Biobanking in Biomedical Research

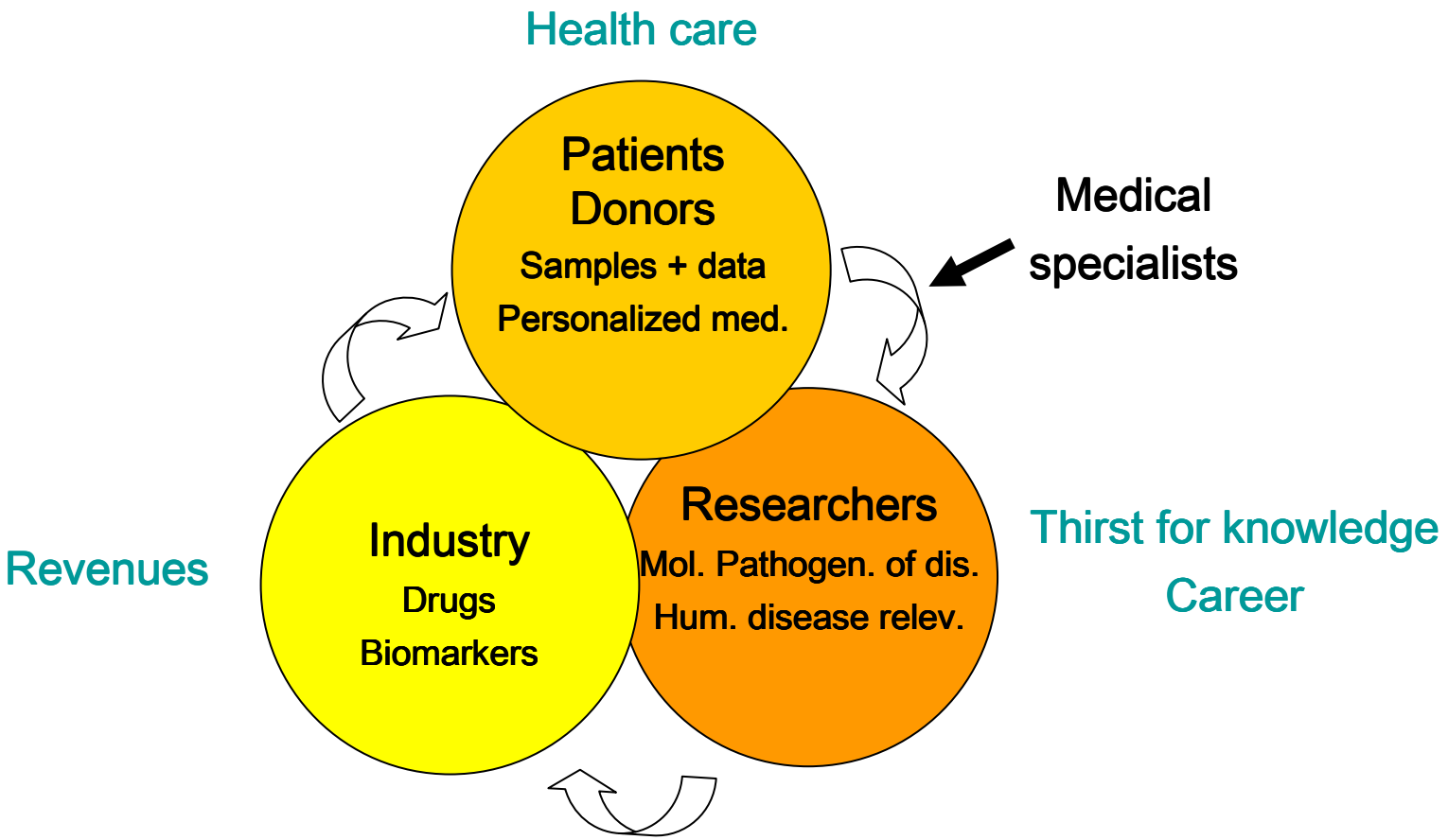
Part 3

ELSI: informed consent, data protection, public perception

Kurt Zatloukal, Medical University of Graz, Austria

Siena, April 2009

Who Needs Biobanks?
Who are the Stakeholders?



Health care providers, politician, lawyers, journalists etc.

ETS 164 Oviedo 1997

Article 22 – Disposal of a removed part of the human body

When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.

