



Ethical, Legal, and Social Implications (ELSI)

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Disclaimer

This is not:

A legal advice

A lecture on research ethics

A reflection on philosophy

Objectives

How to identify potential ethical issues connected to RDM in my project?

How can some ethical issues in RDM be mitigated?

What regulations, guidelines and laws are connected to RDM in my project?



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

Costs of data management

Data analysis

Data brokering

Data management
coordination

Data management plan

Data organisation

Data security

Data sensitivity

Data provenance

Data publication

Data quality

Data storage

Data transfer

Documentation and
metadata

Ethical aspects

Your tasks

Ethical aspects

Ethics refers to moral principles and norms that help us identify right from wrong within a particular context. Ethical issues/concerns typically arise when these principles conflict. Navigating through such concerns often requires one to compare the benefits of an action with its potential harmful consequences. When it comes to research involving human participants, such ethical concerns may appear when accessing, using, or sharing data of a sensitive nature, for example health or personal data. Ethics, however, goes beyond the issue of compliance with legal obligations, and the collection and use of data.

The [Open Data Institute](#) narrows 'ethics' in the RDM context to:

“A branch of ethics that evaluates data practices with the potential to adversely impact on people and society – in data collection, sharing and use.”

Which aspects of RDM might raise ethical issues?

Description

Ethical issues refer to moral principles and standards that guide human conduct and define what is considered right or wrong within a particular context.

Considerations

- There are different aspects in the management of research data that can raise ethical issues. It is important to distinguish between ethical issues and legal behaviour.
 - Ethical standards may vary across cultures, disciplines, and professional organisations. Researchers are expected to adhere to these ethical principles even if certain practices are not explicitly prohibited by law. Often these standards are collected in declarations and guidelines, which may be backed by laws.
 - Legal behaviour, on the other hand, refers to compliance with applicable laws, regulations, and policies. Legal requirements provide a baseline level of conduct that researchers must meet to avoid legal sanctions. However, legal compliance does not necessarily guarantee ethical behaviour. Some actions may be legally permissible but raise ethical concerns, while others may be ethically unquestionable but explicitly prohibited by specific legislation.
- Ethical issues arise most often in research on or involving humans affecting human dignity and autonomy. These issues are partly addressed by the [General Data Protection Regulation](#) (see also the [RDMkit data](#)

On this page

Which aspects of RDM might raise ethical issues?

How can I identify regulations, guidelines and laws connected to ethics in my research context?

Related pages

More information

Relevant tools and resources











Research Data Management kit

What can we help you find?

Search RDMkit

Browse all topics by

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 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

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

Ethics & Law

Ethical standards

May vary across cultures, disciplines, and professional organisations.

You are expected to adhere to these ethical principles even if not legally enforced

Collected in declarations and guidelines (can be backed by laws)

Legal behaviour

Compliance with applicable laws, regulations, and policies

Baseline level to avoid legal sanctions

Legal compliance does not necessarily guarantee ethical behaviour

In your DMP



3b data security and protection of sensitive data

4 LEGAL AND ETHICAL REQUIREMENTS, CODES OF CONDUCT

4a personal data [...]

4b intellectual property rights and ownership [...]

4c What ethical issues and codes of conduct are there, and how will they be taken into account?



Create Project

From Project Template

Custom

Name

Knowledge Model

L

Life Sciences DSW Knowledge Model 2.6.3

Life Sciences customization of DSW Knowledge Model

x

Question Tags

You can either use all questions from the knowledge model or filter them by question tags.

☐ Use all questions

☒ Filter by question tags

☒ ELSI

Create Project

From Project Template

Custom

Name

Knowledge Model

L

Life Sciences DSW Knowledge Model - ELIXIR Norway localization 0.2.7

Life Sciences customization of DSW Knowledge Model

x

IV. Data sensitivity

Ethical and legal issues



1.a.1.a.1 For each data set/cohort

NeLS storage request

Sigma2

☒ Desirable: Before Submitting the Proposal

Potential ethical issues in RDM

  Research with human subjects

 Impact of research outcomes for communities or individuals

 General research ethics considerations reflecting on RDM



Ethics review

Mandatory for certain types of research (animal experiments, medical research)

Might be integral part of your project

Requires time and might require funding

Responsible Research and Innovation (RRI)

Policy Strong focus from **RCN** and in **Horizon 2020**

The idea to anticipate societal impact of research early and make adaptations

Connecting & using different ideas on the relationship of science and society:

