**Author's response to reviews**

**Title:** An evaluation of a data linkage training workshop for research ethics committees

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To whom it may concern,

Thank you for considering the manuscript entitled “An evaluation of a data linkage training workshop for research ethics committees”. Please find the responses to the reviewers’ comments below. In making the suggested revisions the original line numbers have changed. We have included a reference to both line numbers for your convenience. Please find attached a revised copy of the manuscript.

Yours sincerely,

Kate Tan

**Major Compulsory Revisions**

1. A more comprehensive background is needed. What is the problem here? Is there evidence that HRECs are not able to do competent reviews? Is there evidence that research governance in this area is not done well? In relation to data linkage approvals. We know that ethics approval can take time, but it is the site authorisation of requests for access that is usually more complicated. Why then were HRECs targeted and not also custodians, data linkage units and the research governance officers who authorise access at particular sites? (AC)

Amendments have been made to the Background section to elaborate the perceived problem and the need for specialized HREC training in data linkage at L58.

The section discussing the scoping exercise has been amended indicating that although other training needs were identified, the training of HREC members was identified as the priority at L82-L85 as follows.

“The findings revealed a need for training of a number of groups including data custodians and researchers, however, training for HREC members in the area of data linkage was identified as a priority by a number of the data linkage units consulted [10].”

This article is focused only on ethics training. Although there are other challenges for data linkage such as the approval time for release of data and the need for multiple ethics reviews, which are being addressed in various ways, they are not the subject of this article and have not been included.

2. Please include what is said at line 34 at line 1. Why didn’t the strategy target other key groups? This is particularly pertinent as 121-129 indicate that it was participants from these groups that were the most strongly represented categories at the training sessions. (AC)
Line 34 (now 42) refers to the 3 approvals required for data linkage. This information is provided by way of background. Since the processes for data custodian and data linkage approval are not the focus of this article we consider it inappropriate to mention them in Line 1 of the abstract. The reason for giving priority to training HREC members is addressed in the response to Comment 1 above.

3. The National Statement and other guidelines include data linkage (see 3.2 NS). Is the National Statement important here? Did the training consider NS guidelines on data linkage? (AC)

Amendments have been made by the authors clarifying that the content of the training was framed around the National Statement core values and provides particular reference to the data linkage specific issues of chapter 3.2 NS at L105-107.

4. Please include more on the actual content of the training. What is important? (AC)

The authors agree that more information about the content of the workshops should be provided. We think that this is best placed in Stage 2 and have inserted a new paragraph at L97.

1) You mention at L214 that one of the workshop sessions recorded a decrease in knowledge/understanding as a result of the workshop. Either this is meant to read 'increase' rather than decrease (in which case it should be corrected), or else the decrease should be explicitly accounted for. It is confusing to the reader as it goes against the key findings. (NS)

A decrease in knowledge/understanding was recorded for some participants in one of the workshops. To explain this, the paragraph L214 to L217 has been deleted. A new paragraph has been inserted at L213.

Minor Essential Revisions

2) Stage 4: Delivery of training programme discusses numbers and participants but not content of the workshops apart from brief information included at L127. If one of the key questions of this paper is about whether workshops are effective -then it would make sense to list what topics are covered within the workshops, under this section. For example, did the content seek to deal directly with the discrepancies which were taking place in application approvals as identified in the 2011 study? (NS)

The authors agree that more information about the content of the workshops should be provided. We think that this is best placed in Stage 2 and have inserted a new paragraph at L97.

3) Footnote 14 - authors need to insert page number for this reference. (NS)
Corrected.

4) L208 - referencing error. (NS)
Completed now reads “Figure 1” at L239.

5) L68 - need to remove either 'surveyed' or 'selected'. (NS)
Replaced “selected” with “representative” at L88.

6) The authors could be more explicit in outlining the problem that they are tending to earlier on in the paper, the clear research questions aren’t explicitly articulated until the discussion section. (NS)
The authors agree and have inserted the aims of the project in the Background section at L71.

Discretionary Revisions

7) L40-41 - Might be useful for the reader to know what some of these discrepancies were and whether and if so, how, the training workshops would tend to such discrepancies. (NS)
L40-41 have been re-worded at L45-47 as follows:
The study indicated concerns that HREC members were lacking in understanding of the process of data linkage. Findings from this study identified training for HREC members as a priority [10].

8) L124 - relating to footnote 9 - authors might want to include the six categories of composition in the body of the text or at least in the footnote. (NS)
Completed, included as endnote (2) as footnotes not allowed in BMC.

9) At L55-56 authors mention that training remains ad hoc and mention web-based training programmes but could tell us more about their perceived (in)utility. If the paper is discussing the effectiveness of face to face training, then authors could be a bit more explicit and expand on the limitations of web-based training. (NS)
The purpose of this study was not to compare face to face with online delivery of a training course. The manuscript does however describe why the choice of face to face delivery was chosen for this training and what the optimal format for face to face training is. The authors have clarified this in the manuscript by:
• adding “face to face” to the title of the Discussion sub-section “What is the optimal format for ethics training in data linkage?” at L306
• Adding a sentence for clarification in the 2nd paragraph of the same section L311-312
• Deleting the sentence commencing “It is unlikely that these outcomes ….” At the end of paragraph 5
• Adding a new sentence at L339 to explain our conclusions.

10) L106-107 - Although the article is describing training in part of Australia, international audiences may also read the article. As such it would be helpful to clarify the roles of ethics/executive officers. (NS)
The roles of ethics/executive officers vary across Australia. We have deleted reference to ethics/executive officers and just used ethics office staff which we believe will be understood by an international audience at L156.

