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ARTICLE

Access policies in biobank research: what criteria do they include and how publicly available are they? A cross-sectional study

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Access policies of biobanks specify the governance of sample and data sharing. Basic guidance on relevant access criteria exists, but so far little is known about their public availability and what criteria for access and prioritization they actually include. Access policies were gathered by hand searching the websites of biobanks identified via registries (eg, BBMRI and P3G), and by additional search strategies. Criteria for access and prioritization were synthesized by thematic analysis. Of 523 biobank websites screened, 9% included a publicly available access policy. With all applied search strategies, we finally retrieved 74 access policies. Thematic analysis resulted in 62 different access criteria in three main categories: (a) scientific quality, (b) value and (c) ethical soundness. 'Scientific quality' criteria were mentioned in 70% of all policies, 'value' criteria in 33% and 'ethical soundness' criteria in 73%. Criteria for prioritization were specified in 27% of all policies. Access policies differed broadly in number, specification and operationalization of the included access criteria. In order to make biobank research more effective, efficient and trustworthy, access policies should be more available to the public. Furthermore, access policies should aim for precise and more harmonized wording of access criteria. From a public and governance perspective, the issue of how to prioritize access to scarce samples should form part of access policies.
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INTRODUCTION

Human biobanks collect, process, store and distribute human biological samples and associated data. Biobanks are widely recognized as valuable resources for biomedical research, as access to samples and their related data is essential to basic, translational, clinical, epidemiological and diagnostic research. Owing to their growing importance, the number of biobanks has considerably increased worldwide. For instance, the first catalog issued by the pan-European Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) comprised >300 biobanks in 2011. The new BBMRI-ERIC directory, released in 2015, already comprises >500 biobanks. A recent study identified over 600 biobanks in the United States.[1] Notably, public money has been used to establish and build up many of these biobanks.[2] In Germany, for instance, the Federal Ministry of Education and Research (BMBF) allocated about 18 million euros over 5 years from 2011 to fund a national biobank initiative. A second funding round is currently underway.[3] A central aim of such national funding initiatives is to ready local and national biobanks for international cooperation and networking.

As the overall and long-term value of research biobanks rests on the collected samples and data, there is an obvious need for good governance of access to these collections. Accordingly, the issues of sample and data ownership, access to samples and data sharing have been well debated internationally.[4–11]

A core challenge with regard to the governance of access is that stakeholders in biobank research have different and sometimes conflicting interests and responsibilities. First, *biobanks* invest financial and human resources to build the infrastructure for the acquisition, processing, and storage of samples and data. Biobanks therefore seek academic or monetary recognition of their efforts ('compensation') when material or data are used in individual research projects. Second, individual *researchers and their affiliations* (academic/clinical departments) who contribute to the development of a specific biobank legitimately pursue their own interests (eg, career, international reputation via improved local research conditions). Third, if biobanks are publicly funded, the *funders* may oblige biobanks to allow uses of samples and data with high scientific and social value (another sort of 'compensation').[8] Fourth, *sample donors* bear burdens and risks when participating in biobank research; often small, but non-negligible. These mostly comprise potential breaches of confidentiality (eg, re-identification of anonymized or pseudonymized data),[12] and in some cases burdens or risks involved in sample donation (eg, risks of bleedings, local infections and expenditure of time). Risks and burdens borne by sample donors are another (reciprocity-based) reason for biobanks to pursue research of high scientific and social value.[7]

How do these four interests relate to biobanks' access policies? There is a greater likelihood of high scientific and social value (in the interest of sample donors and public funders) when samples and data are also available to external researchers. Researchers are 'external' if they are not affiliated with the biobank and/or have not contributed to the specific sample collection they are interested in. However, they might have very promising, sound research questions.[13] Further, some research questions might require large numbers of samples, access to which would be facilitated by international networking. These broader

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academic and public interests in high value biobank research might conflict with interest of biobank staff and local researchers aiming for prioritized access to local samples, or other benefits, in return for their efforts. This conflict demonstrates the need for reasonable and practice-oriented governance of access to samples and data.

