



Review

A template for broad consent in biobank research. Results and explanation of an evidence and consensus-based development process



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ABSTRACT

Background: Biobanks increasingly presume long-term storage of biomaterials and data that shall be used for future research projects which are today unspecified. Appropriate consent documents for sample donors must therefore explain the breadth of consent and other elements of the biobank governance framework. Recent reviews demonstrated high variability in what issues these documents mention or not and how the issues are explained. This might undermine the protection of sample donors, complicate networked biobank research, create research waste and impact on public trust.

Methods: A systematic analysis of international research guidelines and existing broad consent templates was performed. Based on this information an interdisciplinary expert group from the AKMEK (Permanent Working Party of German RECs) developed a draft template and organized a comprehensive stakeholder consultation. After revision the final template was consented by all 53 German RECs.

Results: This paper briefly explores the spectrum of potentially relevant issues for broad consent forms. It then elaborates the template and how it was designed to be applicable in different types of biobanks.

Discussion: To further improve the validity and applicability of broad consent forms in biobank and other big data research, practice evaluations are needed. We hope that in this regard the presented template supports the development of new consent forms as well as the evaluation and revision of existing ones.

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1. Background

Biobanks are collections of human biological samples and related health and personal information for use in research. High quality biobanks are important resources for health research,

including basic research, questions in personalized or stratified medicine (genetic and other biomarkers) and research in widespread diseases (Zika et al., 2010; Asslaber and Zatloukal, 2007).

The development of large-scale population-based as well as disease-specific biobanks brings new ethical, legal and social challenges. These include issues around the role of ethics committees, data protection, dealing with incidental findings, public involvement measures, and particularly the need for new, or at least updated, models of informed consent for the donors of biomaterials (Herbert, 2012; Budimir et al., 2011).

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Several stakeholders in the field of biobank research and whole-genome sequencing are developing innovative consent documents and procedures (Ayuso et al., 2013; Salvaterra et al., 2008). One major reason that these differ from standard documents in the context of clinical research is the increasing number of research biobanks that presume long-term storage of biomaterials and data. Such materials and data can be used for future research projects which are today unspecified and to some extent unforeseen. In these cases, donors of biomaterials are asked to give 'broad consent' to a framework for future research of certain types, instead of the standard narrow consent to one specific research project. Appropriate consent documents must therefore explain the breadth of consent and other elements of the framework for future research such as, for example, cross-border use of biomaterials and/or data, property rights, commercial use, and data protection (Budimir et al., 2011; Ethikrat, 2011; OECD, 2009; Greely, 2007; Hansson, 2009; Cambon-Thomsen et al., 2007; Pawlikowski et al., 2011; Beskow et al., 2010; McGuire and Beskow, 2010; Hoeyer et al., 2005). Further, a degree of harmonization of the broad consent forms used for biobanks with similar purposes and procedures will be essential to cooperation and networking at the national and international level.

Though information and consent documents do not replace the discussion between biobank researcher and study participant, they are an important component ("a first step") of the informed consent procedure and its documentation, not least legally. Several empirical studies have shown that consent forms are often uncomprehensive, incomprehensible or impractical, and fail to meet participants' needs (Brehaut et al., 2012; Mandava et al., 2012; Padhy et al., 2011; Jefford and Moore, 2008; Lavori et al., 1999). Improvements are necessary to support a balanced and evidence-based decision-making process by participants.

Existing studies of biobanks and their governance strategies indicate challenges in consent procedures (Zika et al., 2010; Herbert, 2012; Hirtzlin et al., 2003). Researchers have proposed a unified consent model and possible content for a consent form in biobank research (Salvaterra et al., 2008; Porteri and Borry, 2008) and for whole-genome sequencing studies in the clinical context (Ayuso et al., 2013). Further consent particularities have been outlined for biobank research with children (Kranendonk et al., 2016; Giesbertz et al., 2016).

As both the general principle and specific requirements of broad consent have generated complex discussion, it is no surprise that biobank chairs at academic sites in Germany reported substantial differences in local RECs' willingness to approve biobank research operating under a broad consent model. Some RECs unwilling to approve biobank research with a broad consent model have referred to the Declaration of Helsinki (DoH) and to different types of data protection regulations, noting that consent to research or to the use of health-related data requires specific information about the project. "Specific" can mean that the objectives of research, the principal investigator and the project's duration are specified. Exemptions for research are possible, but must be justified case by case. Because broad consent does not fulfil these requirements, it is argued that its authorization would contravene current interpretation of data protection laws or the DoH.

Even those German RECs that approved broad consent forms for biobank research differed on what the consent forms should include. A similar controversy exists in the USA. There, a workshop of experts in research ethics, funded by the NIH Department of Bioethics, argued recently that broad consent is ethically acceptable as long as participants are provided with sufficient information to make a reasonably informed decision (besides other safeguards) (Grady et al., 2015). This expert group listed 13 issues that such broad consent forms might need to cover. Similarly, in 2015 the

WMA published a draft "Declaration on Ethical Considerations regarding Health Databases and Biobanks" (World Medical Association (WMA), 2015). This declaration also considers broad consent to be ethically acceptable if individuals are "informed about the purpose of the Health Database or Biobank, the nature of the data or material to be collected and about who will have access to the Health Database or Biobank. They must also be informed about the governance arrangements and the means that will be used to protect the privacy of their information."

