Reviewer’s report

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

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Reviewer: Shona Kalkman

Thank you for the opportunity to review this paper. The paper aims to contribute to a better understanding and operationalisation of the 'public interest criterion' to justify waivers of consent for health research with personal data and human tissue. Strengths of this paper are that it is well-written and its structure allows the reader to really follow the authors' line of reasoning all the way to the end. The authors also present novel insights, most notably when they write about the procedural considerations in setting policy and practice. Over the years, many have tried to tackle the substantive question of how to determine whether a given study is in fact in the public interest or not. Though I do not consider these exercises irrelevant myself, I think it is important to acknowledge that quite a few opponents exist of such exercises because they believe the question is either irrelevant or impossible to answer in ways that address a practical need. Many have come up with frameworks or lists of criteria that could be used to assess 'public interest' or 'social value' for human subjects research more generally. However, very few of those are actually used by IRB members to this day. By not dwelling too long on the actual content of criteria by which public interest could be measured, the authors avoid repeating exercises that could be considered to convey very little value to decision-makers. Instead, they choose to flesh out why criteria could be useful, and what procedures/infrastructure should be in place to maximize consistency and transparency in the criterion's application. I think this work provides helpful leads for further discussion and empirical studies on this relevant topic in human subjects research. Nevertheless, I would like to give back a number of points to the authors to strengthen their paper:

1. The authors limit their argument to the scope of secondary use of data or tissue. But the 'public interest criterion' (in different formulations) is one that arises throughout numerous ethical guidelines and regulation to justify (1) human subjects research per se, and (2) waivers for so-called "minimal risk trials" or "low-intervention studies". Throughout the paper the authors make some references to use beyond the scope of waivers for secondary use, but I think it would be important to be explicit about whether the authors think their work also applies to public interest as a "first threshold" criterion for the justification of human subjects research per se and public interest as a "higher bar" criterion that acts as leverage for bypassing traditional ethical requirements, such as informed consent, in interventional studies.

2. Related to point 1, the title mentions "human health research" but the papers seems to only be addressing secondary use of tissue and data. I would suggest changing the title to better reflect the paper's content.
3. The paper repeatedly talks about "justification of the public interest criterion". To readers it might not be clear what the authors mean by this. For example, if public interest is "amorphous and mutable" do the authors mean that we should justify having such a criterion altogether? Or that if we all seem to have a different understanding or interpretation of 'public interest', that we should justify its use as a criterion in decision-making? Or perhaps justify a certain interpretation of the criterion? These are distinct forms of justification. To compare, "justification of a waiver of consent" is very unambiguous use of the term "justification". Also consider having a look at the the title again.

4. Pages 7 and 8: is 'social value' the same as 'public interest'? Does 'social value' act as a "threshold criterion" and 'public interest' as a "leverage criterion"? If studies can be more or less in the public interest (opposed to with or without public interest), is having a binary understanding of the concept of public interest appropriate (is it perhaps linear with a cut-off point)? Or is the "criterion" binary and the "concept" not? It would help to clarify some of this.

5. Practical implications: could the authors say something about how they predict evaluations would change if their work would be implemented in decision-making? They say the risk of the current interpretation/application of the criterion is that sometimes the bar is set too high and sometimes too low. How will this work affect the outcomes of IRB evaluations for waivers of consent? Will it result in more or less waivers?

6. The ShED tool is definitely an interesting one to mention here, because it could be used to show how theoretical claims about how to establish consistency could be empirically substantiated. The authors cite research that shows that inconsistency between IRB members has reduced over time. I was wondering what the reason was and how that reason relates to the authors' endeavour to reduce inconsistency in application of the public interest criterion.

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