

## Schedule - Day 2: Thursday, 6 June 2024

Time	Activity
09:00-10:00	Key legal requirements, for life sciences research, in GDPR and Health research Act (and a lot more!)
10:00-10:15	Break
10:15-10:45	Relevant Deposition Repositories / Data Archives
11:00-11:15	Licensing of data, biological material and software
11:15-11:30	Hands-on training and assistance to generate a Data Management Plan (DMP)



# Legal Requirements for Data Management



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ELIXIR Norway (University of Oslo)  
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**6 June 2024**

# **Disclaimer**

This is not a legal advice

# Important Relevant Legislations

Research Ethics Act

Health Research Act

Health Registry Act

Biotechnology Act

Archive Act

Patents Act

Copyrights Act



- Health Register Act: <https://lovdata.no/dokument/NL/lov/2014-06-20-43>
- Biotechnology Act: <https://lovdata.no/dokument/NL/lov/2003-12-05-100>
- Archives Act: <https://lovdata.no/dokument/NL/lov/1992-12-04-126>
- Patents Act: <https://lovdata.no/dokument/LTI/lov/2019-06-21-49>
- Copyright Act: <https://lovdata.no/dokument/NL/lov/2018-06-15-40>

# Important Relevant Legislations

Personal Data Act

Regulations on the processing of personal data

General Data Protection Regulation (GDPR)



**The GDPR is an EU Regulation that applies directly to Norway, as a member of the EEA.**



# 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.



The Norwegian National

# RESEARCH ETHICS COMMITTEES

**General guidelines on  
research ethics**

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

**Guidelines for clinical  
trial of drugs**

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

**Guidelines for the inclusion  
of women**

**Guidelines for research ethics and scientific  
assessment of qualitative research projects**

Read more at: [forskningsetikk.no](https://forskningsetikk.no)



The Norwegian National

**RESEARCH ETHICS  
COMMITTEES**

**The Vancouver Recommendations**

**Declaration of Helsinki**

**Oveido Convention**

Otherwise known as: **The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine**

Read more at: [forskningsetikk.no](https://forskningsetikk.no)





# 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: 5 years after end of project – exemptions: approval)



Regional Committees for Medical and Health Research Ethics (REK)





# GDPR: General Data Protection Regulation



Protection of Personal Data



Privacy by Design



Data Protection Impact Assessment (DPIA)



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: 10-20 million, up to 4 % of total turnover of the preceding fiscal year

GDPR: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2016:119:FULL>

News on Datatilsynet: <https://www.datatilsynet.no/en/news/>



# Personal Data Act & Personal Data Regulations

## National Implementation of GDPR



Consent from participants (13 years and older)



Exceptions for archival, public interest, and scientific reasons



Authorities: Privacy Ombudsman, Privacy Committees,  
Data Inspectorates (datatilsynet)

More information at:

- Regulations on the processing of personal data: <https://lovdata.no/dokument/SF/forskrift/2018-06-15-876>
- Transitional rules on the processing of personal data: <https://lovdata.no/dokument/SF/forskrift/2018-06-15-877>
- Personal Data Act: <https://lovdata.no/dokument/NL/lov/2018-06-15-38>

# Let's find out: What is...?

Personal Data





Sensitive Personal Data

Genetics Data

Pseudonymisation

Anonymisation

# What defines personal data?

-  Any information that relates to an identified or identifiable living individual
-  What if data can be de-identified, encrypted, or pseudonymised?
-  **^Still, it is considered personal data!**
-  Truly anonymised → anonymisation must be irreversible.

# What is personal data? Examples:



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 personal data is considered sensitive?

- Personal data revealing racial or ethnic origin, political opinions, religious, or philosophical beliefs
- Trade-union membership
- Genetic data, biometric data processed solely to identify a human being
- Health related data

Further reading - what personal data is considered sensitive?:

[https://ec.europa.eu/info/law/law-topic/data-protection/reform/rules-business-and-organisations/legal-grounds-processing-data/sensitive-data/what-personal-data-considered-sensitive\\_en](https://ec.europa.eu/info/law/law-topic/data-protection/reform/rules-business-and-organisations/legal-grounds-processing-data/sensitive-data/what-personal-data-considered-sensitive_en)

# What defines genetic data?



Genetic data is defined as: “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.” - GDPR article 4(13)



Always both: Personal identifier and sensitive information!