Informed Consent

- Informed consent (IC) is a cornerstone in bioethics.
- IC is not of a single event but a process (continuous information required for reasonable opt-out solutions)
- Is the principle of IC really applicable to (all) biobanks?
- What does “informed” mean in the context of biobanking?
- Are there alternatives?
  - Open consent
  - Informed consent process

WMA Declaration of Helsinki

DoH/Oct2008

25. For medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse. There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations the research may be done only after consideration and approval of a research ethics committee.

OECD Recommendation on Human Biobanks and Genetic Research Databases

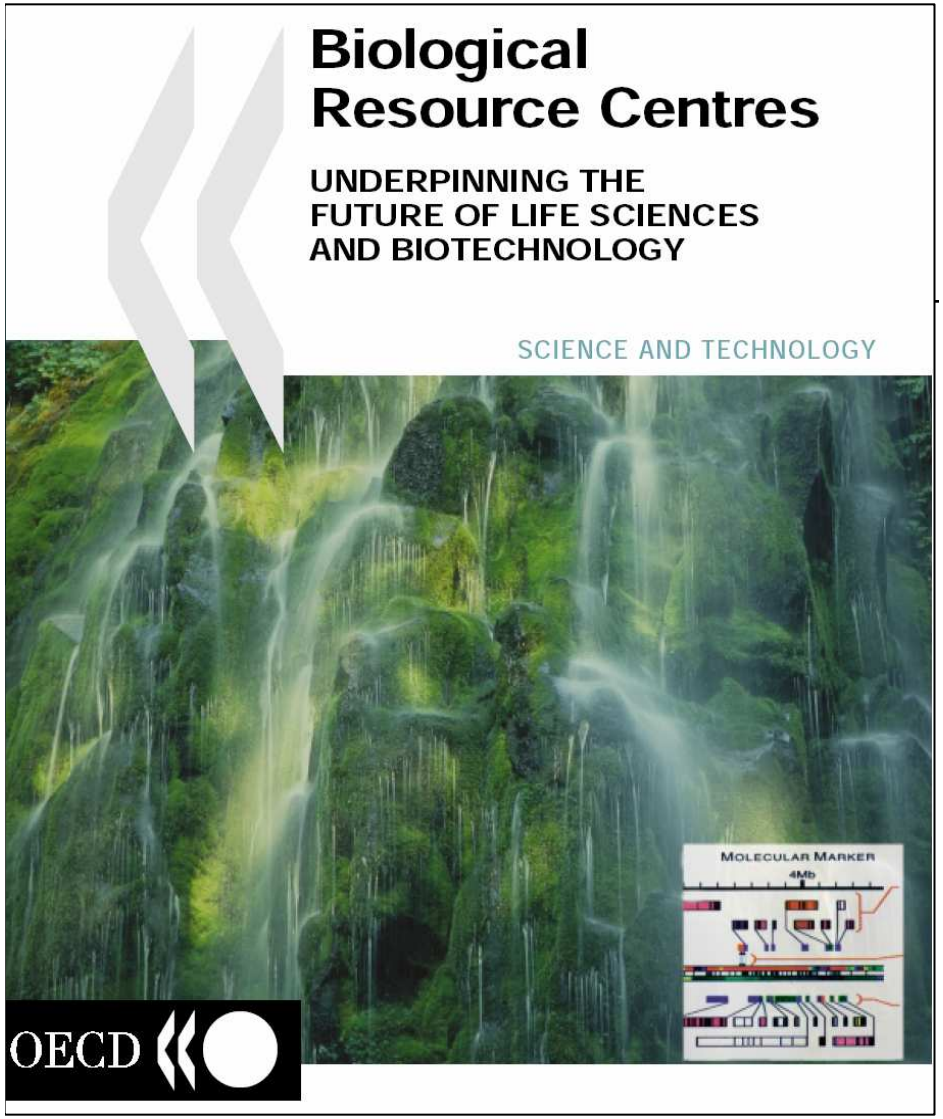
DSTI/STP/BIO(2008)31

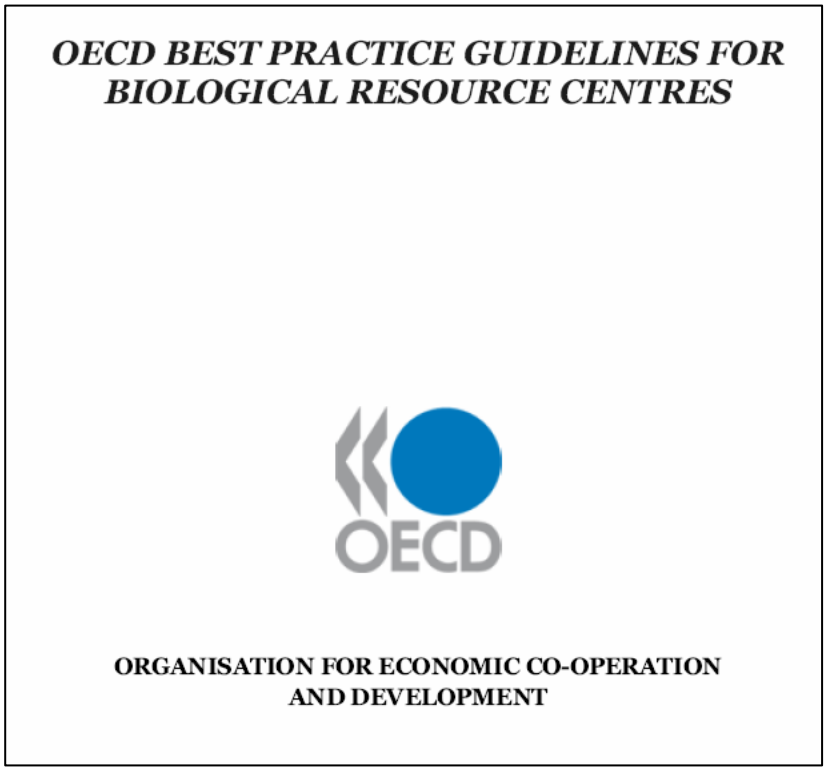
4. Terms of Participation

Principles

4.A Participant recruitment should be carried out in a non-coercive and equitable manner that respects individual freedom of choice.

4.B HBGRDs should obtain prior, free and informed consent from each participant. Where applicable, HBGRDs should provide for obtaining consent/authorisation from the appropriate substitute decision-maker, or for obtaining waiver of consent from a research ethics committee or an appropriate authority.





Endorsed by CSTP in March 2007

"Biological resources – living organisms, cells, genes, and related information – are the essential raw material for the advancement of biotechnology, human health, and research and development in life sciences"

Differences and Similarities of the OECD GBRCN and HBGRD Documents

GBRCN

- Facility
- Personnel
- Biosecurity
- Traceability
- MDS,RDS
- Data protection
- Certification
- (Old collections)

HBGRD

- Informed consent
  - IC process
  - IC document
- Governance
- Stakeholder
- Involvement of donors
- Data protection
- Change of scope
- (Old collections)

Directive 95/ /EC of the European Parliament and of the Council of the European Union