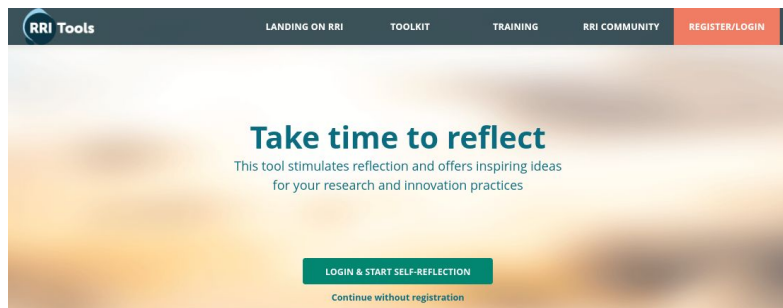
public engagement, open access, gender equality, ethics and governance

<https://rri-tools.eu/about-rri>

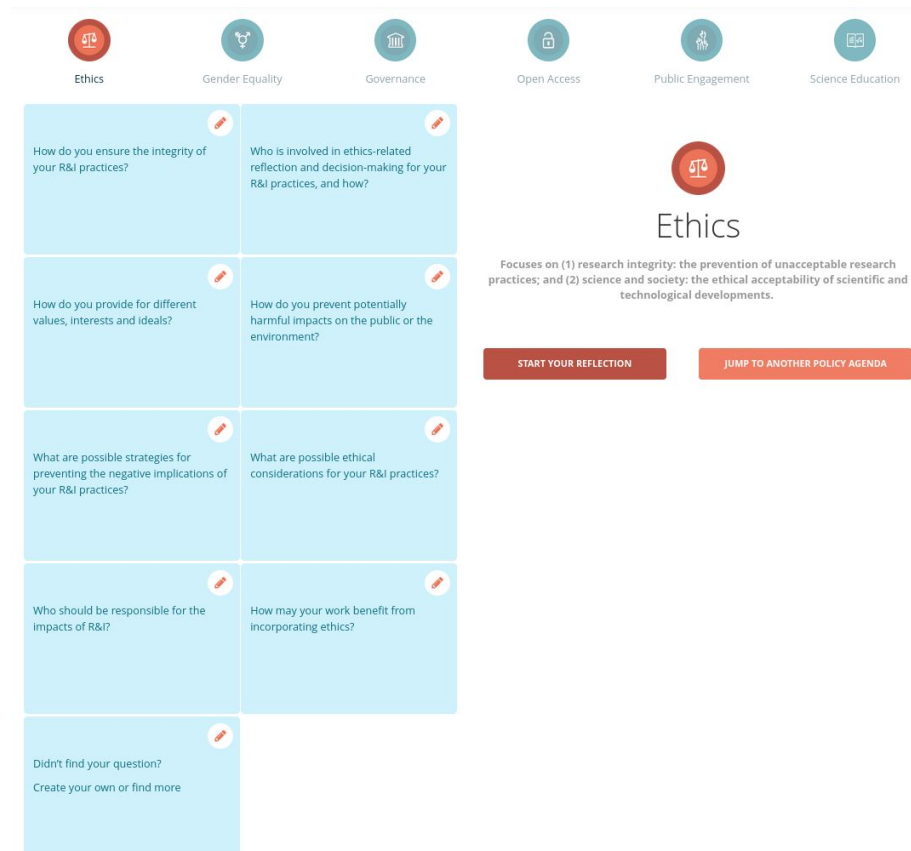
<https://rri-tools.eu/how-tos>

<https://www.digitallifenorway.org>

Getting started on RRI



<https://rri-tools.eu/>



A national centre for biotechnology research and innovation

The Centre for Digital Life Norway (DLN) transforms Norwegian biotechnology research and education to increase innovation and value creation for society. The centre has research projects all over the country. Transdisciplinary collaboration is our trademark.

