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Target-Group-Specific Validation and Optimisation of an Informed Consent Form

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Background and Objectives

In research with humans, informed consent (IC) is considered an important ethical and legal requirement [1,2]. IC-forms aim to give sufficient and comprehensible information to prospective study participants in order to enable them to autonomously decide whether to participate. To ensure that prospective participants' needs for information are met comprehensively, it can be valuable to involve members of the target population in the preparation and validation of consent forms, e.g. by empirically testing for understanding, validity and usability of consent forms [3,2].

Empirical consent research mainly uses quantitative methods to evaluate informed consent forms [2]. Qualitative methods have been applied to analyse biobank donors' general perceptions and views on consent [4]. Our study combines the objective of evaluating and improving an IC-form with a qualitative analysis of participants' needs and demands regarding consent forms.

We used focus group interviews to discuss an exemplary consent form for biobank research with lay people to pursue the following objectives:

a) Evaluating the IC-form's quality and developing proposals for its improvement.
b) Testing our method as a means for patient and public involvement in the participatory development of IC-forms.

Method

In 2015 we conducted 7 guided focus group interviews with 5 to 7 participants each (see fig. 1). Participants were recruited via a postal survey in the German city of Hannover (random selection from register of residents: N=1050, age≥18). After qualitative content analysis of audiotaped discussions and a first revision of the consent form, in Feb./March 2016 another 4 focus groups have been conducted to test the revised version. The results of these additional focus groups have been used for a second revision of the consent form.

For the revision of the original consent form we first grouped the statements of participants from the excerpts into six main categories with several sub categories according to the subject they dealt with. In a second step, we revised the original consent form on the basis of participants' statements. For a transparent and systematic revision we devised a traffic-light system to mark our changes in the original document (see fig 2).

Fig. 2: illustration of changes in original consent form

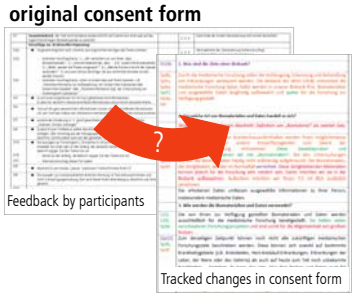


Fig. 3: exemplary changes in original consent form: Text box with central statements and illustrating image

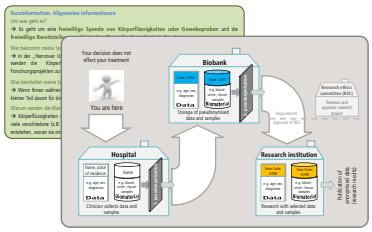
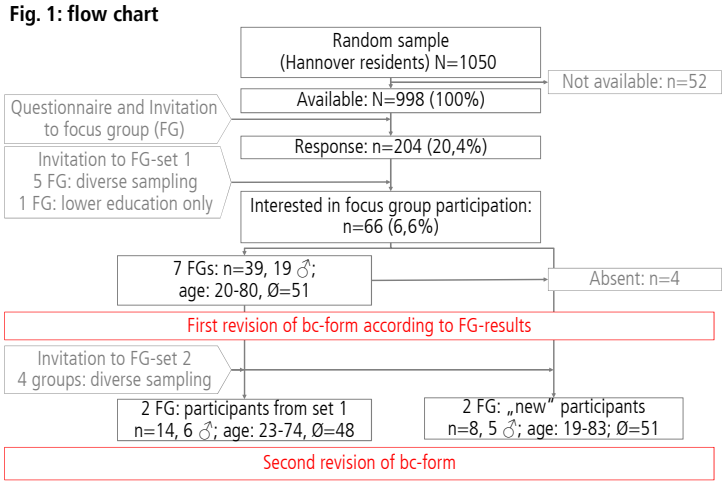


Fig. 1: flow chart



Results

Participants in the first set of 7 focus groups gave feedback on the following aspects: length, structure, language, comprehensibility, completeness and trustworthiness of the IC-form and emotional reactions. After the first revision of our consent form, participants in the second set of 4 focus groups approved most changes and gave some additional feedback. All feedback was used for a second revision. For exemplary changes in the original consent form see Fig. 3.

Discussion

Focus group participants gave valuable feedback for revising the original consent form. Feedback by participants of a second set of focus groups as well as biobank-experts was mainly affirmative. This indicates an improvement of the consent form. But the overall quality of different versions of the consent form has not been systematically assessed. Furthermore, defining rules for how to deal with different types of feedback has proven to be difficult. How should, e.g., contradictory feedback by different participants be dealt with systematically?

Conclusions

Focus group interviews have proven to be a viable means to involve members of the target group in the development of consent forms. In future research, the quality of different versions of the consent form should be systematically assessed, e.g. by means of quantitative methods.

Additionally, it would be useful to establish rules on how to deal with different types of feedback. This would enhance transparency and validity of the revision of consent forms according to feedback from members of the target population.

References

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