Several sets of ethical guidance currently define the required criteria for consent in clinical research, e.g. (Council for International Organizations of Medical Sciences (CIOMS), 2002; World Medical Association (WMA), 2008). Some guidelines also explicitly mention required criteria for consent in biobank research, e.g. (OECD, 2009). At present, however, there is no specific guidance on biobank research and consent procedures that can be used to assess consent forms. Furthermore, we currently lack a broadly accepted "best practice" model for consent forms in biobank research (Herbert, 2012).

Against the background of this controversy, and because of the increased number and scope of biobank projects in Germany, such as the "National Biobank Initiative" and the "National Cohort" (both funded by the German Federal Ministry of Education and Research, BMBF) the Permanent Working Party of the German Medical Ethics Committees (AKMEK, Arbeitskreis Medizinischer Ethik-Kommissionen) established a task force to develop a template for broad consent forms acceptable to all 53 German RECs. This template should address all relevant legal and ethical requirements and be applicable to several types of biobank, with alternative text provided to suit varying ethical and legal requirements.

This paper presents the developed template, and describes its evidence and consensus-based development process.

2. Methods

The development process was informed by two empirical studies: the results of a systematic analysis of international research guidelines (Hirschberg et al., 2014), and a survey and content analysis of existing broad consent templates from German biobanks (Hirschberg et al., 2013). The expert group chose one existing consent form that captured most of the potentially relevant issues, as derived from the first empirical study. Based on this consent form a first draft was developed in six meetings between August 2012 and September 2013. This draft was then circulated for stakeholder consultation, including a working group for biobank research at the TMF (Technology, Methods, Infrastructure for Networked Medical Research), other biobank researchers, all German RECs, data protection experts, and the German association of the pharmaceutical and medical device industry (vfa). The expert group also presented and discussed the draft at an annual meeting of the "Science" working group of the Federal data protection agencies.

After revision the final template was presented and discussed and finally agreed at the annual conference in November 2013.

3. Results

In the following we briefly introduce core findings from the two empirical studies that informed the template's development (Hirschberg et al., 2013, 2014). We then discuss how the final template deals with crucial issues such as differences in biobank characteristics, and hotly-debated topics such as reporting of incidental findings and biobank-related risks.

3.1. Potential issues for broad consent forms in biobank research

The qualitative synthesis of ten guidelines resulted in a framework of 41 issues potentially relevant to consent procedures in biobank research. These issues formed the basis for the assessment of the existing consent templates of 30 German biobanks. The issues were grouped into four main categories: (A) “General information”, covering inter alia the explanation of the type of research and its purpose; (B) “Conditions of participation”, including background on voluntary participation, consent conditions and scope; (C) “Consequences of participation”, comprising issues around risks and benefits; and (D) “Dealing with data and biomaterial”, encompassing issues concerning data protection measures and cooperation with third parties. [Table 1](#) presents the assessment matrix, the number of research guidelines from which each issue derived, the extent to which each issue was mentioned in the 30 German biobank consent forms, and the corresponding text passage in the English language version of the broad consent template presented in this paper (see [Table 1](#)). For a more detailed explanation and discussion of the issues, see ([Hirschberg et al., 2014](#)).

3.2. German consent forms for biobank research

We included 30 consent forms from 33 German biobanks in our status quo analysis. All biobanks were registered with the German Biobank Registry in July 2012. The German Biobank Registry is operated by the TMF (Technology, Methods, and Infrastructure for Networked Medical Research) and is funded by the German Federal Ministry of Education and Research (BMBF). The sample includes biobanks with different characteristics, such as type (population-wide or disease-specific biobank, or clinical study with sample collections), number of participants, organisation and funding, and inclusion of healthy subjects or patients (e.g. inclusion of all admitted patients).

The proportion of the 41 issues covered in each consent form varied widely, from a minimum of 9 (22%) to a maximum of 36 (88%). The median addressed across all 30 consent forms was 25.5 items (62%). For a more detailed explanation and discussion of the results of the analysis, see ([Hirschberg et al., 2013](#)).

3.3. A broad consent template for use in biobank research

The template, in German and English, is available as an online supplement and can be accessed at the [AKMEK website \(http://www.ak-med-ethik-komm.de/index.php?option=com_content&view=article&id=145&Itemid=163&lang=de\)](http://www.ak-med-ethik-komm.de/index.php?option=com_content&view=article&id=145&Itemid=163&lang=de). After drafting and revising the template in six face-to-face meetings of the working group members, the final template covered 38 of the 41 issues presented in [Table 1](#).

Not addressed are the following issues: A) Compensation and insurance cover, B) Dealing with data and material after participants die or become incapacitated, C) Disposal of material after death; if applicable. The insurance issue was not included because the donation of biomaterials does not demand specific insurances beyond standard third-party liability insurances according to German law. The issue on use of biomaterials after death of the donor was considered to build part of the “broad consent” issue as mainly characterized in the issues “use of materials” and “storage of materials”.

There was detailed discussion of how extensively certain issues need to be addressed. Issues such as “Duration of participation or storage” and “Data: type and quantity of data” were addressed in general wording.

