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: 28 January 2008

Reviewer: Jerry Menikoff

Reviewer's report:

This paper highlights what is perhaps the most important issue that needs to be resolved with regard to the effectiveness of research ethics committees: determining what we expect those groups to be accomplishing, and then going ahead to measure the actual accomplishments.

I would suggest only some discretionary revisions. In particular, the points made by the authors to some extent echo similar arguments from others commentators. It would be helpful for them to expand their discussion and citations to reflect that. For example, the article by David Hyman in the Northwestern University Law Review symposium that they cite for other purposes specifically looks at the costs and benefits of IRBs in the U.S.; see also the article in that issue by John Mueller. And more generally, these articles are a part of a recent trend toward examining the costs and benefits of such committees (particularly with regard to social and behavioral research). It would be helpful for the authors to make it clearer how their views relate to that recent line of inquiry.

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 am a co-author with one of the authors on a textbook about the ethics and regulation of research with human subjects.