Reviewer's report

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

Version: 1 Date: 28 February 2006

Reviewer: Jonas H Ellenberg

Reviewer's report:

General

Dr. Vickers has commented on an important and timely issue. My assessment of the author’s arguments is that they are cogent for the most part, except for essential dismissal of the sensitivity of individual investigators to their appropriate yield from their work, as an affront to fair play.

-------------------------------------------------------------------------------

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

1. Author needs to confront the workload and expense associated with the creation of a public domain data set. This will include not only the initial publication of the data set in user friendly form and ready distribution, but also the continuing costs of potential updates, responding to inquiries, etc. It is a non trivial exercise to create a data set that will yield its fruits to investigators having no relation to the original data collection. Commentary is necessary on whether federal agencies have added dollars to grant and contract awards for the creation of public data files (including their long term maintenance and responsibilities for outside inquiries) or whether this has become a new requirement without compensatory increases in funds.

2. Author needs to provide a practical plan for investigators that insure that their investment along with that of the funding agency is fairly compensated. To imply that anything less than complete forfeiture of publication rights would be an offense against the patient participants is neither realistic nor fair. Publications and intellectual productivity are the currency with which investigators survive, for a substantial part of the research community. The author should provide the reader with some broad mechanism that will define a reasonable time and scope of work for exclusivity. This is not an easy task nor will it necessarily yield a universal algorithm.

-------------------------------------------------------------------------------

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. Author needs to pay some attention to the moral, legal, and other obligations of the provider. This would include liability for errors.

2. Author should address the distinction between the argument presented for clinical trials and the case for observational studies

-------------------------------------------------------------------------------

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