To address public, scientific and local needs sustainably, sound criteria and procedures are crucial. In its 2012 Best Practices, the International Society for Biological and Environmental Repositories (ISBER) addresses this point by calling for the establishment of biobank-specific access policies, describing them as a key mechanism for access governance.[14] Basic guidance on the formulation of access policies already exists, and highlights the need for concise evaluation criteria for access decisions.[8,9,15,16]

A recent study by Verlinden *et al*[17] has already revealed interesting features of access policies' formal aspects. The study identifies 21 key conditions, which relate to access to samples or data, such as ownership, custodianship and data protection issues. However, little is known still about the precise criteria individual biobanks apply when researchers request access to samples and data.

Moreover, how biobanks prioritize access to scarce but highly requested samples has not been assessed at all. The issues of priority setting and fair allocation of scarce samples are not new, either. ISBER, for example, says that access to samples should be prioritized when necessary, for example, in cases where demand outstrips supply. Unlike data, biomaterials can be used up. A sample of cancer tissue, for example, cannot be used in an unlimited number of research projects, because within the course of research the sample or at least certain quantities of the sample will be destroyed. Therefore, decisions about access to 'scarce' biomaterials unavoidably become priority-setting decisions.

To enable evidence-based discussion around the current state and potential revisions of access policies in biobank research, this study aimed to chart the public availability of access policies in a cross-sectional study. In this regard, public availability is defined as the possibility to receive the required information easily by consulting the biobank´s specific website. The study further aimed to assess the full qualitative spectrum of access and prioritization criteria currently used in access policies.

METHODS

Search for access policies

First, we contacted all biobanks listed in the BBMRI catalog[18] ($N=333$, as of June 2015) via e-mail and asked for documents describing each biobank's access policy. In our contact e-mail, we explicitly outlined the scientific aims of our study, that all policies would be kept confidential, and that we would not report biobank names in our results. However, owing to the low response rate of $n=14$ (4%), we needed additional search strategies.

Our second strategy was to check biobank websites to identify either downloadable documents or otherwise published information on how access is regulated. This second search strategy was not only used to increase the number of retrieved access polices for the planned text analysis (see below) but also to determine the percentage of biobanks that have publicly available access policies. Our definition of 'publicly available' access policy was narrowed down to 'available via the biobank's website'. In this regard, we did not include other types of availability such as 'availability on request' (via e-mail or telephone) for the following reasons: first, any 'on request procedure' might give the impression that the amount of information with regard to the access regulations is depending on who is asking. Second, there can be substantial delays in getting access to access policies if this involves contacting biobank staff and waiting for their responses. Third, it simply does not cover the true meaning of 'publicly available' if a document is 'hidden' behind an 'on request' procedure.

We searched the websites of all biobanks listed in the catalogs from BBMRI ($N=333$) and the Public Population Project in Genomics (P3G) observatory ($N=164$). We further checked all biobank websites listed on the website of the Australasian Biospecimen Network ($N=26$). Finally, two additional web searches were conducted in Google with the search expression (1) 'access policy' AND 'biobank', and (2) 'access policy' AND 'biorepository'. Here, the first 100 hits (sorting by relevance) were included. Finally, duplicates were removed. The search was carried out between May and August 2015.

We included every written document that described a biobank's access regulations (eg, 'rules for access and use', 'terms for use', 'ethics and governance framework' etc.). We did not restrict our analysis to one specific type of biobank (eg, population banks, disease-specific biobanks).[19] Only access policies in English or German were included.

Analysis and synthesis of access criteria

To extract, analyze and synthesize the relevant information on access criteria, thematic text analysis was applied to all included access policies.[20] First, a subset of 12 policies was systematically analyzed by two researchers independently (HL and HK). Paragraphs that mentioned aspects related to access to samples and/or data were identified. Each paragraph considered relevant was copied in full into an Excel file and a descriptive code was applied. Second, the findings were compared with identify any differences in coding. However, only minor differences occurred, and were resolved by discussion. Coding was performed inductively and deductively. Deductive coding was based on the criteria listed in the 'P3G Model Framework for Access Policy: Core Elements'.[15] Third, criteria mentioned in each access policy were correlated, to collate the various codes and cluster the findings into an initial matrix of categories and subcategories. This matrix served as a starting point for the further thematic analysis of the remaining access policies. One researcher (HL) used the above-described approach to add and modify codes until theoretical saturation was achieved for the main categories and the first-order subcategories. Theoretical saturation implies that no new categories can be generated for the theoretical framework that forms the primary endpoint of the thematic analysis.[21] This resulted in a pre-final matrix of broad and narrow categories for access criteria. Two other researchers (HK and SS) then checked all access policies and the resulting matrix and proposed changes. All researchers discussed and slightly modified the matrix for internal consistency and agreed the final matrix.

