Reviewer's report

Title: Bureaucracy stifles medical research in Britain: a tale of three trials

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Reviewer: Laura Sheard

Reviewer's report:

I enjoyed reading this important and timely paper. The aim of the paper was apparent and the reader is lead through the paper in a clear and concise manner. The authors were able to summarise a large volume of complex information through the use of well designed figures and boxes. I would definitely recommend this paper for publication. It makes an important contribution to the growing body of literature regarding how approvals bureaucracy is stifling important medical research. Moreover, the paper demonstrates that approval difficulties exist across a range of different studies (the authors outline three different trials) and as such are therefore not aligned to an individual study design. The cost increase of around 40% is staggering and very newsworthy.

I have a few comments which I believe may improve the paper:

- I would like to see some quantification of the amount of effort that navigating these bureaucratic hurdles took. It would be illustrative to see the amount of paperwork which goes into these processes and the ‘human hours’ which it has taken to overcome them. However, I appreciate that this is a retrospective study and there may not be the possibility of being able to quantify these elements at this stage. I will leave this point up to the authors to consider.

- I wondered if the authors are able to elaborate more on their very brief practical recommendations for change as a result of their experiences? (last half of last para of Discussion). I feel these could be outlined in more depth.

- Under the ‘Impact on the three sections trials’ at the end of the Findings, the authors give figures for how much extra the trial expenditure was as a result of the approval delays. The amounts are staggering. I wondered if the authors can comment on how this extra funding was granted. Did the trial funders grant an extension or was money found from elsewhere? If it was extension monies, what did the funders say about this issue? Was there a threshold at which the funders would not extend to? I think this section could do with more general comment and detail about how the increased expenditure was funded.

- I found Figure two a bit confusing given all the different keys (some of the keys looked the same). I wondered if the authors could redesign this table with the studies listed vertically? This may or may not possible – up the authors to decide.

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