Reviewer’s report

Title: Comparison of paediatric health research consent forms in Canada: working towards best practices

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Reviewer: Martine de Vries

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Major Compulsory Revisions

This is a very well written, important paper on ethical requirements of paediatric health research consent forms.

1. This manuscript actually can be seen as the sum of three interrelated research enterprises:
   A. An analysis of Canadian paediatric consent forms
   B. A review of the literature on some emerging issues in consent form content, with only limited information from the analysis
   C. Formulation of best practices

This makes the manuscript very rich of information, but also raises questions. The first one concerns the real research question the authors want to pose and answer, and the methods used to answer this question. What is the real goal of the authors: to give an analysis of existing consent forms or to formulate best practices? Do the authors really need the analysis to come to the formulation of best practices? What does it actually add? What is the connection between the analysis of the consent forms and the formulation of best practices? The authors should be more clear on this, especially because some of the emerging issues are so new that the logical result is that many consent forms do not address them. Alternatively, the authors can decide to split the paper into two manuscripts. One dealing with the analysis, and exploring the contexts and reasons behind consent form gaps and variability (which is missing now); and the other dealing with a review of the literature on emerging issues in consent form consent and subsequently formulating best practices. This latter approach would also resolve the problem that the manuscript is very long right now. As it is now, the Discussion paragraph is more a review of the literature on emerging issues than that it is a discussion of the results of the analysis. There is too little connection with the results. The discussion and conclusions are not adequately supported by the data, but are a paper in itself.

The review of the emerging issues itself and the Best Practices formulation are very well written and a valuable contribution to the existing literature. If I had to choose between a paper on the analysis of the consent forms and a paper on the emerging issues and best practices, I would definitely choose the latter one.
The analysis of the consent forms itself is also thorough. The data are sound and the manuscript adheres to the relevant standards for reporting and data deposition.

2. The authors admit on page 25 that they did not address the entire range of emerging issues that are discussed in the literature. In the Data Abstraction paragraph, the authors should explain how they came to their framework to code the consent forms. In other words, how did they come to the a priori codes, especially the ones about the emerging issues? Why were some chosen and others excluded (such as incentives)?

Minor essential revisions
1. Page 3-4: “Inconsistency and lack of… children’s rights”. I do not quite understand why inconsistencies in consent forms impede data and sample sharing. And why does it undermine researchers’ trust? What about parents’ and children’s trust and the trust of society as a whole in research enterprises?
2. Page 6: as well as other sections addressing areas such as… (Chapter 13). Is this a Chapter in the TCPS?
3. Page 6: “a categorical form for analysis…. Emerging issues”. I do not understand what this means, especially not concerning the sentence between brackets. Could the authors elaborate on this?
4. Page 9: Other forms, however, address the right to withdraw only to the parents and not to the child. [TO missing].
5. Page 13: the necessity (and practicality)… actively participating. “and consenting participants” does not seem grammatically right.
6. Page 16: The cumulative burden of… The is one “be” too many.
7. Page 24: “While it may be the case…. Maturing children”. Do you mean “in the absence of explicit disclosure….”? 
8. Page 24: “we suggest some best practices…. research”. Do you mean “to improve consent forms, and to facilitate harmonized….”?

Level of interest: An article of importance in its field

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.