Further reading - what personal data is considered sensitive?:

[https://ec.europa.eu/info/law/law-topic/data-protection/reform/rules-business-and-organisations/legal-grounds-processing-data/sensitive-data/what-personal-data-considered-sensitive\\_en](https://ec.europa.eu/info/law/law-topic/data-protection/reform/rules-business-and-organisations/legal-grounds-processing-data/sensitive-data/what-personal-data-considered-sensitive_en)



# Data Psuedonymisation



“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” - GDPR article 4(13)

- De-identified and not back traceable for the researcher without the identifier
- ⚠ Pseudonymised data is still personal data!

# Anonymous Data

- Anonymous data 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, such as genetic data

## What is...?



Personal Data



Sensitive Personal Data



Genetics Data



Pseudonymisation



Anonymisation

## What does GDPR say about...?

Data subjects, processing, controller, and processors

Storage and processing of personal (sensitive) data: How & When?

- ☐ Fairness and Transparency
- ☐ Data Minimisation
- ☐ Data Accuracy
- ☐ Storage Limitation
- ☐ Integrity and Confidentiality
- ☐ Accountability



# What does GDPR say about:

## Data subjects, processing, controller, and processors

- **Data subject:**  
“the natural person information relates to.” - GDPR article 4(1)
- **Data Processing:**  
“any operation or set of operations which is performed on personal data or on sets of personal data.” - GDPR article 4(2)
- **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**')
        - **Data 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

# Criteria to store/process personal (sensitive) data



Explicit consent from participant

Health Research Act



- 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” - Article 6, GDPR
- “It is not always possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection” - GDPR, Recital 33

## Further readings:

- [https://ec.europa.eu/info/law/law-topic/data-protection/reform/rules-business-and-organisations/legal-grounds-processing-data/sensitive-data/under-what-conditions-can-my-company-organisation-process-sensitive-data\\_en](https://ec.europa.eu/info/law/law-topic/data-protection/reform/rules-business-and-organisations/legal-grounds-processing-data/sensitive-data/under-what-conditions-can-my-company-organisation-process-sensitive-data_en)
- [https://lovdata.no/dokument/NL/lov/2008-06-20-44/KAPITTEL\\_4#KAPITTEL\\_4](https://lovdata.no/dokument/NL/lov/2008-06-20-44/KAPITTEL_4#KAPITTEL_4)



## Criteria to store/process personal (sensitive) data



Explicit consent from participant

Health Research Act



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

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

\* REK: Regional Committees for Medical and Health Research Ethics

\*\* EGA: European Genome Archive

### Further readings:

- [https://ec.europa.eu/info/law/law-topic/data-protection/reform/rules-business-and-organisations/legal-grounds-processing-data/sensitive-data/under-what-conditions-can-my-company-organisation-process-sensitive-data\\_en](https://ec.europa.eu/info/law/law-topic/data-protection/reform/rules-business-and-organisations/legal-grounds-processing-data/sensitive-data/under-what-conditions-can-my-company-organisation-process-sensitive-data_en)
- [https://lovdata.no/dokument/NL/lov/2008-06-20-44/KAPITTEL\\_4#KAPITTEL\\_4](https://lovdata.no/dokument/NL/lov/2008-06-20-44/KAPITTEL_4#KAPITTEL_4)

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- ☐ Accountability



# Fairness and Transparency

- **Fairness:** Not taking advantage of your position as a research institution, and not taking advantage of your position in relation to the data subjects
- **Transparency:** Your data subjects shall be informed of what you do with their personal data, and of how to exercise their/his/her rights
- Provision of the required information in a clear and plain language

