Author’s response to reviews

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

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Ethical tension manuscript Point-by-point response

1. Abstract. Line 21: Check the use of the phrase "unanimous consensus". Would "unanimous agreement" or "consensus" be a better alternative?

Response: This has been changed to unanimous agreement (Line 21)

2. Line 188-199: There is some disconnect with the next sentence. Consider deleting lines 188-199

Response:

Lines 188-199 were deleted. The paragraph now reads as follows (Lines 188-200): The Declaration of Helsinki [26] addresses the dilemma of research without consent by allowing a waiver or modification of informed consent in some RCTs. For RCTs among individuals that are incapable of giving informed consent, the Declaration of Helsinki [26] gives guidance where the need or procedures for informed consent may be modified as manifested in some research in emergency situations [27-32]. The Declaration states that if no surrogate or patient representative is available and the research cannot be delayed, the study may proceed without participant consent under certain conditions: a) the specific reasons for involving patients as RCT participants is a disorder that renders them unable to give informed consent explicit in the
research protocol; and b) the study protocol is approved by a research ethics committee. The conditions for which RCTs may be necessary in emergency obstetric care (such as eclampsia, antepartum hemorrhage and obstructed labor) exist only in pregnancy, and more often as emergencies. Also, the complications may cause severe morbidity, which, as well as ongoing treatment (such as for pain), may be the reason for impaired cognition or decision capacity.

3. Lines 244-246" It is a repetition of lines 231-232. I suggest that the sentence be re-written or deleted.

Response: The sentences has been revised to read as follows: (Lines 237-241)

Exceptions to informed consent may be permissible in emergency obstetric care research, especially pragmatic RCTs [37-39], and where it is possible to conduct community consultations [40]. This approach may be more practical as it provides critical guidance for the conduct of research in learning health systems (where the generation of new knowledge, whilst important, is embedded in ongoing medical practice).