Reviewer’s report

Title: Why Research Ethics Should Add Retrospective Review

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Reviewer: David Resnik

Reviewer's report:

This paper defends the idea of retrospective ethics review as valuable for improving the quality of ethics oversight of human subjects research. 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.

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.

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.

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.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

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