For issues such as “Free and voluntary participation”, “Right to withdraw or alter consent/without disadvantage”, and

“Withdrawal: procedures and consequences regarding biomaterial and data” the authors decided to highlight that donors do not need to give reasons for their withdrawal, nor to fear adverse consequences as a result. Other authors might prefer to further highlight this information, and emphasize that refusal or withdrawal of consent will not result in any disadvantageous consequences for health care at the institution requesting biobank participation.

Other issues, however, can be addressed in more nuanced ways. With regard to “Future development and changes”, for example, the authors found it important to mention explicitly that at present it is not possible to describe all future medical research objectives. These objectives can encompass already-classified diseases, diseases that at present are still partially unknown, and genetic disorders.

With regard to “Dimension of consent: scope, safeguards and conditions” the template includes alternative text passages according to whether the donor of biomaterials can choose to participate in research on specific diseases. The same applies to the information about “Risks”, where the template differentiates between three scenarios: A) Only residual material will be used; B) Additional material will be taken as part of an already-scheduled intervention; and C) An additional intervention is planned to obtain samples.

An international debate exists about the responsible handling of incidental or unsolicited findings. The template offers alternative text passages in this regard for either no feedback on individual results or feedback in cases where significant health-related information is uncovered. Other groups might wish to further elaborate on the difficulties that come with the assessment of whether or how the disease can be avoided or treated. In most cases this type of “early detection” of diseases was never tested for a favorable risk–benefit ratio in randomized controlled trials. However, RCTs on other early detection measures such as PSA screening for prostate cancer have demonstrated the potential for net harm ([Chou et al., 2011](#)). We did not feel competent to make explicit judgments on this issue in the template and therefore leave it to the biobank to specify how health-related findings are reported. However, the group decided to highlight explicitly that the donor who received health-related information might have to reveal that information (e.g. when applying for insurance). Furthermore, the template foresees the option to opt out of information about health-related findings, or from the possibility of any renewed contact.

As for the issue of incidental findings, consent forms may also give more or less detailed information about potential risks regarding “confidentiality”: the authors of the template text decided to mention risk of breaches of confidentiality explicitly. The template also mentions that sample donors increase privacy risks if they make their genetic information available on the internet. The template also mentions the safeguards that the biobank employs to protect privacy.

4. Discussion

This paper outlined the need for and then presented a best-practice template for a broad consent form that is applicable to current biobank research. It further explored the spectrum of potentially relevant issues for such consent forms and how they are addressed in pre-existing broad consent forms.

Some of the above-mentioned challenges in biobank research, such as the reporting of incidental findings and issues of confidentiality, cannot be addressed purely by evidence-based participatory development of a consent form. Beside consent forms, a comprehensive ethics review of biobanks' internal policies for data protection, access, incidental findings and other topics is necessary

Table 1

Representation of broad consent issues in existing consent forms, research guidelines, and the presented template for a broad consent form.

Potentially relevant issues for consent in biobank research		Coverage in german consent templates (n = 30)		Coverage in prominent research guidelines (n = 10)		Text passages from the presented template of a broad consent form ³
		N	%	N	%	
A) General information						
A.1	Research explanation and purpose	28	93%	10	100%	This biobank collects human biological materials such as blood, urine or tissues linked to selected medical information. The analysis of human biological materials and data obtained or to be obtained from them has been recognized as an important instrument for current and future medical research 1. Aims and scope of the biobank [Name of biobank organisation] supports medical research. Human biological materials and selected data are stored long-term and made accessible for medical research in an effort to improve the prevention, diagnosis and treatment of human diseases. [...] <i>The scope of the respective biobank is to be described as specifically as possible.</i> 3. How will the biomaterials and data be used? [...] In order to realize the largest possible public benefit they will be used for a wide range of medical research. At present, it is not possible to describe all future medical research objectives. These can either refer to defined disease areas (e.g. cancer, cardiovascular diseases, brain disorders), to diseases that at present are still partially unknown and to genetic disorders. 6. What are the benefits for society? All current as well as future biomedical research projects aim at enhancing our understanding of pathogenesis and diagnosis, and – based on this – at developing novel or improved therapeutic approaches/strategies. [...]
A.2	Future development and changes	9	30%	5	50%	3. How will the biomaterials and data be used? [...] In order to realize the largest possible public benefit they will be used for a wide range of medical research. At present, it is not possible to describe all future medical research objectives. These can either refer to defined disease areas (e.g. cancer, cardiovascular diseases, brain disorders), to diseases that at present are still partially unknown and to genetic disorders. Thus it is possible that your biomaterials and data may also be used for research purposes which, at this stage, are unknown. [...]
A.3	Biobank design and structure	21	70%	5	50%	[...] The clinic/hospital cooperates with/supports [name of the biobank organisation or body responsible for the biobank]/operates a biobank. This biobank collects human biological materials such as blood, urine or tissues linked to selected medical information.
A.4	Funding and (conflict of) interests	6	20%	6	60%	The clinic/hospital cooperates with/supports [name of the biobank organisation or body responsible for the biobank]/operates a biobank.
A.5	Duration of participation or storage	15	50%	7	70%	3. How will the biomaterials and data be used? <i>If the research project has a limited duration, the donors should be informed as to what will happen to the materials and data at the end of the intended usage period.</i> [...] The biomaterials and data are intended to be stored and made available for medical research for an undetermined period of time. <i>If storage for a limited time is intended, please specify for how long.</i>
A.6	Biomaterial: types and quantity of specimen	27	90%	3	30%	2. What type of biomaterials and data are collected? <i>Please note: this paragraph only refers to tissues, blood, and urine. If there is a plan to collect other/</i>

