Reviewer's report

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

Version: 2 Date: 13 November 2007

Reviewer: Sassy S Molyneux

Reviewer's report:

I think this paper has been significantly strengthened, but I still have some concerns about publication in its' current form.

- Major Compulsory Revisions

1 - The entire paper needs careful editing for typos (and eg gaps between paragraphs and when a new one is needed, full stop positioning etc) and ideally to tighten some sentences, key points and arguments. Re sentences, see for example the first in the abstract, and re the key points and arguments, see some ideas below.

2 - Under background, it's important to highlight the difference between theory and practice in informed consent, and this could help structure the argument (ie first two paragraphas are what informed consent can achieve in theory, then move to challenges in practice, and finally documented efforts to strengthen informed consent processes?)

3 - Under methods I am not clear on how validity and reliability checks would be done on the consent document. Same for study instruments. It would also be very helpful to see the questions asked as an annex to help deal with the concern I am re-raising as point 4.

4- The words for research also mean investigation and are often interpreted in a clinical/illness setting at the individual level (eg investigation on my child's sample to find out what's wrong with him/her). In this paper, where the investigators report that 98% of the participants knew their children were involved in research (NB this figure is 90% in the abstract), are the participants understanding research in the same way that researchers are? This level of understanding is far higher than in the majority of high income settings and therefore of major interest if true. A problem with a lack of
clarity on this issue is that the remaining information - eg on risks, benefits, disease - can be based on a fundamental confusion about the purpose of the activity. If it's impossible to deal with this concern, perhaps it can be mentioned as a limitation needing further exploration in future studies (important given for eg that only about half knew at least one correct reason for taking the blood specimen...)

5 - It would be good to see a table of the results - ie that gives a better indication than Figures 1 and 2 of what comprehension of study risks is considered to be.... eg what did they have to say to get a tick on understanding of study risks.

6 - Clearly a year's recall is huge for informed consent information. This should be mentioned as a key limitation. I believe it would be good to have a whole paragraph in the discussion section highlighting the limitations. The importance of trust and of non information related reasons for joining studies is good to highlight (could also be in intro under informed consent in practice?). It it also worth discussing more. eg does it matter ethically if this is the main reason for joining? Is it a strength? Other papers have discussed this in the literature and might be worth referencing briefly.

7 - Given some of the above concerns, the findings and conclusions are rather unconvincing and do not seem to link well to 'suggested ways to improve upon the existing practices' (study goal). For example it seems very likely in the context that participants join studies for the perceived and probably real benefits of being involved. This has been shown elsewhere and is important. The question is does it matter? Is that not good, especially given that they do understand the research and have important health needs? It's a good balancing of benefits to researchers and benefits to participants? What ethical dilemmas and potential interventions does this introduce for the research centre? How can research review committees 'be proactive in informed consent process and monitoring so as to guarantee the efficiency of the process'? (and if there's significant comprehension of information disclosed what is the main issue that the review committees are having to resolve? Is it that there are too many benefits? - back
to whether or not this matters).

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

**Level of interest:** An article of limited interest

**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