Reviewer’s report

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

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Reviewer: Yann Joly

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While this paper propose some interesting considerations in the assessment and application of the requirement for consent and assent in the context of medical research with children in low-income settings, the poor structure, sloppy writing, minimal research and one-sided argumentation makes it unfit for publication.

- 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.

- A significant recent publication from BMC medical Ethics addressing similar issues has been overlooked: Divya Rajaraman, Nelson Jesuraj, Lawrence Geiter, Sean Bennett, Harleen MS Grewal, Mario Vaz and TB Trials Study Group “How participatory is parental consent in low literacy rural settings in low income countries? Lessons learned from a community based study of infants in South India” BMC Medical Ethics (2011) 12:3. Other related studies that should be reviewed include Hilary Creed-Kanashiro, Beatriz Ore, Maria Scurrah, Ana Gil and Mary Penny “Conducting research in developing countries: experiences of the informed consent process from community studies in Peru” 2005 J. Nutr. 135(4):925-928; Shapiro, et al (2001), Molyneux, et al (2004) to name a few.

- Reference to Wikipedia (See reference No. 14) should be avoided in a scientific paper, especially given the availability of numerous published sources on the subject matter.

- 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 paper has major structural issues needing the grouping of sections, reformulating of premises, for example, the “problems of assent in low-income settings” should be rephrased as points to consider when assessing whether consent or assent should be required from a child. In the same section, subsections should rearrange to flow from one another, for example, the sub-section on “unfamiliarity with medical research” should follow the section on “children may be better informed than their parents”.

4. **Novelty:** The potential novel contribution of the paper is its proposal that a context specific approach should be used when assessing whether consent or assent should be sought from children in low-income settings.

- 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. The second paragraph the accountability section should be moved to discussion section on consent and assent.

Grammar: Far too many typos and important grammatical error to be acceptable for a scholarly publication

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

**Quality of written English:** Not suitable for publication unless extensively edited

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

No competing interest