## Further readings:

- [https://ec.europa.eu/info/law/law-topic/data-protection/reform/rules-business-and-organisations/legal-grounds-processing-data/sensitive-data/under-what-conditions-can-my-company-organisation-process-sensitive-data\\_en](https://ec.europa.eu/info/law/law-topic/data-protection/reform/rules-business-and-organisations/legal-grounds-processing-data/sensitive-data/under-what-conditions-can-my-company-organisation-process-sensitive-data_en)
- <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN#d1e1888-1-1>
- [https://lovdata.no/dokument/NL/lov/2008-06-20-44/KAPITTEL\\_8#KAPITTEL\\_8](https://lovdata.no/dokument/NL/lov/2008-06-20-44/KAPITTEL_8#KAPITTEL_8)

# 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”

## Further readings:

- [https://ec.europa.eu/info/law/law-topic/data-protection/reform/rules-business-and-organisations/legal-grounds-processing-data/sensitive-data/under-what-conditions-can-my-company-organisation-process-sensitive-data\\_en](https://ec.europa.eu/info/law/law-topic/data-protection/reform/rules-business-and-organisations/legal-grounds-processing-data/sensitive-data/under-what-conditions-can-my-company-organisation-process-sensitive-data_en)
- <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN#d1e1888-1-1>

# Data Accuracy

- Important not only in consideration of the data subjects but also for your research
- Obligation to rectify or delete inaccurate personal data
- Your data subject can ask for deletion of the data at any time

## Further readings:

- [https://ec.europa.eu/info/law/law-topic/data-protection/reform/rules-business-and-organisations/legal-grounds-processing-data/sensitive-data/under-what-conditions-can-my-company-organisation-process-sensitive-data\\_en](https://ec.europa.eu/info/law/law-topic/data-protection/reform/rules-business-and-organisations/legal-grounds-processing-data/sensitive-data/under-what-conditions-can-my-company-organisation-process-sensitive-data_en)
- <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN#d1e1888-1-1>

# 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
- REK usually sets requirements for storage beyond the project period for reasons of verifiability - **you may need to include this in your application!**
- Processing personal data for the purpose of verifiability is legitimate
- Personal data may be stored for longer periods so far as the personal data is processed solely for scientific, historical, and/or statistical research purposes

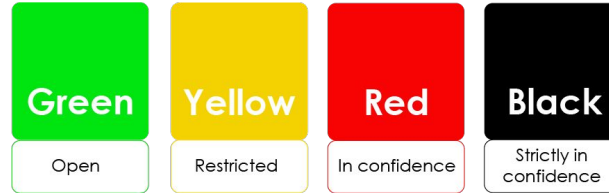
## Further readings:

- [https://ec.europa.eu/info/law/law-topic/data-protection/reform/rules-business-and-organisations/legal-grounds-processing-data/sensitive-data/under-what-conditions-can-my-company-organisation-process-sensitive-data\\_en](https://ec.europa.eu/info/law/law-topic/data-protection/reform/rules-business-and-organisations/legal-grounds-processing-data/sensitive-data/under-what-conditions-can-my-company-organisation-process-sensitive-data_en)
- <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN#d1e1888-1-1>

# 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



- Pseudonymisation
- ◆ Dedicated data analysis platforms

Image Source: <https://uio.no/english/for-employees/support/research/funding/units/hf/imv/data-ethics/colors.html>

More about TSD: <https://www.uio.no/english/services/it/research/sensitive-data/>

# Accountability

- Data controller shall be responsible for, and be able to demonstrate **compliance with the principles**
- Obligation to **document** the processing of personal (sensitive) data
- ⚠ Follow institutional guidelines

## What is...?



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- ☐ Accountability

# Let's learn about (the importance of):



Data Protection Impact Assessment (DPIA)



Derogations for scientific purposes



International Data Transfers



Data Privacy Assessments



Approval/Reporting





# 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
- Your research work is based on:
  - ◆ “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; DPIA helps ensure privacy of your data subject(s)

Tool Resource: <https://www.cnil.fr/en/open-source-pia-software-helps-carry-out-data-protection-impact-assesment>

