Reviewer's report

Title: The impact of consent on observational research: a comparison of outcomes from consenters and non consenters to an observational study

Version: 1 Date: 21 November 2007

Reviewer: Rustam Al-Shahi Salman

Reviewer's report:

This is an important paper, that adds to a body of evidence with huge implications for the governance and ethical review of observational research.

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached):

I would simply suggest addressing the issue of audit being allowed access to medical records, and observational research not (when these two activities are often indistinguishable). Even the authors' original study could be considered an audit! The double standards about the regulation of these two activities are intolerable, but can be exploited to researchers' (and patients') benefit, too.

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)


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Discretionary Revisions (which the author can choose to ignore)

None.

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'