Reviewer’s report

Title: Mixed-Methods Study on Perceptions Towards Use of Rapid Ethical Assessment to Improve Health Research Informed Consent Processes in a Low-Income Setting

Version: 1
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Reviewer: Sassy S Molyneux

Reviewer’s report:

This paper tackles a topical issue, using in general an appropriate methodological approach. It is valuable to have qualitative and quantitative data on researchers’ views on rapid ethical assessments.

Major compulsory revisions

The main clarification needed is that it is unclear to me over reading the paper, what exactly is meant by Rapid Ethical Assessment, and therefore what interviewees or survey respondents are commenting upon. This does appear also to be a problem for research participants in this study, which makes it difficult to draw firm conclusions.

Specifically I don’t quite understand – and I’m not sure if the participants understood:

- What does REA involve? – who should be consulted (what counts as a community?), on what (consent processes or ethical issues more widely - eg risks, benefits, procedures, community entry, feedback of findings - what kinds of information is needed?), by whom (the research team or social scientists/community liaison personnel), at what stage of a research process (pre or post national/institutional approval), and in what kind of depth.

- How does REA differ from, or overlap with, more traditional piloting processes, ‘pre assessments’, and other community consultation or community engagement activities. For example I note there is reference to Molyneux et al. as a ‘pre-assessment’. In fact this quiz was conducted after the trial had begun and was aimed at checking understanding of consent and feeding into on-going community engagement.

- For example if it’s a trial involving six hospitals, is there a suggestion that in each site there should be a four to six week process conducted before the proposal review process, with the outcome woven into the research protocol? Or is it that there should be a process incorporated after the overall national/institutional process (and should the findings be reviewed and if so by whom)? If it’s the latter (ie post general approval), how different is what’s being suggested from community engagement processes that are now widely advocated for – is it that the outcome should be reviewed? In which case the wider concerns about the review process which appear to be very prominent among participants become very critical.
- On reading the paper, and depending on the responses to the above, there appears to be broader fundamental concerns with the whole governance of research in Ethiopia, and that this context is key to the relevance and feasibility and applicability of REA. More could be made of this point?

Linked to the above, it is unclear from the paper what participants were asked and responded to. This could be assisted by the tables including the full questions (and any no answers). Could more information also be provided in the methods as to what development work went into tools (based on the literature, on qualitative interviews, or on previous work by the authors on RAE). Specifically what was asked about RAE and how… did questions follow a short description of what this might involve? I think this is important to ensure that the key finding – eg sentence two of discussion – is supported.

Minor revisions:
- It would have been interesting to differentiate views of PIs and others, and know what proportion were not involved in conducting research at all
- How did those not in the four major institutions of interest get involved?
- There is quite a bit of scope for greater specificity – eg ‘lack of clarity’ in what, what about language, who mostly assumes that Amharic will be used (all page 7), who ‘have to believe it’ (page 8).
- Some typos and sentences needing attention throughout – eg sentence one of results, ie.s throughout, ‘since otherwise’ and last sentence on page 8.
- Are there any community members on review committees now (page 9)?
- What matters about different studies – page 9 – is it about multi site, or type of study, or who’s sponsoring it?
- Page 10 last para – there are some contradictory sentences in here, and does REA really guarantee community members’ role and ensure community concerns are addressed?

Discretionary revisions
Some potentially interesting recent papers (not necessarily to reference, but to explain some of my above points):


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

Quality of written English: Needs some language corrections before being published

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