Reviewer's report

Title: The Best Interests of the Child and the Return of Results in Genetic Research: International Comparative Perspectives

Version: 3 Date: 15 August 2014

Reviewer: Lainie Ross

Reviewer's report:

I appreciate the revisions that the authors have made to their interesting manuscript about the best interest of the child and its application to the return of research results. I find it much clearer and offer only a few suggestions to make it even clearer.

As in the original document, the authors are clear that there is very little guidance about the return of research results to children. They then discuss international norms that define and provide criteria about the best interest of the child by examining the rights of children in various international documents. They extrapolate from the clinical context, a position that I do not fully accept, but in the revised version that they acknowledge this so that the reader can choose whether the arguments work. The first compulsory revision addresses one point that I raise because I am not convinced with the extrapolation. The other compulsory revisions are requirements for clarification and/or to make it clear in the document when the guidance is coming purely from the clinical context and it is the authors who are extrapolating, but not clear whether the providers or courts in these countries would agree.

- Major Compulsory Revisions

1) p. 2-3: “the best interests of the child framework remains the foundation for all decisions concerning children in research....” This is not the case. Minimal risk research can offer no prospect of direct benefit. One may argue it is not in the child’s best interest but still within the purview of parental decision making. If the authors remove the word “all”, the sentence works and allows for the small amount of research that may not be in the child’s best interest (but not against the child’s interests).

2) on page 11, they cite the ESHG, “[i]n the rare case that information about a preventable or treatable early-onset disease is found, [parents] should be notified regardless of their wishes providing the findings are subject to assessment of clinical validity and utility.” They then make the claim: this goes to the notion of giving greater weight to parental authority when the seriousness of the matter increases. .

a. First to whom does their refer “regardless of their wishes”. I think it refers to
the parents.

b. Second If it refers to the parents, then this says, we ignore not only the child but the parents when the seriousness increases. Please clarify.

3) I am still concerned about conflating clinical care with research. All of the British references on pages 13-14 are clearly about clinical care. The same is true in Spain.

4) Page 15 Canada, they discuss “concerning a child shall be taken in light of the child’s interests. And the respect of his rights.” I am not sure if the authors mean to be saying interests or best interests. This is a big difference and if the code only focuses on interests, then it is not necessarily consistent with best interest. Please review and clarify.

Minor Compulsory Revisions

1) On page 3 you use Convention on the Rights of the Child. You need to state that this will be referred to as CRC which you start to use on page 4. You also refer to this document as the Convention. For some readers who are less familiar with the documents you cite, this is confusing so you need to explain that this is another shorthand (or just use of these consistently throughout the whole paper).

2) You do not reference #27

3) Reference 29 should be Ross LF, Saal, HM etc. when you refer to it in the text it is (page 8) according to the American College of Medical Genetics and Genomics and the American Academy of Pediatrics. I have highlighted the words you are missing.

Discretionary Revisions

1) P. 18: To this triangular structure, we could add a fourth actor. Change the word could: we suggest adding a fourth actor. Or we propose adding a fourth actor. As written, I could say, you could but you don’t need to. Since you want to, make it a stronger claim.

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'