Overview of the regulation of biobanks by the Data Protection Agency

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Content of presentation

- What is Medical Research Biobanking?
- What human biosamples are used in research?
- Why are biobanks regulated by the Persondatalovens?
- What are the requirements of the Persondatalovens relating to biobanks in private companies?
- Example of compliance in action
- Coming developments
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What is Medical Research Biobanking?
What is Medical Research Biobanking?

- **Human research biobanking** describes the **activities** associated with:
  - collection,
  - characterisation,
  - processing and
  - storage of human biosamples and associated data for research purposes,
  - all the relevant
    - processes,
    - policies and
    - governance arrangements.
  - management of the **physical structure** where the biosamples and data are stored (biobank)
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Terminology

- Human biosamples
- (Human) biospecimens
- (Human) Samples
- (Human) Specimens
- (Human) Biological Materials
- ...

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What are human biosamples?

- Samples from humans that are used for biomedical research are diverse. Examples include:
  - Biopsies of solid tissues
  - Surgical resections of solid tissues
  - Blood samples and their derivatives
  - Fine needle aspiration biopsies of solid lesions
  - Body fluids, including the fluids in body cavities, joints, abscesses, cysts, “collections” in body spaces, etc (variable in volume)
  - .....
What are human biosamples?

- ....continued
  - Secreted or excreted body fluids, including urine, sputum, saliva, tears, etc
  - Cells shed or scraped from body surfaces including, skin scrapes, buccal scrapes, corneal / conjunctival scrapes, cervical smears, surface imprints, faeces, etc
  - Hair, nail, teeth, skin debris
  - Whole organs, limbs, larger structures
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What is collected for use in research?

Human *biosamples* of a *variety of types* +

*Information* about the donor of the sample, their health, disease, treatment and outcome =

*Powerful research tools*
Biosamples are data

- In governance terms, management of samples should be similar to management of sensitive personal (health) data.
- Biobanking is a form of Data Processing.
- Biobanks are Databanks.
Every biosample is a person
Donor protection

- The interests and welfare of the person, whose biosamples are used prevails over the interests of science and society.

- Personal autonomy, right to a private and personal life, personal integrity, freedom from harm
  - Consent
  - Protection of personal data
  - Fair and purposeful use
Guidance is available

Now published and available via LIF

Lægemiddelindustriforeningen
## Requirements for authorisation - overview

<table>
<thead>
<tr>
<th>Activity</th>
<th>Danish Health and Medicines Authority</th>
<th>Ethical Committee (Regional)</th>
<th>Danish Data Protection Agency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health research project with <strong>identifiable</strong> HBM which will be destroyed after completion of the project</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health research project with <strong>anonymous</strong> HBM</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical trials (with medicinal products) in Denmark (collected HBM will be destroyed after completion of the clinical trial)</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Clinical trials (with medicinal products) in Denmark (additional HBM collected to be stored in a biobank <em>for future research</em>)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Establishment of a biobank in Denmark by a Danish data controller with <strong>identifiable</strong> HBM collected from anywhere in the world <em>for future research</em> (not in connection with a specific health research project /clinical trial)</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Establishment of a collection of <strong>anonymous</strong> HBM in Denmark by a Danish company collected from anywhere in the world <em>for future research</em> (not in connection with a specific health research project /clinical trial)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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Act on Processing of Personal Data

  - Many amendments since, most recently in 2013
  - Compiled version in Danish - [http://www.datatilsynet.dk/lovgivning/persondataloven/](http://www.datatilsynet.dk/lovgivning/persondataloven/)

- Danish implementation of **EU Directive 95/46/EC** on the Protection of Individuals with regard to the Processing of Personal Data and on the Free Movement of such Data.

- Purpose to protect the individual against misuse of data.
Definitions in the Act

- **Personal data** – any information about an *identified* or *identifiable* natural person.
  - *Identifiability* is the key!
  - The Act does not apply if the data cannot be linked to a person.

- **Data subject** – an identified or identifiable natural person.
  - In clinical trial terms = **clinical trial participant**
  - In biobanking terms = **biosample donor**

- **Data subject’s consent** – any freely given specific and informed indication of his/her wishes that shows agreement to his/her personal data being processed.
Identifiability of the donor is key

- Whenever it is possible to link biosamples back to the identity of individual donors by any route, the biosamples are identifiable.
- This applies even if researchers cannot directly identify the donors, but only have a code number.
- In most cases involving clinical investigator sites and clinical trials the biosamples and data are legally identifiable.
Identifiability of the donor is key

Patient/Donor  Intermediary  Researcher

Identified

Identity protected by coding at intermediary
Legally **Identifiable**

**Anonymous** – no link to identity of donor
Definitions in the Act

- **Data processing** – any activities which are performed with personal data, whether by manual or automatic means.
  - In clinical trial and biobanking terms = the handling of the data and biosamples.

