Reviewer’s report

Title: Data Access Committees

Version: 0 Date: 26 Oct 2019

Reviewer: Cason Schmit

Reviewer's report:

The manuscript proposes a framework for facilitating data access and protecting data subjects. This framework uses Data Access Committees (DAC) to make decisions relating to whether data should be released for various purposes. This proposed framework is a worthwhile contribution to the ongoing discussions, deliberations, and debates concerning proposed solutions for both real and perceived barriers to data sharing and data use. However, the manuscript is vague on a number of points that raise meaningful questions on the scope and content of this proposed frameworks. I outline these and other issues below.

Major Issues:
1. page 5 (page numbers relate to PDF package document, where the main document begins at page 5) Line 7: the authors' focus on de-identified data is curious. Most laws only restrict identifiable data, so in most contexts de-identified data faces far fewer barriers to disclosure. It seems to me that the proposed framework would also help address some of the real and perceived barriers for releasing data that is still "identifiable" (e.g., contains at least some direct or indirect identifiers). I would like to see some justification/rationale for this limitation somewhere.

2. Page 5 Line 40-43: "new research methodologies tend to pose fewer risks to participants and at the same time promise benefits at a larger scale," this statement is crazy broad, and consequently, I am highly skeptical of its accuracy. Moreover, the supporting example is so vague that it provides little support for the statement relating to benefits, and does not support the statement relating to risks. The manuscript should either remove this statement or provide stronger evidence for why new research methodologies pose fewer risks and larger scale benefits. A more thorough description of the methodologies would be helpful.

3. Page 5 line 50-60: the manuscript makes an argument for why public health ethics is more appropriate than research ethics. At some point, the manuscript should tell the reader why public health ethics is meaningfully different from the status quo bioethics/research ethics. The manuscript does highlight the common good v. individual protection argument, but this focuses on only one principle from each ethical framework. As the manuscript indicates, public health ethics is comprised of several different ethical principles. Without discussion, some readers might be mistaken that the only meaningful difference between public health ethics and research ethics is the focus on common good.

4. Page 8 line 7: The "goals" of institutions vary wildly. Could this include profit, political objectives, etc? As a reader, I would be interested to know if these types of "goals" would fit in this framework. However, I would respect a decision to not provide specificity on this point.

5. Page 17 line 10-13: The scope limitation is a bit late in the document. I am curious why this limitation at all. Surely there are socially beneficial uses of education data, or government services data. After all, there are many non-clinical datasets that contain information on various social
determinants of health. Are there anticipated problems or pitfalls that the authors are trying to avoid?

6. General. The DAC is proposed to have a complementary role to RECs. One could argue that this only adds a bureaucratic layer to data use. Moreover, since 1) both DACs and RECs involve ethical reviews and 2) the reviews use different ethical frameworks that both analyze different aspects of risk, then DACs could create an additional barrier to data disclosure and use. I would like to see the manuscript address this argument.

Minor Issues:
1. page 5 line 7: The manuscript uses various terms to refer to data that is not identifiable (e.g., de-identified, anonymized), in some cases these are terms of art that might relate to legal definitions. It is not clear to me if these terms are intended to be interchangeable or if some are referring to a term of art. I would encourage consistent terminology, and if relevant, some clarification if they are talking about specific legal definitions, statistical determinations, or if the term is just used generally.

2. Page 7 lines 16-19. Clearly, minimal social value is intended to be a low bar. Does economic benefit count as social value? This question comes up in several places in this document.

3. Page 7 line 33: Moral equivalence is strange in this context, particularly since the comparison involves broad categories of research. I don't know how research using data of child victims of incest fits within this moral equivalence framework. Suggest "Although data research carries risks, it typically involves less risk than enrolling subjects in new clinical or observational research studies."


5. Page 7 lines 50-57: Replace HIPPA with HIPAA. Please separate the legal citations. Currently, it appears as if the HIPAA provision is part of the Common Rule, which is not accurate. Note that BOTH HIPAA and the Common Rule permit the disclosure and use of IDENTIFIABLE data for research. In fact, if data is not identifiable, HIPAA and the Common Rule will not apply. As is, this sentence is a bit misleading.

6. Page 8 line 38: Please specify "disease area". Are you talking about geography?

7. Page 11 lines 52-55: "Reviews should be guided by the data sharing policies of institutions." Is this practical if the DAC is an independent organization?

8. Page 12 Lines 30-35: Suggested revision "If the main function of RECs is to protect research subjects, then there is an implicit presumption that research poses a risk, and puts the burden to rebut the presumption on researchers."

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.
Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

Not relevant to this manuscript

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

Declaration of competing interests
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?

If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

I declare that I have no competing interests

I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to
be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal