Reviewer’s report

Title: Taking patient involvement seriously: A critical ethical analysis of participatory approaches in data-intensive medical research

Version: 1 Date: 19 Jan 2019

Reviewer: Rik Crutzen

Reviewer’s report:

The revisions improved the manuscript; changes were made and points were taken into consideration (although often briefly). There are still some concerns that I think need to be addressed.

First, I’d like to partly reiterate my previous comment about 'big data': It would be worthwhile to reflect on and/or reconsider this term in the light of the question: to what extent is this only relevant to 'big' data or does this apply to (medical) data in general?

The authors now explain, for example, "Thus, in the European Data Protection Directive, medical data, due to their sensitivity, form a separate category that requires stricter regulation." and "Furthermore, regulations on data protection, e.g. concerning anonymization, aim to protect individuals against problematic usage of their data. However, there is increasing awareness that traditional measures may no longer be sufficient..." However, this also applies to smaller sized datasets. So, what makes 'big data' different?

Second, although I respect that the focus is on normative role and practical usage of participation, it is still important to discuss the 'status aparte' of scientific research within the GDPR. This because this is highly relevant for practical usage (of participation, and even data more general).

A more elaborate revision based on these comments would improve the added value of the manuscript. Thank you in advance for considering.

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

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