Author’s response to reviews

Title: Evaluating ethics oversight during assessment of research integrity

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Author’s response to reviews:

Maria Kowalczuk, PhD
Editor,
Research Integrity and Peer Review
2 October 2019
Dear Maria,

Re: RIPR-D-19-00023 Evaluating ethics oversight during assessment of research integrity

Thank you for the opportunity to revise this letter. We are very grateful to the reviewers and editors for their comments. We have submitted a revised version, with changes highlighted in bold text and track changes, and addressed the comments below.

We hope the revised manuscript will be acceptable for publication.

We look forward to hearing from you.

Yours sincerely

Andrew Grey MD
University of Auckland
Editor's comments:

1. Please provide an Abstract briefly summarizing your Letter.
Response: We have added a short Abstract as requested

2. Consent to Publish: please state 'not applicable'. In line with Research Integrity and Peer Review editorial policies Consent to Publish is needed for any manuscripts that include details, images, or videos relating to an individual person from which they could potentially be identified.
Response: We have made this change

Reviewer #1:

1. Each time I read about institution 2 (or institution #), I have to stop and sort it all out. I wonder if capitalizing "Institution 2" might help or something? As a reader, it hangs me up every time.
Response: We have made the suggested change. We hope that improves things. We are happy to consider other suggestions, such as naming the institutions concerned, if the editors think that would be preferable and/or clearer.

Reviewer #2:

With reference to their recent published article (Grey et al., RIPR, 2019), Grey and colleagues made an additional point in this letter that institutional investigations reported by the authors in their previous paper were glaringly lacking in references to ethics oversight as part of the investigation reports. This is of course an important point that should be flagged for discussion. The following points are for the authors' consideration.

1. A reason why ethics oversight was hardly mentioned would be because it was clear that the studies concerned did not have any ethics oversights, either because the boards/committees/processes were not in place, or that ethics approval were inadvertently not sought/deliberately avoided. The authors provided references to indicate that ethics approval processes and mechanisms would have been in place in a good majority of the institutions in Japan (which will concern institutions 1, 2 and 3) from a relatively early time. However, it is not clear in the writings whether institutions 1-3 had ethics boards at the time when work associated with the retracted papers were carried out. Institution 3 appears to be rather slack, but did it (and
when) eventually have an ethics board in place? What about the US institution (4)? Any additional information in this connection would be useful.

Response: Thanks for the comment. In paragraph 3, we report that neither Institution 3 nor one of the hospitals at which research reported in several publications was stated to be conducted had an ethics committee at the time the work was undertaken. That institution’s ethics committee was convened in November 2002. This information was obtained by Jonathan Schulz from the American Heart Association during his evaluation of several papers published in Stroke. We do not know whether the other Japanese institutions had ethics committees in place when the publications they assessed were reported. Many studies were reported to be conducted at hospitals, and references are made to ‘local ethics committees’ or a hospital ethics committee. Similarly, we do not know whether the US institution had an animal ethics committee in place at the time the research in question was undertaken.

What is important, in our view, is that ethics oversight should be evaluated and reported in institutional investigations, especially when concerns have specifically been raised about that aspect of the publication(s). In these investigations, ethics oversight was either not evaluated or not reported.

We strengthened this message by the following adjustments to the text:

Paragraph 1: ‘Institution 1 stated that 4 of 38 papers it assessed (all retracted) had been approved by its ethics committee, but did not report whether the other papers had received ethics committee approval. Neither Institution 2 nor Institution 4 mentioned evaluation of ethics oversight for any papers.’

Paragraph 4: ‘Institutional investigations should evaluate and report the ethical committee (name, reference number and date of review) responsible for each piece of work assessed.’

2. A proper and functional Institutional Review Board (IRB) is in fact a critically important anti-fraud mechanism, as the periodic reporting and audits mandated/conducted would likely heighten researcher diligence and deter attempts at misconduct. However, it is conceivable that some ethics boards may function as nothing more than a registry, with little actual follow up activities that would constitute proper oversight. If such an inadequacy is proven to be a concern as a result of publicised retractions or misconduct investigations, what would the authors recommend?

Response: This point is a very interesting one, but beyond the scope of our letter. We agree that a vigilant IRB/ethics process should help to improve research integrity. In addition to reporting requirements, spot audits may well be helpful