

Laws and Regulations on Biobanks : Present Status and Future Directions



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Outline of Presentation



- Introduction**
- Ethical and Legal Frameworks**
- Governance Structures and Mechanisms**
 - ı International Guidelines**
 - ı National Biobank Laws**
 - ı Other Related Practices**
- Future Directions for Laws and Regulations**

Appropriate Ethical and Legal Frameworks



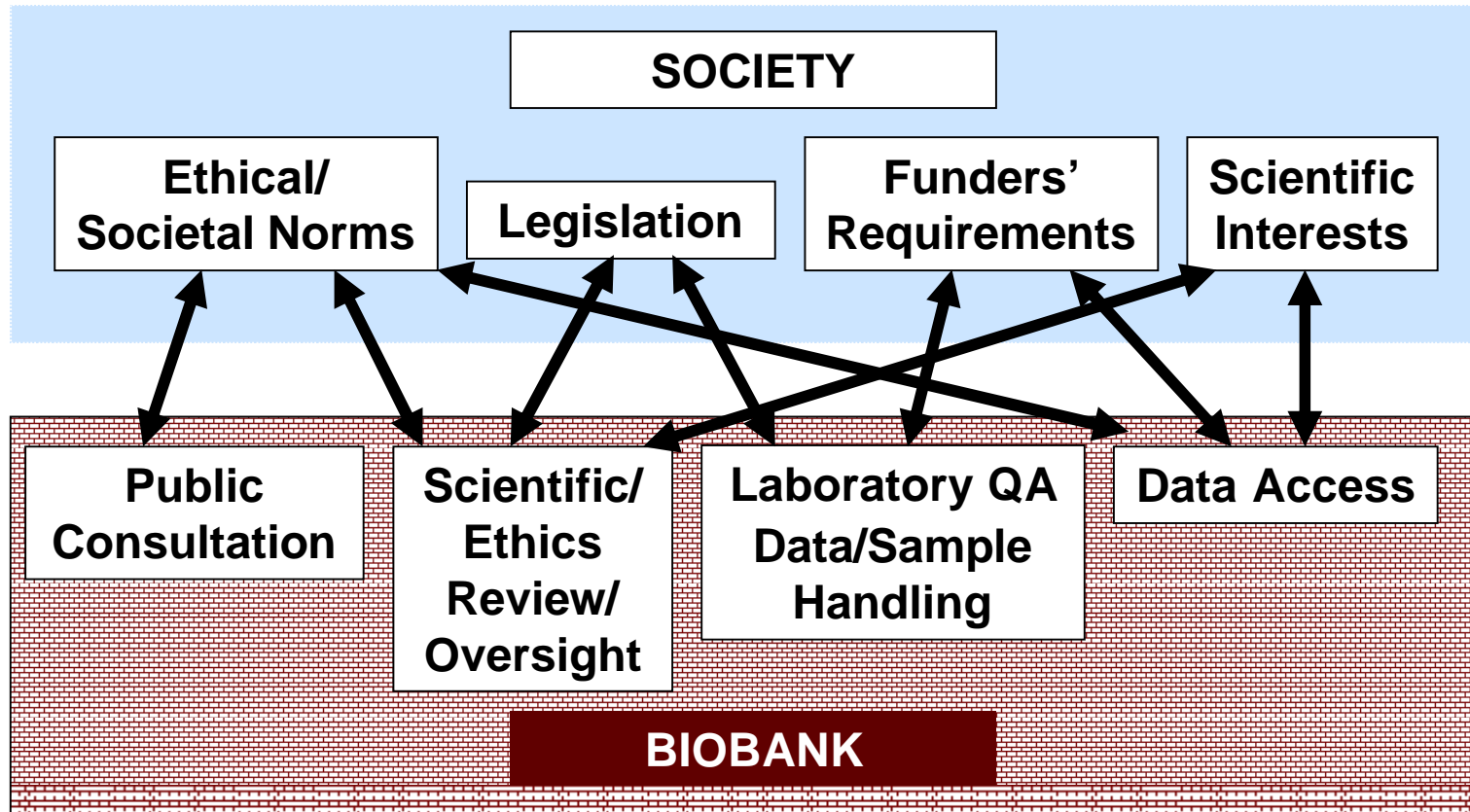
- **Protection of participants**
- **Need for ethical/legal guidelines for the particular context of biobank harmonization**
 - Long term use
 - Research questions not pre-defined
 - Data/samples sharing between studies/countries
- **Protection of eventual intellectual property**
- **Higher degree of data security**

