**Reviewer's report**

**Title:** Participatory improvement of a template for informed consent documents in biobank research. Study results and methodological reflections

**Version:** 0  **Date:** 11 Sep 2017

**Reviewer:** Flavio D"Abramo

**Reviewer's report:**

Review to the draft "Participatory improvement of a template for informed consent documents in biobank research. Study results and methodological reflections"

METH-D-17-00111

The article presents an important topic and a "novel" methodology for the assessment of patients' understanding of informed consent sheets - i.e. focus groups. Moreover, it presents the analysis of emotionally-charged pieces of information contained in the IC sheet which is an aspect seldom used in the bioethical literature.

Minor amendment/explanations seems to be advisable:

Raw 176: it would be useful to indicate the "four tapes" in a temporal length - i.e. minutes/hours

Raw 215, the category n. 6 "trust in text" seems to avoid analysis of human agency - i.e. responsibilities and related allocation to institutions/scientists. Is there any specific reason to explain the use of this terminology?

Row 301-304: There are several issues sketched in the article, some of great importance, as the one about paying research participants. In this respect there is a literature highlighting the need to consider biomedical research participants as people who spend time, resources and who might deserve to be treated as workers - i.e. paid through an employment contract. Specifically, see "Clinical Labur" by Cooper and Waldby (isbn: 978-0-8223-5622-6) and "Biocapital" by Sunder Rajan (isbn: 978-0-8223-3720-1).

Row 302-303 The previous point is of great importance for the consideration you had of participants, which I think is a good step towards the introduction of principles and practices of equality and justice in biomedical research. Nevertheless, when you write: "We decided to treat
focus group participants like we would treat experts, which are usually compensated for their consultation. Therefore all participants were granted a compensation of €60", it is unclear if you really considered participants as experts. In other terms: did you use regular employment contract to engage participants?

In case you didn't, it might be more correct either, to just refer to the compensation or to introduce the fact you didn't use any employment contracts which bring the possibility to access civil rights - e.g. a pension scheme, health care insurance and in general those guaranteed by the German welfare systems.

Raw 390-391: the contradiction represented by participants who expressed the wish for more detailed explanations and the demand for shortening the respective paragraph might be well addressed through ICT - e.g. hypertext allows readers to access further information within texts which are otherwise short. See a possible solution for this specific problem through the literature on dynamic consent, for instance: DOI: 10.1186/s12910-016-0162-9

Flavio D'Abramo

**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.

I am able to assess the statistics
Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

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