Reviewer's report

Title: Whose data set is it anyway? Sharing raw data from randomized trials

Version: 2 Date: 20 April 2006

Reviewer: Jonas H Ellenberg

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General

The addition of Table 2 is a major improvement as it puts into context the rest of the text. It does, however, create a contrast between the rather confident and non yielding language used in the text and the more reasonable language and concepts provided in the Table. I have read the new manuscript in a new light with the table as a good reference point.

The topic remains very important and your approach needs to be considered by the research community. I fear that without additional word smithing, your message may get muddled by what I perceive as dogmatism.

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

Take each declarative statement and make sure it is unambiguous. Make sure it cannot be weakened a bit to allow for exceptions or disagreement. For example, by implication, the annotation for your data set would be trivial because of the existing data analysis set preparation and the ability to resource the primary publication. What if a there is an outcome or covariate that requires adjudication by an independent committee because of its complexity. It may be difficult for a journal to provide the space for the arguments for each outcome determination, yet a reanalysis may very well want to consider another system for assigning outcomes. This sort of annotation may not be trivial. The point is that you need to allow that some of your arguments may have some or many exceptions.

You allow a reader to click to see your entire data set, presumably demonstrating the ease with which the work of many years can be made public. I don't doubt that the transfer is relatively easy, but getting to that stage and how fast, will likely not be as easy as a click. Further, in the new Table 2, you offer that only the data for already published primary analyses be released in a timely fashion, allowing for a 5 year time frame to release the entire data set. This is reasonable. Your click is not.

In contrast to total release, you argue that the clinical trials should decide how detailed the release should be. You use an example of the SF 36. I'm not sure how this fits with your argument for complete release.

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

In Table 2, it should be made clear that the offer of co-authorship is not gratuitous but rather would serve the purpose of having the clinical trialist involved in the new analysis.

Discretionary Revisions (which the author can choose to ignore)

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article of importance in its field

Quality of written English: Acceptable