Reviewer's report

**Title:** How Do We Know That Research Ethics Committees are Really Working? The Neglected Role of Outcomes Assessment in Research Ethics Review

**Version:** 1  **Date:** 22 January 2008

**Reviewer:** Colin Gavaghan

**Reviewer's report:**

Major Compulsory Revisions - none.

Minor Essential Revisions - none.

Discretionary Revisions - while not central to the piece, I found myself wondering about the comment on p.8, that 'in New Zealand, participants in clinical trials will not receive compensation for injuries unless the study was approved by a committee accredited by the national Health resource Council.' Does this mean it is incumbent on participants to satisfy themselves that the study is so approved? What of the participant who is injured during participation that s/he was led to believe had been so approved? Does this apply only to the no-fault scheme, such that recourse to civil litigation would be an option? While I have no reason to doubt the accuracy of this statement, I feel that, if it is worth including at all, I would like to know just a little more about its implications.

**What next?:** Accept after discretionary revisions

**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 that I have no competing interests.