Appropriate Ethical and Legal Frameworks



- **Public support is needed to ensure the successful creation, running and financing of a biobank**
- **Participants must trust that:**
 - i The biobank will have an appropriate and effective governance structure
 - i The research will be conducted ethically and will be beneficial for society
 - i Their personal information will be protected

Interaction of Biobank with Society



Governance Mechanisms



- 1. International Guidelines**
- 2. Legislation specific to biobanks**
- 3. Other general related practices**

International Guidelines



- **Human Genome Organization (HUGO)**
- **International Bioethics Committee (IBC) of UNESCO**
- **Organisation for Economic Co-operation and Development (OECD)**
- **International Council on Harmonisation (ICH)**
- **Council of International Organizations of Medical Services (CIOMS)**

Human Genome Organization (HUGO)



- **Statement on the Principled Conduct of Genetic Research (1996)**
- **Statement on DNA Sampling: Control and Access (1998)**
- **Statement on Human Genomic Databases (2002)**

International Bioethics Committee (IBC) of UNESCO



- **Universal Declaration on the Human Genome and Human Rights (1997)**
- **International Declaration on Human Genetic Data (2003)**

Organisation for Economic Co-operation and Development (OECD)



- **OECD Best Practice Guidelines for Biological Resources Centres**
- **OECD Draft Guidelines on Human Biobank and Genetic Research Databases (HBGRDs) (2008)**

P³G Guidelines Comparison Chart

www.p3gobservatory.org



Guidelines Comparison Chart

For each guideline, the table addresses biobanking development steps in either of the following three detail levels:

- mentioned or
- guidelines (detailed enough to dress a protocol/ model), or
- protocols/ model ready to be followed, to be used

Author(s)/organization	OECD	ISBER	IARC, WHO	NCI, NIH, HHS	ABN	EHRM	RAND	INSERM, AFNOR	
Publication date	2007	2006	2007	2007	2007	2002	2003	2008	
Title	OECD Best practices guidelines for Biological Resource Centres	Best Practices for Repositories II: Collection, Storage and Retrieval of Human Biological Materials for Research	Common Minimum Technical Standards and Protocols for Biological Resources Centres Dedicated to Cancer Research	National Cancer Institute Best Practices for Biopreserver Resources	Australian Biocollection Network: Biopreserver Protocols	European Health Risk Monitoring (EHRM) Recommendation for indicators, international collaboration, protocol and manual of operations for chronic disease risk factor surveillance	Case Studies of Existing Human Tissue Repositories Best Practices* for a Biopreserver Resource for the Genomic and Proteomic Era	Management system of a BRC and quality of biological resources from human or non-organism origin	
Country	International (28 countries)	International Forum based in United States	Worldwide Directors of National Cancer Centres	United States	Australia	Finland	United States	France	
URL	http://www.oecd.org/home/0,3487,en	http://www.isber.org	http://www.iarc.fr/	http://www.cancer.gov	http://www.abn.net	http://www.ktd.fi/tem/	http://www.rand.org/sites/default		
Sample type(s)	wide: Human, animal and plant, and micro-organism	Human: Blood, urine, saliva, nails, tears; milk, tissues, etc	Human: blood (plasma, serum, white blood cells), buffy coat, urine, buccal cells, saliva, bronchoalveolar lavage, bone marrow aspirate, fine needle aspirate, cerebrospinal fluid, semen, cervical and urethral swabs, sweat	Human: blood and solid tissue mentioned but not extensively	Human: Blood (serum, plasma, white blood cells, buffy coat), Urine, Buccal cells, bone marrow	Human: Blood	Human: blood, serum, tumor, tissues	wide: Human	
