



Legal requirements for Data Managing



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

Disclaimer

This is not a legal advice

Relevant laws

- Research Ethics Act



Relevant laws

- Research Ethics Act
- Health Research Act



Relevant laws

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



Relevant laws

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



Relevant laws

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



Relevant laws

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



Relevant laws

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



<https://lovdata.no/dokument/SF/forskrift/2018-06-15-876>
<https://lovdata.no/dokument/SF/forskrift/2018-06-15-877>
<https://lovdata.no/dokument/NL/lov/2014-06-20-43>
<https://lovdata.no/dokument/NL/lov/2003-12-05-100>
<https://lovdata.no/dokument/NL/lov/1992-12-04-126>
<https://lovdata.no/dokument/NL/lov/2018-06-15-38>
<https://lovdata.no/dokument/NL/lov/2017-04-28-23>
<https://lovdata.no/dokument/LTI/lov/2008-06-20-44>
<https://lovdata.no/dokument/LTI/lov/2019-06-21-49>
<https://lovdata.no/dokument/NL/lov/2018-06-15-40>
<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2016:119:FULL>



Research Ethics Act



Withhold-, mislead about-, or selectively/secretly dispose of undesired results



Research Ethics Act



Withhold-, mislead about-, or selectively/secretly dispose of undesired results



Conceal of scientific efforts and / or scientific achievements. Improper allocation of authorship etc.



Research Ethics Act



Withhold-, mislead about-, or selectively/secretly dispose of undesired results



Conceal of scientific efforts and / or scientific achievements. Improper allocation of authorship etc.



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



Research Ethics Act



Withhold-, mislead about-, or selectively/secretly dispose of undesired results



Conceal of scientific efforts and / or scientific achievements. Improper allocation of authorship etc.



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



National/Regional Ethic committees

...



Health Research Act



Prior approval for Health Research



Health Research Act



Prior approval for Health Research



Consent from participants



Health Research Act



Prior approval for Health Research



Consent from participants



Data access rights for participants



Health Research Act



Prior approval for Health Research



Consent from participants



Data access rights for participants



Biobank regulations



Health Research Act



Prior approval for Health Research



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)



Health Research Act



Prior approval for Health Research



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)



Regional Committees for Medical and Health Research Ethics (REC)

...



General Data Protection Regulation



Protection of Personal data



General Data Protection Regulation



Protection of Personal data



Privacy by Design



General Data Protection Regulation



Protection of Personal data



Privacy by Design



Privacy Impact Assessment



General Data Protection Regulation



Protection of Personal data



Privacy by Design



Privacy Impact Assessment



Processing of Personal Data



Technical and organisational measure to secure data



General Data Protection Regulation



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



General Data Protection Regulation



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



General Data Protection Regulation



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.



Personal Data Act & Personal Data Regulations

National implementation of GDPR



Personal Data Act & Personal Data Regulations

National implementation of GDPR



Consent from participants (≥ 13 yrs)



Personal Data Act & Personal Data Regulations

National implementation of GDPR



Consent from participants (≥ 13 yrs)



Exceptions for archival, public interest and scientific reasons



Personal Data Act & Personal Data Regulations

National implementation of GDPR



Consent from participants (≥ 13 yrs)



Exceptions for archival, public interest and scientific reasons



Authorities: Privacy Ombudsman, Privacy Committees,

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 → anonymisation must be irreversible.

What is Personal Data?



A name and surname

What is Personal Data?



A name and surname



A home address

- . . . -

What is Personal Data?



A name and surname



A home address



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

What is Personal Data?



A name and surname



A home address



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



Location data

What is Personal Data?



A name and surname



A home address



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



Location data



An Internet Protocol (IP) address

What is Personal Data?



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

What is Personal Data?



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;**
- **Health-related data**

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.

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**

How to store & process Personal (Sensitive) Data?

Keep in touch with your data protection officers

Follow institutional guidelines



Dedicated platforms (TSD, EUTRO)

Responsible authorities

NSD NORSK SENTER FOR FORSKNINGSDATA



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

Approval/Reporting

Type of project

Approving authority

Advisory authority

Research on personal data which are not health-related?

Privacy protection officer + NSD

Datatilsynet/Privacy Protection ombud

Approval/Reporting

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

Approval/Reporting

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

Health data?

REK + NSD

Datatilsynet + REK

Approval/Reporting

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

Approval/Reporting

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
Health data?	REK + NSD	Datatilsynet + REK
Involving test persons?	REK + NSD	REK
Medicines, dietary supplements, natural substances or other substances?	Norwegian Medicines Agency + REK +NSD	Norwegian Medicines Agency + REK

Approval/Reporting

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
Health data?	REK + NSD	Datatilsynet + REK
Involving test persons?	REK + NSD	REK
Medicines, dietary supplements, natural substances or other substances?	Norwegian Medicines Agency + REK + NSD	Norwegian Medicines Agency + REK
Medical equipment is used on humans?	The Norwegian Directorate of Health + REK + NSD	The Norwegian Directorate of Health

Approval/Reporting

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
Health data?	REK + NSD	Datatilsynet + REK
Involving test persons?	REK + NSD	REK
Medicines, dietary supplements, natural substances or other substances?	Norwegian Medicines Agency + REK +NSD	Norwegian Medicines Agency + REK
Medical equipment is used on humans?	The Norwegian Directorate of Health + REK + NSD	The Norwegian Directorate of Health
Radiation on humans?	REK + NSD	REK

Contacts



Personvernombud UiT

Joakim Bakkevold personvernombud@uit.no

Juridisk rådgivning, GDPR, Helseforskningsloven, EUTRO

Jannicke Persen jannicke.persen@uit.no

Frank Tore Mengkrogen frank.t.mengkrogen@uit.no

Personvern og forskning

Olaug Husabø olaug.husabo@uit.no

Sølvi Brendeford Anderssen solvi.anderssen@uit.no

REK Nord

Veronica Sørensen

Lill Martinsen

Maren Johannessen Melsbø

Monika Rydland

Sekretariat: May Britt Rossvoll

rek-nord@asp.uit.no

NSD - nsd.no



NSD NORSK SENTER FOR FORSKNINGSDATA

https://uit.no/om/enhet/artikkel?p_document_id=212253&p_dimension_id=88108

https://uit.no/forskning/art?p_document_id=335891&dim=179056

<https://rekportalen.no/#home/REK>

<https://nsd.no/>