

# Schedule

**16.06.2021**

0900 - 1000 Key legal requirements for research in the GDPR and Health research act

1000 - 1015 Short break

1015 - 1045 Relevant deposition repositories/ data archives

1100 - 1115 Licensing of data, biological material and software

1115 - 1300 Hands on training and assistance to generate a data management plan



# Legal requirements for Data Managing



Korbinian Bösl  
Data management coordinator  
ELIXIR Norway/Digital Life Norway



Data life cycle	+
Your role	+
Your domain	+
Your problem	-
Compliance monitoring	
Data analysis	
Data management plan	
Data organisation	
Data protection	
Data publication	
Data quality	
Data storage	
Data transfer	
Identifiers	
Licensing	
Documentation and metadata	
Sensitive data	
All tools and resources	
Tool assembly	+

Link to RDMkit: <https://rdmkit.elixir-europe.org/>

# Disclaimer

This is not a legal advice

# Relevant laws

- Research Ethics Act



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





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National/Regional Ethic committees

...



The Norwegian National

# RESEARCH ETHICS COMMITTEES

**Defines relevant guidelines:**

**General guidelines for research ethics**



# The Norwegian National RESEARCH ETHICS COMMITTEES

**Defines relevant guidelines:**

**General guidelines for research ethics**

**Guidelines for Research Ethics in Science and Technology**



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**General guidelines for research ethics**

**Guidelines for Research Ethics in Science and Technology**

**Guidelines for the use of genetic studies of humans**



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**Guidelines for Research Ethics in Science and Technology**

**Guidelines for the use of genetic studies of humans**

**Guidelines for the inclusion of women**



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**Ethical guidelines for clinical trial of drugs**



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**The Vancouver Recommendations**





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**The Vancouver Recommendations**

**Declaration of Helsinki**

**Oviedo Convention**



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**The Vancouver Recommendations**

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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)

...





# General Data Protection Regulation



Protection of Personal data



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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



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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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National implementation of GDPR



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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.

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

 **Health-related data**

# Genetic data

xxx GDPR art. 4(13): Genetic data: “personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person”

Always both: Personal identifier and sensitive information!

# Pseudonymisation



GDPR art. 4(5): the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person

De-identified and not back traceable for the researcher without the identifier

Pseudonymised data is still personal data!

# Anonymous information



...cannot in any way be used to identify individuals in a data material, either directly by name or personal identification number or indirectly by additional information.

Not possible for many data types (e.g. genetic data) !



# Data subjects, processing, controller & processor

Data subject: the natural person information relates to, GDPR art. 4(1)

- Processing: “any operation or set of operations which is performed on personal data or on sets of personal data” , GDPR art. 4(2)

Basically all handling of data such as:

Collecting

Storing

Analysing

Deleting

Anonymising

...

Data Controller: determines the purposes and means of the processing of personal data

Data Processor: processes personal data on behalf of the controller

# 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')

**Accuracy**

**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')

**Accountability → Immediate reporting of incidents**

# Lawfulness: When are we allowed to store/process personal (sensitive) Data ?

At least one of:

**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.

Tasks carried out in the public interest

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 collection”

# Lawfulness: When are we allowed to store/process personal (sensitive) Data ?

At least one of:

Explicit consent of the individuals

**If you are using consent as your legal basis:**

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

**Make sure your consent form (& REC approval)  
allows controlled access deposition (e.g. to EGA)  
...before you start!**

Tasks carried out in the public interest

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# Fairness & Transparency

Fairness: We must not take advantage of our position as a research institution, we must not take advantage of our position in relation to the data subjects

Transparency: The data subjects shall be informed of what we do with their personal data, and of how to exercise his/her rights

Provision of the required information in a clear and plain language

# Data minimisation

The amount of personal data shall be limited to that necessary to achieve the purpose of data processing

Obligation to avoid collecting, storing or in any other way processing personal data that is not strictly necessary, even if it may be “nice to have”

# Accuracy

Personal data shall be accurate:

important not only in consideration of the data subjects but also for your research

Obligation to rectify or delete inaccurate personal data

The data subject can ask for deletion of the data at any time

# Storage limitation

Personal data shall not be stored for longer than necessary to fulfil the purpose

Once the purpose has been achieved, the data shall in principle be deleted or made anonymous

REC usually sets requirements for storage beyond the project period for reasons of verifiability (you might have to include this in your **application!**)

Processing personal data for the purpose of verifiability is legitimate

Personal data may be stored for longer periods insofar as the personal data will be processed solely for ... scientific or historical research purposes or statistical purposes



