Author’s response to reviews

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

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Authors’ Responses to Editor and Reviewer Comments

Manuscript title: Participatory improvement of a template for informed consent documents in biobank research. Study results and methodological reflection

Editor comments:

Comment: a. Page 5, MS line number 124-5: When you mention the two sets of focus groups, you could indicate that their composition is discussed further below. I was curious at this point as to whether they were undertaken with the same or different participants as the first set; and you clarify this later in the paper.

Response: We included a short explanation:

“Two groups in the second set were conducted with new and two with repeat participants (for an explanation of focus group composition, see below).”
Comment: b. Page 5, MS line number 135-6: At this (and one other) point, you mention that the IC forms you were evaluating were designed for the public (c.f. patient) participants, and to this end you undertook focus groups with participants. However, in your introduction, you mention both 'patients' and 'participants' as groups in whom it is important to undertake engagement. You might therefore wish to reflect (in the Discussion?) as to whether such engagement with patient populations, as opposed to the public, might be similar or different?

Response: We added a short section in the Discussion reflecting on potential differences between different target populations:

“Secondly, as mentioned above, the IC documents we tested were designed for informing members of the general public about participating in biobank research. To gain information about this group’s specific needs and potential problems in understanding the IC documents, we invited members of the public to participate in our focus groups. However, other IC documents in clinical research or care aim at informing and recruiting other groups – e.g. patients, their relatives or carers. Hence, for effectively testing and improving these IC documents members of the respective target population should be included. We believe, that the results of our study are applicable to other target populations, too. Despite several differences between target populations, most of them do not possess medical expert knowledge and can therefore be perceived as lay people. Learning about lay peoples’ perception of the tested IC documents can help improving their quality in the above described manner. However, further empirical research is needed to confirm this perception and to analyse potential differences between patients, research participants and members of the general public as sources for improving IC documents.”

Comment: c. Page 5, MS line number 139: after "education)" edit to read: "was used to enable diverse composition..."

Comment: d. Page 6, MS line number 155: delete "interview" and replace with "focus group"

Comment: 3. Page 6, MS line number 158: suggest replacing "the guide was only adjusted in minor details" with "there were only minor adjustments to the guide" (edit to English expression)

Comment: e. Page 6, MS line number 164: suggest adding the number of focus groups (between "set of" and "focus groups") for clarity
Response: We thank the editor for these detailed and very helpful suggestions. We revised the manuscript according to comments c through e.

Comment: f. Page 6, MS line number 175: What do you mean by: "detailed excerpts"?

Response: We added a short explanation to clarify the term:

“Detailed excerpts were made from the tapes by carefully listening to the whole tapes and paraphrasing all relevant content. Especially relevant statements were transcribed verbatim.”

Comment: g. Page 6, MS line number 176: which four groups were transcribed?

Response: We included this information:

“focus groups 1, 2, 5 and 6 from the first set of seven focus groups”

Comment: h. Page 10, MS line number 295: would "living with" be better than "suffering from", to recognise that having a condition does not necessarily imply suffering?

Comment: i. Page 11, MS line number 331: please fix error - "both, new and participants" does not make sense

Response: We revised the manuscript according to comment h and i.

Comment: j. Page 12, MS line number 357: consider briefly listing Beskow et al's key points?

Response: We included a short summary of Beskow et al.’s key points:
“This includes: purpose of data and specimen collection, necessary procedures, duration of data and specimen storage, risks, confidentiality protections, benefits and costs, voluntariness, discontinuing participation, whom to contact for questions, Commercialization of stored material, and handling of new findings with relevance to the subjects’ own health.”

Comment: k. Page 12, MS line number 363: consider adding an example of a misunderstanding?

Response: We added an example of one misunderstanding and how it’s identification helped us to improve the IC documents:

“… e.g. a discussion in one focus group revealed that some test-readers presumed that all donated specimen were analysed by the biobank and, hence, they believed that participants could hope for diagnostic benefits. This believe made them indignant about the formulation in the IC document that “only incidental findings with direct relevance to your health” would be communicated. After identifying this misunderstanding, we were able to clarify the formulation in the IC documents.”

Comment: l. Page 12, MS line number 366: is "positive" a better word than "affirmative" here?

Response: We changed “affirmative” to “positive”

Comment: Table 2: it is not clear to me what the traffic light system achieved? Could a short explanation be added to the table as to how decisions were made between green, orange (amber) and red?

Response: We tried to clarify the purpose of the traffic light system in the manuscript:

“Colour marking was performed to help track our changes and to distinguish at a glance to what degree changes were directly based on test-readers’ feedback.”
In addition, we added a short explanation about how decisions between colours were made to table 2:

“Decisions between colours were made together by the authors directly involved in drafting the revised IC documents (UH, SB, DS). Colour markings are not completely distinctive as some paragraphs required a combination of different kinds of changes, e.g. changes directly based on test-readers’ feedback (green) and more general changes (red) at the same time. However, the colour system was one measure we took to make revisions as transparent as possible.”

