Author's response to reviews

Title: Evaluation of the quality of informed consent in a vaccine field trial in a developing country setting

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Version: 2 Date: 21 July 2008

Author's response to reviews: see over
RESPONSES TO REVIEWER’S COMMENTS

Reviewer: Roger Davis

A. GENERAL

The authors wish to thank the reviewer for the analysis of the issues and hope that the new revision of the manuscript addresses the issues satisfactorily.

B. MAJOR ISSUES

1. The erroneous referral to risk ratio as a measure of association was noted and duly corrected in the indicated texts.

2. Authors agreed that the inference that
   a) Valuation as to what standard of informed consent is acceptable, and that
   b) Public health research could tolerate lower standards of quality of informed consent,

and modified the manuscript accordingly.

3. The analysis was mainly conducted on two levels:
   a) Number of respondents answering correct for each question, and
   b) Number of correct answers for each of the three “test”, recall, understanding and health rights knowledge.

   While provision has to be made for chance occurrence of a correct answer, the authors do not believe that the effect of chance occurrence is significant to warrant re-analysis, as the responses were exclusively used as binary entities (correct vs incorrect).

4. The comment about comparison of this consent study with studies in industrial countries is acknowledged, and modified to reflect the authors’ revised thoughts, hopefully to the reviewer’s satisfaction.

5. The issue about the reference to association of the consent quality with the knowledge of health rights was modified as suggested.

C. MINOR ISSUES
1. Associations identified as opposed to causality – modified as suggested.

2. Description of distribution – modified as suggested.

3. Editorial issue about non-sequential reference to tables – corrected in manuscript

Thank you

DEON MINNIES