Reviewer’s report

Title: Ethical tensions in the informed consent process for randomized clinical trials in emergency obstetric and newborn care in low and middle-income countries

Version: 0 Date: 02 Aug 2018

Reviewer: Janet Seeley

Reviewer's report:

This is a very interesting a wide-ranging paper. It represents a considerable scholarly endeavour to draw the diverse pieces together. The title is much more specific than the actual content of the paper. I think the authors could consider three possible papers from the material they present! I would suggest, for the purposes of this submission they focus on the content implied in their title. This suggests that the paper would rest on the content from pages 17 onwards. The background would therefore be condensed to two or three pages before that to provide a brief overview of the challenges of consent in emergency settings and the broader background on RCTs in emergency obstetric care settings globally before coming to the specific focus on LMIC. The information on page 16 on autonomy is important (although I would suggest the authors are not so definitive in their claims of it being an alien concept... some for settings in LMIC that is not the case) and can be reworked into the material that follows. One point that I think should come out more strongly is the fears over care being denied because of not consenting to research and indeed consent to an emergency procedure being confused with consent for research participation - or seen as intimately linked (particularly when the staff involved are or seem the same). Another area, which is important in RCT, and indeed much clinical research is the pressure to recruit - and how this translates into how researchers and nursing staff view `consent'.

If this paper can be focused much more on the LMIC obstetric setting, then the material on defining vulnerability can be taken and turned into another paper. And indeed the much more general discussion of the meaning of concepts used in ethics and the case of emergency care more general, can provide material for a third paper.

As it stands, I think the authors are trying to do too much in this paper and it will be a much more powerful piece if it is more focused. It is a very important piece and has the potential to be extremely useful. Indeed all three potential papers are important!
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
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Unable to assess

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