Reviewer's report

**Title:** Variability in research ethics review of cluster randomized trials: Scenario-based survey in three countries

**Version:** 1  **Date:** 21 November 2013

**Reviewer:** sarah edwards

**Reviewer's report:**

This paper presents new data to answer a well posed question and is, therefore, worth publishing. Any limitations of the methods used to collect these data are sensibly discussed by the authors, and the conclusions drawn from the evidence presented are sound.

I would suggest only two discretionary revisions before publication.

The first concerns whether the variability the authors identify and seek to iron out is always morally problematic. A discussion of this point would strengthen the authors' recommendations to use the Ottawa Statement. For analysis of the issue of differences between ethics committees see Edwards SJL., Ashcroft RA., Kirchin S. Are discrepancies between research ethics committees always morally problematic? Bioethics 2004; 18(4): 408-427.

The other point is minor: the terms individual- and cluster-cluster trials were first coined in Edwards SJL., Braunholtz DA., Lilford RJ., Stevens AJ. Ethical issues in the design and conduct of Cluster Randomised Controlled Trials. BMJ 1999; 318: 1407-1409. However, while the terms have become commonplace, their origin is rarely acknowledged in subsequent burgeoning literature.

**Level of interest:** An article of outstanding merit and interest in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I sat on the Expert Working Group for the Ottawa Statement to which this paper refers and was, as such, reimbursed expenses for this work from the Canadian project which also funded this project.