Further reading: <https://gdpr-info.eu/art-35-gdpr/>



## 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, there are following derogations in the Norwegian Data protection act:

- Right to access
- Right to rectification
- Right to restrict processing



# International Data Transfers

Key relevance in scientific research

Countries outside the EU/EEA (“Third countries”)

Transfer mechanism pursuant to GDPR chapter 5

Adequacy Decision

Most common: Standard Contractual Clauses (SCCs) adopted by the European Commission (EC)

Additional safeguards - e.g. Pseudonymization

EC has recognized:

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

## Further reading:

- [eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN#d1e4319-1-1](https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN#d1e4319-1-1)
- [ec.europa.eu/info/law/law-topic/data-protection/reform/rules-business-and-organisations/obligations/what-rules-apply-if-my-organisation-transfers-data-outside-eu\\_en](https://ec.europa.eu/info/law/law-topic/data-protection/reform/rules-business-and-organisations/obligations/what-rules-apply-if-my-organisation-transfers-data-outside-eu_en)
- <https://gov.uk/government/news/eu-adopts-adequacy-decisions-allowing-data-to-continue-flowing-freely-to-the-uk>



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Guernsey, Israel, Isle of  
Man, Japan, Jersey,  
New Zealand, Switzerland,  
Uruguay, and the UK



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

Further reading:

- [eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN#d1e4319-1-1](https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN#d1e4319-1-1)
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- [gov.uk/government/news/eu-adopts-adequacy-decisions-allowing-data-to-continue-flowing-freely-to-the-uk](https://gov.uk/government/news/eu-adopts-adequacy-decisions-allowing-data-to-continue-flowing-freely-to-the-uk)



# Data Privacy Assessments

Sikt carries out privacy assessments on behalf of Norwegian universities.  
**Processing personal data in project → Apply to Sikt**

**Minimum 30 days** before data collection starts



<https://sikt.no/en/data-protection-services>



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**Processing personal data in project → Apply to Sikt**

**Minimum 30 days** before data collection starts



**Medical and health research** projects → **Apply in parallel to NSD+REK**  
(depends on faculty and institution)



# Responsible Authorities





## Approval/Reporting

### Type of project

Research on personal data which are not health-related?

### Approving authority

Privacy protection officer + Sikt

### Advisory authority

Datatilsynet/Privacy Protection ombud



# Approval/Reporting

## Type of project

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Research on personal data which are not health-related?

Privacy protection officer + Sikt

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Human biological material?

REK + Sikt

REK

# Approval/Reporting

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REK + Sikt

REK

Health data?

REK + Sikt

Datatilsynet + REK

# Approval/Reporting

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Human biological material?	REK + Sikt	REK
Health data?	REK + Sikt	Datatilsynet + REK
Involving test persons?	REK + Sikt	REK

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Health data?	REK + Sikt	Datatilsynet + REK
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Radiation on humans?	REK + Sikt	REK

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Involving test persons?	REK + Sikt	REK
Radiation on humans?	REK + Sikt	REK
Medicines, dietary supplements, natural substances or other substances?	Norwegian Medicines Agency + REK + Sikt	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 + Sikt	Datatilsynet/Privacy Protection ombud
Human biological material?	REK + Sikt	REK
Health data?	REK + Sikt	Datatilsynet + REK
Involving test persons?	REK + Sikt	REK
Radiation on humans?	REK + Sikt	REK
Medicines, dietary supplements, natural substances or other substances?	Norwegian Medicines Agency + REK + Sikt	Norwegian Medicines Agency + REK
Medical equipment is used on humans?	The Norwegian Directorate of Health + REK + Sikt	The Norwegian Directorate of Health

# Contact Information

## Data Protection Officers

UiB Janecke.Veim@uib.no

NTNU: thomas.helgesen@ntnu.no

UiT personvernombud@uit.no

NMBU personvernombud@nmbu.no

UiO personvernombudet@uio.no

## REK

rek-vest@uib.no

rek-midt@mh.ntnu.no

rek-nord@asp.uit.no

rek-sorost@medisin.uio.no

**Sikt** - sikt.no



[rekportalen.no/#home/REK](https://rekportalen.no/#home/REK)



# Research Data Management kit

[Data management](#)[About](#)[Contribute](#)[GitHub](#)

## The Research Data Management toolkit for Life Sciences

Best practices and guidelines to help you make your data FAIR (Findable, Accessible, Interoperable and Reusable)

### What can we help you find?

### Browse all topics by



#### Data life cycle

Start here to get an overview of research data management based on stages in the data life cycle.



