Webinar 2- ELSI - Topic 2
Key aspects of international normative ELSI perspectives on biobanking

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B3 Africa
BRIDGING BIOBANKING AND BIOMEDICAL RESEARCH
ACROSS EUROPE AND AFRICA

Topic 2: Key aspects of international normative ELSI perspectives on biobanking

Learning objectives. At the end of the training session, participants will be able to:

- Discuss key aspects of international normative ELSI perspectives on Biobanking.
- Identify the applicable frameworks from the national perspective.
- Understand the interplay between hard law and soft law, as well as between the international, regional, and national regulatory levels.

Target audience: biobankers, researchers, research administrators, members of ethics review boards and similar bodies

ELSI

Law

- Lack of appropriate biobank regulation
- Varying interpretation of national regulations by national institutions
- Varying requirements from oversight bodies
- Within-country legal disparities

Ethics

- Varying design, scope and interpretation of consent
- Return of individual research results to research participants
- Privacy and data protection

Societal/political challenges

- Lack of knowledge surrounding biobank research among the general public
- Lack of public debate surrounding biobank research
- Different views on how biobank resources should be used

+ Financial and educational challenges

- Insufficient funding of national infrastructure
- Lack of expertise among researchers and members of ethics committees regarding biobank research
- Lack of tradition and incentive to encourage sharing of stored biobank resources

Source: I. Budin-Ljøsne et al. ELSI challenges and strategies of national biobank infrastructures, 2012

Privacy as the key aspect

A participant perspective

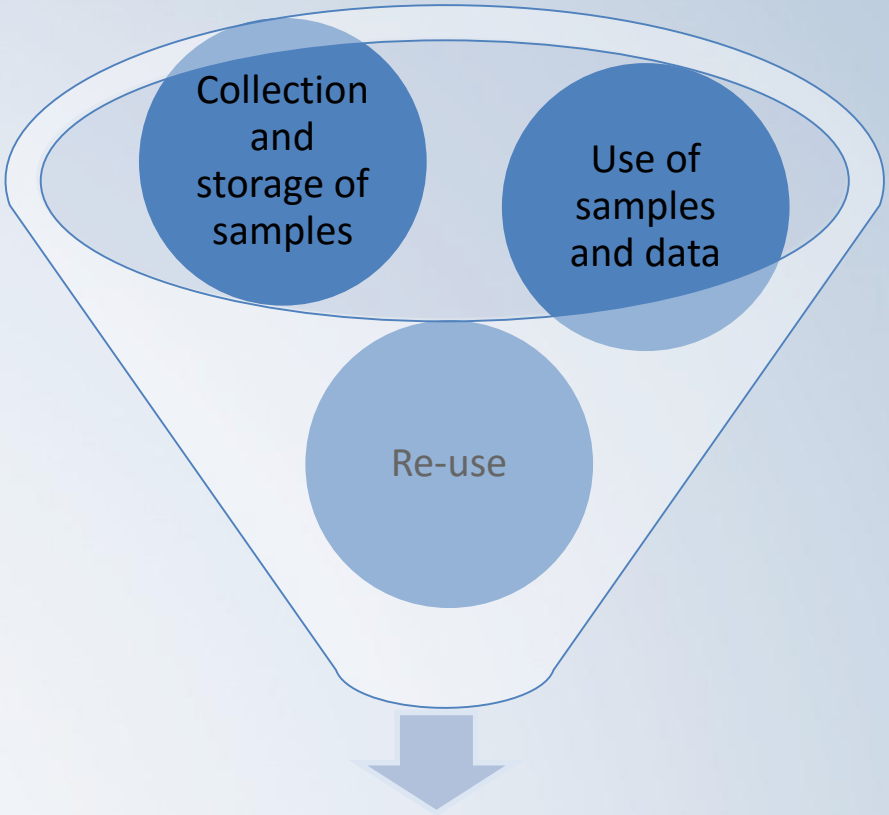
Key areas:

- Spatial privacy of the sample donor (consent or protection mechanisms in place)
- Informational privacy (consent, data protection mechanism in place)

Why privacy?