Join us

...as a project

Data & models



Cross-disciplinary & cross-project activities



...or Postdoc|PhD

Innovation and industry collaboration



Responsible research and innovation (RRI)



Education, training and career development



Communications





Research with human subjects

Handling data connected to humans

Data Psuedonymisation

Anonymous Data

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

Controlled access data sharing

Data Processor

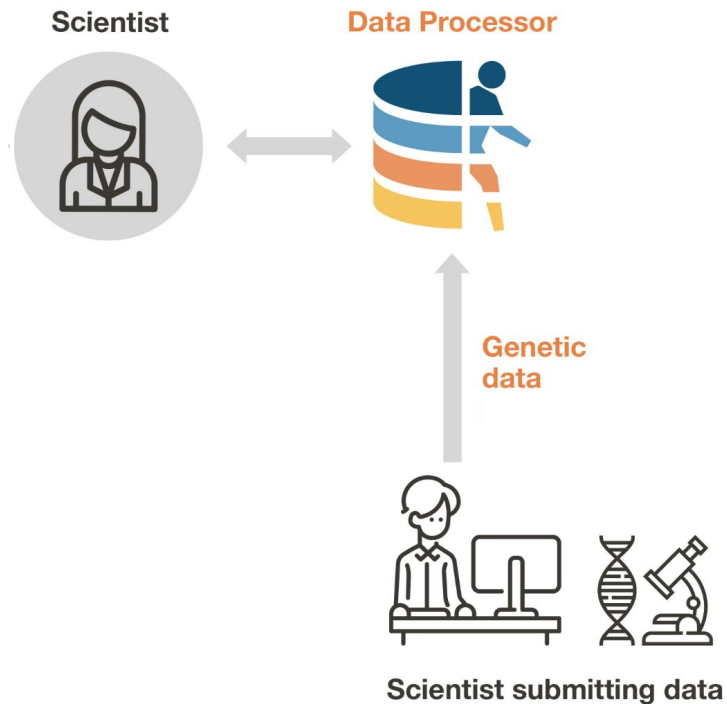


Genetic data

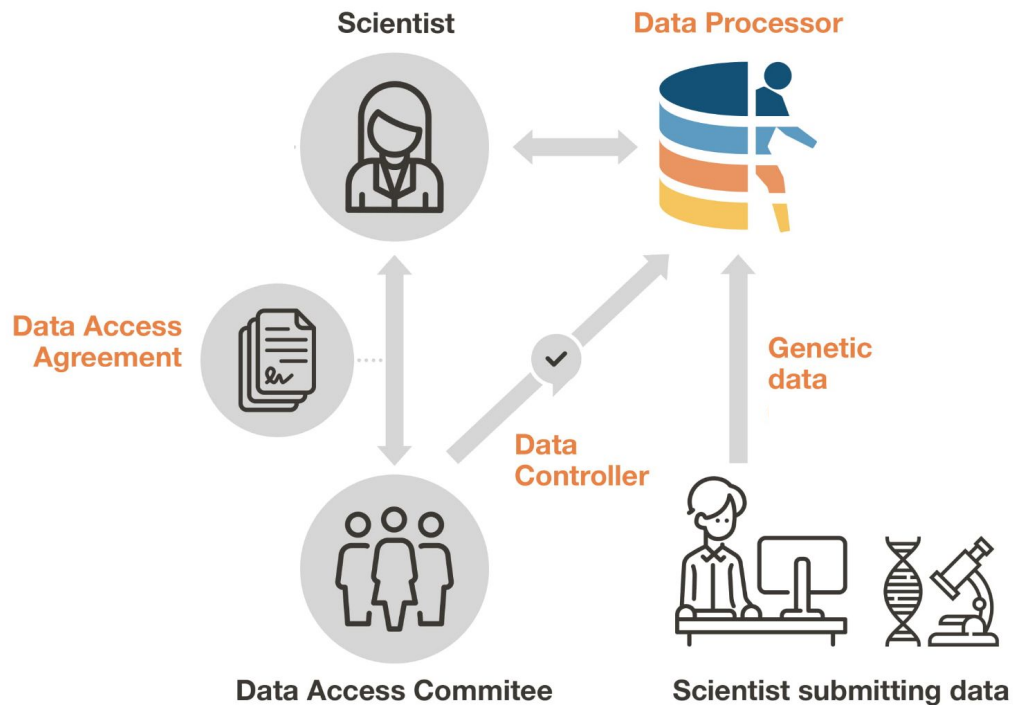


Scientist submitting data

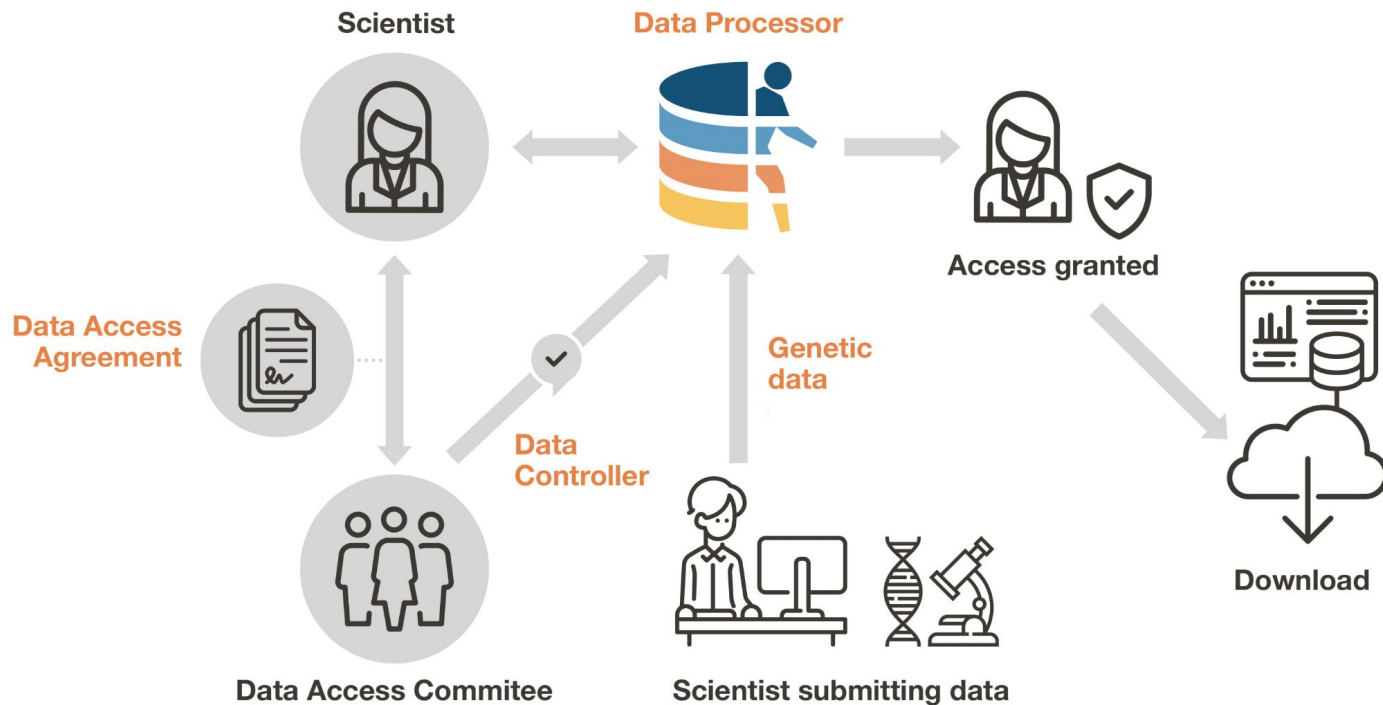
Controlled access data sharing



Controlled access data sharing

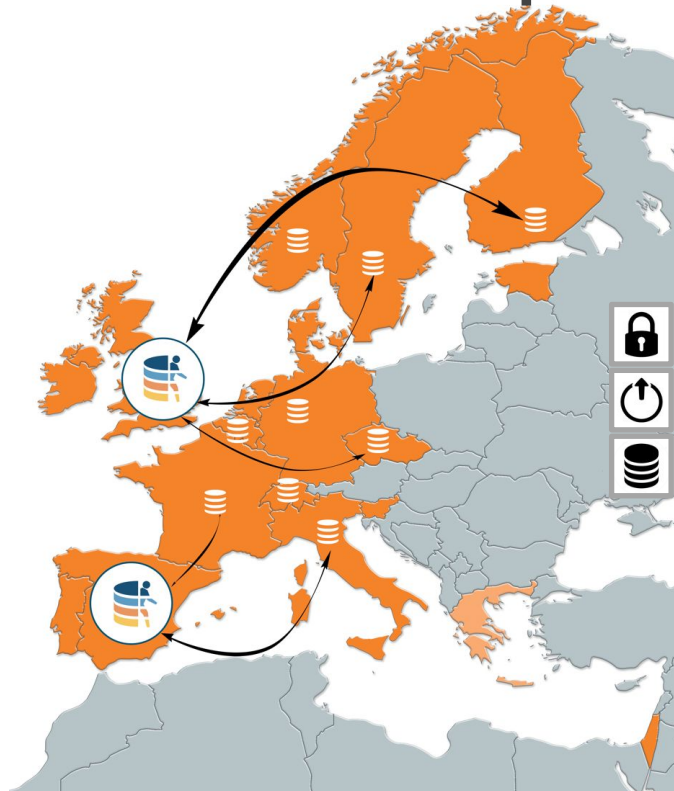


Controlled access data sharing



Federated genome/health data across Europe

- Many national datasets from human research participants needs to be stored locally
 - European Genome phenome Archive (EGA)
- ELIXIR developing a federation with shared metadata (FAIR) and local data store (secure)
 - Based on suite of interoperable, reusable, adopted, and fit-for-purpose standards
