to any claim about the process, including the candidates' awareness of the IC process. As will be suggested below, the authors ought to recognize, explicitly, the limitations of self-reported data or evidence of having obtained consent. At the very least, they

ought not comment on the process of consent taking, as they report no data on the process(es) pursued by candidates.

page 11 -- The authors comment: "In research that was not related to human subjects, only one study gave evidence of obtaining ethical approval." Given the focus on human subjects protection regulations and guidelines and the Institutional Review Board system in the US, the question will arise, at least for US readers, "what sort of ethical approval is required for research not involving human subjects?" The authors should explain the nature of ethical approval with nonhuman animals, as some (perhaps many) readers would not be familiar with that process. Indeed, there might be confusion that an IRB-like body was mistakenly asked to give ethical approval for a study not involving human subjects.

page 12 -- Speaking of the need for debate about the appropriate levels of ethical approval, the authors comment "this is especially applicable to countries where ethics review capacity is limited." By this comment the authors seem to imply that it is permissible for research capacity to outstrip or exceed the capacity for ethical review. This is very troubling. It would seem that if the capacity to review research protocols for their ethical permissibility is limited, then the number (or nature) of protocols should be similarly limited. It is true that in the presence of scarce resources, including scarce ethics resources, review of protocols that present only minimal risk might be expedited. But the general sentiment expressed in the quoted comment is probably not what the authors intend to express.

page 13 -- Why do the authors consider "unintentional exploitation" as the only concern that may arise due to lack of local ethical review? First, this focus on the risk of exploitation seems to buy into the view of those in the developing world as primarily subject to exploitation, as likely/potential victims, as perhaps less susceptible to ethical concerns that affect subjects in developed world (e.g., research burden and risk, psychological disruption, undue pressure to participate). Second, while ethical review may be suitable to guard against exploitation, the process of informed consent is a particularly poor means of avoiding exploitation. Whether the ethical review adequately guards against exploitation will depend on whether the review is primarily focused on review of the informed consent protocol/process or whether it evaluates the ethics of the study design itself.

page 13 -- Contrary to the authors' commentary, the ICMJE already incorporates the issue of ethical approval and informed consent into the requirements. See:

"II.F. Protection of Human Subjects and Animals in Research

When reporting experiments on human subjects, authors should indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000 (5). If doubt exists whether the research was conducted in accordance with the Helsinki Declaration, the authors must explain the rationale for their approach, and demonstrate that

the institutional review body explicitly approved the doubtful aspects of the study. When reporting experiments on animals, authors should be asked to indicate whether the institutional and national guide for the care and use of laboratory animals was followed." It is troubling that the authors are not aware or do not acknowledge this inclusion.

page 14 -- The authors claim "Similarly research that has not been subjected to ethical review or fails to meet accepted ethical standards should be considered as unacceptable science." Why? I agree with the claim, but then I am already persuaded by others' arguments. The authors need to offer an argument in support of this claim, especially for publication in a medical ethics journal. Their presentation of data alone does not constitute such an argument. Moreover, it is not clear that something that is unethical is necessarily unacceptable qua science. For "unacceptable as science" to follow immediately as a conclusion from "unacceptable on ethical grounds" would imply or rely upon a view of science that is at best controversial. Again, the authors would need to supply an argument for this view.

page 14, final line -- Again, I question why the authors choose to raise the risk of exploitation as the only risk mentioned.

Final recommendation -- I would suggest that the authors include a brief paragraph in which they summarize the limitations of their study. These include (a) the limitations of self-reported data (although the authors suggest that more degree candidates and published researchers may have sought ethical approval than report it, it is also possible that some are reporting having sought such approval but, in fact, did not); (b) the inability to review all of the articles for which abstracts were found (given space limitations, it is reasonable to anticipate that ethical review would not always be stated in the abstract); and (c) lack of study of the actual content of ethical review, the actual process of informed consent, and the actual level of understanding of research subjects both of the research, the consent process, and the meaning of informed consent. Although the authors mention several of these factors (a-c) in their text, it would be helpful to summarize them briefly as limitations of the study.

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

p. 5, "The other is looking" -- delete s from end of 'provides'

p. 10, insert a comma after '1989'

p. 12 -- in the abbreviation for versus -- vs -- the v should not be capitalized

p. 13, line 4 -- delete the comma after 'mandatory'

p. 13, par 2 -- the verb 'occur' should be 'occurs' -- add an s

Table 1 -- I recommend changing the headings as follows:

Not mentioned about ethical approval --> Ethical approval not mentioned

Mentioned about ethical approval --> Ethical approval mentioned

Table e -- here and in the text, the term 'verbal' is misused. Instead the authors probably mean 'oral' (i.e., spoken not written). 'Verbal' means "expressed in words, written or spoken."

Discretionary Revisions (which the author can choose to ignore)

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: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I declare that I have no competing interests.