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Research Guideline Recommendations for Broad Consent Forms in Biobank Research and How They Are Currently Addressed in Practice

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Grady and colleagues (2015) observe that broad consent is ethically acceptable as long as participants are provided with sufficient information to make a reasonably informed decision (besides other safeguards). They also highlight the importance of understanding what broad consent entails, and mention that workshop participants had diverse opinions on which issues should be included in the consent form (especially the initial consent).

The relevant issues that most workshop participants agreed on were (1) storage of donated samples, (2) sharing of samples with other researchers and institutions and the conditions under which sharing would be allowed, (3) that general health information accompanies the biospecimen, (4) the possibility of commercial or therapeutic applications, (5) the oversight process for proposed research, (6) the potential for re-contact or ongoing communication, and (7) and the possibility of donors opting out of further research on their stored biospecimens in future. Other potential issues for broad consent on which only some workshop participants agreed were (8) that any research was allowed unless specifically limited in the consent form or disallowed by the oversight body, (9) a broad but non-exhaustive description of possible research topics, including the possibility of genetic analyses, (10) keeping cells for indefinite periods, (11) information that biospecimens could be used for research on donors' diseases, or unrelated diseases, (12) information that certain kinds of sensitive or controversial research might be conducted (with examples), and (13) information about long-term disposal of samples after the donors' death.

Finally, Grady and colleagues point out that further efforts are needed to design broad consent forms and processes. In this peer commentary we aim to support future discussion about and developments of broad consent forms for biobank research by highlighting further potential issues that might be relevant to designing broad consent forms. These further potential consent issues were identified in a systematic review of international research guidelines (Hirschberg, Kahrass, and Strech 2014). In total, this review found 41 potentially relevant issues to broad consent forms as directly or indirectly described in research guidelines (see Table 1). These 41 issues cover the 13 issues mentioned by Grady and colleagues. A direct comparison is insufficient without a deeper understanding of the concepts of particular issues. For example, issues 8, 9, 11, and 12 of Grady and colleagues all aim to specify the scope of research aims of biobanks. In our review findings, however, we covered these specific issues under a broader heading (A1, "Research explanation and purpose"; see Table 1).

We neither claim that all 41 issues are of equal importance nor that each is relevant to every broad consent form. However, we believe that groups developing new broad consent forms as well as groups developing new guidelines for biobank research should be aware of a more comprehensive set of potentially relevant consent issues.

SYSTEMATIC REVIEW OF CONSENT ISSUES

Our systematic review purposively selected a sample of nine internationally recognized legal and ethical guidelines and one German guideline that include recommendations for consent procedures in biomedical research (Organization for Economic Cooperation and Development [OECD] 2009; U.S. Department of Health and Human Services 2009; Council for International Organizations of Medical Sciences [CIOMS] 2002; Council of Europe 1997; 2005; 2006; European Parliament and the Council of the European Union 2001; European Medicines Agency [EMA] 2002; Harnischmacher et al. 2006). Our reasons for selecting these research guidelines, the methodology for the qualitative analysis and synthesis of consent issues, and more detail on which guidelines mention which consent issues are described in the original publication (Hirschberg, Kahrass, and Strech 2014).

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Table 1. Potentially relevant issues for consent in biobank research

A)	General information	C)	Consequences of participation
A.1	Research explanation and purpose (*8, 9, 11, 12)	C.1	Direct benefit for participant
A.2	Future development and changes	C.2	Indirect benefit for subgroups or society
A.3	Biobank design and structure	C.3	Risk
A.4	Funding and (conflict of) interests	C.4	Payment/allowance or additional costs
A.5	Duration of participation or storage (*10)	C.5	Benefit sharing
A.6	Biomaterial: types and quantity of specimen	C.6	Feedback on findings or incidental findings
A.7	Data: type and quantity of data	C.7	Publication of data only unlinked
A.8	Description of collection procedures and additional tests	C.8	Recontacting of participant: purpose and conditions (*6)
A.9	Sample collection: further examination needed/follow-up points	C.9	Contact person/point
A.10	Rights/ownership of samples and data and their transfer	D)	Dealing with data and biomaterial
A.11	Opinion or approval of ethical review board/committee (*5, 8)	D.1	Confidentiality of records and data/extent and limits of confidentiality
B)	Conditions of participation	D.2	Privacy rights and procedures/safeguards for privacy, data processing, and identifiability of data and samples
B.1	Dimension of consent: scope, safeguards and conditions (*5, 7, 8, 9)	D.3	Use of health data and records and its purpose (*3)
B.2	Free and voluntary participation	D.4	Storage of data and biomaterial (*1)
B.3	Right to withdraw or alter consent/without disadvantage (*7)	D.5	Policy for genetic information/consent to genetic analyses (*9)
B.4	Withdrawal: procedures and consequences regarding biomaterial and data	D.6	Contact (with) or disclosure to/by participants' physician
B.5	Decision on participation/withdrawal without affecting medical care or relationship with physician	D.7	Policy on use/disclosure to third parties for nonresearch purpose
B.6	Compensation and insurance cover	D.8	Sharing data and material with other researchers/policy and process (*2)
B.7	Options (partial consent)	D.9	International cooperation/transborder use
		D.10	CommercialiZation and collaboration with profit-making entities (*4)
		D.11	Right of access to personal data
		D.12	Disposal or destruction of data and material
		D.13	Dealing with data and material after participants die or become incapacitated (*13)
		D.14	Disposal of material after death

Note. The starred numbers (*1–*13) represent the 13 consent issues described by Grady and colleagues (2015) that also appear in our list of 41 consent issues.

