Author’s response to reviews

Title: Health researchers’ experiences, perceptions, and barriers related to sharing study results with participants

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Author’s response to reviews:

January 14, 2019

Dear Ms. Gonzalez-Mcquire,

We are pleased to submit a revision of our original manuscript entitled, “Health researchers’ experiences, perceptions, and barriers related to sharing study results with participants” (ID# HRPS-D-18-00272), for consideration for publication in Health Research Policy and Systems.

We are grateful for the reviewers’ careful review and constructive comments and suggestions regarding our manuscript. We have taken all of these into consideration and have
made numerous improvements to the manuscript. Please find our detailed responses to each reviewers’ comments below. As requested, we have submitted a tracked changes version of the manuscript. All page numbers referenced in our responses coincide with page numbers of the tracked changes version of the revised manuscript.

The study was funded by several NIH National Center for Advancing Translational Sciences grants (#1U54TR001629-01A1, UL1TR002366, 8UL1TR00004, and UL1TRO01427). All study procedures were reviewed and determined to be exempt by the University of Arkansas for Medical Sciences’ Institutional Review Board (#205983).

This manuscript has not been previously published and is not under consideration at another peer-reviewed journal. All co-authors listed have contributed sufficiently to the project to be included as authors. No conflicts of interest, financial or otherwise, exist. We thank you for your time.

Sincerely,

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Responses to the reviewers.

Reviewer #1: This is a well written paper that tackles an important issue in research. The survey design is sound, based on a mixture of a priori and emergent themes. In the authors' own account, the main results confirm existing research, although with a larger survey population. The novel aspects of the findings are not as clear to me - the study has unpacked some of the barriers to contacting study participants, but these seem fairly commonsensical - other than the
rather bizarre 'systemic' obstacle of a lack of incentives in tenure and career progression. However, overall the paper mainly confirms existing research adding a little to unpack the reasons for researchers behavior in this area.

Response: We thank the reviewer for his/her comment and have changed systemic to “systems” barriers to improve clarity. We have also additional discussion to help unpack the reasons for researchers’ behavior, including clarifying that typical Institutional Ethics committees in the US do not require health researchers to return results to participants (page 4 line 79 and following). We agree with the reviewer that many of the findings are similar to findings in smaller studies more focused on specific research areas. However, we believe these findings based on the experiences of a diverse range of researchers from across the US document researchers reasons for sharing results, their misgivings about sharing results, and barriers that they face in sharing results, all which is useful information for funders and policymakers who are interested in increasing in developing policies and procedures to encourage researchers to share findings with research participants.

Specific points:

Abstract. The journal allows up to 350 words in the Abstract. The one provided (less than 100 words) is inadequate. more details of the research methods could be given and the findings are far too vague and general.

Response: We thank the reviewer for his/her comment and have expanded the abstract to include much more detail with respect to method and results.

The works cited give reasons that are far more specific than a 'general interest'. There are major ethical dilemmas at every point in this debate - some of these emerge in the paper, but it would strengthen it if these were drawn out from the literature at the start. This would move the argument away from what often seems to be an 'all or nothing' position where researchers seem to be either for or against sharing. Recent literature such as Thorogood et al 2014 An implementation framework for the feedback of individual research results and incidental findings in research in BMC Medical Ethics have presented much more nuanced accounts of the levels of dilemma in sharing with participants (in this case in genomic research). If the research problem recognised this ethical complexity from the start, the presentation of the findings could raise more interesting questions.
Response: We thank the reviewer for his/her comment and have expanded the discussion of ethical issues and the ethical literature cited in the Discussion on pg. 20 lines 460 and following. We reviewed Thorogood et al 2014 paper referenced by the reviewer and note that those authors are focused on return of individual results and incidental findings, neither of which are the focus of the present paper. We agree with Thorogood et al 2014 that “the return of individual research data raises distinct ethical and policy issues from the return of general results.” Because the present study focuses on the return of aggregate study results (i.e., what Thorogood et al 2014 refer to as “General Results”), we have revised the paper so that it now mentions in the Abstract, Background, Method, Discussion, and Conclusions that the present study focuses on sharing aggregate results with participants. In addition, we now cite Thorogood et al 2014 in the Limitations section of the Discussion to point readers to their framework for return of individual level results.

