Reviewer's report

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

Version: 3 Date: 19 July 2012

Reviewer: Alan R Tait

Reviewer's report:

This study compares pediatric consent forms extracted from various sites across Canada with respect to adherence with the required elements of informed consent and inclusion of six emerging themes. Using qualitative techniques, the authors reported that compliance with the required elements of informed consent varied from 35% to 100%. Furthermore, the authors identified several gaps in the consent forms with respect to addressing each of the 6 emerging issues. The authors advocate for the development of best practices for drafting pediatric consent forms to ensure uniformity of content. This is an important topic and one that is particularly pertinent to the pediatric research field. The manuscript is well written and comprehensive but, by the same token, is far too long.

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.

Although the content of the consent forms was analyzed, there was no examination of the presentation of information. For example, it would be really interesting to know if all were written at the recommended 8th grade reading level. What about document length or the use of techniques to improve formatting e.g., different font sizes, use of bolding or bulleted to highlight important elements. It may be that a consent form contains all the required elements but is written at the 12th grade reading level with dense text that is difficult for the layperson to read and understand. Thus, 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.

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 these barriers with a view to providing best practices that include innovative and understandable consent documents.

Compulsory major revisions

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. Eight figures and 2 tables are excessive and while the content is interesting, I found myself getting distracted by the sheer length of the manuscript. Importantly, the discussion can be pared down considerably without losing the message. Some of the results are repeated in the discussion which further adds to the overall length.

**Level of interest:** An article whose findings are important to those with closely related research interests

**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'