Author’s response to reviews

Title: Do patients and research subjects have a right to receive their genomic raw data? An ethical and legal analysis

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Author’s response to reviews:

Point-by-point response letter to the editors and reviewers

We thank the editors of BMC Medical Ethics for their comments and sending our manuscript to external reviewers.

We particularly thank the reviewers for considering and reviewing our revised manuscript and for their constructive and positive feedback.

Following the reviews and comments received on our already revised manuscript, we did not add further (substantial) revisions to the text, but mainly improved formal aspects and the declaration section.

In the new manuscript you will not find the former revisions indicated in track-change function anymore since we have “accepted” these revisions as they were responses/reactions to the reviews of the first reviewers. However, the new and rather “formal” changes added to manuscript as responses to the editor’s comments are indicated by the track changes function. This holds in particular for the former endnotes which were turned into footnotes, for the reformatting of the headings and for the declarations.

Please find below a detailed point-by-point response to the reviewers’ comments and suggestions. (In the point-by-point response we refer to the revised version of our paper.)

On behalf of the authors, I very much thank the editors and reviewers for their helpful comments on the revised version of our manuscript. If you have any questions, please do not hesitate to contact me.

Yours sincerely

Eva Winkler
Prof. Dr. med. Dr. phil. Eva Winkler
Attending physician and head of the research program "Ethics and patient oriented care" at the National Center of Tumor Diseases (NCT), Heidelberg, Germany.
Point-by-point response to the editor’s and reviewers’ comments

Editor Comments:

1. Please change the Discussion heading in the Abstract to Results.

Reply: We have changed that.

2. Please use footnotes instead of endnotes, please see our editorial guidelines:
https://bmcmedethics.biomedcentral.com/submission-guidelines/preparing your-manuscript/research-article

Reply: We have changed that, using footnotes instead of endnotes.

3. Please indicate the role of the funding body in the design of the study and collection, analysis, interpretation of data and in writing the manuscript in the Funding section.

Reply: There was already an indication in the funding section that the funding body did not participate in any form in the production of the text, but we tried to improve that indication and added a further remark concerning the funding body supporting the open access publication. We do not refer to “collection, analysis, interpretation of data” for we did not carry out any collection or analysis of data.

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4. The Availability of data and materials section refers to the raw data used in your study. We strongly encourage all authors to share their raw data, either by providing it in a supplementary file or depositing it in a public repository and providing the details on how to access it in this section. If you do not wish to share your data, please clearly state this in this section along with a justification. Data availability statements can take one of the following forms (or a combination of more than one if required for multiple datasets):

• The datasets generated and/or analysed during the current study are available in the [NAME] repository, [PERSISTENT WEB LINK TO DATASETS]

• The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

• All data generated or analysed during this study are included in this published article [and its supplementary information files].

• The datasets generated and/or analysed during the current study are not publicly available due [REASON WHY DATA ARE NOT PUBLIC] but are available from the corresponding author on reasonable request.
• The data that support the findings of this study are available from [third party name] but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of [third party name].

Please note that if you do wish to share your raw data and do not have consent from all patients to publish this data it will need to be de-identified.

Please also note that if you include your raw data as a supplementary file you will need to provide, after the References, a section titled “Additional files” where you list the following information about each of your supplementary files: * File name (e.g. Additional file 1), * Title of data, * Description of data. All additional files will also need to have been cited in the main manuscript.

Reply: There was already included a section on availability of data and materials in which we stated that it was not applicable. Our article is conceptual-normative, not empirical. We have now added a short explanation to the Availability of data and materials section stating that our article is not based on any kind of data or other empirical material. Page 20

5. Consent for publication refers to consent for the publication of identifying images or other personal or clinical details of participants that compromise anonymity. Seeing as this is not applicable to your manuscript please state “Not Applicable” in this section.

Reply: We have changed that replacing the former statement by a “Not applicable” statement in the consent for publication section. Page 20.

6. Please reformat your manuscript to ensure that all of the main text headings and the general formatting of your manuscript is correct:
https://bmcmedethics.biomedcentral.com/submission-guidelines/preparing_your-manuscript/research-article

Reply:

a) We have changed the headings according to the guidelines provided on the website given. Each section has a section heading in capital letters and the subheadings are slightly larger than the body text and bold. The subheadings you provided for the Abstract (Background, Methods etc.) are on the same formatting level manuscript as the subheadings we put within the sections of the actual article (e.g.: “The international legal framework”). We have checked the manuscript against the guidelines and are confident that the version provided is in line with all of them.

b) One brief remark in the case this information got lost during the past months. As to the headings in the manuscript, we had a mail exchange (between April 9 and May 6.) with the former editor (Ms Talusik) and received feedback by the reviewers stating that they preferred the option that we had described as follows:

“As a first alternative option, we could subsume one part of the article as a methods sections and another long part of the paper as discussion section, so that the article would have a background, methods, discussion and conclusion section.”
7. Please update the Response to Reviewers box to include only the response to the comments in this email.
Reply: We tried to update the reviewers box and hope we technically succeeded in doing so.