#### Your role

Identify your role in research data management, find data management resources relevant for you, and information to help you progress in your career path.



#### Your domain

Learn about data management tasks that affect your domain or research community, and the solutions adopted to address them.



#### Your tasks

Find guidelines and solutions for tackling common data management tasks.



#### Tool assembly

Find concrete combinations of tools and resources assembled into an ecosystem for research data management.



#### National resources

Find pointers to country specific information resources and national research data management practices.



#### All tools and resources

Browse the RDMkit's catalogue of tools and resources for research data management.




#### All training resources

Browse all training resources mentioned in RDMkit pages.

 <https://rdmkit.elixir-europe.org>



- Data management
  - Data life cycle ▾
  - Your role ▾
  - Your domain ▾
  - Your tasks ▲
  - Compliance monitoring
  - Data analysis
  - Data brokering
  - Data management plan
  - Data organisation
  - Data protection
  - Data publication
  - Data quality
  - Data storage
  - Data transfer
  - Documentation and metadata
  - Existing data
  - Identifiers
  - Licensing
  - Machine actionability
  - Sensitive data
  - Tool assembly ▾

Search Type here... 

## Compliance monitoring & measurement

Measure compliance to data management regulations and standards

Related pages ▾



## Data analysis

How to make data analysis FAIR

Related pages ▾



## Data brokering

Information on brokering data to data repositories on behalf of data producers

## Data management plan

How to write a Data Management Plan (DMP)

Related pages ▾

## Data organisation

Best practices to name and organise research data

Related pages ▾



## Data protection

How to make research data compliant to GDPR

Related pages ▾













# Research Data Management kit

What can we help you find?

Search RDMkit

Browse all topics by

-   
**Data life cycle**  
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Identify your role in research data management, find data management resources relevant for you, and information to help you progress in your career path.
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Find guidelines and solutions for tackling common data management tasks.
-   
**Tool assembly**  
Find concrete combinations of tools and resources assembled into an ecosystem for research data management.
-   
**National resources**  
Find pointers to country specific information resources and national research data management practices.
-   
**All tools and resources**  
Browse the RDMkit's catalogue of tools and resources for research data management.
-   
**All training resources**  
Browse all training resources mentioned in RDMkit pages.

 [https://rdmkit.elixir-europe.org/national\\_resources](https://rdmkit.elixir-europe.org/national_resources)

# RDMkit: National resources in Norway



National resources

## Norway

### Introduction

This page provides an overview of the data management resources in Norway. The target audience is the Norwegian scientific community in the life sciences and collaborators. The [Data Stewardship Wizard instance from ELIXIR Norway](#) provides an interactive way to navigate these recommendations and resources. You can also find condensed information in the interlinked [RDM LookUp from ELIXIR Norway](#).

The Norwegian Ministry of Education and Research's "[National strategy on access to and sharing of research data](#)" from 2018 is an initiative aimed at fostering open, equitable, and efficient sharing of research data in Norway. For researchers in Norway and their international partners, this strategy lays the groundwork for creating a robust, collaborative research environment where data is shared freely but responsibly. The national strategy underscores Norway's commitment to scientific advancement and maintaining ethical and legal standards in a data-driven era.

#### On this page

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Introduction

**Funder policies on research data**

Institutional policies on research data

Support services

Data Management Planning

Life science-specific infrastructures/resources

Ethical committees and general authorities

Relevant ethical guidelines

Laws and regulations relevant to life sciences research data

 [https://rdmkit.elixir-europe.org/no\\_resources](https://rdmkit.elixir-europe.org/no_resources)

# Thank you!



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