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 Auhtority 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)

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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 prodecedure 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.

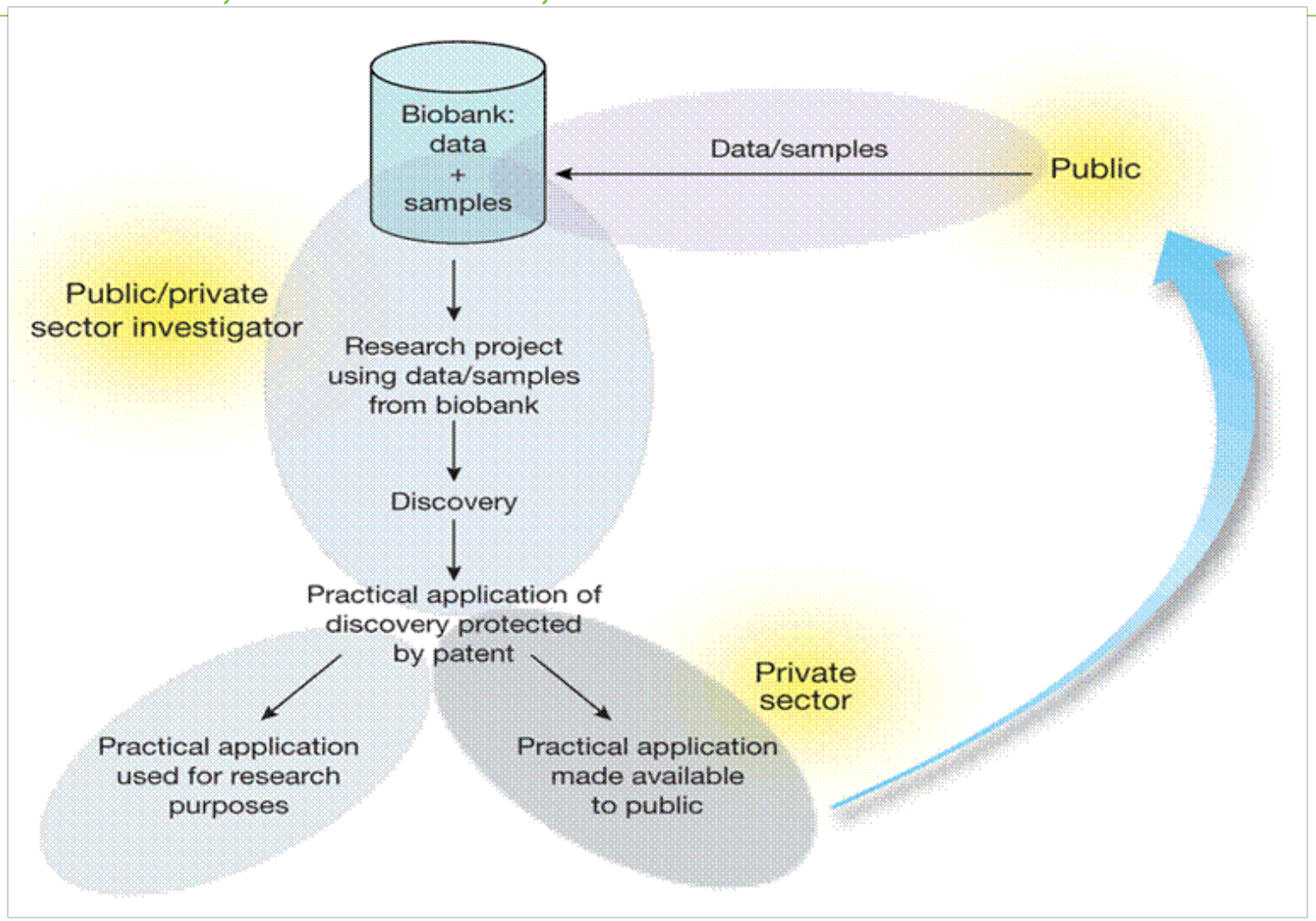
Law's role and law's image

LAW'S ROLE	LAW'S IMAGE Threat	LAW'S IMAGE Umpire
Facilitative - Instrument to shape social behavious	Proscribe contact with threat of sanctions	Create and polices boundaries of space for free and secure participation
Expressive: - Institutionalises values	Legitimates coercion	Reflects shared or agreed morality of players

Source: Morgan & Yeung: Introduction to law and regulation 2007, pg. 339.

Innovation cycle in publicly funded biobanks

Pathamasiri et al., Nat Biotech 2011;29:321.



Conclusions

- Biobank Act and its bureacracy 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 bureacratic 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.