Reviewer's report

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

Version: 2 Date: 23 September 2013

Reviewer: Yann Joly

Reviewer's report:

The grammar and structure of this second version of the article were greatly improved.

Major Compulsory Revisions:

Nonetheless, the main substantive points raised by the reviewers in terms of addressing counter arguments, substantiating the position asserted and addressing the need for safeguard mechanisms to prevent potential abuse was not addressed. The specific elements from our first review that have not been addressed include:

- Aside from reference to some international instruments, the paper fails to present or acknowledge any counter arguments from current literature and relies solely on excerpts from selective guidelines.

- The paper should define low-income settings and the specific application it refers to as it is currently too broad. For example, even within low-income settings, there are different types of populations, income levels, urban vs. rural areas, indigenous people, long-term vs. short term research, type of harm involved with the research, etc; these elements cannot be broadly compressed together since they have very different implications.

• The points referred to as problems of assent are actually points to consider when assessing whether consent can be obtained directly from the child. However, this need to be nuanced and safeguards from abuse should also be discussed, including cases where the child refuses to consent while his/her parents have agreed to the research (in the case of the emancipated child).

• The paper also fails to provide any criteria in determining when parents are not acting in the best interest of the child when refusing to consent.

• The waiver of the signature of a consent form by the parent of the child, should be documented by the researcher and the appropriateness of not using a form should be justified

• Additionally, the role of ethics boards and enforcement procedures should be clarified as too much discretion seems to be left in the hands of the researcher. (emphasis added)

Similar comments from the other reviewer were also underlined and yet not
addressed in this second version of the paper:

p. 13 -- While I agree with the idea of the research not the child documenting consent/assent -- should there not be a copy of the form put on the trial files? Yes, I realise this is part of the `strangling of clinical research’ through paperwork that the authors refer to, but for all practical purposes the procedures are being followed diligently in many places and I fear that if the documentation is not requested for the clinical trial files then people may come to see the child's consent/assent as unimportant. That is the downside of what the authors suggest -- provide flexibility and for some that may be an excuse to do away with the process of asking children. A key challenge is, indeed, how to manage cultural and social diversity when deciding who should or should not be asked for consent -- the authors might mention the risks involved in what they suggest in eroding rather than enhancing child rights, if taken in the wrong spirit.

Given that the thesis of the paper is to depart from current international norms and rules (including current national rules in high and middle-income countries including some low-income countries – For example, South Africa requires parents’ consent and children assent; see Wendler D S ‘Assent in paediatric research: theoretical and practical considerations’ 2006 J Med Ethics 32(4):229-234), the authors will be expected to persuasively present their arguments by substantiating them and addressing both counter points and the limits of their proposition. Despite recommendations from the reviewers, this was not done in this second version of the paper. Therefore, the paper, as it stands, should not be recommended for publication.

**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.