Author’s response to reviews

Title: Maternal cortisol and stress are associated with birth outcomes, but are not affected by lipid-based nutrient supplements during pregnancy: an analysis of data from a randomized controlled trial in rural Malawi

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Author’s response to reviews: see over
December 3, 2015

Dear Editor,

In response to your question below:

- While we understand that in Malawi participants <15 are considered able of providing consent, we kindly ask that you provide a reference to the relevant legislation which states this in your consent statement.

The regulations about the age of consent and emancipation of minors is a bit ambiguous in the Malawi constitution (http://sdnp.org.mw/constitut/dtlindx.html), which provides for Marriage of minors between ages of 15 to 18 with parental consent. The constitution further clarifies rights of children but uses a different age in another section which is 16 (child protection Act). National Sexual and reproductive health policies have interpreted this to provide for children 14 and above to be able to provide informed consent especially in documents related to HIV.

When we started the project we specifically sought IRB guidance which drew its interpretation from the liberated minor concept and they advised that having so been liberated and attained majority by engaging in sex and being pregnant, the individual 15 and above should be able to give consent for health interventions (especially those for which spousal consent further disadvantages the girl child e.g. sexual and reproductive health issues). In our study nonetheless we asked participants to discuss with spouses before consenting to take part. We have included a letter from the IRB (attached) stating their guidance on this issue.

Please let us know if you have any further questions.

Best regards,

Christine Stewart

Assistant Professor of Nutrition
Associate Director of the Program in International and Community Nutrition
University of California, Davis
2nd December 2015

Prof. Ken. Maleta
College of Medicine
P/bag 360,
Chichiri,
Blantyre 3.

Dear Prof. Maleta,

RE: Waiver on recruitment of participants under legal age of consent

I write to affirm to you that COMREC allows for a waiver on the recruitment age at which participants give consent. This waiver is given for pregnant women who are 15 years of age. The waiver is granted based on the premise that they are emancipated minors.

If in doubt or need further clarifications please do not hesitate to contact COMREC Secretariat on 01871911 or comrec@medcol.mw.

Yours sincerely,

Dr. C. Dzamalala
Chairperson, COMREC
CD/km