Reviewer's report

Title: When is informed consent required in cluster randomized trials in health research?

Version: 1 Date: 27 June 2011

Reviewer: Charlie Goldsmith

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In general, this manuscript is well done. However, there are a few suggestions that will hopefully improve the manuscript for readers.

1. P(age) 1, second to last author. Is there a reason why her email address is NOT underlined?

2. P 8, p(aragraph) 2, l 8. Suggest dropping [in order] in front of [to] as the words are redundant in English. Also P 28, p 2, l 2.

3. P 11, p 1. Try to reword your text to be gender neutral. You always place the male before the female. Is this intentional? So in l 2 suggest replacing [he or she] by [the person]. Likewise on l 4 suggest replacing [his or her] by [their] and on l 5 replacing [him- or herself] by [themselves]. Other variations can also work but still keeping gender out of the language when it is NOT needed. There are many more in the rest of the manuscript; however, they will not be noted.

4. P 11, p 3, l 3. While here you place a description of the study interventions as desirable information to disclose, later you suggest it is not needed. Should you not be consistent? See P 19, p 3, l 8 is in conflict with this because of possible bias. Also P 24, p 2, l 7 and 8 as well as what follows.

5. P 12, p 3, l 9. Since data is a plural word, suggest replace [is] by [are].

6. P 13, p 3, l 4. What is the time frame for incidence here? Is should always be clear, and is usually stated. Also P 13, p 3, l 13. Also P 18, p 3, l 5.

7. P 17, p 2, l 4. This would be a good place to provide an example of such a state.

8. P 18, p 1, l 6. Suggest replacing [population] by [group]. Few investigators get a chance to study a population. There may be a target population, however nobody ever successfully accesses all of the members, it is usually a sample.

9. P 19, p 3, l 11. This needs to be properly discussed. Not all bias is bad. It can be over or under estimate an effect, however, if the magnitude is underestimated and still be of clinical interest, the effect can still influence a policy. However, if bias makes an effect seem important when it is not by overestimating the effect, then that makes it invalid. This depends on the measurement properties of the tool used to measure the outcome of clinical interest. This also is needed on P
20. P 1, l 1 to justify the waiver here.

10. P 21, p 1, l 3. Suggest replacing [failing] by [inability]. The word failing is too strong as it implies it MUST be done. For a subject, they may not want to consent so how can it be a failure?

11. P 21, p 2, l 3. Suggest replacing [significant] by [important]. If this is meant to imply it is statistically significant; you need to say what is the referent category. If this is an opinion, then the word important is more suitable.

A random sample of 10 R(eferece)s was checked for citation accuracy.

13. P 34, R 6 and 7, l 3. Add [London ON] at the end of each. I was not able to verify these.
14. P 35, R 9 should have authors listed as [Faden RR, Beauchamp TL, King NMP].
15. P 35, R 10 should have two initials as [RM].
17. P 36, R 17, l 1. The third author is [Iqbal J]. There is no [u] in the name.
18. P 38, R 33 and 37 appear correct.
19. P 38, R 34 could not be verified.