Reviewer's report

Title: Sharing data from clinical trials: the rationale for a controlled access approach

Version: 2 Date: 23 December 2014

Reviewer: Deborah Ashby

Reviewer's report:

1. Is the question posed by the authors new and well defined?

Yes- data sharing is very topical, but much of the discussion is of principles, rather than addressing some of the very practical issues that are raised when sharing individual level data rather than just summaries. This paper addresses these issues.

2. Are the methods appropriate and well described, and are sufficient details provided to replicate the work?

The paper describes its ‘methods’ clearly, although as a ‘Methodology’ paper they are a little different from the study-specific methods this question implies. It is primarily a report of the practice of the MRC CTU in data-sharing, and very valuable for that, being based on actual rather than hypothetical experience. The supplemental tables are a useful resource for others who wish to take a systematic approach to this issue.

3. Are the data sound and well controlled?

N/A

4. Do the figures appear to be genuine, i.e. without evidence of manipulation?

N/A

5. Does the manuscript adhere to the relevant standards for reporting and data deposition?

Yes, in so far as they apply- the issues and practicalities of this is the topic of the paper!

6. Are the discussion and conclusions well balanced and adequately supported by the data?

The commentary is particularly helpful, as it raises new issues such as disclosure of data to the individual themselves outside the consulting environment. I suspect some might feel they are being paternalistic on this one, but it is very important to have the issue named so it can be part of the debate. Equally there will be different views on ‘data distortion’, but it is valuable to know the policy of this unit-
and for the record I agree with them on this one.

7. Do the title and abstract accurately convey what has been found?
   Yes

8. Is the writing acceptable?
   Yes.

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

None

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

1) Box 1 and Box 2 have the same title, but are referred to at different points in the text. It would be better to have different titles

Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore)

None

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests