Reviewer's report

Title: Consent and assent in paediatric research - recommendations for low-income settings

Version: 1 Date: 15 April 2013

Reviewer: Janet Seeley

Reviewer's report:

This is a very thoughtful and well written paper. I suggest the following minor essential revisions:

define `competent' and `incompetent' the first time the words are used in the paper (instead of towards the end). I would hope this paper will be read by people beyond those usually interested in ethics, so the use of the terms may not be clear.

p. 9 'Emergency situations' -- GCP guidelines state that there is a provision to waive consent/assent in emergency situations. That should be mentioned here.

Proof-read carefully -- there are a number of small errors.

Discretionary revisions

The two sentences on page 4, beginning `In addition, this require is seen as yet...' seems to express a strong opinion which may be better placed at the end of the paper -- in the conclusion. It rather distracts from the factual delivery.

p. 13 -- While I agree with the idea of the research not the child documenting consent/assent -- should there not be a copy of the form put on the trial files? Yes, I realise this is part of the `strangling of clinical research' through paperwork that the authors refer to, but for all practical purposes the procedures are being followed diligently in many places and I fear that if the documentation is not requested for the clinical trial files then people may come to see the child's consent/assent as unimportant. That is the downside of what the authors suggest -- provide flexibility and for some that may be an excuse to do away with the process of asking children. A key challenge is, indeed, how to manage cultural and social diversity when deciding who should or should not be asked for consent -- the authors might mention the risks involved in what they suggest in eroding rather than enhancing child rights, if taken in the wrong spirit.

Level of interest: An article of importance in its field

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 I have no competing interests