

## **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:** 19 December 2007

**Reviewer:** Søren Holm

### **Reviewer's report:**

This is an interesting and thoughtful paper. It is well written and well argued.

The main question discussed seems to be "How do we assess whether RECs are actually improving the protection of human subjects?"

In answering this question it is important to realise that it can be read in two ways and the paper does not distinguish clearly enough between them.

The question the paper does discuss extensively is "How do we assess that an existing REC system is actually improving the protection of human subjects?", but this is distinct from the question which is important for many developing countries "Will the introduction of a REC system actually improve the protection of human subjects?"

The introduction of a REC system may improve the protection of human subjects merely by forcing researchers to submit protocols and get some kind of consent from research participants. It may do this even if it is not a very well functioning or well resourced system. In the pre-REC era in developed countries there was a significant amount of poorly planned research and research without any form of consent, and whatever view one takes of RECs and their function the introduction of a REC system at least weeded out most of those kinds of ethically problematic research.

I therefore think that the paper needs to make it clearer what question it is actually answering.

**What next?:** Accept after minor essential 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