Access policies

What criteria do they include and how publicly available are they? A cross-sectional study

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Background: Access Policies

organizational structure of the repository, the Director may have other responsibilities including: (i) ensuring that the repository operates within budget, (ii) ensuring that the repository has adequate funding for operations which may require the development of cost-recovery strategies to ensure the repository's short and long-term financial stability, (iii) ensuring that an adequate policy is in place for access to the specimens stored in the repository and that requests for specimens are met in a timely fashion, (iv) serving as a liaison to key users (v) ensuring confidentiality of data and (vi) ensuring that standard operating procedures (SOPs) and best practices are in place and in general use.

OECD

Federal Ministry of Education and Research

isber
INTERNATIONAL SOCIETY FOR BIOLOGICAL AND ENVIRONMENTAL REPOSITORIES

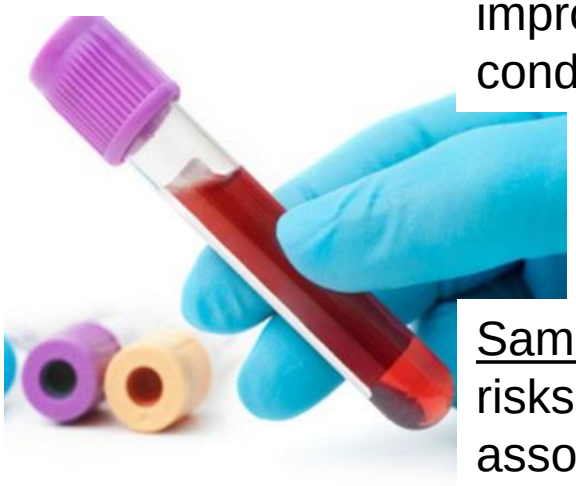
COUNCIL OF EUROPE CONSEIL DE L'EUROPE

other (x)			
Sample / data sharing			
Public accountability according to German Ethics Council implemented (y, n)			
Access policies implemented and publicly accessible (y, n)			
Sample request form publicly accessible (y, n)			
Registered in the German Biobank Registry (y, n)			
Europe-wide sharing possible, provided consent permits (y, n, p=partly)			
Samples requested / issued locally in 2014 (n=../n=..)			
Samples requested / issued nationally in 2014 (n=../n=..)			
Samples requested / issued internationally in 2014 (n=../n=..)			
Projects to which samples were issued (no. in 2014)			
Publications originating from samples issued (no. in 2014)			

Stakeholder interests

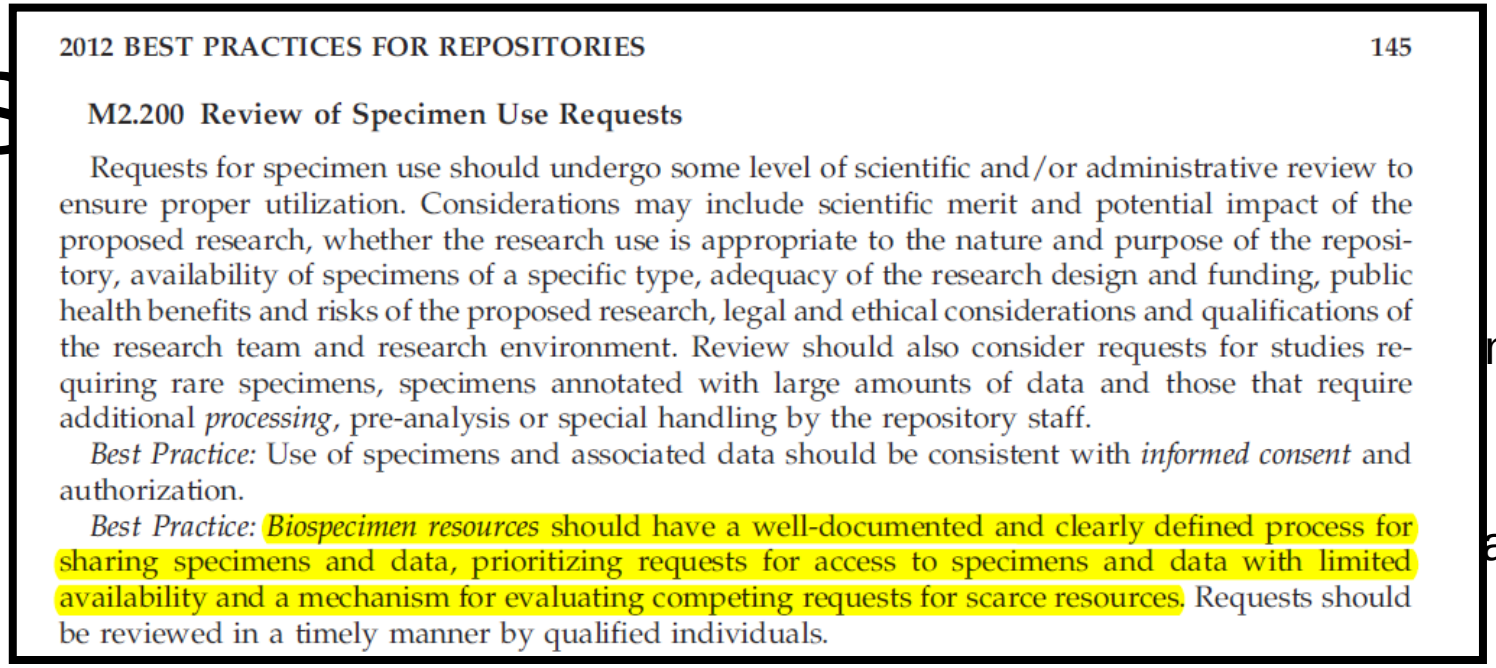
Biobanks: recognition for efforts and investment of financial and human resources ("return on investment" or compensation).

