Author’s response to reviews

Title: Development of a consensus operational definition of child assent for research

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Author’s response to reviews:

We thank the reviewers for their thoughtful and insightful comments. We have responded to all the comments as described below and have highlighted the changes in the text in bold.

Reviewer #1 (Dr. Hein)

P5, phase 1, and P8, line 10: Could the authors explain why they did not include parents from young patients and adolescent patients themselves in the expert panel? This seems to be a missed chance, since their input would have been particularly valuable.

We agree this is a valid point and one that we had seriously considered. The purpose of a Delphi panel is to secure input from a variety of experts. While children would be considered stakeholders, we do not believe that they necessarily have the expertise to consider the information from an ethical perspective or as a means to develop an operational definition. While we did include parental input, we felt that younger children, in particular, would have difficulty completing the Delphi questionnaire and in assigning relative percentage values to each of the elements. We have added this as a potential limitation of the study (see discussion).

P4, line 23: The authors might add some data from more recent research (indicating that age is a fairly good indicator for capacity) which suggest that the age-based approach might be feasible from the clinical perspective.

Thank you for this helpful suggestion. We have added some data to address this including Dr. Hein’s own work. We apologize for our oversight of this highly relevant work. We have also cited Dr. Hein’s work in other areas of the manuscript.

P5, line 25: I would suggest the authors to elaborate more on the search strategy of the literature review, which terms and databases were used (if any)?

We based our search on our own knowledge of the literature, MEDLINE/PubMed, and Google Scholar. We have added this to the text.
P7, line 10: The authors might like to cite more recent key literature that is relevant here, the ones mentioned are published over 20 years ago.

We have removed some of the older references and cited some that are more recent. Many of the references to Delphi are old but are classic references and have been retained.

P7, line 13: Could the authors please explain why voluntariness is missing here as a construct? Could the authors please add the references which are referred to here?

We considered voluntariness as part of the disclosure i.e., that children need to be informed that their participation is voluntary and that they can withdraw at any time without penalty. We have added a citation with respect to the generation of constructs.

P11, line 19: Although the Delphi method seems a reliable method for qualitative research, it is surprising that only societal benefit is mentioned in the "Information for adolescents" and that risks of research participation are left out. Could the authors explain this?

In the initial iteration for adolescents, we had included “risks” of research participation, however, during the subsequent iterations, the panel chose to rephrase this to reflect how the child might experience the risks rather than risks per se. We believe that this reflects the way in which children often perceive risks i.e., as a perceived burden: will it hurt and/or how might this affect me; will it keep me away from my usual activities and friends? We have now added this to the text (see discussion).

P16, limitations: Could the authors explain whether the consensus definition is based on expert opinions of American scientists and clinicians and if any conclusions can be drawn for other nations? Eg., are the experts all from the United States or from other nations as well, and might cultural beliefs play a part in the final definition? Would the definition be apt for international use or would every nation need its own operational definition? Why would definitions in other countries be the same or different?

This is a good point. We had in fact approached a number of potential stakeholders from both the USA and abroad but unfortunately only received responses from US experts. However, in formulating our initial definition of assent we did consider several current definitions from countries outside of the USA. These definitions were in essence similar to the current US version so that while we cannot say how our new definition might be viewed in other countries, we would expect some degree of generalizability. We have added this to the text as a potential limitation.

Reviewer # 2 (Dr. Chapman)

It would be helpful in your final summation to go over the changes in your original conceptualization as well as what you have done to state the final conceptualization.
Thank you, we have added a summary in the discussion of the major changes that occurred from our original to final conceptualizations (see discussion).

Reviewer # 3 (Dr. Shackel)

(i) There is a need for more in depth discussion and reflection on the importance of presenting age appropriate information to child participants on the risks and benefits of the research so that they can properly be assessed by child participants as part of their decision as to whether or not they wish to participate in the research.

We have now added this to our discussion.

(ii) More detailed discussion of 16+ year olds is warranted and recognition of their maturity and autonomy approximating that of an adult. Of particular interest to this age group (but also more generally) is the question of how to manage potential conflicts between a young person who does not assent or is unsure about whether they wish to participate, and a parent that is strongly in favour of their child participating in the research.

We agree, these are excellent points. We have reinforced the importance of child maturity and autonomy but given that the ability to manage conflicts between parents and children was not a primary focus of this study we did go into this in detail. Certainly this would be a good approach for a future study.

(iii) The issue of privacy and confidentiality also needs closer consideration as a key component in the process of assenting children/young people. Often these issues are understood differently by children/young people and/or prioritised in different ways to parents/adults.

We agree and were somewhat surprised that confidentiality/privacy was ranked relatively low by the panel. It is important, certainly for children transition to adolescence.

(iv) It would be useful also to further explore specific issues around assent of child participants in the context of very different types of research e.g. clinical v non-clinical, medical/health v social/educational etc.

We agree that these are important issues. Unfortunately, as we stated, it is difficult to include all the nuances of assent within one definition. We had attempted to address this in terms of differences in age and risk profile of the study but agree that there are many other variables that could subtly affect the definitions. We should note that we do not necessarily hold our version to be definitive. Our purpose was to generate an operational definition that was practical and which covered the most important aspects of assent and which could serve as a source for future discussion and refinement.

Reviewer # 4 (Dr. Warner)
Thank you for the kind comments.