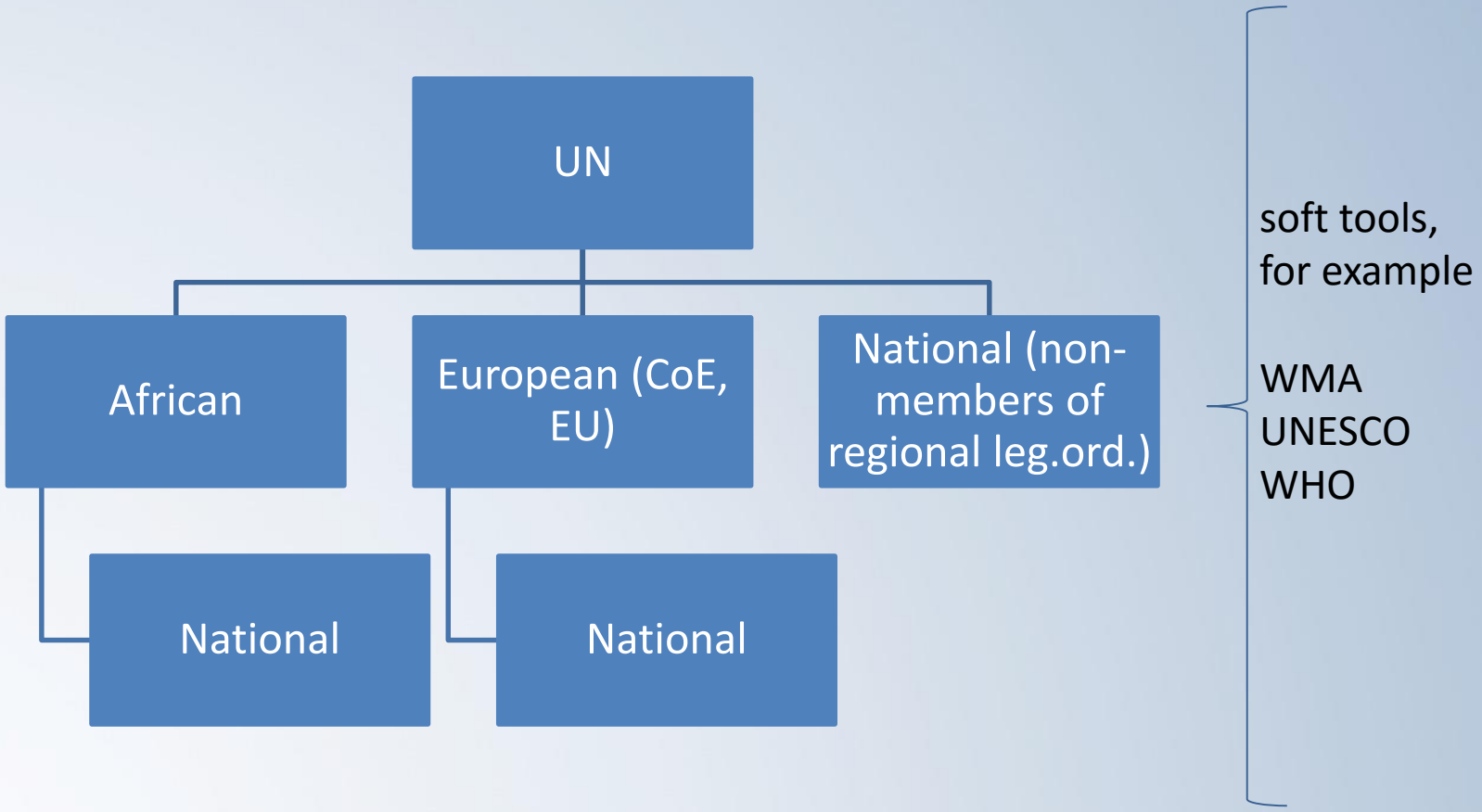
- Discrimination (prohibition of discrimination)
- Stigmatization (prohibition of sitgmatisation)
- Simply because it feels personal

