Author’s response to reviews

Title: Why Research Ethics Should Add Retrospective Review

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Comments from Reviewer DR

The authors develop some convincing arguments for their position and consider some relevant objections. I think this is a good idea worth pursuing. My main concern has to do with implementing this retrospective review. The authors do discuss this at some length, but I have a few more questions they could address.

Authors' Response:

Thank you for these comments. We acknowledge that there will be challenges in implementing this process, but our main aim here is to defend the need for this approach and how it might be beneficial.

Comments from Reviewer DR1

1. Given that retrospective review is burdensome and time-consuming, would all studies be retrospectively reviewed? Prudence would suggest a kind of triage system in which some studies would not be retrospectively reviewed but other might be, depending on the level of risk, complexity of the issues, etc. For example, there might be no need for retrospective review of an anonymous survey or low-risk sample collection study. Other studies, such as gene therapy protocols, Phase I trials, community-based studies, etc. might be more suitable for retrospective review.

Authors' Response:
This is a good point and we appreciate the opportunity to respond. We have added some comments about a “triage” system in some places. We will identify comments using the page and line numbers in the previously submitted manuscript. These comments are on p. 5 line 15; p. 6 line 21; and p. 8 line 60.

Comments from Reviewer DR2

2. What would be done with the information obtained from retrospective review? Who would use it? I could see that oversight committees might use it for improving their prospective review in the future. For example, they could learn that risks would not well-managed in a study or that there were problems with the consent process. They could use this information for future oversight decisions.

Authors' Response:

We address this issue on p. 7 and have added further comments starting on line 25.

Comments from Reviewer DR3

3. How would the information from retrospective review be stored, analyzed, tracked? Who would have access to it? Why? I could be useful to develop some kind of database that could be used for quality improvement efforts.

Authors' Response:

We do not go into this in depth as it would depend on the type of retrospective review undertaken. We provide additional comments on p. 7 line 54.

IG

This paper suggests that the current model of prospective ethics review is limited in advancing the objectives of research ethics and proposes to supplement it with retrospective ethics review. The authors argue that retrospective review is better situated in terms of thinking through actual ethical challenges. The purpose of the paper is not to offer a particular model of retrospective ethics review, or to challenge the institutions of prospective and ongoing review, but to offer an argument that retrospective ethics review may help to enhance the research ethics dimension. The authors also discuss a number of possible objections to the adoption of retrospective ethics review - cost and potential bureaucratization, redundancy, and resistance from unethical researchers.
Authors' Response:

Thank you for this summary of our paper and the way you have captured our purpose.

Comments from Reviewer IG1

Major limitation of the paper is that it doesn't engage with the review model in general and prospective ethics review more critically. The authors adopt the review model as an adequate mechanism of ethical governance in research involving humans. Meanwhile, much of the criticisms of prospective review would also apply to retrospective review. Why not an ethics education model, for example, continuous and reflexive?

Authors' Response:

We appreciate this criticism and note that while we make some critical comments, we could have elaborated on these. We have added a paragraph developing this criticism on p. 3, and added some additional references to point to some of the literature on this. We also point to the importance of ethics education and other initiatives on p. 4 line 35; p. 5 line 45; and p. 6 line 11.

Comments from Reviewer IG2

One of the ideas to consider is whether an ethics spectacle is a good approach to ethics oversight and ethical governance in general? Many alternative models of ethical governance have been proposed in the past decade and it would make sense to introduce them in a paper like this, from complete deregulation, voluntary participation, random audits, to numerous specific modifications of ethics review.

Authors' Response:

We agree with these points. In the section on Why prospective research ethics review is not enough”, starting on p. 5 line 20, we have added a number of comments to make this more clear.

Comments from Reviewer IG3

Ethics review emerged as an attempt to overcome the limitations of the peer review model and withstand the pressures of research sponsors (initially government, and now also pharma and others) to advance our/their knowledge through unethical means. Has it been successful? Is the review model even capable of addressing such issues? Why do we focus on researchers rather than research sponsors? These are some of the questions that might be helpful in developing a stronger argument.
Authors' Response:

We have added some comments on p. 3 and included this concerns in the new paragraph on that page. We think that addressing all the stakeholders in research would require expanding the paper excessively, though we agree that many others beyond researchers need to focus on ethics. We have added some additional comments about other stakeholders.

Comments from Reviewer Ed1

I do think more could be done to acknowledge and engage with those who are critical of the current approach to the ethical governance of research, particularly in the context of the social sciences.

Authors' Response:

As noted above, we have added some comments, references, and a paragraph addressing these criticisms starting on p. 3.

Comments from Reviewer Ed2

What might be the negative and/ or unintended consequences of this administrative burden?

Authors' Response:

We address 3 of the main ones in the last section, and acknowledge that many more exist. Some additional comments have been added on p. 9.

Comments from Reviewer Ed3

Does this presume that researchers do not or are unlikely to reflect on ethics during the course of a research project or following its conclusion? If it does not, then would implementation of this proposal add anything of particular value? Is this added value an idealisation of what would likely take place in practice?

Authors' Response:

We acknowledge that some ethics reflection does occur, and appreciate the opportunity to clarify this. We have added some additional comments on p. 4 line 55 and p. 9 line 46.