RESULTS

Of 523 biobank websites, 48 (9%) offered a publicly available access policy. Fifteen policies (5%) were from the 333 BBMRI biobanks, 20 policies (12%) from the 164 P3G biobanks and 13 policies (50%) from the 26 biobanks linked on the Australasian Biospecimen Network website. Another 12 policies were identified via the additional Google search. Together with the 14 policies received via the initial e-mail survey of BBMRI biobanks (see Methods), we analyzed a total of 74 access policies (Table 1).

Via thematic text analysis, we identified and categorized a total of 62 access criteria in three main categories: 'scientific quality', 'ethical soundness' and 'value'. Table 2 presents the 62 criteria under their main categories together with quantitative data for their representation in the 74 access policies (Table 2). In addition, some biobanks categorically exclude access to samples and data for specific reasons (Table 3).

Also, procedures and technical conditions for access differed widely, but we did not assess these issues systematically. An extended table illustrating the spectrum of 62 access criteria with exemplary text passages from the access policies can be found in the annex (Online Supplement). Of the 62 subcriteria, 48 were mentioned in fewer than 10 access policies, and 24 were mentioned only once.

Fifty-nine access policies (80%) refer to the main category 'scientific quality'. At the meso level, scientific quality is further specified by 'quality safeguards', 'methodological quality' and/or 'capacities and infrastructure' (Table 2). Examples for 'methodological quality'

Table 1 List of all access policies included in analysis

ID	*Name of biobank*	*Country*	*Name of document*	*Date last updated*
1	1958 British Birth Cohort Study	UK	Policy for use and oversight of samples and data arising from the Biomedical Resource of the 1958 Birth Cohort (National Child Development Study)	Apr 2014
2	Airwave Health Monitoring Study (AHMS)	UK	Airwave health monitoring study: protocol for research tissue bank	July 2013
3	Avon Longitudinal Study of Parents and Children (ALSPAC)	UK	Access policy	Jun 2015
4	CEPH Families Reference Panel	FR	CEPH families reference panel access policy	n.n.
5	CONSTANCES Cohort	FR	Procedures for access by the scientific community	Jul 2014
6	EORTC Prospective Tissue & Biofluid Collection	BE	Human biological material collection, storage and use	Jun 2015
7	Epidemiology of health in Sweden	SE	Ethics policy	Nov 2010
8	VAS-EUROPEAN BIOBANK ON VASCULAR DISEASES (VAS-EBVD)	IT	Regulation of the VAS-European biobank on vascular diseases	n.n.
9	European Human Frozen Tumor Tissue Bank TUBAFROST	EU	Rules for access and use	n.n.
10	Galliera Genetic Bank (GGB)	IT	Guidelines	n.n.
11	German National Cohort	DE	Nutzungsordnung/use and access policy	n.n.
12	Inselspital Bern, Mitglied der Stiftung Biobank Suisse	CH	Reglement der Gewebebank Bern	2010
13	IARC International Agency for Research on Cancer Biological Resource Centre	FR	IARC policy on access to human biological materials	Nov 2013
14	LifeGene	SE	Life gene access and IP policy; plus: life gene ethics policy	Aug 2011; Sep 2010
15	LifeLines Cohort Study	NL	Data and biomaterials access policy	Jun 2015
16	Million Women Study	UK	Data access and sharing policy	Jun 2015
17	Biobank Graz Medical University	AT	Access rules	n.n.
18	Norwegian Mother and Child Cohort Study	NO	Terms and conditions for access to data and biological materials	Sep 2013
19	P2N Popgen 2.0	DE	Information for researchers	n.n.
20	CIBERES Pulmonary Biobank Consortium	ES	Terms of use	Jun 2010
21	Study of Health in Pomerania	DE	Regelungen der Universitätsmedizin Greifswald zur Nutzung von Daten und Probenmaterial der Studien 'Leben und Gesundheit in Vorpommern' (SHIP) 'Community Medicine im Neugeborenenalter' (SNiP) 'Greifswald Approach to Individualized Medicine' (GANI_MED)	Jul 2012
22	Trentino Biobank	IT	n.n.	n.n.
23	Banco Nacional de ADN	ES	Access to samples/conditions of use	n.n.
24	BBMRI Large Prospective Cohorts	EU, FI, SE, NO, IS, UK, NL, FR, DE	Transnational access to large prospective cohorts in Europe	n.n.
25	Brain Net Europe	EU, FI, NL, UK, ES, FR, AT	Model Brain bank Regulations	May 2009
26	CRIP	EU, AT, DE	CRIP rules for access	n.n.
27	The European Prospective Investigation into Cancer and Nutrition (EPIC) study	EU, DK, FR, DE, GR, IT, NO, ES, SE	The EPIC access policy	2014
28	Hannover Unified Biobank HUB	DE	n.n.	n.n.
29	Telethon Network of Genetic Biobanks (TNGB)	IT	TNGB charter	Nov 2014
30	Australasian Leukamia and Lymphoma Group	AUS	Process for obtaining samples from the ALLG discovery centre	May 2012
31	Australian Breast Cancer Tissue Bank	AUS	Access policy	n.n.
32	Australian Ovarian Cancer Study	AUS	Access policy	Apr 2007
33	Australian Pancreatic Cancer Genome Initiative (APGI)	AUS	BioSpecimen and data access policy	Aug 2014
34	Australia Prostate Cancer BioResource	AUS	BioResource tissue access policy	Oct 2013
35	Clear Study (Cancer, Lifestyle & Evaluation of Risk)	AUS	Data and biospecimen access policy	Aug 2014
36	Genetic Repositories Australia (GRA)	AUS	Access policy	Nov 2007
37	Gynaecological Oncology Biobank at Westmead	AUS	Application form; policy for access to biological specimen	n.n.
38	Lifepool	AUS	Biospecimen and data access policy	Jun 2012
39	New South Wales Brain Banks (NSWBB)	AUS	Guidelines for researchers	Mar 2015
40	Pediatric Tissue Bank Westmead	AUS	Tumour bank application form; conditions of use for tumour bank samples	Oct 2012
41	Queensland Children's Tumour Bank	AUS	Application for biological specimens; conditions of use for Qld children's tumour bank samples	Jan 2014
42	Victorian Cancer Biobank (VCB)	AUS	How to apply and conditions of use	Dec 2014
43	Canadian Partnership for tomorrow	CAN	Data access policy	Mar 2015