Article 8 The processing of special categories of data

1. Member States shall prohibit the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life.

2. Paragraph 1 shall not apply where:

(a) the data subject has given his explicit consent to the processing of those data, except where the laws of the Member State provide that the prohibition referred to in paragraph 1 may not be waived by the data subject giving his consent.; or

Data Protection

Problems to be addressed:

- Requirements for informed consent
  - Specific IC, recontacting
  - Application to old collections
  - Anonymization/coding of genetic data
- Prevention of non-scientific use
- Is there a need for an EU biospecimen research directive?

Issues for Discussion

- Is biobanking research?
  - Do research exemptions apply?
- What are the criteria for coding and anonymization?
  - Can genetic data be anonymized at all?
- The principle of open consent

Possible Solutions

- Separation of biobanking from research projects
- Specific IC for biobanking
  - Data are coded/anonymized
- Research projects approved by research ethics committee
  - Only coded/anonymized data are used
- Information on ongoing research projects as basis for „informed“ withdrawl

Data Protection at Biobank of the Medical University of Graz

- Approval of biobank and IC by REC
- Registration of biobank at data protection agency
- Specifc IC for biobanking; broad consent for research use
- Coding of samples in biobank
- Approval of research projects by REC
- Research projects may use only coded data and samples

Data Protection Measures

- Coding of samples (pseudonymization)
  - optl. second code for anonymization
- Separate data bases
- Prevention of re-identification (k-anonymity)
- Controlled access (password - computer)
- Documentation of logins and queries

Data Protection: Check for k-Anonymity

Definition: **The release of data must be such that combination of values of quasi-identifiers can be distinctly matched to at least k individuals (Samarati-Sweeney, 1998).**