Reviewer reports:

Reviewer 2 (Reviewer 2): PEER REVIEWER ASSESSMENTS:

OBJECTIVE - Full research articles: is there a clear objective that addresses one or several testable research questions? (Brief or other article types: is there a clear objective?) Yes - there is a clear objective

DESIGN - Is the current approach (including controls and analysis protocols) appropriate for the objective? Yes - the approach is appropriate

EXECUTION - Are the experiments and analyses performed with sufficient technical rigor to allow confidence in the results? Yes - experiments and analyses were performed appropriately

STATISTICS - Is the use of statistics in the manuscript appropriate? N/A - there are no statistics in this study

INTERPRETATION - Is the current interpretation/discussion of the results reasonable and not overstated? Yes - the author's interpretation is reasonable

OVERALL MANUSCRIPT POTENTIAL - Has the author addressed your concerns sufficiently for you to now recommend the work as a technically sound contribution? If not, can further revisions be made to make the work technically sound? Yes - current version is technically sound

PEER REVIEWER COMMENTS:

GENERAL COMMENTS: Good overall manuscript, contributes meaningful data, very thoughtful responses to critique points by authors.

REQUESTED REVISIONS:
The article contributes some interesting information and should be ready to go.

ADDITIONAL REQUESTS/SUGGESTIONS:
No, the authors did a good job on the responses.

Reply: We very much thank the reviewer for the positive feedback. For the reviewer did not request or suggest any revisions, we did not introduce any revisions according to the review.
Reviewer 3 (Reviewer 3): PEER REVIEWER ASSESSMENTS:

&gt;

&gt; OBJECTIVE - Full research articles: is there a clear objective that
&gt; addresses one or several testable research questions? (Brief or other
&gt; article types: is there a clear objective?) Yes - there is a clear
&gt; objective
&gt;

&gt; DESIGN - Is the current approach (including controls and analysis protocols) appropriate for the
&gt; objective? Yes - the approach is appropriate
&gt;

&gt; EXECUTION - Are the experiments and analyses performed with sufficient technical rigor to
&gt; allow confidence in the results? N/A - no experiments or analyses
&gt;

&gt; STATISTICS - Is the use of statistics in the manuscript appropriate? N/A - there are no statistics in this study
&gt;

&gt; INTERPRETATION - Is the current interpretation/discussion of the results reasonable and not
&gt; overstated? Yes - the author's interpretation is reasonable
&gt;

&gt; OVERALL MANUSCRIPT POTENTIAL - Has the author addressed your concerns sufficiently for you to now recommend the work as a technically sound contribution? If not, can further revisions be made to make the work technically sound? Yes - current version is technically sound
&gt;

&gt; PEER REVIEWER COMMENTS:

&gt;

&gt; GENERAL COMMENTS: The manuscript deals with an issue that is
&gt; contemporary and relevant to concerns about genetic data in research studies. The authors have
done a good job dealing with the questions of the initial reviewers. It would be unfair to reject the paper
because of my rejection of liberalism, so my verdict is that the paper should be published. However, I
would like the authors to think about the following issues (dealing with them in the text of the article
would be prohibitively lengthy). First, Richard Zaner and Alasdair MacIntyre have argued against the
idea of autonomy based on the Aristotelian view that human beings are naturally social animals
involved in a network of relations with one another. Such relations are not separate from an individual's
identity, but help to create the identity of the person living in history. Second, if genetic data can be
used to determine paternity, this raises obvious issues for other parties involved. Third, liberalism and
autonomy are primarily Western values. Asian societies downplay autonomy and tend to value the
group (especially the family, as in Japan) over the individual. With Europe becoming increasingly
diverse, individuals who reject the Western idea of autonomy may cause tension in a society that
imposes such values upon them. They may consider doing such as cultural imperialism.

&gt;

&gt; REQUESTED REVISIONS:
&gt; none

&gt; ADDITIONAL REQUESTS/SUGGESTIONS:
&gt; I hope they consider what I wrote in my evaluation paragraph, though I do not think it essential
that they respond to my points in their paper.
Reply: We very much thank the reviewer for this feedback. We very much appreciate the three points indicated by the reviewer in the general comments. We will take into consideration the concerns which touch on fundamental philosophical issues when further developing and shaping our normative framework in the future. As stated by the reviewer, unfortunately we cannot take them into account in this manuscript for reasons of space. We therefore added no revisions to the manuscript in regards to this review.