Privacy in biobanking



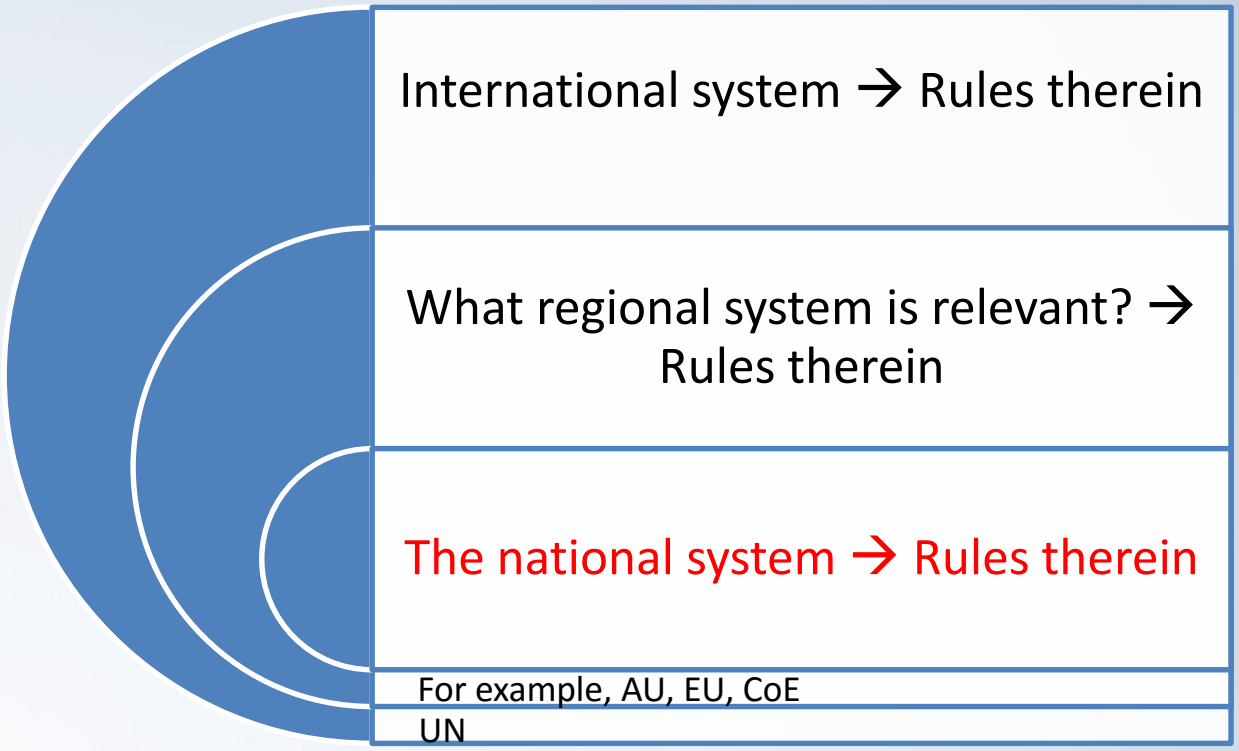
Research results

Normative Framework for ELSI




Internatio
nal level
Regional
level
Hard and
soft laws
National
level
Profession
al
organizati
ons

How not to get lost in the regulatory jungle?



What room is left for soft sources, such as recommendations?

A quiz question

Mr X wishes to resign from participating in a study focusing on BRCA1/2. Mr X knows that having an inherited BRCA1/2 mutation is negatively perceived in the community and he would not wish anyone to know that he might have it.

Mr X does not want:

- To face stigmatization
- To face discrimination
- Have the sense of guilt

A quiz question

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A case analysis

The national legal framework was developed in 2000 and requires specific consent for each research project.

Dr Emem, Chairperson of the **National Biobanker's Society**, intends to conduct a research project. To do this, he designs an Informed Consent Form to recruit the research participants.

Dr Emem is also a member of the R**egional Biobanker's Society** and has discussed with his colleagues the possibility of using broad consent, which complies with the applicable regional and international law and would also allow the researchers greater flexibility.

The **Regional Biobanker's Society** considered the Consent Form to be compatible with regional and international human rights norms and supported the proposal by the **National Biobanker's Society** to amend the national law.

Dr Emem has subsequently submitted a request to the legislature and the **National Biobanker's Society** has issued guidelines on how to comply with the broad consent requirements that have now been proposed.

Dr Emem now wonders whether he can apply the broad consent requirements as elaborated in the ethical guidelines and request research participants to give their broad consent in a situation when the amendment is still pending.

A quiz question

Dr.Emem:

- May comply with the guidelines
- Needs to comply with the current national law

A quiz answer

Dr.Emem:

- May comply with the guidelines
- Needs to comply with the current national law

Questions?