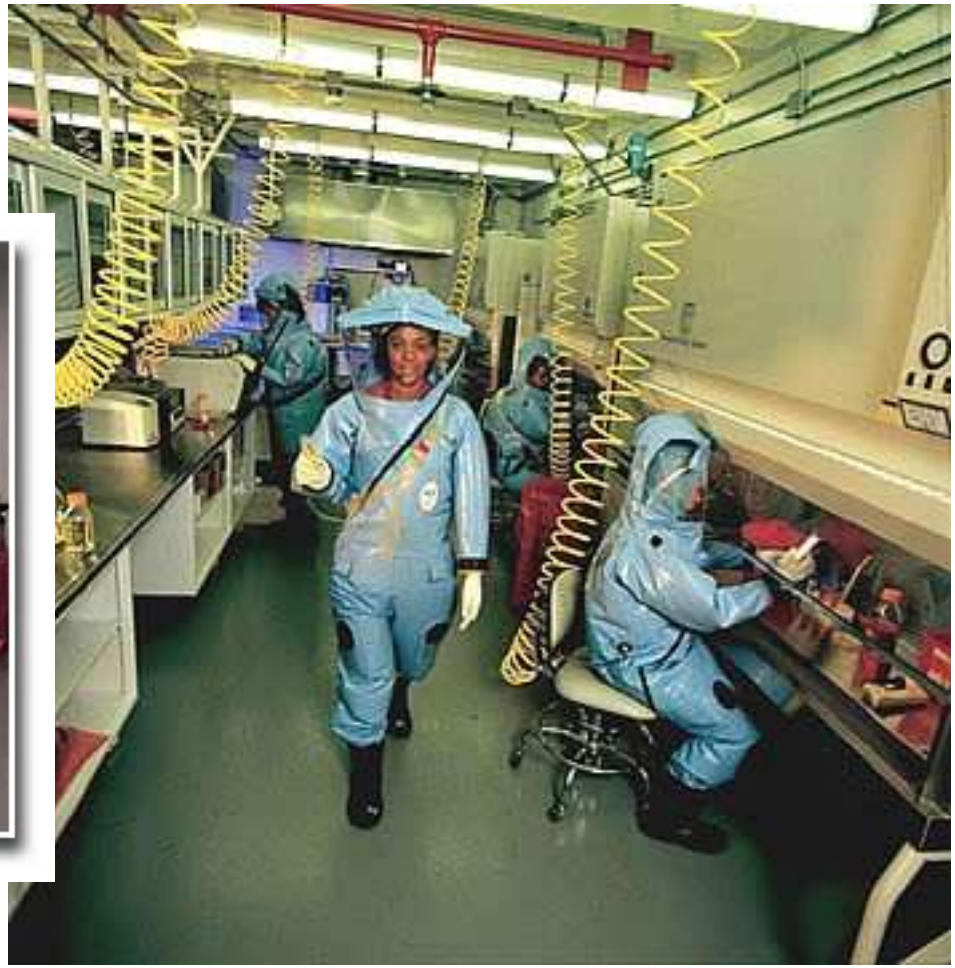
The approach:

- Access to and combination of data via Data Mart
- Check for data twins
- Indication of identifying attributes
- User-driven transformation of attribute values to guarantee minimal information loss

Biosafety and Biosecurity

BSL 3

BSL 4



Risk Perception in Laboratories

Biosafety risks:

Laboratories as source of accidental infection

- History of lab-acquired infections
  - Often attributed to carelessness or poor technique
  - Exposure to airborne pathogens most plausible cause
  - Brucellosis is most common

Biosecurity risks:

Laboratories as source of material for malicious use

- Bioterrorism has emerged as a threat to international security
  - 1984 Rajneeshee religious cult attacks in the US
  - 1990s Aum Shinrikyo attempts in Japan
  - 2001 Anthrax attacks in the US

Risk Perception in Laboratories

Biosafety risks:

Laboratories as source of accidental infection

- Sporadic infections in community
  - 1950—2 cases of Q fever in household of scientist
  - 1973 and 1978—England 3 cases of smallpox
  - 1990—1 case of Monkey B virus from animal handler to wife
  - 2003—9 cases of SARS,

Biosecurity risks:

Laboratories as source of material for malicious use

- Examples of illicit acquisition
  - 1990s—Aum Shinrikyo *Clostridium botulinum*
  - 1995—Larry Wayne Harris, a white-supremacist, *Yersinia pestis*
  - 1995—Laboratory technician Diane Thompson removed *Shigella dysenteriae* Type 2 from hospital's collection and infected co-workers