One surprising aspect of the paper is the assumption that Institutional Ethics committees do not regard participant feedback as a normal aspect of the approval process. In Australia there is a standard question: Outline how feedback will be made available to participants (e.g. via a lay summary or newsletter)? Similar questions are standard in the UK and Canada.

Response: We thank the reviewer for pointing out this distinction across countries. We have clarified in the paper that this is not a normal part of the approval process for Institutional Ethics committees (or “Institutional Review Boards”) in the US. Many US researchers would be equally surprised that these questions are standard in Australia, UK, etc. (pg. 4 lines 79 and following).

Were participants given a definition of 'research results?' Most of the responses imply that this refers to scientific, population level research, but some of the concerns sound more concerned with the return of individual data eg "may not understand that these data are to be used for research purposes and are not the same as personal health data they receive from their physicians". This should be clarified, at present it reads as though apparent differences result from readings at cross purposes. It is possible to strongly report reporting of scientific results to participants while being even more strongly opposed to giving any access to individual clinical or other data.

Response: We thank the reviewer for his/her suggestion. We provide a definition of “research results” in the Method section on page 4 lines 96 and following (ie, “Throughout the survey, the investigative team defined sharing results with participants as the returning of de-identified,
aggregate information about study findings and/or study progress updates to study participants, through means other than publication of peer-reviewed manuscripts.”). This definition is now noted in the Abstract, Background, Discussion, and Conclusions, as well. We have added an acknowledgement in the limitations section of the Discussion that some participants may have misunderstood that definition.

The all or nothing approach is also found in objections around privacy. Here the question is being interpreted not as 'should participants be given access to results' but 'must all participants be given the results'. Again, the Thorogood study shows that there are several layers of consent here. The usual practice has been to invite participants to request information on the study, not to automatically send this to everyone, regardless of preference.

Response: We thank the reviewer for his/her comment and have expanded the discussion of ethical issues and the ethical literature cited in the discussion. Specifically we have added discussion that emphasizes the importance of participant consent (i.e. allowing participants to opt-in to receive plain-language results summaries of aggregate study findings) on page 21 lines 470 and following.

In the conclusion the authors' express concerns with the institutional barriers to sharing knowledge with participants. The inclusion of questions about this type of communication in Ethics clearances would be one way to embed this in institutional practices, and would certainly make it impossible for researchers to say the possibility had not occurred to them.

Response: We thank the reviewer for his/her comment and have included a recommendation to include appropriate discussion of results sharing throughout the Institutional Ethics process on page 21 line 464 and following.

Reviewer #2: Kia ora Thanks for the opportunity to review your work. It is an interesting paper that alarms me about the practices of some of our colleagues. As a reader I want to know the viewpoint of the authors on the issue they are investigating. I would love to see some minimum and best practice guidelines in relation to feeding back to participants. I think the paper would be strengthened by engaging with the indigenous sovereignty data literature.
Response: We thank the reviewer for his/her comment. The goal of this paper was to objectively report researchers’ self-reported practices. We agree that the results reported are in contrast to practices advocated by community engaged researchers and within the indigenous sovereignty literature, and we refer readers to these literatures on page 19 lines 418 and following.

Other points for your consideration:

I am used to an ethics process where dissemination to participants is a requirement. Is this not the case in the USA? It might be useful to contextualise your study more clearly in the USA for those of us not familiar with your system.

Response: We thank the reviewer for his/her comment and have clarified in the paper that the present study focuses on researchers in the United States, where there are not necessarily policies to require the return of aggregate study results to participants, and that other countries have different policies (page 4 line 79 and following).

