Author's response to reviews

Title: Consent and assent in paediatric research - recommendations for low-income settings

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To the Editor
BMC Medical Ethics

Dear Sir/Madam

Submission of Revised Manuscript

MS: 1863580689963243
Consent and assent in paediatric research - recommendations for low-income settings
Authors: Phaik Yeong Cheah and Michael Parker

Please find attached, a revised version of our paper “Consent and assent in paediatric research - recommendations for low-income settings” for your consideration. We have incorporated the suggested changes from the two reviewers for which we are very grateful, and believe that the paper is greatly improved as a result. We very much hope that you will think that the paper is suitable for publication as a result.

In what follows, we outline in more detail the ways in which we have responded to the reviewers’ comments and suggestions.

Reviewer 1: Janet Seely

We are very pleased that the first reviewer is very positive about the paper and considers it to be thoughtful and well written. We have responded to all her specific comments and suggested changes as follows:

1. We have provided a definition of competence. See “Discussion” section in the abstract.
2. We have included a discussion of the ICH GCP guidelines in emergency situations and explored their implications. See page 10, under “Urgency and Emergency Situations”.
3. We have proof read the paper and made the necessary corrections.
4. We have also made the two discretionary editorial suggestions and have included discussion of the protections that need to be in place to ensure that high levels of consent and assent practices are maintained. See section entitled, “Judgement and Accountability”, page 14.

Reviewer 2: Yann Joly

We are also pleased that the second reviewer identified a number of changes required for the paper to be publishable in BMC Medical Ethics. We found these suggestions and comments incredibly helpful and have made significant changes to the text in response to these. In response to the specific suggestions, we have done the following:

1. In addition to dealing with potential counterarguments to our position at relevant points within the paper, we have also included a section towards the end of the paper which identifies and discusses potential objections. See “Some Possible Objections”, pages 14-16.
2. We have included references to a greater range of relevant literature including some of those suggested by the reviewers i.e. reference numbers 11, 12 and 20.

3. We have replaced the Wikipedia reference with the UNICEF webpage which discussed the international variation in age of majority and its implications i.e. reference 17.

4. We have provided a definition of low-income settings, drawing on the definition adopted by the World Bank. See Endnotes 1 and 2.

5. We have made structural changes in the paper and believe that the paper is greatly improved in this regard. In addition to improving the presentation throughout, we have also accepted and implemented the changes requested by this reviewer. In particular:

We have emphasized in the abstract and summary that our primary argument is that a context specific approach when considering whether consent or assent should be sought from children. We are grateful to the reviewer for highlighting this.

As suggested by the reviewer, we have retitled our section heading “Problems of Assent in Low Income Settings” to “Challenges arising when assessing whether consent or assent should be required from a child for research participation in low-income settings”. See page 5.

The subsection “Lack of familiarity with medical research” now follows the subsection “Children may be better informed than their parents”. See page 7.

6. We are pleased that the reviewer highlighted the potential novelty of the paper. We have made changes in the abstract and throughout the paper to emphasize this.

7. We have discussed the potential for abuse of the proposed approach. See section “Some possible objections”, pages 14-16.

We have discussed the potential tensions between parents and children. See subsection, “There is increased potential for tensions to arise between parental consent and childhood refusal (dissent)” under “Some Possible Objections”, page 15.

8. Regarding best interest, see discussion under “Assent should be sought from incompetent children in addition to the obtaining of parental consent” on page 13, paragraph 1.

9. We have discussed the waiver of the signature of the child and have proposed the documentation requirements. See paragraph 2, “Judgement and Accountability”, page 14.

10. Finally we have outlined the role of ethics committees and enforcement procedure in ensuring good practice. See paragraph 1, “Judgement and Accountability, page 14.

We very much hope that you will agree that these changes have greatly improved the paper and that it is now publishable. We look forward to hearing from you. Thank you very much.
Kind regards.

Phaik Yeong Cheah     Michael Parker