Table 1 (Continued)

ID	Name of biobank	Country	Name of document	Date last updated
44	CONOR Cohort of Norway	NO	Guidelines for access to CONOR materials	Dec 2004
45	Born in Bradford	UK	Guidance and conditions for collaborators on the Born in Bradford programme	n.n.
46	Atherosclerosis Risk in Communities Study	USA	Ancillary studies policy; ARIC ancillary study review criteria	May 2014
47	CARDIA Study	USA	Ancillary studies policy	n.n.
48	Framingham Heart Study	USA	n.n.	n.n.
49	Agricultural Health Study	USA	Guidelines for collaboration	n.n.
50	Beta-Carotene and Retinol Efficacy Trial (CARET)	USA	n.n.	n.n.
51	Black Womens Health Study	USA	n.n.	n.n.
52	Breakthrough Generations	UK	n.n.	n.n.
53	Canadian Longitudinal Study on Aging (CLSA)	CAN	Data and sample access policy and guiding principles	Sep 2014
54	CARTaGENE	CAN	CARTaGENE	n.n.
55	Generation Scotland	UK	Management, access and publication policy	Sep 2013
56	Growing up today study (GUTS)	USA	Guidelines for use of the growing up today study: external collaborators	Apr 2012
57	China Kadoorie Biobank (CKB)	China	CKB data access and sample preservation policy	n.n.
58	Marshfield Clinic Personalized Medicine Research Project (PMRP)	USA	Data and tissue access guidelines	Jul 2010
59	Pathology, Epidemiology & DNA Information: a Genetic Research Enabling Enterprise (PEDIGREE)	AUS	Policy and procedures: access to data and biospecimens	Sep 2012
60	Nord-Trøndelag Health Study (HUNT)	NOR	Guidelines for administration and use of research data from the HUNT study	n.n.
61	Nurses' Health Study	USA	Guidelines for external collaborators: use of the nurses' health studies biospecimens	n.n.
62	UK Biobank	UK	Access procedures: application and review procedures for access to the UK biobank resource	n.n.
63	Manchester Cancer Research Centre	UK	MCRC biobank access policy	Aug 2012
64	Newcastle Biomedicine Biobank	UK	Access policy	Jan 2013
65	LANDMark BioBank (LBB)	AUS	Tissue access policy	Nov 2011
66	UCL Eastman Biobank	UK	Management protocol	May 2012
67	Northern Ireland Biobank	IR	Access policy	Feb 2013
68	Integrated Biobank Luxembourg	LUX	Privacy, ethics and access policies	n.n.
69	McGill University Faculty of Medicine	CAN	General guidelines for biobanks and associated databases	Mar 2015
70	AMGEN	USA	Biobanking of human samples policy	Dec 2013
71	Mayo Clinic Biobank	USA	Individualized medicine Mayo Clinic biobank Access committee	n.n.
72	Canadian Health Measures Survey Biobank	CAN	Access requirements and protocols for the Canadian health measures survey biobank	Oct 2014
73	Type 1 Diabetes Trial Net	USA	Sample and data sharing policy	n.n.
74	Prostate Cancer Biorepository Network	USA	Tissue and data access policy	Nov 2014