Table 1 (continued)

Potentially relevant issues for consent in biobank research		Coverage in german consent templates (n = 30)		Coverage in prominent research guidelines (n = 10)		Text passages from the presented template of a broad consent form ^a
		N	%	N	%	
A.7	Data: type and quantity of data	19	63%	3	30%	<p><i>additional biomaterials (e.g. liquor, saliva, smears, stool), the text has to be adapted accordingly.</i></p> <p><i>For patients:</i> The biological materials which we would like to store and use for research are tissues and body fluids that have been collected for diagnostic/therapeutic purposes in the course of your present hospital stay, but which are no longer required for such purposes and would, therefore, be destroyed otherwise.</p> <p>2. What type of biomaterials and data are collected?</p> <p>[...] The data collected include selected information about your person: in particular, medical/health data (<i>specify additionally collected data, e.g. genetic data, as required</i>).</p>
A.8	Description of collection procedures and additional tests	26	87%	8	80%	<p>4. What are the risks associated with your donation?</p> <p><u>Case 1:</u> Only residual material will be used. As we intend to use only biomaterials that will be collected in the context of your diagnosis or treatment and that, otherwise, would be destroyed as residual material, the donation does not entail any additional health risk for you.</p> <p><u>Case 2:</u> Additional material will be taken in the frame of an already scheduled intervention. For diagnostic or therapeutic reasons we need to take some blood samples from you. On this occasion we would like to take an additional ... ml of blood (corresponding to approximately ... table spoons). Taking this sample does not entail any additional health risk for you. If applicable: please adapt for sampling of other body material!</p> <p><u>Case 3:</u> An additional intervention is planned to obtain samples. For medical research, we would like to draw ... ml of blood (corresponding to approximately ... table spoons). Your willingness to donate blood for the biobank is only associated with the low risks of routine blood sampling. In rare cases, secondary bleeding from the puncture site may occur, or in very rare cases nerve or blood vessel damage may occur that under certain circumstances may persist long-term. If applicable: please adapt for sampling of other body material—to the extent that this is permissible!</p>
A.9	Sample collection: further examination needed/follow-up points	23	77%	2	20%	<p>4. What are the risks associated with your donation?</p> <p><u>Case 3:</u> An additional intervention is planned to obtain samples. For medical research, we would like to draw ... ml of blood (corresponding to approximately ... table spoons). Your willingness to donate blood for the biobank is only associated with the low risks of routine blood sampling. In rare cases, secondary bleeding from the puncture site may occur, or in very rare cases nerve or blood vessel damage may occur that under certain circumstances may persist long-term. If applicable: please adapt for sampling of other body material—to the extent that this is permissible!</p>
A.10	Rights/Ownership of samples and data and their transfer	17	57%	2	20%	<p>9. Will there be any financial benefit for you from the use of your biomaterials and/or data? [...]</p> <p>By giving [name of biobank's legal entity] permission to use your biomaterials and/or</p>

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Table 1 (continued)

Potentially relevant issues for consent in biobank research		Coverage in german consent templates (n = 30)		Coverage in prominent research guidelines (n = 10)		Text passages from the presented template of a broad consent form ^a
		N	%	N	%	
A.11	Opinion or approval of Ethical Review Board/Committee	16	53%	5	50%	<p>data, you also transfer ownership of the biomaterials to [name of biobank's legal entity]. Further—more, you agree that [name of biobank's legal entity] uses your data.</p> <p>7. What are the constraints and safeguards for the use of your biomaterials and data? c. [...] A mandatory pre-requisite for the use of the biomaterials and data for a specific medical research project is a review by an ethics committee. The ethics committee assesses/ evaluates the ethical and legal aspects of the respective research project.</p>
B) Conditions of participation						
B.1	Dimension of consent: scope, safeguards and conditions	15	50%	5	50%	<p>3. How will the biomaterials and data be used?: <i>Broad donor consent generally requires a well-defined framework. In particular, broad consent should only be sought in cases where the scope of the biobank cannot be restricted to specific diseases, research purposes and/or diagnostic tests. If the research project has a limited duration, the donors should be informed as to what will happen to the materials and data at the end of the intended usage period.</i></p> <p><u>Broad consent:</u> Your donated biomaterials and data will be made available exclusively for medical research purposes. In order to realize the largest possible public benefit they will be used for a wide range of medical research. At present, it is not possible to describe all future medical research objectives. These can either refer to defined disease areas (e.g. cancer, cardiovascular diseases, brain disorders), to diseases that at present are still partially unknown and to genetic disorders. Thus it is possible that your biomaterials and data may also be used for research purposes which, at this stage, are unknown. If applicable: Consequently, it is also possible that genetic analyses will be performed that might involve sequencing your whole genome. The biomaterials and data are intended to be stored and made available for medical research for an undetermined period of time. If storage for a limited time is intended, please specify for how long.</p> <p><u>More restricted consent:</u> Your donated biomaterials and data will be made available exclusively for the investigation of the following diseases/for the following research-areas ... However, the exact research question(s) can often not be specified at this stage. If applicable: Consequently, it is also possible that genetic analyses will be performed, which might involve sequencing your whole genome. The biomaterials and data are intended to be stored and to be made available for medical research for an undetermined period of time. If storage for a limited time is intended, please specify for how long.</p> <p>[...] Your biomaterials and/or data will be stored in [biobank] under standardized quality and security conditions (if applicable: for an undetermined period of time) and are available for (medical) research purposes on request only. They are protected against unauthorized access according to the current state of technology.</p> <p><u>Either:</u> You can choose to restrict your consent (e.g. exclusion of certain research areas,</p>

