Author's response to reviews

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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Dear Editor,

We would like to thank the reviewers for their helpful comments on the manuscript. We have acknowledged their contribution in the revised manuscript.

Please find on the following pages our response to their comments and the changes we have made in the manuscript to incorporate their suggestions.

Reviewer: An-Wen Chan

Major compulsory revisions

• **Point 1:** In response to this suggestion, we have included the following text in the discussion which describes a potential solution which may allow for this type of methodological research to be undertaken with greater ease: “For example, prospectively informing trialists that their ethics application may be used in future methodological research or audits.” [page 20, paragraph 2]

• **Point 2:** We have changed the text in this paragraph to incorporate this suggestion: “In addition, we were concerned that the proportion of investigators who would provide consent for us to access their ethics applications would be low [Hahn et al 2002]; providing little yield for a large effort. Moreover, it could prejudice the scientific value of the study since trialists with less exacting reporting practices might be less likely to allow us access to their ethics applications, thus biasing and undermining the results of the study.” [page 7, paragraph 3]

• **Point 3:** We have altered the text to make it clearer that issues of confidentiality and anonymity apply to all trials, whether published or unpublished [page 8, paragraph 1]. We planned to publish research not only on selective outcome reporting, but also on the natural history of all submitted ethics applications, including those for trials which are not published.

• **Point 4:** We have included the additional suggestions of why there may be variation in ethics committees’ decisions: “Reasons for this variation may include concerns about legal contractual obligations, litigation, and fear of upsetting multinational sponsors who may take their trials elsewhere.” [page 18, paragraph 1]

• **Point 5:** We have changed the text “…would have the option of not taking further part in the project.” to “… would have the option of not completing the questionnaire.” to clarify that trialists could only opt out of the survey part of the project [page 12, paragraph 1].

Minor essential revisions

• **Point 6:** We are unaware of any ethics committees which have been held accountable for trialists misreporting or suppressing results. However, we do believe that ethics committees may have concerns that poor reporting of trials which they have approved may reflect badly on them, and subsequent ramifications. We have altered the text from “…even a concern that identified failures of good reporting practice may implicate ethics committees themselves.” to “…a possible, unwarranted,
concern that identified failures of good reporting practice may implicate ethics committees themselves.” [page 20, paragraph 3].

- **Points 7 and 8:** In this study we planned to investigate the reporting of trials submitted to New Zealand Regional Ethics Committees. These committees review health and disability research proposals that involve human participants, including clinical trials of healthcare interventions. The University of Otago Human Ethics Committee is an institutional ethics committee which does not assess clinical trials of healthcare interventions (please note that this information is depicted in Figure 2). However, they do review randomised controlled trials assessing the effect of interventions in areas other than health care, for example, psychology, education, and physical education. So while the University of Otago Human Ethics Committee in this instance did not have the dual role of reviewing both the ethics applications of RCTs included in our study and reviewing our ethics application to undertake this methodological research, we believe that they may have had somewhat of a conflict of interest stemming from a concern about being included in future methodological research. We have altered the text to reflect this [page 21, paragraph 1].

- **Point 9:** In some cases we believe it is difficult to fully anonymise data when reporting by particular combinations of variables which result in few observations per category. This was why we included this statement in our ethics application and subsequent correspondence with the ethics committee.

- **Point 10:** We have altered the reference.

**Discretionary revisions**

- **Point 11:** We thought this was a good suggestion and tried to make changes to anonymise both the Committee and University’s identity. However, because of our affiliations and acknowledgement of our funding support it became impossible to conceal the University’s identity, and in turn, the ethics committee’s identity. We have therefore retained the names of the institution and ethics committee.

- **Point 12:** While we concur with the suggestion that the comment regarding potential embarrassment may be perceived as antagonistic, we would prefer to include this statement since it is representative of what occurred and inclusion of it therefore provides a balanced and fairer representation of the correspondence which occurred between the ethics committee and ourselves. On reflection, we felt that the comment was a mistake on our part.

**Reviewer: Davina Ghersi**

- **Point 1:** Dr Ghersi has raised the issue of why obtaining “‘consent’ in the ethical sense is even relevant in this instance given the proposed research was on the documentation submitted as part of an application for ethics approval and not research on human beings”. We believe, and have stated in the manuscript (page 9, paragraph 1), that there were sensitivities involved in accessing ethics applications without gaining informed consent from trialists to do so. While the subject of the research is the ethics application and associated publications, these documents are reflective of the work of the trialists. The ethical issue associated with this is therefore one of potential harm to the trialists. Moreover, the University of Otago Human Ethics Committee’s ruling regarding this research indicates that they felt ethical concern regarding this research.

- **Point 2:** Dr Ghersi raises the issue of accountability and transparency of human research ethics committees which we had not addressed in our previous manuscript. We have now included the following text in the discussion to address this issue: “Finally, there is a groundswell of researchers advocating for increased transparency of decision making processes by ethics committees and refuting concerns about the threat such transparency poses to researcher confidentiality and academic
interests [Ashcroft et al 2001; Schüklenk et al 2005]. Greater transparency of decisions may confer many benefits. It may lead to greater protection of those who participate in clinical trials, improve the quality of the research, promote improved trust of ethics committees’ decisions from the perspectives of researchers and the public, and provide researchers with opportunities to learn about the ethical review process. Importantly, a more open process of ethical review encourages the questioning of decisions and is consistent with the principles of quality improvement.” [page 22, paragraph 2].

We look forward to hearing from you.

Yours sincerely,

Joanne McKenzie (on behalf of Peter Herbison, Paul Roth, and Charlotte Paul)