include subcriteria such as 'sound methodology' and 'sound sample size'. Examples for 'capacities and infrastructure' include subcriteria such as 'relevant expertise of researchers' and 'sufficient resources and funding'.

'Value', the second main category, is addressed in 31 (42%) access policies and further divided into 'scientific value' and 'health related value' (Table 2). Examples of 'scientific value' include subcriteria such as 'scientific research purposes only' and 'novelty and innovation'. Examples of 'health related value' include 'expected impact on clinical practice' and 'expected impact on public health'.

The third main category, 'ethical soundness', is referred to in 56 (76%) access policies, and comprises two criteria, 'adherence to ethical statutes and guidelines' and 'donor protection' (Table 2). Examples of 'adherence to ethical statutes and guidelines' include subcriteria such as 'independent ethical approval' and 'conformity with biobank statutes'. Examples of 'donor protection' include subcriteria such as 'conformity with donor consent' and 'data protection'.

Of those criteria that specify how to make access decisions, we distinguished 14, which immediately deny access ('a priori exclusion criteria') (Table 3). These criteria can be either project related or researcher related. Examples of project-related exclusion criteria include 'research for commercial purposes' and 'research with final aliquots'. Examples for researcher-related exclusion criteria are 'previous non-compliance with guidelines' and 'local researchers only'.

Prioritization is referred to in 20 access policies (27%), and a total of 15 subcriteria were identified for the prioritization of sample allocation (Table 4). The criterion most often used for prioritized access was 'priority for active members (contributing/collecting)' ($n=4$), followed by 'priority for network members', 'regional or national benefit' and 'indication' (each $n=3$). The other 10 criteria are mentioned in only one access policy each.

Finding the biobanks' websites was often complicated by missing or incorrect links in the respective registries (Table 5). For 74 (22%) biobanks in the BBMRI catalog and for 15 (9%) biobanks in the P3G

Table 2 Access criteria

Main category	No. of access policies addressing this category			No. of access policies specifying this category		Criteria	Subcriteria	Count
	Explicit	Implicit	N.a.	Yes	No			
1. Scientific quality	33	26	15	52	22	Quality safeguard	Peer review	13
							Quality management	2
							Reliability of preanalytical measurements methods	1
						Methodological quality	Sound methodology	17
							Sound sample size	13
							Feasibility	10
							Relation to existing research	10
							Sound research question	5
							Reproducibility	2
							Consistency	1
						Capacities and infrastructure	Relevant expertise of researchers	19
							Sufficient resources and funding	16
							Sufficient infrastructure	8
							Possibility for cooperation and networking	7
2. Value	12	19	43	25	49	Scientific value	Scientific research purposes only	24
							Contribution to scientific knowledge	12
							Novelty and innovation	9
							Proportionate sample size	3
							Typology of resources	3
							Potential to increase the quality of the samples or data sets	1
							Expected audience for results	1
						Health-related value	Expected impact on clinical practice	4
							Expected impact on public health	1
							Utilitarian value	1
							Individual benefit for participants/donors	1
3. Ethical soundness	14	42	18	54	20	Adherence to ethical principles	Independent ethical approval	43
							Conformity with biobank statutes	16
							Conformity with current ethical standards, laws and regulations	13
						Participant/donor protection	Conformity with donor consent	24
							Risk of identification of participants/donors	7
							Data protection	8
							(Re-) Contacting	6
							Potential harm to donor compliance	3

catalog, we were not even able to find a website, either from a link in the catalog or by additional Google searches.