Table 1 (continued)

Potentially relevant issues for consent in biobank research		Coverage in german consent templates (n = 30)		Coverage in prominent research guidelines (n = 10)		Text passages from the presented template of a broad consent form ^a
		N	%	N	%	
B.2	Free and voluntary participation	24	80%	10	100%	<p>exclusion of the transfer of donated materials/data to third parties).</p> <p><u>Or:</u> For logistic reasons, the biobank is not able to handle individual consent restrictions (e.g. exclusion of certain research areas, exclusion of the transfer of donated materials/data to third parties). If you are not willing to fully accept the type and duration of use described above, your biomaterials and data will not be used for the biobank.</p> <p>Please note that your participation is entirely voluntary. If you do not want to participate, you may decline or withdraw your consent at any time without any negative consequences for you.</p> <p>7. What are the constraints and safeguards for the use of your biomaterials and data?</p> <p>a. A mandatory pre-requisite for the acquisition and use of your biomaterials and related personal data for research purposes is your written consent. Your consent is voluntary and can be withdrawn at any time (see also Item 11 “What does your right of withdrawal include?”).</p>
B.3	Right to withdraw or alter consent/without disadvantage	29	97%	10	100%	<p>11. What does your right of withdrawal include?</p> <p>You are free to withdraw your consent for the use of your biomaterials and/or data at any time without giving a reason and without any fear of detriment. [...]</p> <p>I know that my participation is voluntary and that I can withdraw my consent at any time without giving reasons, and without having to fear detriment.</p> <p>[...] I have been informed that I can withdraw my consent given to [name of biobank organisation] at any time without giving reasons.</p>
B.4	Withdrawal: procedures and consequences regarding biomaterial and data	24	80%	5	50%	<p>11. What does your right of withdrawal include?</p> <p>[...] In case of withdrawal it is up to you to decide whether your biomaterials are to be destroyed and the corresponding data to be deleted, or whether they may be used in an anonymized form (that is, without any link to your person, see Item 8e) for further medical research projects. [...]</p> <p>For withdrawal, please contact: [name, address, and contact data of the contact office/biobank organisation]</p>
B.5	Decision on participation/withdrawal without affecting medical care or relationship with physician	15	50%	5	50%	<p>11. What does your right of withdrawal include?</p> <p>You are free to withdraw your consent for the use of your biomaterials and/or data at any time without giving a reason and without any fear of detriment. [...]</p> <p>I know that my participation is voluntary and that I can withdraw my consent at any time without giving reasons, and without having to fear detriment.</p>
B.6	Compensation and insurance cover	5	17%	8	80%	<p>Not explicitly addressed. According to German law the donation of biomaterials does not demand specific insurances beyond standard third-party liability insurances.</p>
B.7	Options (partial consent)	16	53%	3	30%	<p>3. How will the biomaterials and data be used?</p> <p>[...] You can choose to restrict your consent (e.g. exclusion of certain research areas, exclusion of the transfer of donated materials/data to third parties).</p>

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Table 1 (continued)

Potentially relevant issues for consent in biobank research		Coverage in german consent templates (n = 30)		Coverage in prominent research guidelines (n = 10)		Text passages from the presented template of a broad consent form ^a
		N	%	N	%	
C) Consequences of participation						5. What benefits can you expect from the donation? [...] If you do not want to be informed, please deny the possibility of re-contact (see Item 10) by ticking the respective box on the consent form. 10. Will you be contacted again? [...] If you do not wish to be re-contacted, please indicate this by ticking the respective box on the consent form. I agree that I may be re-contacted at a later date (if not agreed, please tick "No")
C.1	Direct benefit for participant	15	50%	10	100%	5. What benefits can you expect from the donation? <u>Either:</u> You cannot expect any direct personal advantage or benefit for your health from your donation of biomaterials and data. Investigational/analytical results obtained will exclusively serve medical research purposes. We will not feedback any individual results obtained through the investigation/analysis of biomaterials. <u>Or:</u> You cannot expect any direct personal advantage or benefit for your health from your donation of biomaterials and data. Results obtained will exclusively serve medical research purposes. Feedback of research results is possible in cases where information concerning your health is significant. This is the case when a (possibly life-threatening) disease can be prevented or a previously undiagnosed health disorder can be treated. Please note that you might be obliged to disclose such information somewhere else (e.g. when applying for insurance).
C.2	Indirect benefit for subgroups or society	19	63%	10	100%	6. What are the benefits for society? All current as well as future biomedical research projects aim at enhancing our understanding of pathogenesis and diagnosis, and – based on this – at developing novel or improved therapeutic approaches/strategies. If applicable: General information on the activities of the biobank can be found at ... [Internet address/ biobank homepage].
C.3	Risk	21	70%	10	100%	4. What are the risks associated with your donation? a. Health risks: <u>Case 1:</u> Only residual material will be used. [...] the donation does not entail any additional health risk for you. <u>Case 2:</u> Additional material will be taken in the frame of an already scheduled intervention. [...] Taking this sample does not entail any additional health risk for you. <u>Case 3:</u> An additional intervention is planned to obtain samples. [...] In rare cases, secondary bleeding from the puncture site may occur, or in very rare cases nerve or blood vessel damage may occur that under certain circumstances may persist long-term. b. Further risks: Any collection, storage and transfer of data related to your biomaterials in the context of (medical) research projects entails the risk of breaches of confidentiality (e.g. the possibility of identifying you), particularly regarding your genetic information. These risks cannot be completely excluded and rise with increasing amounts of linked data, particularly when you

