Reviewer’s report

Title: Improving the process of research ethics review

Version: 0 Date: 30 Apr 2017

Reviewer: Edward S. Dove

Reviewer’s report:

Dear authors,

Thank you for submitting this manuscript to Research Integrity and Peer Review. I enjoyed reading it, in no small part due to my research interest in research ethics/research ethics committees. I think it offers good recommendations to the research ethics community, and so recommend its acceptance for publication subject to some minor revisions, which I list below and are numbered (they are not in order of importance).

1. It would be helpful to clarify (or more accurately, limit) the scope of your review. I recommend you state in the beginning that the scope is Canadian REBs. It is fine in the Abstract and in the second paragraph of the Background to refer to US IRBs (or even 'research ethics committees', the common term internationally), but the paper itself really has direct application to Canada. Some of the recommendations may apply outwith Canada, but given that e.g. research ethics committees for biomedical research in the United Kingdom are under the NHS and not institutions (i.e. universities) and are centralised under the Health Research Authority, many of the recommendations will not carry over.

2. There is a mix of capitalisation of 'institutions' and 'Institutions' in the paper. Obviously consistency is the main point; I recommend the lower-case 'institution', but either works.

3. I recommend a table of recommendations in the paper. You have a number of good recommendations for stakeholders. How about a table that summarises the recommendations and to which stakeholder they apply?

4. Can you think of any case studies or examples of success where changes to a REB improved the timelines and/or quality of review? A case study or example could really drive home your recommendations or portray a narrative as to the challenges confronting the system.

5. I have written with colleagues in Canada and elsewhere about the systemic challenges of research ethics review of multi-site biomedical research across borders (i.e. inter-Canada and international). There is no need to cite our work (e.g. in Science: http://science.sciencemag.org/content/351/6280/1399), but it might worth pointing out that another challenge in the current system is duplicative review that only adds time and doesn't seem to add to quality of review, much less added protection of participants. In Canada specifically, see also the work of the CCTCC: http://www.cctcc.ca/index.cfm/our-
6. In the Keywords, perhaps you can add 'research ethics committees' as this is a commonly used term in other countries (aside from REB and IRB).

7. In the Abstract, some suggested edits: '...does not yet proceed unless ethical standards and regulations...'. '...particularly the duration from submission to decision, is common within...'

8. In the Background section, again, I would clarify the scope of your review along the lines of stating that your review and recommendations are most readily applicable to Canada given the structure of the REB system. Certainly some application will be to the US as well, which is similar, but again, will be less applicable to other countries (e.g. in Europe).

9. The last sentence in the Background ('The operationalization...') implies that the (various) outcomes are entirely dependent on financial and administrative resources, but of course as you state in the following section and on p. 13, there are other factors. I suggest you revise the sentence to not give this false impression of a causative relationship.

10. At the bottom of p. 4 (second paragraph beginning with 'Factors associated...') are missing commas following the citations. The same occurs in the following paragraph (beginning with 'Consequences of slow...').

11. In the paragraph beginning 'To enhance review efficiency...', you may want to discuss here the issues surrounding cross-border ethics review problems, in our work (Dove et al. 2016) and in others (just a suggestion!).

12. In that same paragraph, you should remove the comma between 'enhanced' and 'training'.

13. In the final paragraph of this section on p. 5, it should be 'REBs' rather than 'REBS'. The final sentence could be revised to read: '...and illustrates how each stakeholder makes contributions to the time an application spends in the process of review'.

14. At the top of p. 6, I would change the pathway (my suggestion) to: SUBMIT>REVIEW>OUTCOME (or DECISION) as it is clarifies that approval is not always the final result of a review (at least in the UK for NHS RECs, about 10% of applications receive an Unfavourable opinion, i.e. rejection, not even a 'provisional' which is essentially a 'please revise and return to us').

15. On page 6, you revert to the unabbreviated 'Research Ethics Board', but of course at this point in the paper it should just be 'REB'.

16. Consider a sentence revision to: '....and the Chair, until the application is deemed ready for approval (if ever). Again, this clarifies that the outcome is not always approval. On the same page, another suggested revision could be: '...permits better understanding of the workflow...'. I would remove the comma between 'exist' and 'so' in the same paragraph.
17. Regarding the model and Figure 1, this is very interesting and you may want to expand on the genesis of this for research ethics. I do wonder, though, if it sufficiently reflects the nature of ethics review. Given that process is not linear like in factory production (it's much more circuitous or rhizomic with flows back-and-forth and around, between different actors and leading to various outcomes, not always favourable), how would you account for this in the model, which seems built on a unidirectional, linear flow? It might be good to tease this out more in this section.

18. On p. 8, you revert to 'research ethics board' (this time lower case, too). It should be 'REB members'.

19. In the parenthetical clause under Researchers on p. 8, you may want to clarify that PRE is in Canada and NIH and FDA are in the US -- not all of the journal's readers may know this.

20. On p. 9, you need a space between reference 32 and the sentence beginning 'Moreover,...'. In the same paragraph, I suggest a revision to a sentence to read: '...that researchers should be required, rather than merely expected, to have an understanding of legal and ethics standards...'

21. On p. 11, you say that administrators 'are aware of areas where applicants may struggle'. It's not clear to me how they are aware. Can you please explain how? Is it because of past experience or knowledge the researchers/research team? In the same paragraph, and to match the same word in the same sentence, I suggest rephrasing to: '...and reviews that are consistently submitted late may provide impetus...'

22. At the top of p. 12, you say that 'Similar to the administrator's...'. I think it should be 'Similar to administrators', but I'm not quite clear on the similarity. What is the comparison made to? In the same paragraph, you state that it is good practice to match members' expertise to the application to be reviewed -- but of course this is contingent on the member not being consistently late in returning reviews (i.e. your previous point)!

23. Also on p. 12, a period is needed after reference 15 and the sentence that begins, 'This...'.

24. On p. 12, and the section on 'Institution', again it would be good to clarify that this is the case in Canada (and US), though of course there are also private REBs/IRBs, and in countries like the UK, there is a mixed REC system (in universities for non-biomedical research broadly speaking and subject to their own institutional guidelines, and in the NHS for biomedical research broadly speaking and subject to stricter standards, regulations and laws).

25. On p. 13, you suggest a model target turn-around time could be about six weeks. You may want to mention the turn-around times in the EU under the Clinical Trials Directive (60 days), and target times for NHS RECs (30 days I believe). The forthcoming EU Clinical Trials Regulation will demand faster turn-around times for RECs. The point is that (sometimes) regulating turn-around times helps drive needed reform, including forcing institutions/organisations to act (e.g. put more resources in RECs, as the NHS did in the early 2000s).
26. On p. 14, in your Conclusion, I suggest you revisit your proposed model, highlighting its strengths and what value you think it adds to the debate around RECs and research ethics -- and more generally, what your review adds to the literature. Some hints of this are here, but bringing it out a bit more would really end the paper well, I think.

I hope you find these comments useful in improving the manuscript. I appreciate the opportunity to read and comment on it.

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