Figure 1: Numbers of participants by gender are reported using males only. Does this imply that all other participants identified as female? (and I note that this indicates 'male' as the 'default

Response: We included numbers of female participants to figure 1. There were no participants who identified themselves as other than male or female.

Reviewer #1 (Wendy Lipworth)

Comment: * I would have liked more information in the introduction about the broad principles that have emerged from other similar interview or focus group-based information-refining processes. The authors make a good case that the process they applied "works" at a practical level, but it is not entirely clear what (if anything) it adds conceptually to related health communication scholarship.

Response : As pointed out in the introduction, there have been so called user testings using individual interviews to test and revise different kinds of written information, including IC documents. However, we believed that focus groups instead of or in addition to individual interviews can help gather additional information about test readers’ perceptions and emotional responses. Therefore, in our study we used focus groups to analyse whether this methodology is suited for testing IC documents and what kinds of information they can reveal. Although there already are examples for focus group studies testing written information, these studies focused on health information and decision aids, only. In addition, they did not report in what way the tested documents were revised or whether they were re-evaluated after revision.
Hence, our study combines the systematic approach of user testings (individual interviews) with focus group methodology. Our main purpose was to analyse feasibility and utility of testing, revising and re-testing IC documents by means of focus groups.

On the basis of the relevant literature as well as our own experiences, in another paper (Bossert, Strech 2017. An integrated conceptual framework for evaluating and improving ‘understanding’ in informed consent. In Trials (forthcoming)) we reflect on conceptual and methodological challenges of testing and improving consent and propose an integrated mixed-methods model. Therefore, in the current manuscript, we focused on presenting our methodology and discussing on its strengths and weaknesses. Discussing all relevant conceptual issues would go way beyond the scope of the current manuscript.

In the Discussion and Conclusion sections we discussed some aspects our approach could add to the current health communication literature as well as conceptual challenges which still need to be addressed.

e.g. on the advantages of focus groups over individual interviews: “In contrast to individual interviews used by most “user testings” [2-4, 22-24, 30], the discursive focus group setting also allowed for controversial discussion amongst the participants, which helped reveal contrasting opinions and misunderstandings, e.g. a discussion in one focus group revealed that some test-readers presumed that all donated specimen were analysed by the biobank and, hence, they believed that participants could hope for diagnostic benefits. This believe made them indignant about the formulation in the IC document that “only incidental findings with direct relevance to your health” would be communicated. After identifying this misunderstanding, we were able to clarify the formulation in the IC documents.”

e.g. on definitions of ‘understanding’ when testing written information: “how can we better distinguish the different dimensions of “understanding” with regard to health care or research-related texts, including IC documents? Research on informed consent in clinical research has attempted to better distinguish between misconceptions, misestimates and optimism [33]. These conceptual dimensions, however, all deal with testing understanding in the above-mentioned paradigm of objective, survey-based IC research. In our study we often dealt with a complementary but more preliminary dimension of understanding, that is, whether a reader has the subjective impression of grasping the text message. Further conceptual and empirical research is needed to assess the theoretical and practical relevance of integrating subjective and
objective dimensions of understanding in evaluating and improving health and research-related texts.”

e.g. on whom exactly to involve in testing and improving IC documents: “as mentioned above, the IC documents we tested were designed for informing members of the general public about participating in biobank research. To gain information about this group’s specific needs and potential problems in understanding the IC documents, we invited members of the public to participate in focus groups. However, other IC documents in clinical research or care aim at informing and recruiting other groups – e.g. patients, their relatives or carers. Hence, for effectively testing and improving these IC documents members of the respective target population should be included. We believe that the results of our study are applicable to other target populations, too. Despite several differences between target populations, most of them do not possess medical expert knowledge and can therefore be perceived as lay people. Learning about lay peoples’ perception of the tested IC documents can help improving their quality in the above described manner. However, further empirical research is needed to confirm this perception and to analyse potential differences between patients, research participants and members of the general public as sources for improving IC documents.”

Comment: * I think that in its current form, the article would be of interest primarily to those with a specific interest in health communication and/or those involved in the development of standard/template consent forms (e.g. at a government level). If the authors want to broaden the appeal of the article, they could reflect upon whether there might be ways to modify the process so that it is feasible for use by individual researchers who are designing their own participant information sheets and consent forms

Response: Thank you for this advice. We added a paragraph to the Discussion-section to address this aspect:

“Finally, the methodology we applied in our study is rather complex and costly and hence might not be feasible in many contexts. E.g., in some cases there might not be enough potential participants for a high number of focus groups. Also, conducting and analysing focus groups takes a lot of time which might not be available. To comply with limited resources, one could e.g. reduce the number of focus groups or the number of participants in each focus group. Other user tests have used individual interviews to test, revise and retest written information [e.g. 2, 3,
This might also make the process less costly and more feasible. However, additional conceptual and empirical research is needed to systematically compare different methods for testing and revising written information and to analyse the respective advantages and disadvantages of each method.