Table 1 (continued)

Potentially relevant issues for consent in biobank research		Coverage in german consent templates (n = 30)		Coverage in prominent research guidelines (n = 10)		Text passages from the presented template of a broad consent form ^a
		N	%	N	%	
C.4	Payment/Allowance or additional costs	10	33%	6	60%	make further genetic information available on the internet (e.g. for purposes of genealogy). [Name of biobank organisation] will take all appropriate measures according to the current state of technology to protect your privacy and will transfer samples and/or data only to researchers/projects who can demonstrate appropriate data protection and confidentiality safeguards (see Item 8: "Who has access to your biomaterials and data?"). 9. Will there be any financial benefit for you from the use of your biomaterials and/or data? You will not receive any remuneration for donating your biomaterials and/or data for medical research purposes. Should such research result in commercially exploitable results, any profits will not be shared with you. [...] The biobank may charge a reasonable compensation for providing biomaterials and/or data to users.
C.5	Benefit sharing	18	60%	3	30%	5. What benefits can you expect from the donation? <u>Either:</u> You cannot expect any direct personal advantage or benefit for your health from your donation of biomaterials and data. [...] We will not feedback any individual results obtained through the investigation/analysis of biomaterials. <u>Or:</u> [...] Feedback of research results is possible in cases where information concerning your health is significant. This is the case when a (possibly life-threatening) disease can be prevented or a previously undiagnosed health disorder can be treated.
C.6	Feedback on findings or incidental findings	20	67%	6	60%	9. Will there be any financial benefit for you from the use of your biomaterials and/or data? [...] Should such research result in commercially exploitable results, any profits will not be shared with you. 5. What benefits can you expect from the donation? <u>Either:</u> [...] We will not feedback any individual results obtained through the investigation/analysis of biomaterials. <u>Or:</u> [...] Feedback of research results is possible in cases where information concerning your health is significant. This is the case when a (possibly life-threatening) disease can be prevented or a previously undiagnosed health disorder can be treated. Please note that you might be obliged to disclose such information somewhere else (e.g. when applying for insurance). If you do not want to be informed, please deny the possibility of re-contact (see Item 10) by ticking the respective box on the consent form. 10. Will you be contacted again? [...] In addition, re-contact would allow [...] to provide feedback on research results that are significant for your health to you/your attending physician/study physician (see Item 5 above).
C.7	Publication of data only unlinked	17	57%	2	20%	8. Who has access to your biomaterials and/or data and how are they protected? e. Research results for scientific publication will be anonymized, i.e. data will be published only in a form that does not allow re-identification of the donor.

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Table 1 (continued)

Potentially relevant issues for consent in biobank research		Coverage in german consent templates (n = 30)		Coverage in prominent research guidelines (n = 10)		Text passages from the presented template of a broad consent form ^a
		N	%	N	%	
C.8	Recontacting of participant: purpose and conditions	18	60%	4	40%	10. Will you be contacted again? In certain cases it might be useful to contact you again at a later date to ask you for further (follow-up) information and/or for the donation of additional biomaterials. In addition, re-contact would allow obtaining your consent for integration with other data sources or to provide feedback on research results that are significant for your health to you/your attending physician/study physician (see Item 5 above). Explain who [biobank or medical institution] will contact whom [patient/participant/ attending hospital physician/researcher/ general practitioner], and how [in writing/by telephone]. If you do not wish to be re-contacted, please indicate this by ticking the respective box on the consent form.
C.9	Contact person/point	18	60%	5	50%	If any points remain unclear, please ask your attending physician or your study physician before giving your consent. If you have any further questions at a later stage, you may also contact ... (fill in a contact/contact person)
D) Dealing with data and biomaterial						
D.1	Confidentiality of records and data/extent and limits of confidentiality	24	80%	9	90%	4. What are the risks associated with your donation? b. Further risks: Any collection, storage and transfer of data related to your biomaterials in the context of (medical) research projects entails the risk of breaches of confidentiality (e.g. the possibility of identifying you), particularly regarding your genetic information. These risks cannot be completely excluded and rise with increasing amounts of linked data, particularly when you make further genetic information available on the internet (e.g. for purposes of genealogy). [...] 8. Who has access to your biomaterials and/or data and how are they protected? b. <i>The following paragraph assumes that the biobank does not hold any identifying data and that such data are held by the institution (clinic/ physician) in which they were obtained. Such conditions are preferable, because the personal identifying data are then protected by medical confidentiality and legal access restriction. If any other procedure is planned, this must be clearly stated:</i> Data that directly identify you (personal identifying data) remain at the hospital in which the biomaterials and data have been obtained and will be stored separately from the biomaterials and related clinical data. Access to personal identifying data is necessary only in case additional or missing medical data is needed from your medical records, or in case of a need to re-contact you personally if you have agreed to this (see Item 10). In no case will personal identifying data be transferred to scientists and/or other unauthorized third parties, such as insurance companies or employers.
D.2	Privacy rights and procedures/safeguards for privacy, data processing, and identifiability of data and samples	27	90%	6	60%	8. Who has access to your biomaterials and/or data and how are they protected? <u>a.</u> Any data that directly identify you (name, date of birth, address, etc.) are replaced by a code (pseudonymized, encoded) immediately after they have been obtained. (If applicable, as

