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Access policies in biobank research

What criteria do they include and how publicly available are they?

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1. Background & Objectives

Human biobanks collect, process, store, and distribute human biological samples and associated data. Samples and data stored in international biobanks are highly valuable resources, as they can be accessed for various scientific purposes. Because 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. However, governance of access needs to take into account different and sometimes conflicting interests and responsibilities of the various biobank stakeholder groups:

1) **Biobanks** seek recognition for their efforts and investment of financial and human resources for the acquisition, processing, and storage of samples and data ("return on investment").
2) **Researchers** and their academic/clinical departments who contribute to the development of a specific biobank legitimately pursue their own interests (e.g. career, international reputation via improved local research conditions).
3) **Public funders** may oblige biobanks to allow uses of samples and data with high scientific and social value (another sort of "return on investment")
4) Risks and burdens borne by **sample donors** are another (reciprocity-based) reason for biobanks to pursue research of high scientific and social value.

The likelihood of high scientific and social value increases when samples and data are accessible by external researchers with promising and sound research questions. Further, some research questions might require large numbers of samples, access to which would be facilitated by international networking. These broader academic and public interests 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.

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 they actually include. Even less is known about how biobanks prioritize access to scarce but highly requested samples. Unlike data, biomaterials can be used up. Therefore, decisions about access to stored biomaterials unavoidably become priority-setting decisions.

Thus the aim of this study was to systematically assess the current status quo of international access policies, that is their public availability and the range of criteria applied to regulate access to samples and data.

2. Methods

Access policies were gathered by hand-searching the websites of international biobanks identified via registries and by additional search strategies. Criteria for access and prioritization were synthesized by thematic analysis. Figure 1 shows details.

Figure 1: Search strategy and methodology of analysis

Search for access policies		Selection	Data Extraction and Synthesis
BBMRI catalogue Mail survey (n=333) Website search (n=333)	**P3G observatory catalogue** Website search (n=164)	**Inclusion:** • **written documents describing biobank's access regulations** • **English and German**	• **Extraction of relevant text passages** • **Classification of extracted text passages** • **Theoretical Saturation** • **Internal consistency**
Web search Google: "access policy" AND "biobank" OR "biorepository" (n=200)	**Australasian Biospecimen Network** Website search (n=26)		

3. Results and Discussion

With all applied search strategies we finally retrieved 74 access policies. Response rate to mail survey was very low (n=14; 4%). Only 9% of 523 websites from international biobank registries provide an access policy or other relevant access information. Public availability differed across biobank networks. While 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. See Table 1 for details.

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%. Access policies differed broadly in number, specification and operationalization of the included access criteria.

For instance, 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". Examples of "Adherence to ethical statutes and guidelines" include sub-criteria such as "Independent ethical approval" (n=43; 58%) and "Conformity with biobank statutes" (n=16; 22%). Examples of "Donor protection" include sub-criteria such as "Conformity with donor consent" (n=24; 32%) and "Data protection" (n=8; 11%). Table 2 lists all main categories and criteria.

Criteria for prioritization were specified in 27% of all policies. 15 sub-criteria were identified for the prioritization of sample allocation. 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)

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.

The lack of publicly-available access policies does not necessarily indicate that no access policy or explicit access criteria are in use. Reasons for the apparent wide-spread lack of "access to access policies" might be manifold (e.g. administrative barriers, lack of awareness) and need further evaluation. However, this current lack of information entails other challenges:

Better access to access policies

Opaque or unavailable access policies would contradict this obligation of stewardship and could diminish public trust, willingness to donate samples, and public funding. Biobanks, therefore, should have meaningful access policies and make them publicly accessible. Publicly-accessible access policies would not only facilitate networking with interested researchers, but would also indicate to sample donors that access to their samples is subject to meaningful and transparent procedures.

Guidelines or templates to improve quality and harmonization of access policies

Available guidance on the design and formulation of access policies also fails to reflect the variety of potentially relevant access criteria. A systematically-derived template for access policies might be more useful than or at least complement improved guidelines. The 62 access criteria presented in this study would be a good starting point for 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. Even when the need for prioritization is mentioned in some access policies, not all criteria currently applied to priority setting seem equally useful. 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.

Table 1: Identification of biobank websites via registries of BBMRI and P3G

	BBMRI (N=333)	P3G (N=164)	Total (N=451, removing 46 double listings)
Website of biobank is linked in the catalogue	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 Google	Yes 30 (9%) No 33 (10%)	Yes 28 (17%) No 9 (5%)	Yes 48 (11%) No 41 (9%)
Not linked, no website found via Google	74 (22%)	15 (9%)	87 (19%)

Table 2: Access criteria

Main category	Addressing this category			Specifying this category		Criteria	Sub-Criteria	Count
	Expl.	Impl.	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 datasets	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

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