Legal requirements for Data Managing



Korbinian Bösl Data manager Digital Life/ELIXIR Norway 21 February 2020

Disclaimer

This is not a legal advice

• Research Ethics Act



- Research Ethics Act
- Health Research Act



- Research Ethics Act
- Health Research Act
- Health Registry Act



- Research Ethics Act
- Health Research Act
- Health Registry Act
- Biotechnology Act



- Research Ethics Act
- Health Research Act
- Health Registry Act
- Biotechnology Act
- Archive Act



- Research Ethics Act
- Health Research Act
- Health Registry Act
- Biotechnology Act
- Archive Act
- Patents Act

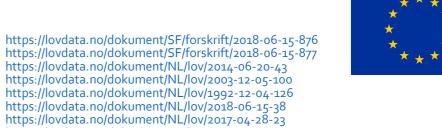


- Research Ethics Act
- Health Research Act
- Health Registry Act
- Biotechnology Act
- Archive Act
- Patents Act
- Copyright Act



- Research Ethics Act
- Health Research Act
- Health Registry Act
- Biotechnology Act
- Archive Act
- Patents Act
- Copyright Act
- Personal Data Act
- Regulations on the processing of personal data
- General Data Protection Regulation





- Research Ethics Act
- Health Research Act
- Health Registry Act
- Biotechnology Act
- Archive Act
- Patents Act
- Copyright Act → Licensing
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Conceal of scientific efforts and / or scientific achievements. Improper allocation of authorship etc.







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Destruction of research data / material to prevent investigations of misconduct.

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National/Regional Ethic committees











Consent from participants







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Data access rights for participants







Consent from participants



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Biobank regulations







Consent from participants



Data access rights for participants



Biobank regulations



Maximum data storage time for non archived data (default: 5yrs after end of project – exemptions: approval)







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Regional Committees for Medical and Health Research Ethics (REK)





Protection of Personal data





Protection of Personal data



Privacy by Design





Protection of Personal data



Privacy by Design



Privacy Impact Assessment





Protection of Personal data



Privacy by Design



Privacy Impact Assessment



Processing of Personal Data





Protection of Personal data



Privacy by Design



Privacy Impact Assessment



Processing of Personal Data



Technical and organisational measure to secure data





Protection of Personal data



Privacy by Design



Privacy Impact Assessment



Processing of Personal Data



Technical and organisational measure to secure data



Records of Processing Activities





Protection of Personal data



Privacy by Design



Privacy Impact Assessment



Processing of Personal Data



Technical and organisational measure to secure data



Records of Processing Activities



Access rights, Right to be forgotten, Right on Information





Protection of Personal data



Privacy by Design



Privacy Impact Assessment



Processing of Personal Data



Technical and organisational measure to secure data



Records of Processing Activities



Access rights, Right to be forgotten, Right on Information



Fines: up to 20 million €, ... up to 4 % of their total global turnover of the preceding fiscal year, whichever is higher.



National implementation of GDPR



National implementation of GDPR



Consent from participants (>= 13yrs)



National implementation of GDPR



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Exceptions for archival, public interest and scientific reasons



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Authorities: Privacy Ombudsman, Privacy Comittees, Data Inspectorate (datatilsynet)

What is Personal Data?

Any information that relates to an identified **or identifiable** living individual

De-identified, encrypted or pseudonymised → still personal data

Truly anonymised \rightarrow anonymisation must be irreversible.

What is Personal Data?



A name and surname

What is Personal Data?



A name and surname



A home address



A name and surname



A home address



An email address such as name.surname@company.com;







Cocation data



- A home address
- An email address such as name.surname@company.com;
- Location data
- An Internet Protocol (IP) address



- A home address
- An email address such as name.surname@company.com;
- Location data
- An Internet Protocol (IP) address
 - A cookie



A name and surname



A home address



An email address such as name.surname@company.com;



Location data



An Internet Protocol (IP) address



A cookie



Data held by a hospital or doctor, which could be a symbol that uniquely identifies a person.

What is Sensitive Personal Data?

Personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs

Trade-union membership

Data concerning a person's sex life or sexual orientation.

Genetic data, biometric data processed solely to identify a human being;



Are we allowed to store/process Sensitive Data?

Explicit consent of the individuals

The data is processed for archiving, scientific or historical research purposes or statistical purposes on the basis of EU or national law.

GDPR, Recital 33: "it is not always possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collectio"

Conditions to store/process Personal (Sensitive) Data

Lawful and transparent manner ('lawfulness, fairness and transparency')

Specific purposes ('purpose limitation')

Only the personal data that is **necessary** to fulfil that purpose ('data minimisation')

Stored for no longer than necessary ('storage limitation')

Technical and organisational safeguards that ensure the security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technology ('integrity and confidentiality')

→ Immediate reporting of incidents

Derogations for scientific purposes

Further processing and storage limitation (Articles 5(1)(b) and (e) GDPR)

Processing of special categories of data (Article 9(2)(j) GDPR)

Information provided by third parties (Article 14(5)(b) GDPR)

Right to erasure (Article 17(3)(d) GDPR)

Right to object (Article 21(6) GDPR).

In addition, the following derogations in the Norwegian Data protection act:

The rights to access

The right to rectification

The right to restrict processing

The right to object

How to store & process Personal (Sensitive) Data?

Keep in touch with your data protection officers

Follow institutional guidelines ———

Dedicated platforms (e.g. TSD)

Responsible authorities

NORSK SENTER FOR FORSKNINGSDATA





REGIONAL COMMITTEES FOR MEDICAL AND HEALTH RESEARCH ETHICS









From 01.01.2020 (most universities)

NSD privacy assessments on behalf of the Norwegian universities.

→ processing personal data in project → apply to NSD

min 30 days before data collection starts.

Medical and health research projects → apply in parallel to NSD+REK

Application procedure depended on institution

Type of project

Research on personal data which are not health-related?

Approving authority

Privacy protection officer + NSD

Advisory authority

Datatilsynet/Privacy Protection ombud

Type of project	Approving authority	Advisory authority
Research on personal data which are not health-related?	Privacy protection officer + NSD	Datatilsynet/Privacy Protection ombud
Human biological material?	REK + NSD	REK

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Health data?	REK + NSD	Datatilsynet + REK

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Health data?	REK + NSD	Datatilsynet + REK
Involving test persons?	REK + NSD	REK

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Medicines, dietary supplements, natural substances or other substances?	Norwegian Medicines Agency + REK +NSD	Norwegian Medicines Agency + REK

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Radiation on humans?	REK + NSD	REK

Contacts

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NSD - nsd.no





