Author’s response to reviews

Title: Improving the process of research ethics review

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Improving the process of research ethics review
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Research Integrity and Peer Review

Dear Dr. Boughton,

Thank you for your consideration of our manuscript and thank you to the two reviewers for their thoughtful, constructive feedback. We believe the paper is much stronger.

We have addressed the reviewer’s suggestions as detailed below.

Reviewer 1
1. Model elaboration

    We have incorporated this suggestion with that of Reviewer 2 and have significantly elaborated on the model and its contribution in the Conclusion section.

Reviewer 2
1. Clarify/limit applicability to Canadian REBs
Thank you for this suggestion. The sentence “This model focusses on REBs operating within academic institutions, typical in Canada and the US” has been added to the background section (page 5). We have also broadened the initial terms used to describe REBs in the background (second paragraph) to recognize our European colleagues.

2. Inconsistency with respect to capitalization and “Institution.”
   
   Revised, now all instances are lower case.

3. Table of recommendations

   Now included, but defer to the Journal editor’s preference as to whether this is desired.

4. Case study

   Yes, we agree that describing/undertaking such a case study would be informative but such a study is beyond the scope of the present commentary, we do not have data available.

5. Duplicative review

   We have added more explicit wording regarding duplicative reviews and included the reviewer’s citation.

6. Addition to keywords

   “research ethics committees” added

7. Edits to the abstract

   We chose not to add “yet,” as we did not feel it improved the sentence, however we have made the second suggested change “from submission to decision”

8. Clarify/limit applicability to Canadian REBs

   Please see previous response to point 1.

9. Last sentence, Background section

   We have tempered the sentence to remove implication of direct causation. The sentences now read: The operationalization of “necessary and sufficient” is subjective and likely to vary widely. To the extent that the desired outcomes (i.e., timely reviews and approvals) depend on these resources, they too will vary.

10. Missing commas following citations

    Added
11. Issues surrounding cross border reviews.

Please see #5 above. We agree that there are additional challenges created with cross-border reviews. We prefer to develop this issue in detail within this manuscript as our intent is to provide a means to evaluate (and ideally improve) REB functioning within a single institution.

12. Extra comma

Added

13. REBS

Corrected to REBs. Suggested revisions to phrasing not made as we felt there involved too much word repetition.

14. Wording change to “Decision”

Done – good suggestion, thank you.

15. Abbreviation to REB

Done

16. Sentence revisions (wording, comma)

Wording revised to meet spirit of reviewer suggestion

17. Model

Our model is based on the methods advanced by Ishikawa and is used as a means of understanding time delays in processes. The resulting diagram is consistent with that theoretical model.

The model is intended primarily to illustrate the overall, high level process. Specifically, that multiple stakeholders are at work in the research ethics review process and that each stakeholder is accountable for specific tasks. The text expands on how time delays can occur. We believe that the model’s’ development is well explained as currently presented (pp 6-7).

18. REB abbreviation

Revised to REB members

19. Parenthetical clause

Country clarification added in nested brackets
20. Spacing and suggested revision to text

Corrected and text added, thank you.

21. Clarification and rephrasing requested

Yes, the implication was that based on past experience, administrators may understand
issues. This has now been stated explicitly in the text.

Wording revised to “consistently.”

22. Clarification/rephrasing requested

The comparison was in reference to the use of standardized tools. This has been stated
explicitly.

23. Period needed

Added.

24. Clarification re: limit to Canada and the US.

Thank you again for suggesting this. Consistent with the revision in the background
section, we have stated this applies to reviews undertaken by REBs operating under the auspices
of post-secondary institutions. We have also added the references to TCPS and 45 CFR 46.

25. Turn-around times in EU and UK

Referenced as recommended.

26. Conclusion

We have revisited the model in the discussion per both reviewers’ suggestions.

Thank you again for your consideration, we look forward to hearing from you.

Sincerely,

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