Reviewer's report

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

Version: 4
Date: 10 January 2014

Reviewer: Yann Joly

Reviewer's report:

I have read with great attention the third version of this manuscript: “Consent and assent in paediatric research – Recommendations for low-income settings”. The authors have provided much needed clarifications, among which the context of their assessment by defining of the terms “low-income setting”; their perspective, which is based on their field work conducted in low-income settings; and the role of REBs. However, new and previous major compulsory concerns remain:

1. The practical experiences of the authors, which would be a great contribution, are lacking in the paper. Various parts of the paper emphasize that the manuscript is based on the field experiences of the authors (pp. 1, 4, 20) and yet, the paper does not contain any specific illustration (experience, example, case or study) or discussion of specific normative disposition(s) (in laws, guidelines, or norms) in a low-income country to attest of the issues raised. Furthermore, while South Africa, Thailand and Malaysia are mentioned on page 5, their relevant guidelines or norms are not discussed to illustrate the authors’ position.

2. Many affirmations in the paper are not supported by any references (previous compulsory revision). For example, the position of the authors on assent, as defined on page 15 (and which should have been included in the introduction of the paper) is similar to other authors such as Sibbey A, Sheehan M, Polland AJ, “Assent is not consent” J Med Ethics 2012, 38:3. Other examples can be found throughout the paper and should easily be addressed by including illustration from the practical cases experienced by the authors or through cases and studies reported in the literature see for example Molyneux CS, Peshu N, Marsh K, “Understanding of informed consent in a low-income setting: three case studies from the Kenyan Cost” Soc Sci Med 2004, 59(12):2547-59.

3. There are many contradictions in the paper (includes previous compulsory revision). For example, the authors’ proposal criticizes the use of written documentation for the consent/assent processes (such as at pp. 6, 10-11) but yet offers the same reporting means as a solution for safeguard mechanisms (see pp. 15, 16, 20). Potential alternatives are not discussed (see for example Molyneux et al –cited above, identifying video or audio recording as viable alternatives). Additionally, the term “competent” child is not defined by the authors, nor are clear factors provided to assist researchers in this assessment. We note that the proposal criticizes the used of chronological age and school age...
qualified as arbitrary and yet relies on the fact that children in low-income setting may be better informed than their parents because they had the opportunity to attend school (see p.9). The author should clarify the minimum age required for a child to be assessed and deemed competent if other factors are present or emphasize that age should not be “the” but one factors in this assessment.

4. The paper fails to properly present and address counter arguments (previous compulsory revision). Among the five counter arguments presented by the authors, only the point on the potential tendency of a researcher to exaggerate competence (p.18) is actually presented, discussed and addressed. The section on scenarios on page 19 does not present a counter argument and should rather be used to illustrate the issues about defining competence (p. 18). All other counter arguments were not presented or discussed (i.e. only the authors point of view was provided under the sub-heading). As requested in the previous evaluation, the paper fails to determine the elements that could be taken into consideration when assessing when the best interest of the child is not being served. Example of parents refusing consent despite the fact that the research would provide access to medical services and goods (see p. 15) is insufficient given that such refusal could be justified by associated research risks; and research in low-income is likely to provide such advantages. Elements to take into consideration could be based on international or local norms and principles.

**Level of interest:** An article of limited interest

**Quality of written English:** Acceptable

**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