Reviewer's report

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

Version: 1 Date: 30 June 2008

Reviewer: Roger Davis

Reviewer's report:

General Comments:

This paper examines the recall and understanding of information provided as part of an informed consent process for a clinical research study that was conducted in a developing country. This is a very important topic, but one that has not been studied extensively.

Major Issues:

In reporting the results of the logistic regression models (both in the abstract and in the results section), the authors have indicated that one group is xx ‘times more likely’ to have high scores than some other group. This is not correct. The summary measure from a logistic regression model is an odds ratio, not a risk ratio. Unless the event is a rare event, the odds ratio does not approximate the risk ratio. If you remove the phrases ‘five times’, ‘almost three times’, ‘almost five times’ and ‘2.17 times’, this will fix the problem.

In the abstract, the conclusion states that quality of informed consent found ‘can be considered acceptable for public health research.’ This is really a value judgment and no objective standard has been provided. One could present the same results and be outraged that a half of the participants had at more than a third of the recall questions incorrect.

Further, since the recall questions were multiple choice questions with only three possible answers, by chance alone, the average score should be 33%. The categories used in table 2 (high, high-medium, low-medium and low) are really somewhat misleading. To fall into the low category requires doing worse than chance. Similarly, the understanding questions were essentially true/false questions and answering at random would give an average score of 50%.

The comparison with results of studies in industrialized countries (second paragraph of discussion) is only valid only to the extent that the structure of and content of the questions used in those studies was similar to those used in the
current study.

In the last sentence of results, the association should probably not be referred to as being significant. The p-value is just below 0.05. However, no adjustment has been made for multiple comparisons, and there were clearly many associations examined.

Minor Issues:

Since this is an observational study, only associations can be identified, not causality. In the conclusion of the abstract, ‘predictive of’ should be replaced by ‘associated with,’ and in the second objective, ‘affected’ should be replaced by ‘were associated with.’

In the second paragraph of the results section, replace the phrase ‘non-normally distributed with skewing’ by ‘skewed.’ Since the outcome is not a continuous measure, it cannot be normally distributed.

Editorial:

Figure 5 is referred to in the text before figure 4.