



# Legal requirements for Data Managing



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21 February 2020

# Disclaimer

This is not a legal advice

# Relevant laws

- Research Ethics Act



# Relevant laws

- Research Ethics Act
- Health Research Act



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



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- 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



<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>

# 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**



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# Research Ethics Act



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



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



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



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



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



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National/Regional Ethic committees

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# 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)



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Regional Committees for Medical and Health Research Ethics (REK)

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# 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



# 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



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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



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National implementation of GDPR



Consent from participants ( $\geq 13$  yrs)



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Exceptions for archival, public interest and scientific reasons





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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



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Human biological material?

REK + NSD

REK

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Human biological material?	REK + NSD	REK
Health data?	REK + NSD	Datatilsynet + REK

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Involving test persons?	REK + NSD	REK

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

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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

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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



## Data Protection Officer UiT

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## Legal advice, GDPR, Health Research Act, EUTRO

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## 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/om/enhet/artikkel?p_document_id=212253&p_dimension_id=88108)

[https://uit.no/forskning/art?p\\_document\\_id=335891&dim=179056](https://uit.no/forskning/art?p_document_id=335891&dim=179056)

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

<https://nsd.no/>