Biosecurity Risk Assessment: Malicious Use Risk Groups I

- Nonpathogenic
  - Malicious use would have insignificant or no consequences
- Low Malicious Use Risk (LMUR)
  - Difficult to disseminate, and/or
  - Malicious use would have few consequences
- Moderate Malicious Use Risk (MMUR)
  - Relatively difficult to disseminate, and
  - Malicious use would have localized consequences with low to moderate casualties and/or economic damage, and potentially cause pervasive anxiety

Biosecurity Risk Assessment: Malicious Use Risk Groups II

- High Malicious Use Risk (HMUR)
  - Not particularly difficult to disseminate, and
  - Malicious use could have national or international consequences, causing moderate to high casualties and/or economic damage, and the potential to cause mass panic and significant social disruption
- Extreme Malicious Use Risk (EMUR)
  - Would normally be classified as HMUR, except that they are not found in nature (eradicated)
  - Could include genetically engineered agents, if they were suspected of being a HMUR

[GATiB Subproject II]: Biobanks and their local/global, socio-economic, scientific-technological, ethical, and political context

Team leader: Herbert Gottweis

Team members: Robert Mitchel, Gisli Palsson, Catherine Waldby, Ingrid Schneider, Robert Triendl, Ingrid Metzler

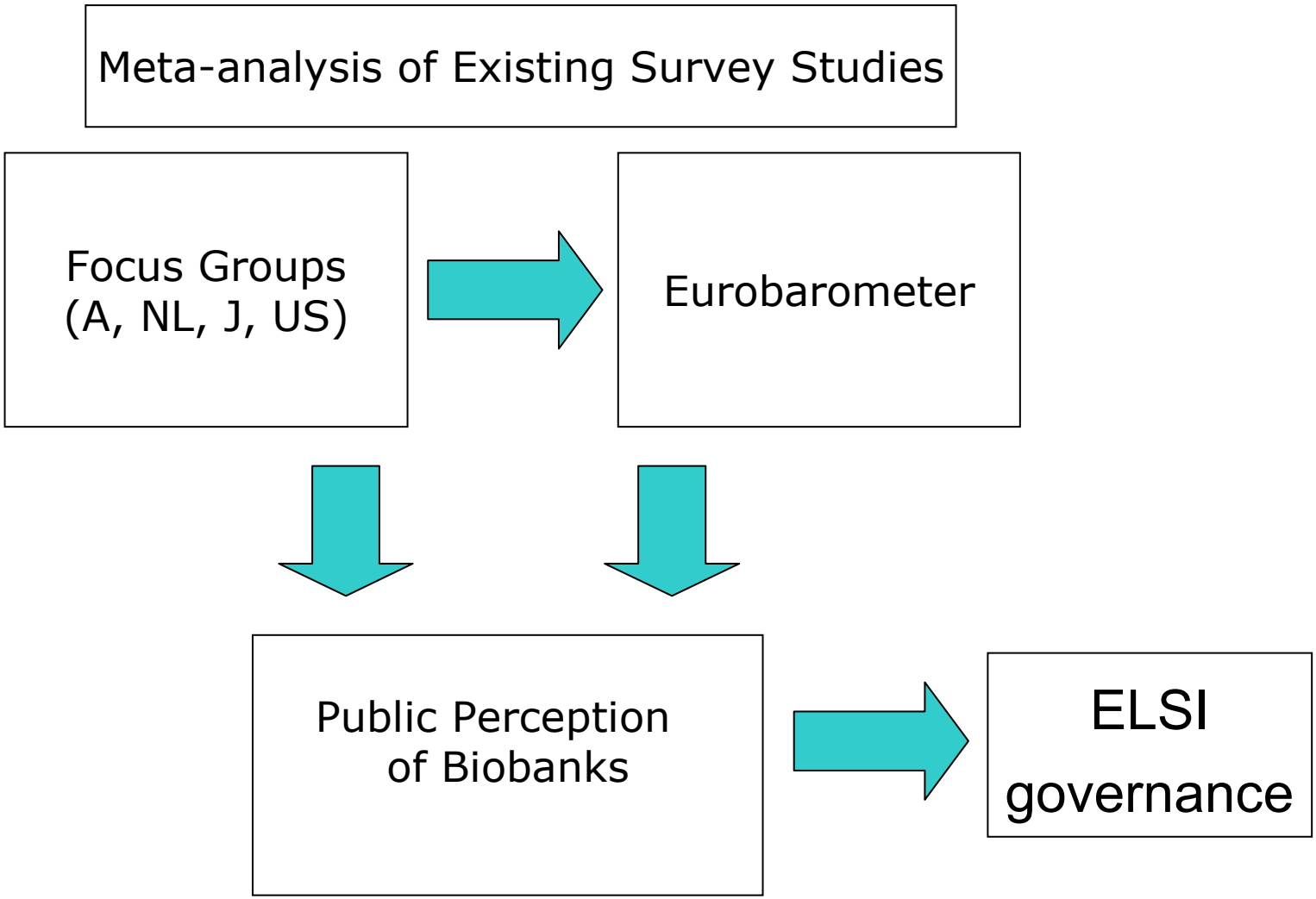
PCC Meeting, March 2009

ELSI: A Theoretical Approach (H. Gottweis, Vienna; GATiB)

We hypothesize that biobank building is a complex, multi-faceted process that

- is not determined by a single factor and that
- needs to be embedded carefully into the interplay of different, interrelated parameters.

Experimental approach



What is a Biobank?

Focus Groups

- Medical experts: Focus group with experts from medical science (1)
- Societal experts: Panel with society experts (1)
- Lay people: Focus groups with mixed lay publics (4-5)
- Participants/Donors: Focus group with participants in biobank studies (2-3)
- International Biobank Experts: Panel with biobankers (1)

Themes

- Theme 1: what are biobanks?
- Theme 2: why biobanks?
- Theme 3: problems/special issues in biobanks
- Theme 4: biobanks in international/transnational context

Consent

- broad consent vs narrow consent (conflict with autonomy, procedural vs substantive accounts of autonomy)
- blanket consent/consent to biomedical research/consent to research on specific disease/consent to a specific study
- right to withdraw
- secondary uses
- open consent: volunteers consent to unrestricted re-disclosure of data originating from confidential relationship