Table 1 (continued)

Potentially relevant issues for consent in biobank research	Coverage in german consent templates (n = 30)		Coverage in prominent research guidelines (n = 10)		Text passages from the presented template of a broad consent form ^a
	N	%	N	%	
D.3 Use of health data and records and its purpose	20	67%	4	40%	<p>it should generally be required) Following this, the encoded data set is re-coded again before it is stored. Based on current knowledge, this double encoding/pseudonymization procedure minimizes the possibility that you may be re-identified by unauthorized parties. The biomaterials and/or data will only be made available for research purposes in this form (i.e. double pseudonymized).</p> <p><i>b.</i> The following paragraph assumes that the biobank does not hold any identifying data and that such data are held by the institution (clinic/physician) in which they were obtained. Such conditions are preferable, because the personal identifying data are then protected by medical confidentiality and legal access restriction. If any other procedure is planned, this must be clearly stated: Data that directly identify you (personal identifying data) remain at the hospital in which the biomaterials and data have been obtained and will be stored separately from the biomaterials and related clinical data. Access to personal identifying data is necessary only in case additional or missing medical data is needed from your medical records, or in case of a need to re-contact you personally if you have agreed to this (see Item 10). In no case will personal identifying data be transferred to scientists and/or other unauthorized third parties, such as insurance companies or employers.</p> <p><i>c.</i> Based on pre-defined criteria and following a request/application, the double-encoded biomaterials and medical data may be transferred to other universities, research institutes and research companies, including those in foreign countries, for medical research. Under certain circumstances these data may be linked to medical data from other databases, provided that all legal and regulatory requirements are met.</p> <p><i>d.</i> Biomaterials and/or data that are transferred to third parties may only be used for the research purpose indicated in the application and must not be passed on by the recipient for other purposes. Material that has not been utilized will be returned to the biobank or destroyed.</p> <p><i>e.</i> Research results for scientific publication will be anonymized, i.e. data will be published only in a form that does not allow re-identification of the donor. Please note that this rules out publication e.g. of a whole genome sequence without specific individual consent!</p> <p>1. Aims and scope of the biobank [Name of biobank organisation] supports medical research. Human biological materials and selected data are stored long-term and made accessible for medical research in an effort to improve the prevention, diagnosis and treatment of human diseases. [...]</p> <p>3. How will the biomaterials and data be used? Your donated biomaterials and data will be made available exclusively for medical research purposes. In order to realize the largest possible public benefit they will be used for a wide range of medical research. At present, it is not possible to describe all future medical research objectives. [...] Thus it is possible that your</p> <p style="text-align: right;"><i>(continued on next page)</i></p>

Table 1 (continued)

Potentially relevant issues for consent in biobank research		Coverage in german consent templates (n = 30)		Coverage in prominent research guidelines (n = 10)		Text passages from the presented template of a broad consent form ^a
		N	%	N	%	
D.4	Storage of data and biomaterial	20	67%	5	50%	<p>biomaterials and data may also be used for research purposes which, at this stage, are unknown.</p> <p>7. What are the constraints and safeguards for the use of your biomaterials and data?</p> <p>b. Your biomaterials and/or data will be stored in [biobank] under standardized quality and security conditions (if applicable: for an undetermined period of time) and are available for (medical) research purposes on request only. They are protected against unauthorized access according to the current state of technology.</p>
D.5	Policy for genetic information/consent to genetic analyses	12	40%	4	40%	<p>3. How will the biomaterials and data be used? [...] Consequently, it is also possible that genetic analyses will be performed that might involve sequencing your whole genome.</p> <p>4. What are the risks associated with your donation?</p> <p>b. Further risks: Any collection, storage and transfer of data related to your biomaterials in the context of (medical) research projects entails the risk of breaches of confidentiality (e.g. the possibility of identifying you), particularly regarding your genetic information. These risks cannot be completely excluded and rise with increasing amounts of linked data, particularly when you make further genetic information available on the internet (e.g. for purposes of genealogy). [...]</p> <p>11. What does your right of withdrawal include? [...] Please note that, even in case of withdrawal, it is not possible to completely rule out that genetic information may be traced to you via other sources.</p>
D.6	Contact (with) or disclosure to/by participants' physician	19	63%	3	30%	<p>10. Will you be contacted again? [...] In addition, re-contact would allow obtaining your consent for integration with other data sources or to provide feedback on research results that are significant for your health to you/your attending physician/study physician (see Item 5 above). Explain who [biobank or medical institution] will contact whom [patient/participant/attending hospital physician/researcher/general practitioner], and how [in writing/by telephone].</p>
D.7	Policy on use/disclosure to third parties for non-research purpose	7	23%	3	30%	<p>8. Who has access to your biomaterials and/or data and how are they protected?</p> <p>b. [...] In no case will personal identifying data be transferred to scientists and/or other unauthorized third parties, such as insurance companies or employers.</p> <p>d. Biomaterials and/or data that are transferred to third parties may only be used for the research purpose indicated in the application and must not be passed on by the recipient for other purposes. [...]</p> <p>3. How will the biomaterials and data be used? <u>Either:</u> You can choose to restrict your consent (e.g. exclusion of certain research areas, exclusion of the transfer of donated materials/ data to third parties). <u>Or:</u> For logistic reasons, the biobank is not able to handle individual consent restrictions (e.g. exclusion of certain research areas, exclusion of the transfer of donated materials/data to third parties).</p>