# Integrity and confidentiality

Personal data must be processed in a manner that ensures appropriate security of the personal data protect personal data against unauthorised access, unlawful processing, accidental loss, distribution, amendment or damage

Follow institutional guidelines

Pseudonymization

Dedicated platforms (e.g. TSD)



# Accountability

The controller shall be responsible for, and be able to demonstrate compliance with the principles

Obligation to document the processing of personal (sensitive) data

Follow the guidelines at your institution

# Data protection impact assessment - DPIA

“Where a type of processing ... is likely to result in a high risk to the rights and freedoms of natural persons”

- Based on new technologies, the nature, scope, context and purposes of the processing

E.g.: “Processing of genetic data in conjunction with at least one other criterion”, and

“Processing of personal data using innovative technology in conjunction with at least one other criterion”

Identify risks and take measures to reduce the risk - Ensuring the privacy of the data subject

Specialized tools

# 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 derogation in the Norwegian Data protection act:

- The rights to access

- The right to rectification

- The right to restrict processing

- The right to object

# International data transfers

Key relevance in your research?

Third country = all countries outside the EU/EEA

Transfer mechanism pursuant to GDPR ch. V

Adequacy decision

Privacy Shield: discontinued

Most common: Standard Contractual Clauses adopted by the EU Commission

- Additional safeguards - e.g. Pseudonymization

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EC has recognized:

Andorra, Argentina,  
Canada, Faroe Islands,  
Guernsey, Israel, Isle of  
Man, Japan, Jersey,  
New Zealand, Switzerland  
& Uruguay

UK post Brexit: **pending**

# International data transfers

The perspective in the **US** on personal (sensitive) data and medical research in e.g. the **Health Insurance Portability and Accountability Act (HIPAA)** is very different

Exchange of personal data & biological material (for research) in any direction requires special and careful additional consideration!

# Responsible authorities

**NSD** NORSK SENTER FOR FORSKNINGSDATA





**Since 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 (depends on faculty & 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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Type of project	Approving authority	Advisory authority
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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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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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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

## Data Protection Officers

UiB [Janecke.Veim@uib.no](mailto:Janecke.Veim@uib.no)  
NTNU: [thomas.helgesen@ntnu.no](mailto:thomas.helgesen@ntnu.no)  
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NMBU [personvernombud@nmbu.no](mailto:personvernombud@nmbu.no)  
UiO [personvernombudet@uio.no](mailto:personvernombudet@uio.no)

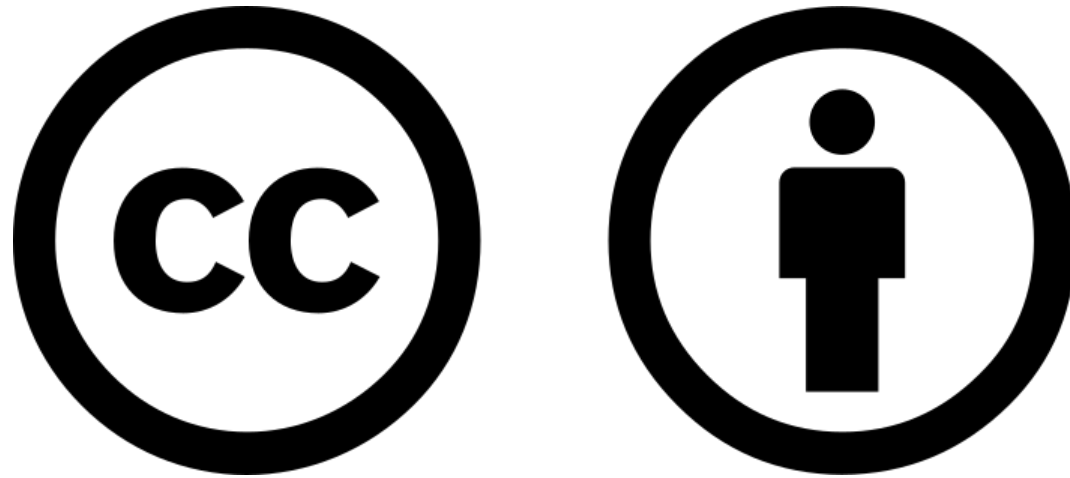
## REK

[rek-vest@uib.no](mailto:rek-vest@uib.no)  
[rek-midt@mh.ntnu.no](mailto:rek-midt@mh.ntnu.no)  
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**NSD** NORSK SENTER FOR FORSKNINGSDATA



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