Role of Law in Biobanking - Increased Bureaucracy or Facilitation of Research?

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Key features of Biobank Act (in force since Sept 1, 2013)

- Broad consent for future research purposes
- Transfer of old samples
- Supervision under Valvira (National Supervisory Authority for Health and Welfare)
- Metadatabase for preliminary info about available samples and data
- Equal access for all researchers that meet the access criteria
- Return of analysis results to biobank
- Can be combined with patient records and national health registers
- Right to check one’s information at biobank (incl. health)
When is a biobank legal?

- Processes have been evaluated by TUKIJA (preceding detailed descriptions and documentation)
- Registered at Valvira’s biobank register (preceding detailed documentation)
- A responsible person in charge of a biobank nominated
- Policies and processes exist regarding sample processing, data protection and security
- Quality assurance and risk management are appropriate
Comparison – researcher’s perspective

Traditional medical research procedure
- Research protocol
- Ethical review
- Collect samples and data (incl. IC procedure) or
- Apply for access to old, but do previous consents enable this? Recontacting, or if dead, permission procedure at various authorities (samples / data under different regulation).

Biobank research procedure
- Check metadata of biobank, if fits to your research needs
- Make a research plan
- Make an application to a biobank
- Sometimes ethical review may be needed; biobank considers
- Get access to biobank samples and data (subject to conditions of MTA)
- Return analysis results to biobank
What is needed to access biobank material?

• Intended use corresponds biobank’s defined field of activity and consent
• Appropriate professional and scientific competence to process samples and data
• Relevant link to recipient’s tasks
• Capability to comply with laws, and conditions set by the biobank
• Research plan, opinion of REC (case-by-case) or other necessary description for biobank’s assessment process
• Clear process to handle samples and data
• Biobank’s decision (subject to appeal in administrative courts)
• Material transfer agreement
Restrictions for access

• the intended use is against the biobank’s field of activities and other restrictions,
• safeguarding on-going primary research,
• safeguarding IPR,
• preservation of rare or limited precious collections for very significant purposes,
• safeguarding privacy (small collection, where data exposure likely),
• reasons related to research ethics
Is biobank consent ethical?

• Broad consent precedes lots of information detailed in law
• How informed must one be to be informed? Sufficiently?
• Why a piece of tissue makes things complicated; you can research patient records and health registries without a consent (subject to research permission, of course) – why the fuss with a blanket or proxy consent here?
• Fear deal to know that one is subject to several research protocols in the future, can follow them, and withdraw, if does not like.
• Safeguards:
  - Procedures in supervised strictly regulated infrastructures
  - Access to information about use of own data and samples
  - Right to withdraw any time
  - Public information: biobank is obliged to publish information
• N.B.: Privacy breach is not an ethical issue, it is a crime.
# Law’s role and law’s image

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<th>LAW’S ROLE</th>
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<tr>
<td>Facilitative</td>
<td>Threat</td>
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<td>- Instrument to shape</td>
<td>Proscribe contact with threat of</td>
<td>Create and polices boundaries of</td>
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<td>social behaviours</td>
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<td>space for free and secure participation</td>
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<td>Expressive:</td>
<td>Legitimates coercion</td>
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<td>- Institutionalises values</td>
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Innovation cycle in publicly funded biobanks
Conclusions

• Biobank Act and its bureaucracy is needed as it also facilitates these activities
  – It creates governance structure and requires compliance with good governance principles, data management, quality and professionalism
  – It facilitates research and harmonises practices
  – It presupposes sufficient information for the participant
  – It promotes open access and sharing of research resources on equal grounds
  – It renders biobank activities under supervision

• The biggest bureaucratic step is to establish and to register a biobank – but should not all the serious actors reflect and describe their practices and processes anyway?

-> Doing medical research within the frame of biobank is justified and ethical from individual and societal perspective
Wishes for the future

- One stop Front Desk / authorisation to access research repositories

- People understand that use of samples and data for research is not particularly dangerous; but instead, not using them, might be.