Contributing researchers: legitimately pursue own interests (e.g. career, international reputation via improved local research conditions).



Public funders: oblige biobanks to allow/care for uses of samples and data with high scientific and social value (another sort of "return on investment").

Sample donors/patients: risks and burdens associated with donating samples = (reciprocity-based) reason for research of high scientific and social value.



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M2.200 Review of Specimen Use Requests

Requests for specimen use should undergo some level of scientific and/or administrative review to ensure proper utilization. Considerations may include scientific merit and potential impact of the proposed research, whether the research use is appropriate to the nature and purpose of the repository, availability of specimens of a specific type, adequacy of the research design and funding, public health benefits and risks of the proposed research, legal and ethical considerations and qualifications of the research team and research environment. Review should also consider requests for studies requiring rare specimens, specimens annotated with large amounts of data and those that require additional *processing*, pre-analysis or special handling by the repository staff.

Best Practice: Use of specimens and associated data should be consistent with *informed consent* and authorization.

Best Practice: *Biospecimen resources* should have a well-documented and clearly defined process for sharing specimens and data, prioritizing requests for access to specimens and data with limited availability and a mechanism for evaluating competing requests for scarce resources. Requests should be reviewed in a timely manner by qualified individuals.

- ntific
- ated by

- Need for prioritization (ISBER): Samples = always finite resource, sometimes scarce (e.g. rare diseases)

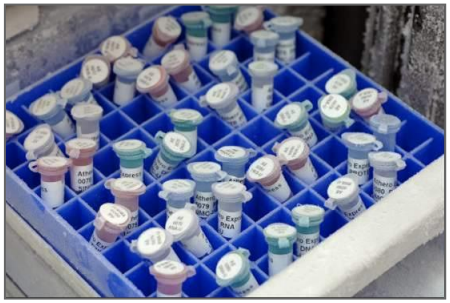
Objectives

Assessing international status quo of access policies in a cross-sectional approach

(1) How publicly available are access policies?

(2) What criteria are in use?

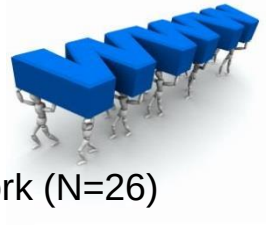
(3) How is prioritization adressed?



Methods

1. Search methods

Mail survey
BBMRI (N=333)



Website search
BBMRI (N=333)
P3G (N=164)
Australasian Biospecimen Network (N=26)
Google

2. Selection

Inclusion:
- written documents describing biobank's access regulations
- English and German

3. Data Extraction and Synthesis

Thematic Text analysis
- Extraction of relevant text passages
- Classification of extracted text passages
- Theoretical Saturation
- Internal consistency

4. Results

74 access policies
Matrix of 62 access criteria
- **3 main categories**
  1. **scientific quality**
  2. **value**
  3. **ethical soundness**
- **prioritization criteria**

Results

Main category	Subcategory	Criteria	n
1. Scientific Quality	**Quality Safeguard**	Peer review	13
		Quality management	2
		Reliability of preanalytical Measurements	1
	Capacities and Infrastructure	Relevant expertise of researchers	19
		Sufficient resources and funding	16
		Sufficient infrastructure	8
		Possibility for cooperation and networking	7

Results

Main category	Subcategory	Criteria	n
3. Ethical soundness	**Adherence to ethical principles**	Independent ethical approval	43
		Conformity with biobank statutes	16
		Conformity with current ethical standards	13
	Participant / donor protection	Conformity with donor consent	24

Results

Prioritization

- referred to in 20 access policies (27%)
- a total of 15 criteria
- criterion most often used: “Priority for active members (contributing / collecting)” (n= 4)
- followed by “Priority for network members”, “Regional or national benefit” and “Indication” (each n=3)
- other 10 criteria are mentioned in only one access policy each.

Discussion

- „Access to access policies“
  - What are the challenges?
  - Lack of standards? Lack of material (e.g. check-lists)

- International heterogeneity of access policies
  - A matter of individuality?

- „Beyond Access“
  - „first come, first serve“?
  - Quality and relevance of research
  - Multi-criterial procedures with different levels of prioritization necessary

Conclusion

Facilitating practice:

- Future conceptual and normative analysis needed to define practically feasible and normatively appropriate criteria for access and prioritization
- Empirical studies on potential barriers and facilitators
- Template-design: involving all relevant stakeholder groups in biobank research (e.g. biobank researchers, biobank managers, policy makers, patient groups)
- Study findings as background material to inform discussion and decision making (empirical evidence)

Thank you for your attention!

Contact information

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