Author's response to reviews

**Title:** Emerging issues in paediatric health research consent forms in Canada: working towards best practices

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**Author's response to reviews:** see over
October 8, 2012

Adrian Aldcroft
Executive Editor, *BMC Medical Ethics*

RE: Revised Manuscript Submission
Manuscript No: 1046224025749487

Dear Dr. Aldcroft,

Thank you for your letter of September 18, 2012 communicating the peer reviewer’s comments and inviting resubmission of the above mentioned manuscript. Following a consideration of these comments and a substantial revision of our manuscript, we are resubmitting "Emerging issues in paediatric health research consent forms in Canada: working towards best practices" for further consideration for publication in *BMC Medical Ethics*.

We are pleased the reviewers recognized our paper as an “important topic and one that is particularly pertinent to the pediatric research field” and that “this is a very well written, important paper on ethical requirements of paediatric health research consent forms” with a Best Practices formulation that is “a valuable contribution to the existing literature”.

As requested, we have addressed the points suggested by the reviewers. For your convenience, a point-by-point elaboration of the reviewer comments is attached. We trust that these revisions will satisfy the concerns of the reviewers and believe the recommended changes now significantly strengthen this manuscript.

Many thanks for your kind consideration.

Sincerely,

Edward S. Dove, B.C.L., LL.B.
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Responses to Reviewers’ Comments

Reviewer #1

1. **Given that consent forms were solicited from across Canada, I am surprised that only 43 forms were obtained. How many institutions (if any) declined to supply consent forms? I am concerned regarding whether this sample was large enough to be representative of the pediatric consent forms used across Canada.**

We agree with the reviewer’s assessment that our original description of the methodology was unclear about the type of study we had undertaken and why we analyzed 43 consent forms (from a total collection of 65). We have revised the manuscript to emphasize that our study was qualitative and intended to analyze a collection of consent forms to see how well they address emerging issues, rather than a survey-based, quantitative study that intended to represent paediatric consent forms used across Canada. Our sampling of consent forms was purposive to reflect a range of research designs, and was solicited from professional contacts such as the Mother Infant Children Youth Research Network (MICYRN), which links all 17 child health research organizations situated in medical schools of Canada. Considering this is a qualitative analysis, we acknowledge in the limitations section that our findings are not generalisable. As now described, we believe our manuscript reflects the original research undertaken, and more clearly distinguishes it from a quantitative research study.

2. **Although the content of the consent forms was analyzed, there was no examination of the presentation of information. ... While it is important that there be some uniformity in the included elements of consent across documents, they must also be easy to understand. I think this issue needs to be addressed in the article.**

We agree with the reviewer that presentation of information and its comprehension by participants are extremely important and relevant issues. While we recognize the significance of these issues, the aim of this paper is to identify specific issues that should be addressed and incorporated into consent forms. The quality of consent forms regarding readability was not a focus of our review. Given the complex nature of this topic, it would deserve a separate analysis of its own, and is one we hope to address in the future. In our Limitations section, we acknowledge that our data focuses on emerging ethical issues rather than on the context of the consent process or on the quality of consent form information and its actual comprehension by participants, which are discussed elsewhere in the literature but are certainly deserving of more future in-depth study.

3. **Much of the variation in consent documents is a reflection of the individual institutional REB or IRB, many of which are very inflexible with respect to modifying existing document templates for wording and formatting. The authors may want to discuss how we, as researchers, can overcome some of these barriers with a view to providing best practices that include innovative and understandable consent documents.**

The reviewer raises a critical point. Encouraging REBs to become more flexible and innovative with consent form templates is challenging. However, the focus of our review was not on REB variability. Our paper attempts to highlight some of the gaps regarding several emerging issues. By pointing out gaps, we hope to draw research and REB attention to best practices, with a goal towards allowing for flexibility depending on the nature of the study and local contexts. We state that ultimately it is a matter for each REB to keep abreast of emerging issues in paediatric research and to ensure that their consent forms reflect these issues, with a view towards adaptability as new issues arise or the other situations change. Moreover, we state that it is important for REBs and researchers to maintain an open dialogue to ensure that each inform each other of emerging issues and to not rigidly adhere to document templates for wording and formatting.
4. Although the manuscript is well written, it reads more like a dissertation than a research paper. The authors need to be able to condense the information for readability.