- veracity: telling the truth, should precede autonomy?
- levels: transnational exchange is one form of secondary use

Privacy, Data Protection, Security

- privacy
- confidentiality problem of re-contacting participants, possibility to withdraw
- dissemination of results
- data protection and security: how?
- risks (discrimination, mistakes, “accidents”)

Property rights, common goods, commercialization

- property rights, property status of samples
- commercialization
- benefit sharing: what could this be?
- biobanks as public common goods (Knoppers et al)/new communitarianism)

Governance

- governance: who governs biobanks? National/Supranational? Who supervises?
- Legal structures: law or not? Self-regulation? Working with existing laws?

Transnational Dimension/Context

- National vs Transnational: design of studies, funding, implications
- What happens when data/tissue/DNA travels and circulates internationally?
- Is this acceptable?

The Public does not Exist: It emerges Around Issues

5 Types of Publics

- the general public: created by public opinon polls etc
- the pure public, lay people citizen juries, citizen conferences and youth conferences
- the affected public: patients, patient groups
- the partisan public: Stake holders, lobbyist, NGOs
- spontaneous publics:

[**Emerging Themes From Austrian-Dutch Focus Group Research** (Life Science Governance Institute, Vienna, Centre for Society and Genomics, Nijmegen and Athena Institute, Free University, Amsterdam)]

- Knowledge Gap: Broad Lack of Knowledge and Understanding of Biobanks
- Absence of Context Awareness
- Information – Attitude link: Positive Correlation
- Pessimistic View of Data/Information Handling by Medical Researchers: Patient Rights Awareness Partially Bioethics Myth
- Non-Patients Often Uneasy About Medical Research
- Anonymity More Important than Consent Issues: Consent More an Issue for Scientists and Bioethicists than for Lay Publics
- Diversity of Publics Crucial
- Opposition Towards Broad Consent Forms
- Collaboration Between Biobanks Seen as "Obvious" Thing to Do
- European Collaboration Seen In Positive Light
- Call for Regulations, European Regulations for European Projects
- Biobank (Science) Communication: Unresolved Issue

The Socio-Economic Impact of Biobanks

- Justify long-term financial comittments
- What are the costs of biobanking?
- How to make access to high quality biospecimens affordable?
- Cost recovery models
- Quantify impact on society (research, industry, health care)

Thank you