Reviewer’s report

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

Version: 0 Date: 22 Dec 2016

Reviewer: Irma Hein

Reviewer’s report:

Interesting manuscript, relevant for various disciplines (ethicists, clinicians, researchers, psychologists). I have some concerns.

Major concern:

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.

Minor concerns:

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.

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)?

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.

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?

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?

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?
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Unable to assess

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

Not relevant to this manuscript

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

Declaration of competing interests
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?
If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

'I declare that I have no competing interests'

I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal