Reviewer's report

Title: Obstacles to researching the researchers: A case study of the ethical challenges of undertaking methodological research investigating the reporting of randomised controlled trials

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Reviewer: An-Wen Chan

Reviewer's report:

Overall comments:
The authors present an interesting narrative case study about their difficulties in accessing trial protocols for methodological research. The manuscript is well-presented and easy to follow. I have a few comments that I hope will improve clarity and understanding of this important paper.

MAJOR COMPULSORY REVISIONS

1. Ethics committees often cite confidentiality agreements they have with researchers, particularly industry, when denying access to submitted protocols. The title pages of industry protocols that I've reviewed as part of methodological studies have written in large letters that the confidential document is only to be used by the ethics committee for ethics review. Should this issue be discussed in the paper, as well as potential ways to address it? Should the committees explicitly state in their application instructions that they reserve the right to conduct audits or methodological studies using the protocols?

2. Page 7, paragraph 3 – Another feasibility issue is that the overall proportion of trialists who would grant permission to access their protocols is generally low (eg. Hahn S et al, J Evaluation Clinical Practice 2002), rendering little yield for a large amount of effort.

3. Page 8, para 1 – “...so any commercial or intellectual secrets were already in the public domain.”

The authors would be accessing both published and unpublished protocols, so the latter would not be in the public domain. Even for published trials, some argue that there may be sensitive information in the protocol that does not appear in the publication. Would it be useful to explicitly distinguish confidentiality and anonymity in handling these concerns? ‘Secrets’ in published trials would be addressed with both confidentiality and anonymity via reporting of aggregate data, whereas ‘secrets’ in unpublished trials would be addressed with confidentiality.

4. Page 17, para 2 – Should the authors also mention here other major reasons for variation across ethics committees: perception of legal contractual obligations/barriers, fear of litigation (this was cited as the primary reason by a
university after I had obtained ethics approval), and fear of upsetting multinational sponsors who may take their trials elsewhere?

MINOR ESSENTIAL REVISIONS

5. Page 12, para 1 – “...would have the option of not taking further part in the project.”

Can the authors specify whether this means that trialists could opt not to participate in only the survey part of the project, or the entire study (ie. the protocol would not be used for comparing to publications)? If it’s the latter, then response bias would be introduced as this would be similar to obtaining consent up front from trialists.

6. Page 20, para 2 – “…identified failures of good reporting practice may implicate ethics committees themselves.”

Can the authors clarify how ethics committees would be implicated? As far as I am aware, ethics committees have not been held responsible for any misreporting or suppression of trial results, as auditing of reporting practices is viewed as beyond their remit.

7. Page 20, para 2 – “…the UOHEC did not have this dual role…”

The earlier description on page 8 explained that UOHEC reviewed category A studies, which presumably included trials?

8. Page 20, para 2 – “…suggesting that it had somewhat of a conflict of interest.”

Can the authors clarify how this represents a conflict of interest?

9. Page 21, para 1 – “…it could not be guaranteed that studies would not be identified by a small number people…”

If aggregate data are reported, and examples are fully anonymized, then how can anyone identify a specific study?

10. Reference 31 – the full title is “Research protocols: Waiving confidentiality for the greater good”

DISCRETIONARY REVISIONS

11. Is it necessary to identify the specific ethics committee in the paper? While it may be difficult to anonymize (given that the author affiliations are listed), explicitly naming the committee may be unnecessarily inflammatory without much added benefit.

12. Page 21, para 1 – “there was potential for embarrassment of trialists if it was pointed out that they may not have acted with complete scientific and ethical integrity and that this may not be a “bad thing”.”

Is this comment necessary to repeat in the paper? In order to gain acceptance and allay fears of this type of methodologic research, it may be better to present a less antagonistic approach. It is clear that there are many reasons for
discrepancies between protocols and publications, and some are legitimate. This type of methodologic research may cause embarrassment if misconduct is identified, but it also enables us to identify other potential reasons and explore the trialists’ decision-making process for selecting results to report.

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

**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