- **Data processor** – any natural or legal person,..., or any other body which processes personal data on behalf of the Data controller.
  - In clinical trial and biobanking terms = the staff handling of the data and biosamples.

- **Data controller** – any natural or legal person,..., or any other body which determines the purposes and means of processing of personal data.
  - In clinical trial and biobanking terms = the management responsible for owning and managing the trial.
Geographical Territory of the Act

- Data controller established in Denmark.
  - Data processing is:
    - In Denmark
    - Elsewhere in the European Community.

- Data controller established in another EC Country or another country.
  - Data Collection or Processing is in Denmark
Requirements of the Act relating to Private Research

• Only process identified or identifiable biosamples / data if justified.
• Only process identified or identifiable biosamples / data with consent.
• Only store identified or identifiable biosamples / data for future use with prior approval of the Data Protection Agency.

- Transfers, changes in intended uses, disposal / closure of a biobank must be approved by Datatilsynet.
- Identified or identifiable biosamples / data are sensitive personal data and must be safeguarded by high security measures.
- Internal policies and procedures must exist to secure data protection.
Consent Requirements

• Only process identified or identifiable biosamples / data with consent.
  • The normal principles of informed consent apply (as per *Sundhedsloven §35*).
  • When biosamples are collected for unspecified future use, there is no formal approval of consent documents.
    • However, before the biosamples / data are to be used in a research project, approval by an Ethics Committee is required, and the consent in place must be able to be judged as valid and approved at that point.

• Data subjects must have the right to withdraw consent.
  • After which future uses must stop.
  • Biosamples may need to be destroyed and associated personal data deleted.
Requirements for Approval

• Only store identified or identifiable biosamples / data **for future use** with prior approval of the Data Protection Agency.

• Collection and / or storage of biosamples / data for **future research** (a biobank for future research), must be notified to and authorisation received from Datatilsynet.
  • Biosamples collected directly from donors **for future uses.**
  • Extra biosamples collected during an Ethics Committee approved project **for future uses.**
  • Storage of left over biosamples from an Ethics Committee approved project at the end of the project (if consent is in place / obtained) **for future uses.**

• A general approval for the establishment of a biobank for future research can be obtained from Datatilsynet.
Requirements for Notification

- Transfers, changes in intended uses, disposal / closure of a biobank must be notified by Datatilsynset.
  - Transfer of part or a complete biobank to another data controller.
  - Changes to intended use.
  - Closure

- Transfers of Data to Third Countries
  - Data subject has given consent.
  - Data Protection Agency authorisation is in place.
  - Only if there is adequate level of data protection.
    - Contractual protection in place, using standard clauses approved by the European Commission.
Requirements for Security

- Identified or identifiable biosamples / data are sensitive personal data and must be safeguarded by high security measures.

- Stored securely under lock to prevent unauthorised access.
  - Access only granted on a “needs-must” basis.

- Stored securely to prevent:
  - Accidental loss or destruction.
  - Malicious loss, damage or theft.

- An internal policy / procedure must be in place and updated at least yearly.
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Collection and storage of human biosamples collected as part of a clinical trial

- Clinical trial takes place in Denmark.
- Data Controller is in Denmark.
- Biobank is in Denmark.

- **Collection and storage** of biosamples for **use in a specific research project:**
  - **No need** for prior approval from Datatilsynet.
  - Other provisions of the Persondatalovens apply.
Collection and storage of human biosamples collected as part of a clinical trial

- **Collection** of extra biosamples in connection with a clinical trial to be **stored for future use**:
  - Prior approval from Datatilsynset required.
  - Provisions of the Persondatalovens apply.
  - (Future uses may require further Ethics Committee approvals.)
Collection and storage of human biosamples collected as part of a clinical trial

- **Fate** of residual biosamples collected in connection with a clinical trial at the end of the study:
  - **Choices are:**
    - Approval from Datatilsynet required before retention for future uses, *OR*
    - Anonymisation of biosamples / data before retention, *OR*
    - Disposal of biosamples.
Further Guidance

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Revision of the EU Data Protection Law.
Thank you
Novo Nordisk Global Biobanking Management