Comment: * One other minor point is that the authors seem to place a lot of emphasis on what consent can/should achieve. A more qualified introduction would put the method described in a more realistic context. Having said this, there is nothing wrong with getting consent as right as possible, but it would be good to acknowledge the limitations of even the best consent processes.

Response: Of course, we are aware of the limitations of informed consent. In this manuscript, however, our focus was mainly to introduce our method of testing and improving consent documents. Because, agreeing to the reviewer, we believe it is important to get the consent process and the used consent documents as right as possible – irrespective the flaws of the concept itself. To acknowledge the limitations of informed consent itself, we revised the first part of the introduction as follows (bold text-passages are new). However, to maintain the focus of the manuscript on consent-improvement, we would prefer not to engage more deeply in discussing limitations and problems of informed consent in general.

“In human subject research as well as in clinical care, informed consent (IC) is considered an ethical and legal requirement, supporting the protection of participants’ and patients’ rights and maintaining public trust [5-7]. Although there are several well-known limits to informed consent [8, 9], its general importance remains mainly uncontested. For valid informed consent, it is crucial that prospective research participants understand as well as possible all that their consent entails [1].”

Reviewer #2 (Flavio D’Abramo)

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

Response: We added this information to the manuscript:
“(focus groups 1, 2, 5 and 6 from the first set of seven focus groups, each between 00:57 and 1:08 hours)”

Comment: Row 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?

Response: We changed “trust in text” into “trust in given information”.

Comment: 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 Labour" by Cooper and Waldby (isbn: 978-0-8223-5622-6) and "Biocapital" by Sunder Rajan (isbn: 978-0-8223-3720-1).

Response: Thank you for the hint towards these relevant pieces of literature. In general we agree that research participants should be treated with as much appreciation and respect as any other persons involved in research projects (including other kinds of “experts”). However, for a one-time engagement as for participation in a focus group, arranging employment contracts for each participant would not be possible administratively and, in addition, is not compatible with German law and labour agreements (Tarifvertrag) in the field of civil service (to which Universities belong). In our research projects we 1) take out an insurance policy which covers all injuries or accidents research participants face on their way to their appointment, during the appointment and on their way home; 2) we refund all expenses (e.g. travel-costs); and 3) we compensate each research participant according to the time and effort they are asked to take for their participation (e.g. 60 € for a one-time-consultation). This is how we treat all persons who are involved in our research projects for a short period of time (e.g. one-time consultation).

Comment: 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.

Response: Thank you for raising this important point. Before we started our study, we discussed carefully within our group how we would perceive our prospective focus group participants. We have been conducting expert interviews with several different kinds of experts in the past and all of them were compensated by means of one single payment for each one-time-consultation (between 60 € and about 100 € depending on the length of the interview and the nature of the interview partners’ expertise). We deliberately decided to treat focus group participants exactly as the experts in our prior studies. However, for neither of the different kinds of experts we have consulted in the past actual employment contracts were used. They all (as our focus group participants) were asked to fill in a reimbursement-form or to issue an invoice which was then payed by our institute. We tried to phrase the respective sentences more precise in the manuscript:

“We decided to treat focus group participants as experts, which are usually compensated for each one-time-consultation. Therefore all participants were granted a compensation of €60 for each focus group they participated in.”

Comment: Row 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

Response: Thank you for the hint toward this publication (and the related body of literature). Actually, the participants of our focus groups made some suggestions (like using a electronic version of the ICD with hyperlinks for more information on certain topics) which could be part
of a solution as well. We added this additional feedback to the results-section: and to Table 5 (citations from focus groups):

“Several test readers also made additional suggestions for the design of the tested document or for the consent process as a whole – e.g. to use multimedia devices or videos to support written information (cit. 16) or to add a short version with the key aspects at the beginning of the ICD (cit. 17).”

We also included this possible solution in the discussions-section:

“Furthermore, some reasonable requirements were hard to meet simultaneously – like the wish for more detailed explanations and the demand for shortening the respective paragraph. Some solutions for this particular Problem – e.g. using videos or electronic ICDs to present information in a dynamic way (cit 17 and 18 in table 5) – have already been suggested by our test-readers’ themselves and by the literature on dynamic consent [34]. However, for a transparent revision of tested documents, systematic solutions for how to address unambiguous or contesting kinds of feedback can be addressed in the revision process.”