Reviewer's report

Title: Understanding and Retention of informed consent process among Parents in a Rural Northern Ghana

Version: 2 Date: 24 October 2007

Reviewer: Christine Grady

Reviewer's report:

General

-------------------------------------------------------------------------------------------------

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

Thank you for the opportunity to review the revisions that the authors made to their paper. The revisions have improved the paper, as it is now much clearer what the primary malaria study involved as well as how and when the parents of enrolled children were interviewed. I would recommend some further revision of the discussion/conclusions to highlight what this particular study contributes to the literature on informed consent.

As the authors said, they found ‘significant but varied knowledge…” (p.17). However, rather than celebrating the significant knowledge they seemed to find, they go on to note that other studies have shown that “…many parents have poor understanding of study information, particularly among those from low income areas where poor reading skills and lower education are prevalent.” Although their population is described as poor and not well educated, their level of knowledge a whole year after consenting to the malaria study was very impressive. The authors found that more than 90% of parents knew that their child was participating in research, that the research was related to malaria, could name at least one research procedure, knew that a blood specimen was taken from the upper arm, could name one direct benefit to their child, knew they would not be paid for participation, and remembered being told that participation was completely voluntary. That is better than most other published consent studies done anywhere! Some discussion of, and speculation about, why this is so would be very helpful.

In a similar way, the authors suggest that it was problematic that more parents recalled study benefits than recalled study risks. Given that the malaria study was a low risk study (a blood draw and questions every 2 months) with possibly significant benefit to the enrolled children (diagnosis and treatment of malaria), the parents recall seems absolutely appropriate- why should they remember risks when the risks are so minimal? The authors conclude (p.20) that “there is a need to continue to evaluate existing practices in order to ensure that information disclosed during the informed consent process rather than anticipated benefits influence research participation.” I am not sure why, unless the anticipation of
benefits is misguided and the information in the consent would correct the misconception. Neither of which seems to be the case here. Also, although I absolutely agree that there is a need to evaluate and improve existing practices, their findings suggest that their practices are fairly effective in informing participants.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)
A couple of additional points:
p. 16 mentions Table 1- but it is not included
p. 18 2nd par starts with “This finding…” – not sure which finding they are referring to.

Discretionary Revisions (which the author can choose to ignore)

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

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

Quality of written English: Needs some language corrections before being published

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