We have extensively revised the manuscript to reflect this suggestion, simplifying all sections.

As it is now presented, we condensed considerably the Discussion section to reflect our results, and also removed our analysis and discussion of the generally required elements of informed consent so as to focus exclusively on the emerging issues. Taking the reviewer’s advice, we have also substantially reduced the number of figures (from 8 to 1). The total word count has been reduced from 7,330 to 4,200.

We thank the reviewer for these helpful comments. Addressing them provided the opportunity to focus and limit our discussion to emerging issues. As a result, we have clarified our message surrounding the variability of the consent forms we analyzed in terms of addressing emerging issues, reasons for this, and how the best practices can ameliorate this.

Reviewer #2

We thank the reviewer for the kind words of praise on the manuscript, and agree that future studies should undertake an integrated approach for comparing consent forms and the “practice of consenting”. In our Conclusions section, we write that consent forms really must go beyond mere duties of disclosure to actually achieve understanding by participants. As the reviewer states, this would likely require some sociological work, and we hope to study this important issue in the future.

Reviewer #3

1. 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? ... The authors should be [clearer] 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. ... As it is now, the Discussion...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.

We thank the reviewer for this very important question and comment. We have fully revised our manuscript to emphasize our rationale for the paper: namely, to assess Canadian paediatric consent forms in light of emerging ethical issues in paediatric consent practices, to identify the many gaps and inconsistencies between the forms, how best practices could make a big difference in remedying these gaps and inconsistencies. To address this comment, which is similar to the comment provided to us by Reviewer #1, we condensed considerably the Discussion section to reflect our results, and also removed our analysis and discussion of the generally required elements of informed consent so as to focus exclusively on the six emerging issues we identified.

We think that as a result of these extensive revisions, the paper now reads as a cohesive, coherent whole. Our streamlined manuscript, at 4,200 words, is much clearer and focused; each section now directly connects to the other, and in particular, the link between the consent form analysis and best practices is clear. To address this reviewer’s comment, we also acknowledge in this revised version that not all emerging issues may be applicable to a given paediatric study, given either the novelty of the issue or because of the study context (e.g. type of study, location, size, etc.).

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)?
We thank the reviewer for these questions. We have revised our Methodology section and Limitations section to address why we looked at these six topics, namely because these are six topics that the paediatric research literature (see reference numbers 14-24) most extensively identifies as emerging, and that these six, while the most important, are certainly not exhaustive as the reviewer rightly suggests. We agree that more research should be done in the future to explore how consent forms address other issues such as incentives to participate in research, and we intend to do so with the consent forms we have collected.

3. 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?

We thank the reviewer for raising these important questions. We revised the points raised about why we consider consent form variability problematic, namely because 1) many large-scale study forms that do not consider the growing importance that many significant research funders place on broad data sharing may impede its flow through varying modalities of consent, data or sample coding, and data or sample transfer policies; 2) from an ethical viewpoint, inconsistency and a lack of harmonisation may unevenly protect research participants; and 3) it can undermine the trust that parents, children, researchers and society place in research enterprises, and ultimately cause harm to children’s rights.

4. Page 6: as well as other sections addressing areas such as… (Chapter 13). Is this a Chapter in the TCPS?

Yes, although we have now removed this sentence from the manuscript.

5. 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?

The section on data abstraction has been substantially revised to clarify our methodology. The section now describes how, following a modified qualitative thematic content analysis, the content of the consent forms was coded using an ‘a priori’ coding approach based on emerging issues falling under six domains, as represented in Figure 2.

6. Page 9: Other forms, however, address the right to withdraw only TO the parents and not to the child. [TO missing].

Page 13: the necessity (and practicality)... actively participating. “and consenting participants” does not seem grammatically right.

Page 16: The cumulative burden of... There is one “be” too many.

Page 24: “While it may be the case…. Maturing children”. Do you mean “in the absence of explicit disclosure....”?

Page 24: “we suggest some best practices…. research”. Do you mean “to improve consent forms, and to facilitate harmonized....”?

These errors have now been corrected.