11) In relation to the point directly above, although the article is specific in its description of training offered in Australia, the article needs to speak to the
international audience - what could the rest of us take away from the Australian experiences? Are the authors recommending the uptake of face to face workshops all over or do we need more research and country-specific research on whether such training is/would be effective? (NS)

The authors think that the Australian experience is generalizable to other countries. A sentence has been added to the Conclusion to reflect this at L388-390.

12) 170 - were participants asked about whether they had previously received training (not necessarily via attended workshops but via web-based training)? (NS) Participants were asked if they had previously received training but they were not asked specifically whether the training was face to face or online. We have deleted the word “attended” on L201 and replaced with “received” as the word “attended” may have suggested that we specifically asked about face to face training.

13) L277 - particular methodologies such as...? (NS) We have inserted some examples “e.g. data linkage, genomics” at L303.

14) What about discrepancies? Is there any way of actually checking whether or not there are still discrepancies across HRECs regarding approval of applications? If so, has the level of discrepancy increased/decreased? I think you touch upon this in the limitations section but it might be expressed more explicitly in relation to HRECs rather than individual participants. Perhaps something to test in future work. (NS) We have expanded this discussion in the Limitations section and suggested some future work at L394 as follows:

“it would be necessary to conduct further research. Such research should assess whether the training had an actual impact on participants’ skills and include a follow up of the scoping study to determine if the concerns regarding HRECs capacity to review data linkage projects were addressed as a result of the training. This could only be achieved through pre and post training measurements of participants’ understanding of ethical principles and the legal framework pertaining to data linkage [27] and follow up interviews with DLU staff.”

Given that data linkage projects are not usually reviewed by the majority of HRECs, especially those established at Universities, would the authors consider commenting about the need for on-going education? (KW) We have added a sentence to the end of the Discussion section to address this question. L379 “This training was designed for members of HRECs who regularly review data linkage projects. The sustainability of the results is more likely to be significant for those who have the opportunity to practice the skills regularly.”

Projects that link data or use linked data are not commonly reviewed by the majority of Australian HRECs. But data linkage projects, as the authors maintain, are ‘rapidly’ increasing. HREC members who do not have the relevant research expertise may not realise that they are reviewing data linkage projects, or alternatively, miss the ethical significance of such projects. It would be helpful if the discussion included more information and explanation about projects which link data or use linked data - what these look like and what is ethically important about them - so HREC members
can identify the research as data linkage projects and identify why they should receive training to review them. It might also be useful to readers not familiar with data linkage projects if the information/explanation about data linkage projects included examples. (KW)
The authors agree that more information about data linkage would be helpful to readers. This has been added to the beginning of the Background section not the Discussion as suggested by the reviewer at L25-L31.

Minor Issues Not for Publication

1. Under ‘Methods’ (2nd to last sentence). No need for ending sentence with (87%) has the sentence began with this statistic. (FB)
   Deleted

2. Under “Pre- and post-workshop (T1 and T2) responses”:
   a. the first paragraph after authors’ insertion of Table 2, starting with “Prior to the training”, duplicates the first paragraph after authors’ insertion of Table 1. (FB)
   Duplicated paragraph deleted.
   b. 2nd paragraph after authors’ insertion of Table 2, paragraph beginning with “Table 2 highlights the relationship….”, Error! Reference source not found appears. This should be removed and corrections made as needed. (FB)
   Corrections made at L239.

3. Language corrections to address Essential Minor Revisions comment # 1:
   a. Under “Stage 5: Survey of participants”, 2nd to last paragraph: “Pre- and post-training surveys included eight impact statements measuring participants’ knowledge, perceived levels of skills development and confidence”. Survey did not test for knowledge. (FB)
   Added “self-reported levels of” before “knowledge” at L175.
   b. Under “Pre- and Post-workshop (T1 and T2”, sentence beginning with “Prior to the training”. To ensure that readers are clear that this survey did not test actual knowledge, sentence should read “…. Participants… overall reported lower understanding., less awareness…. Less knowledge, etc.” or equivalent, rather than as currently written. (FB)
   Added “self-reported” to 227.
   c. Last sentence of same paragraph currently reads “It also demonstrates that both groups improved following the training”. For clarity: “It also demonstrates that both groups reported improvements following the training.” (FB)
   Change made as suggested at L241.
   d. Last sentence of 5th paragraph under “Deferred survey (T3) responses: “The deferred web-based survey revealed that the training had a positive impact of participant’s ability to review...” Clarify as “The deferred web-based survey
revealed that the training had a positive impact on participants’ self-reported or perceived ability to review...." (FB)

Change made as suggested at L271.

e. Under “What is the optimal format for ethics training in data linkage” last paragraph: Sentence: “The number of participants at a workshop impacted on participants’ learning”. Better with “participants’ self-reported learning”. (FB)

Change made as suggested at L355.

4. Under “Deferred survey (T3) responses, 2nd paragraph, 1st sentence: “Confidence in reviewing data linkage applications improved as a result of the training for 87% of the participants.” Clarify that this result was reported by 87% of the participants who completed the Deferred Survey. Same issue reappears in first sentence under “Can a training workshop increase participants’ confidence and ability.....” (FB)

Deleted “participants” and replaced with “respondents” at L261.

Deleted “participants” and replaced with “who completed the deferred survey” at L366.

5. Under “Can a training workshop increase participants’ confidence and ability to make informed decisions when reviewing data linkage applications?”: Problem with tables. Table T1 does not appear to be relevant to second sentence. (FB)

T1 does not refer to Table 1. It refers to assessment time (T1) as described in Stage 5 and used throughout the manuscript. To clarify, the following has been inserted in the first sentence of the section “Can a training workshop increase participants’ confidence and ability to make informed decisions when reviewing data linkage applications?”: “who completed the deferred survey (T3)” at L366.