Reviewer’s report

Title: The challenges of multi-centred clinical trials in neonatal units

Version: 4 Date: 22 March 2009

Reviewer: Diana Elbourne

Reviewer’s report:

- Major Compulsory Revisions

1. This paper is called a Commentary but it is really a case study which, while containing some interesting information, is not a category of submission that is currently allowed for in TRIALS. Commentaries should be “either (i) a discussion of a research article that was recently published, or (ii) a discussion of an issue that is relevant to the scope of the journal”. The paper as it is currently written falls uneasily between these two stools. Of course multicentre clinical trials are within the scope of the journal, but I don’t find this essentially descriptive paper substantial enough to stand alone as (i), but I wonder if it could be revised as (ii) discussing the recent Commentary by Vickers on cancer trials in the USA (Vickers AJ. Do we want more cancer patients on clinical trials If so, what are the barriers to greater accrual. Trials 2008, 9:31 http://www.trialsjournal.com/content/9/1/31), and spelling out whether the same arguments apply for UK trials and for neonatal trials, or whether, as the paper currently applies, UK and neonatal trials are substantially different? As this suggestion is for such a substantial re-write, it isn’t easy to comment on the details of this paper as currently written.

2. The title should be changed to reflect the fact that this is really only about the UK.

3. The authors should clarify whether they think the recent major regulatory changes for investigational medicinal products have merit and are just currently difficult to implement as people and institutions gain experience, or whether their argument is about all or part of the changes in principle and if so, why?

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Declaration of competing interests:

Not really competing interests, but ‘interests’ in so far as I have worked with Mike Weindling over many years and have considerable respect for him