Table 1 (continued)

Potentially relevant issues for consent in biobank research	Coverage in german consent templates (n = 30)		Coverage in prominent research guidelines (n = 10)		Text passages from the presented template of a broad consent form ^a
	N	%	N	%	
D.8 Sharing data and material with other researchers/policy and process	24	80%	2	20%	8. Who has access to your biomaterials and/or data and how are they protected? <u>a.</u> [...] The bio-materials and/or data will only be made available for research purposes in this form (i.e. double pseudonymized). <u>b.</u> [...] In no case will personal identifying data be transferred to scientists and/or other unauthorized third parties, such as insurance companies or employers. <u>c.</u> Based on pre-defined criteria and following a request/application, the double-encoded biomaterials and medical data may be transferred to other universities, research institutes and research companies, including those in foreign countries, for medical research. Under certain circumstances these data may be linked to medical data from other databases, provided that all legal and regulatory requirements are met. <u>d.</u> Biomaterials and/or data that are transferred to third parties may only be used for the research purpose indicated in the application and must not be passed on by the recipient for other purposes. Material that has not been utilized will be returned to the biobank or destroyed.
D.9 International cooperation/transborder use	7	23%	2	20%	8. Who has access to your biomaterials and/or data and how are they protected? <u>c.</u> Based on pre-defined criteria and following a request/application, the double-encoded biomaterials and medical data may be transferred to other universities, research institutes and research companies, including those in foreign countries, for medical research. Under certain circumstances these data may be linked to medical data from other databases, provided that all legal and regulatory requirements are met.
D.10 Commercialisation and collaboration with profit-making entities	17	57%	5	50%	8. Who has access to your biomaterials and/or data and how are they protected? c. Based on pre-defined criteria and following a request/application, the double-encoded biomaterials and medical data may be transferred to other universities, research institutes and research companies, including those in foreign countries, for medical research. [...] 9. Will there be any financial benefit for you from the use of your biomaterials and/or data? You will not receive any remuneration for donating your biomaterials and/or data for medical research purposes. Should such research result in commercially exploitable results, any profits will not be shared with you. [...] In no case will personal identifying data be transferred to scientists and/or other unauthorized third parties, such as insurance companies or employers.
D.11 Right of access to personal data	5	17%	3	30%	9. Will there be any financial benefit for you from the use of your biomaterials and/or data? [...] You retain the right to correct any data that might have been incorrectly stored or processed at any time.
D.12 Disposal or destruction of data and material	21	70%	3	30%	8. Who has access to your biomaterials and/or data and how are they protected? d. [...] Material that has not been utilized will be returned to the biobank or destroyed. 11. What does your right of withdrawal include?

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Table 1 (continued)

Potentially relevant issues for consent in biobank research		Coverage in german consent templates (n = 30)		Coverage in prominent research guidelines (n = 10)		Text passages from the presented template of a broad consent form ^a
		N	%	N	%	
D.13	Dealing with data and material after participants die or become incapacitated	0	0%	2	20%	[...] In case of withdrawal it is up to you to decide whether your biomaterials are to be destroyed and the corresponding data to be deleted, or whether they may be used in an anonymized form (that is, without any link to your person, see Item 8e) for further medical research projects. [...]
D.14	Disposal of material after death	1	3%	2	20%	Not explicitly addressed. Was considered to build part of the issue D3 (use of material) and D4 (storage of material). Not explicitly addressed. Not explicitly addressed. Was considered to build part of the issue D3 (use of material) and D4 (storage of material).

^a Stemming from the “Broad consent template” as developed by the German Working Group of Research Ethics Committees; “Arbeitskreis medizinischer Ethikkommissionen”.

to maintain ethical conduct and public trust in biobank research (Strech, 2015). The same group that developed the presented template also drafted “Recommendations for the ethics review of human biobanks”, which is already available in German, and will soon be translated into English (Arbeitskreis Medizinische, 2015).

Also, even the best-motivated and most disinterested experts might draft consent forms which potential participants, who have to read and sign them, find hard to understand. The working group therefore collected feedback on the presented template and aim to revise it continuously. Recently, a first “usability test” was conducted with focus groups of laypeople to investigate the comprehensibility of the broad consent form.

To further improve the validity and applicability of broad consent forms in biobank and other big data research, practice evaluations are needed. We hope that in this regard the presented template supports the development of new consent forms as well as the evaluation and revision of existing ones.

Appendix A. Supplementary data

Supplementary data related to this article can be found at <http://dx.doi.org/10.1016/j.ejmg.2016.04.002>.

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