DISCUSSION

This is the first study to investigate the public availability of individual biobanks' access policies. It demonstrates that only 9% of 523 websites from biobanks provide an access policy or other relevant access information. Public availability differed across biobank networks. Although 50% of the 26 biobanks in the Australasian Biospecimen Network have publicly available access policies, only 5% of the 333 BBMRI-registered biobanks and 12% of the P3G-registered biobanks do.

This study does not represent all existing biobanks but only those identified via the websites from internationally well-known biobank networks and additional Google searches. Furthermore, the lack of publicly available access policies does not necessarily indicate that no access policy or explicit access criteria are in use. For instance, in this study, 'conformity with donor consent' was found in only 32% of all access policies, but we assume that many more biobanks would require this conformity. Reasons for the apparent wide-spread lack of access to access policies might be manifold (eg, administrative barriers and lack of awareness) and need further evaluation. However, this current lack of information entails other challenges, which are described in the following sections.

This study also analyzed the full text of 74 access policies, and revealed a qualitative spectrum of 62 different access criteria that can be grouped under three main criteria. We did not aim to further complement our sample of 74 access policies, because we could demonstrate theoretical saturation (an essential validity criterion in qualitative research) for our primary endpoint, namely the qualitative spectrum of access criteria. The assessed policies varied widely in terms of which criteria they included and how they were further elaborated.

Table 3 A priori exclusion criteria

Exclusion criteria	*Exclusion*	*Restriction*	*Inclusion*	*Not mentioned*
Project related				
Commercial purposes	16	1	8	49
Research on genetics of criminality	2	0	0	72
Final aliquots	2	2	0	72
HIV testing	1	0	0	73
Research on genetics of sexual orientation	1	0	0	73
Research on genetics of intelligence	1	0	0	73
Research on cloning	1	0	0	73
Research on genetic manipulation	1	0	0	73
Sample use inside biobank only	1	1	0	72
Animal research	1	0	0	73
Patents	1	2	0	71
Disease prognosis markers assessment	1	0	0	73
Researcher related				
Previous non-compliance with guidelines	3	0	0	71
Local researchers only	4	0	17	53

Table 4 Criteria applied to prioritize access to samples and data

Criteria	*Count*
Priority for active members (contributing/collecting)	4
Priority for network members	3
Regional or national benefit	3
Prioritization by indication	3
Scientific merit	2
First come, first serve	1
Provincial research prioritized	1
Low impact on sample quality	1
Only small sample quantity requested	1
Innovation	1
Linkage of data and samples	1
Broad access	1
Peer review	1
Funding	1
Potential value	1

Criteria for priority setting, that is, criteria to guide biobanks in challenging decisions on who gets more or less prioritized access to finite samples, were specified in a minority (27%) of access policies.

The argument for better access to access policies

A large majority of biobanks are non-profit organizations. Results from a US survey indicated that only around 5% of biobanks operate on a for-profit basis.[22] As outlined in the Introduction section, public funding as well as burdens and risks borne by sample donors put some (reciprocity-based) obligation on biobanks to pursue research with high scientific and social value. Against this background, some authors have argued for a 'stewardship model', requiring biobanks to prioritize best use and avoid underutilization of samples.[23–26] Thus, biobanks ought to make all necessary arrangements that facilitate the best possible utilization of the samples. A key task in this regard would be to facilitate the access to informative access policies.

The lack of publicly available access policies would not only contradict this obligation of stewardship but could also diminish public trust, willingness to donate samples and public funding. Biobanks, therefore, should have meaningful access policies and make them publicly accessible.

To improve the current status quo research infrastructrures such as BBMRI-ERIC and P3G could require access policies as a prerequisite to listing in their registries. Similarly, public funders might require (and not only recommend) publicly available access policies with at least some opportunity for external access.

