Reviewer’s report

Title: Clarifying how to deploy the public interest criterion in consent waivers for health data and tissue research

Version: 0 Date: 26 Feb 2020

Reviewer: Stephen Holland

Reviewer's report:

I think this is a very nicely written contribution to an important ongoing debate about the public interest criterion for waiving consent to secondary use of data/samples in biomedical research. So, it's clearly motivated, well researched, and makes sensible and judicious suggestions about the public interest criterion. I had a few minor cosmetic points.

1) The title: (a) I think the main direct aim of the paper is to clarify, not 'better justify', the public interest criterion (see Abstract: 'This paper clarifies ...'). (b) I didn't really understand the phrase, 'A socio-ethical approach', and couldn't see much evidence of this in the paper. So, I suggest something along the lines of 'An analysis of the public interest criterion for waiving consent in human health research'.

2) Headings: (a) I didn't like the metaphor, 'Setting the bar' (p.9); why not something clearer, such as, 'Determining that the public interest criterion has been met'? (b) 'Periodic review' (p.18) seemed to me to be a sub-subheading, not a subheading.

3) Is footnote 3 at odds with l.127-8? The footnote recommends interpreting 'greater' as 'magnitude' not 'scope', but l.127-8 seems to allow either interpretation.

4) Are l.135ff. and l.173 at odds? In the discussion about how to interpret 'groups of concern' (l.135ff.), 'society or humanity' are rejected; but l.173 mentions 'national impact', which sounds like 'society' again.

5) l.415: typo (should be '/samples' (plural)).

To be clear, all these are merely suggestions, nothing more substantive (I think any substantive responses are best made in the literature to which this paper contributes).
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