You have clearly outlined your method but not your methodology; this might be useful to include.

I find it unusual that you have calculated frequency in relation to particular themes. (p6). Can you please include a reference or explanation to explain this approach to your qualitative data.

Response: We thank the reviewer for his/her comment and have added additional references for to cite our methodology. Specifically, we cite King 2004 and Nadin 2004, which discuss the use of templates for analyzing large numbers of open-ended responses. As well as Sandelowki 2003 that outlines classifying findings in qualitative studies.

As a critical scholar mainly doing qualitative research as part of my methodological approach my engagement with participants is ongoing; we are part of the same community. I suspect the methodological approach one takes to research, impacts on how findings are feedback and its relative importance. Was this addressed in your study? Indigenous research methodologies for instance are often relational.
Response: We thank the reviewer for his/her comment. We agree and most of our research is community-engaged research that engages participants in the research interpretation. However, this study required a different methodology. The goal was to objectively report researchers’ responses. We agree that a shift in research practice is called for, and we are hopeful this research may contribute to that shift.

P7 Did you do an analysis of the ethnic makeup of correspondents? If not why not?

Response: We did not capture data related to researchers’ ethnicities. In developing the survey, we placed a premium on keeping the survey as brief as possible in order to encourage busy researchers to respond. For this reason, we were forced to eliminate many questions of interest to our research team, including many important demographic questions that were not going to play a central role in the analytic plan.

P8 "Among the specific studies where results were not shared with participants, 13.6% of 186 respondents had told participants that they would receive results". Is it not problematic and unethical for researcher to lie to participants? Is there a professional body for health researchers that this information needs to be reported to?

Response: We thank the reviewer for his/her comment. We agree this is problematic, and findings like these are one reason we designed this project to objectively report researchers’ responses. As we noted above, we agree that a shift in research practice is called for and this research may help create that shift.

P9 why would researchers not include in their budget money to feedback to participants? Is this not a requirement of health funders and ethics committees?

Why would researchers need incentives to feedback to participants? Without participants they couldn't do research. If they don't know how to engage with participants are they competent to be doing the research with them? This could be discussed in your discussion - alarm bells are ringing for me.
"concerns about how participants will understand or use the results" - is it not the researchers responsibility to explain the findings in a manner participants understand. If the participants can't understand how did they give informed consent?

Response: We thank the reviewer for each of these comments. We agree these issues are all problematic (eg it is not a requirement for United States researchers to provide feedback to participants, and funders in the United States do not normally require researchers to provide feedback to participants). As noted above, we have clarified that the present study focuses on researchers in the United States, where there are not necessarily policies to require the return of aggregate study results to participants, and that other countries have different policies. Because this manuscript’s goal is to objectively report researchers’ responses, we have increased the discussion of ethical practices and citations related to the ethical concerns, including description of a set of principles emphasizing the return of concise plain-language summaries that participants should be able to understand (page 21 lines 464 and following).

P12 The paternalism of the researchers who choose not to share results is distressing to me as their global colleague.

Response: We thank the reviewer for his/her comment. As above, we agree this is problematic, and this is part of our motivation for implementing this project to objectively report many researchers’ responses to the survey questions.

P13 why would participants have to explicitly ask for the findings? Should access to the findings not be covered during the informed consent process?

Response: We thank the reviewer for his/her comment. We have specifically added recommendations in the Discussion to add a question regarding the receiving of results in the consent process (page 21 lines 472 and following).

I don't understand how receiving findings from a study you participate in can cause harm or bias future research? Please clarify.
Response: While we cannot speak beyond the data, we suspect that some researchers who expressed this concern were addressing situations in which the same sample of participants would be recruited for a sequence of studies, trials-within-trials, or some types of longitudinal projects. For example, we suspect that they were concerned that receiving specific findings might influence participants’ willingness to participate in future research. In the process of creating the revised version of this manuscript, we reviewed the coded responses for more specific detail to add to the paper (or to this response) but did not find any.