An improved public accessibility of access policies might also facilitate networking with interested researchers.

More practice-oriented and context-specific normative analysis would be needed to determine how individual biobanks should balance (A) local interests in prioritized access to stored samples or other approaches to appropriate return on investment and (B) the above-mentioned interests of sample donors and public funders.

Guidelines or templates to improve quality and harmonization of access policies?

The 'P3G Model Framework for Access Policy: Core Elements' gives extensive advice on the format and wording of access policies, but restrict its advice to 10 access criteria, of which some are rather broad and would need to be further elaborated to be used in practice. Other available guidance on the design and formulation of access policies also fails to reflect the variety of potentially relevant access criteria.[8,9,15,16]

Although guidelines with more fine-grained advice might improve the quality of access policies, it is questionable whether they would also support harmonization of access policies. Harmonization in biobank governance is important to international cooperation and networking in biobank research.[19] To this end, a systematically derived template for access policies might be more useful than or at least complement improved guidelines. Such a template would include precise text passages for potentially relevant access criteria and allow a quick adjustment for biobank-specific characteristics, national laws or other local sensitivities. A template for harmonized consent forms in German biobank research was published recently.[27] If a similar type of

Table 5 Identification of biobank websites via registries of BBMRI and P3G

	BBMRI (N = 333)	*P3G (N = 164)*	*Total (N = 451, after removing 46 double listings)*
Website of biobank is linked in the catalog	228 (68%)	134 (82%)	323 (72%)
Link is correct	165 (49%)	97 (59%)	234 (52%)
Not linked, but website easily detectable via Google	31 (9%)	15 (9%)	41 (9%)
Website is linked, but link is not correct	63 (19%)	37 (22%)	89 (20%)
Website could be found via	Yes	Yes	Yes
Google	30 (9%)	28 (17%)	48 (11%)
	No	No	No
	33 (10%)	9 (5%)	41 (9%)
Not linked, no website found via Google	74 (22%)	15 (9%)	87 (19%)

template will be developed for access policies it should be an evidence based and participatory effort, involving all relevant stakeholder groups in biobank research (eg, biobank researchers, biobank managers, policy makers and patient groups). The 62 access criteria presented in this study build important evidence in this regard and might function as a starting point for the template development.

Insufficient awareness of prioritization

Most of the analyzed access policies did not clearly differentiate between (A) access to materials and data and (B) prioritized allocation of scarce materials. Prioritization, however, should be regarded as following the initial access decision. For example, demanding a 'sound methodology', 'relevant expertise of the researchers' and 'positive ethics approval' might all be relevant criteria to the decision on access ('yes/no'). But such binary criteria do not meaningfully inform how to prioritize access ('more/less') if two or more competing sample requests are made that fulfill the basic access criteria.

Even when the need for prioritization is mentioned in some access policies, not all criteria currently applied to priority setting seem equally useful. For instance, the 'first come first serve' approach (Table 4) is a simple and effective way to prioritize samples, but can at the same time prevent samples being used in a way that optimizes scientific and social value. Prioritization should ideally be based on criteria that allow for a ranking. But even criteria that allow rankings might be more or less justifiable. For instance, an assessment of scientific merit might be challenging for several reasons. One reason is that it requires advanced expertise and method knowledge but also expertise with regard to current developments in very specific scientific communities. Another reason is that biobank research is a dynamic field driven by technical innovations that demand a non-rigid understanding of scientific merit.

Future conceptual and normative analysis is needed to define practically feasible and normatively appropriate criteria for prioritized access to samples stored in biobanks. The presented spectrum of 62 access criteria might function as important background material to inform discussion and decision making in this regard.

Our search for access policies coincided with the release of the new directory BBMRI-ERIC (European Resources Research Infrastructure Consortium), which was launched in July 2015. The BBMRI registry used in this study was no longer updated; the new directory now comprises >500 biobanks. Thus, our finding that currently only 9% of all 523 analyzed biobank websites offer information on access policies should be reassessed in the future, together with empirical studies on potential barriers and facilitators for more transparent and meaningful access policies.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHOR CONTRIBUTIONS

Conceived and designed the research study: HL and DS. Acquired the data: HL and SS. Analyzed the data: HL, HK and SS. Wrote the manuscript: HL and DS.

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