Step/area covered	Infrastructure/ Apartments	guidelines (apartments maintenance)	protocols (ventilation, temperature, lighting etc.)	protocols (temperature for devices)		guidelines		guidelines	
	Biosafety	guidelines	guidelines	guidelines	guidelines	guidelines			
	Staff training	guidelines	guidelines	mentioned	guidelines	mentioned		guidelines	
	Ethics	guidelines	guidelines (privacy rules, consent form, IRB)	mentioned	guidelines (recruitment, privacy protection)	Model (consent form)	guidelines	guidelines	
	Intellectual Property			mentioned	guidelines			guidelines	
	Clinical Data Management			protocols	guidelines	guidelines	model (questionnaire, protocols for anthropometric measures)		
	Sample Traceability/ Labelling	mentioned	guidelines	guidelines	guidelines		guidelines	guidelines	
	Sample type choice		discussion (advantage-inconvenient, balance)	discussion (advantage-inconvenient, balance)	discussion (advantage-inconvenient, balance)	discussion (advantage-inconvenient, balance)			
	Sample Collection and Processing	mentioned	guidelines (sample type-dependent)	protocols (sample type-dependent)	guidelines	protocols (sample type-dependent)	protocols	guidelines	mentioned
	Sample-derived data management	recommended data set: MD5 and RDS	guidelines	guidelines (minimum information)	guidelines		guidelines	guidelines	guidelines
	Sample Storage	guidelines (sample type-dependent)	guidelines (aliquoting)	protocols (sample type-dependent)	guidelines	protocols (sample type-dependent)	protocols	guidelines	mentioned
	Quality Control	guidelines (methods validation, sample quality)	guidelines	guidelines	guidelines	guidelines (matrices and sample type-dependent), protocols (RNA)	guidelines	guidelines	protocols (in all topics)
	Transportation/ shipping	mentioned	guidelines	protocols	guidelines	guidelines (sample type-dependent)			mentioned
	Funding Sustainability	mentioned		mentioned				guidelines	
Access to data/ Transfer	mentioned		guidelines	Model (material transfer agreement)	guidelines	guidelines	guidelines	guidelines	
Informatics support	guidelines	mentioned	mentioned	guidelines (barcode system)		guidelines	guidelines	guidelines	
Other	Recapitulative tables on requirement for each topic (sample type-dependent): maintenance, storage, ethics etc..	Source: websites for every topic (biosafety, shipping, accession, protocols etc.)	table mentioning 16 other biopreserver guidelines (ISBER, ABN, OECD, NCI, WHO, RAND, etc.)		protocols for RNA and genome DNA isolation and stable cell line generation Laboratory supplies suggestion (for reagent and apparatus) Suggestion of the sample future use depending on the sample type	Useful guidelines to build a study/biobank Indicators for risk factors that could be used for background, Sample size discussion, target population, recruitment procedures, duration of surveys, questionnaire administration etc..	Evaluation and comparison of tissues and processes from 12 tissue repositories in USA Comparison table for all 12 biobanks	Table that lists all documents required to assess good quality at each step Table comparing ISO 9001:2000 norms and BRC standards	
certification-oriented?	Yes (3 phases)						IAND evaluation	Yes ISO 9001	