The resulting 41 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 (see Table 1). The 10 research guidelines themselves differed substantially with respect to (a) the comprehensiveness with which they deal with issues potentially relevant to biobank consent procedures, (b) the specification and explanation of the issues, (c) which guideline chapters describe the issues, and (d) how directly or indirectly the issues are mentioned as relevant to the consent procedure. The two international guidelines that either focused on biobank/genetic research or included comments on biobank-specific aspects were the most comprehensive (OECD 2009; Council for International Organizations of Medical Sciences [CIOMS] 2002).

Some issues mentioned in these guidelines but not by Grady and colleagues are, for example, (i) whether further examination of participants and follow-up data from, for example, future hospitalizations or additional voluntary appointments are envisaged, (ii) rights to and ownership of samples and data, (iii) risks for participants, including remarks on the extent and limits of confidentiality, (iv) whether feedback on findings or incidental findings is envisaged and if so how it is regulated, (v) the biobank policy on disclosure to third parties for nonresearch purpose (e.g., criminal prosecution, health insurance companies), and (vi) whether international cooperation and transborder use of material and data are envisaged. Our review paper explains the content dimensions of selected consent issues in more detail (Hirschberg, Kahrass, and Strech 2014).

PRACTICE VARIATION ACROSS CONSENT TEMPLATES FOR BIOBANK RESEARCH

It is not just international research guidelines and the workshop recommendations described by Grady and colleagues that differ in the set of consent issues described. In another study published elsewhere, we used the set of 41 consent issues as a matrix to assess a sample of 30 German biobank consent documents (Hirschberg, Knuppel, and Strech 2013). The assessed consent forms' coverage of the 41 items varied widely. For example, the items "Right to withdraw consent (without disadvantage)," "Policy for genetic information/consent to genetic analyzes," and "International cooperation/transborder use" were addressed in 97%, 40%, and 23% of the consent forms, respectively. The number of items covered by a single consent form ranged from 9 to 36 (22–88% of 41 items). Besides variation, however, this status quo assessment of German consent forms in biobank research also demonstrated that some biobank consent forms already cover most of the 41 issues identified in our review.

Based on these findings, a German working group representing all 53 German research ethics committees (RECs) developed a best practice broad consent template, then discussed and reviewed the template with other stakeholders (e.g., researchers, research ethics committees, potential biobank participants, patients' representatives, and ethicists) (Arbeitskreis Medizinischer Ethik-Kommissionen in der Bundesrepublik Deutschland 2013). An English translation of this broad consent template, with details of its development, will be published soon. For earlier access to the English translation, contact the corresponding author.

Grady and colleagues suggest that consent content information should be based on reasonable person standards or empirical studies on public attitudes and values; we furthermore suggest an evaluation phase prior to the intended use. The German consent form is currently evaluated in a so-called usability test that aims to evaluate and improve lay understanding of this broad consent template.

EVIDENCE-BASED GUIDELINE DEVELOPMENT NEEDED?

Our systematic review of potentially relevant consent issues as presented in research guidelines raises the question of whether a more evidence-based guideline development procedure for regulations in biomedical research is needed and how it might look. Evidence in a broader understanding is not restricted to clinical outcome data but refers to the best available body of information that supports sound and unbiased decision making. In this regard, a full set of issues potentially relevant to consent in clinical or biobank research, drawn from a synthesis of existing guidelines, would form an important source of information (evidence) for the development and revision of guidelines and workshop recommendations. Additionally, a systematic review of the literature and empirical studies would enable a search for further possibly relevant issues for inclusion in the guidelines. See the in-depth analysis in this regard in our review paper (Hirschberg, Kahrass, and Strech 2014). ■

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The U.S. National Biobank and (No) Consensus on Informed Consent

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Research involving the banking of biological samples and health and lifestyle information is a major health research initiative in the postgenomics era as it provides a platform to study complex, gene–phenotype interactions. Several countries have made significant investments in creating and supporting large-scale biobanks. Most recently, in a State of the Union address, President Obama announced the precision medicine initiative involving the creation of a new, national-level biobank with the aim of recruiting 1 million American volunteers (Kaiser 2015). Such a large initiative is not so straightforward concluded a panel of research experts at a recent National Institutes of Health workshop, and they pointed to several practical issues including which diseases will be studied, who has access to the data, and who will be recruited. If the goal of recruiting 1 million participants is to be achieved, an ethically and legally appropriate system of obtaining informed consent will be important.

Based on a workshop discussion, Grady and colleagues (2015) raise the typical set of arguments in favor of board consent—an alteration of a (specific) reconsent policy typically used in research. While there were some dissenting opinions, the conclusions of the workgroup are that broad consent is appropriate because of practical reasons (saving resources and reducing costs), that public perception data tells us that the majority of participants accept broad consent with few limitations, and that broad consent shows respect to (many) donors, offering limited control and permitting the rest to have a choice on whether to participate (Grady et al. 2015). What was surprising was the weight given to public opinion data at shaping consent policy.

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