National Biobank Laws



- **4 examples of national legislation on biobanks**

Country	Scope and Purpose	Organisation or Establishment of a biobank	Conditions of closure	Condition of storage	Condition of access and scope of research	Consent and rights of donors
Norway	X	X	X	X	X	X
Estonia	X	X		X	X	X
Sweden	X	X	X	X	X	X
Spain	X	X	X	X	X	X

National Biobank Laws



Country	Controls, appeals and penalties	Confidentiality and coding	Commercialisation, IP and licensing	Discrimination
Norway	X	X		
Estonia	X	X	X	X
Sweden	X	X	X	
Spain	X	X		

Details about Scope and Purpose



– What is the purpose of the legislation?

Different approaches:

- ∅ some are specific to one biobank,**
- ∅ some relate to any biobank in the country, and**
- ∅ others have a broader scope and only discuss biobank in a chapter within the law.**

Summary



– **Common principles:**

- i Broad consent
- i right of the donor to withdraw
- i conditions of storage

– **Diverse approaches:**

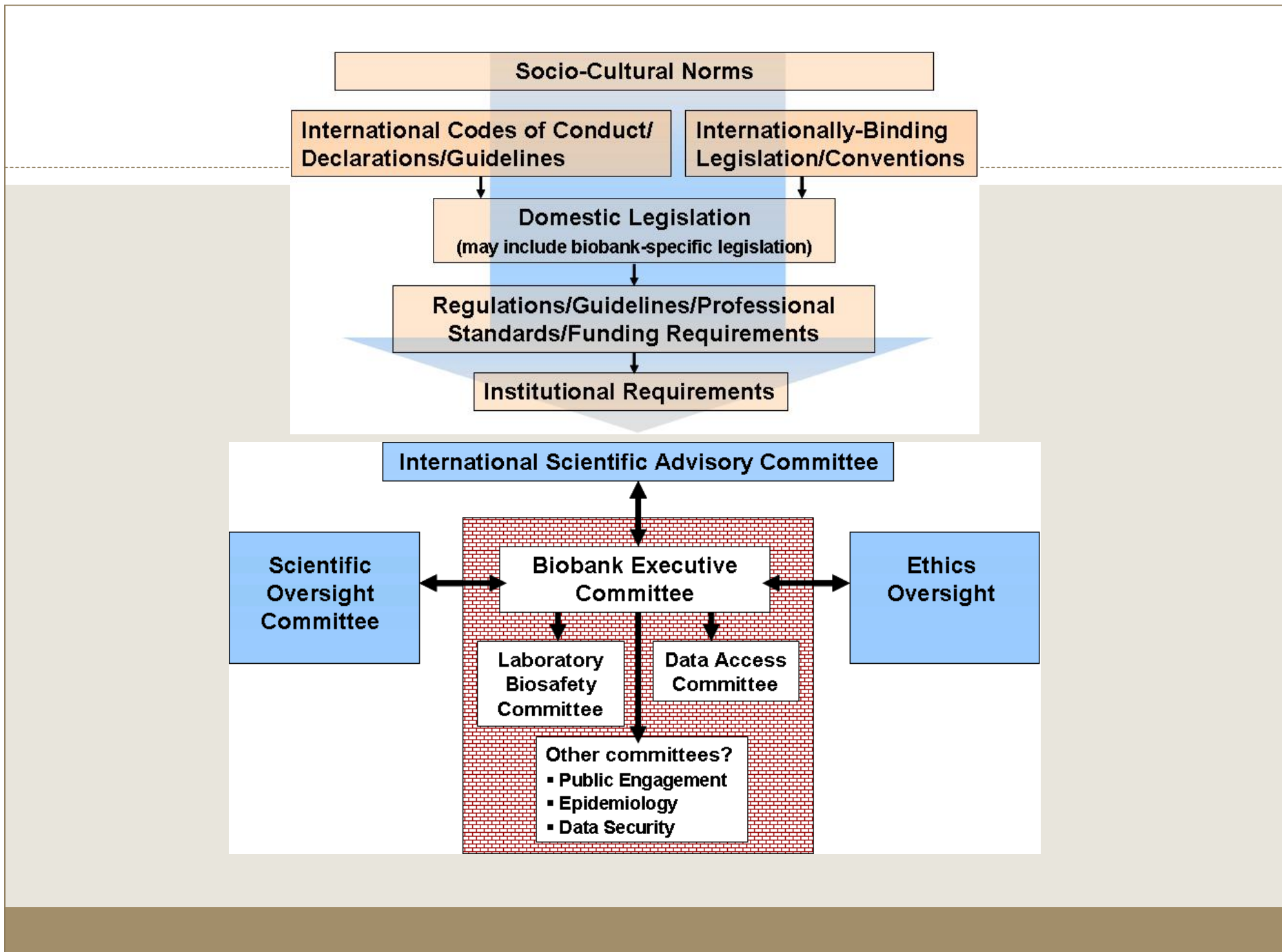
- i access by researchers
- i scope of the law
- i organisation
- i Extent of protection and oversight

How can we promote harmonisation?

Other Related Practices



- **Applicable legislation/regulations and standards**
 - Human rights; data protection; health and safety; statistics; use of human tissue; blood and other biomaterials; protection of humans involved in research
- **Scientific and ethics review**
- **Professional and institutional guidelines**



Conclusions



- **No one governance framework can apply to all biobanks**
- **Frameworks must be context-driven**
- **However, frameworks should ensure certain aspects**



— ***Scientific Aspects:***

- i The research conducted will advance science and benefit the population and individuals in the future.**
- i The resource's procedures and activities will receive regular independent scientific review.**



– ***Ethical aspects:***

- i The confidentiality of personal information will be protected.**
- i The resource's procedures and activities will receive regular independent ethics review.**
- i All requests for access to data and samples will be reviewed at some level.**
- i The resource will comply with all relevant legislation, guidelines and standards.**



– ***Expertise:***

- i There will be expert representation on all governance and oversight committees as appropriate (i.e., epidemiologists, bioinformaticians, sociologists, geneticists, etc.)



— ***Communication:***

- i The population will be kept generally informed of the research conducted using their data and samples.
- i Participants will be able to register their comments, queries and complaints with the resource, with the assurance that any complaints will be addressed.

Future Directions for Laws and Regulations on Biobanks



- Reframe the rights of donors to withdraw in the context of international use and sharing of samples and data?
- Make provisions for the closure of a biobank
- Provide re-contact/general communication models
- Facilitate access for researchers without compromising confidentiality and quality of the research

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