 - Norway in piloting role
- Linking Federated EGA to national clouds and international access (Life Science login)



17 ELIXIR Nodes involved are part of the Federated Human Data Community

Informed Consent



The consent form is **part of the research ethics application**

It should include the **general principles** you will apply on

- Scientific Aims/Purpose

- Data collection

- Data processing/analysis

- Data archival

- Restrictions for Data Access - e.g. research subjects, geographical (adequacy!)

- Controlled Access & Data Access Committees

It should be possible to give **granular consent**

Also describe already how you will deal with **withdrawal of consent** or if this is not possible (e.g. due to anonymization)

Standard consent clauses



Global Alliance
for Genomics & Health
Collaborate. Innovate. Accelerate.



**Regulatory & Ethics
Toolkit**

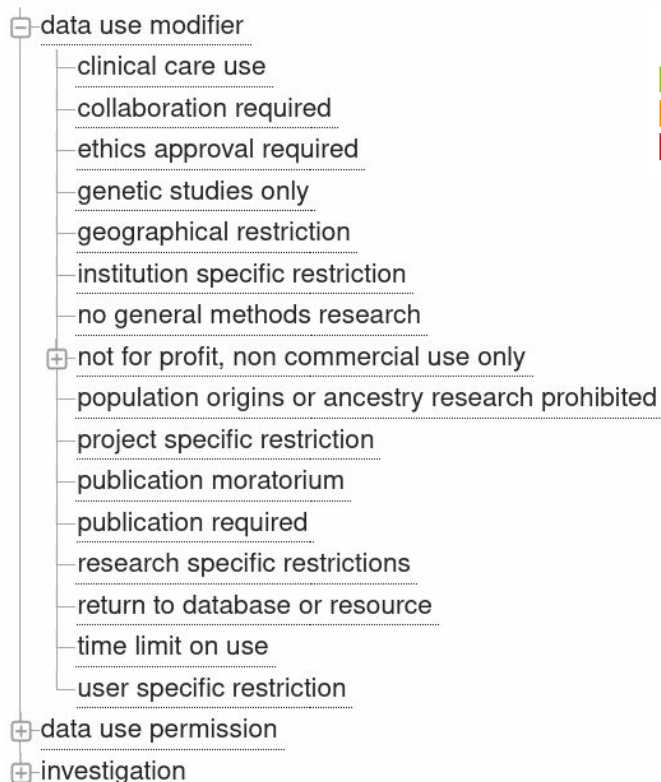


BBMRI-ERIC[®]

ELSI TOOLKIT



Modelling consents - Data Use Ontology (DUO)



Global Alliance
for Genomics & Health
Collaborate. Innovate. Accelerate.

DUO:0000021 ethics approval required

DUO:0000022 geographical restriction

Stakeholder involvement

Patient organisations can provide feedback on your RDM (and research)

Safeguarding data subject perspectives in Data Access committee

Transparency on collection, processing, storage,... increases trust

You might have to set off funding & time for this!

Research Ethics Approval - for Health Research

Should outline:

- Consent
- Data collection
- Data processing/analysis
- Data archival
- Length of Data storage
- Data sharing
- Sharing restrictions
- Data Access Committee



Important Relevant Legislations

Privacy Act

Research Ethics Act

Health Research Act

Health Registry Act

Biotechnology Act

Archive Act



Health Register Act: <https://lovdata.no/dokument/NL/lov/2018-06-15-38>

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>

Archives Act: <https://lovdata.no/dokument/NL/lov/1992-12-04-126>

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Impact on communities & individuals

Impact on communities & individuals

Fair management of intellectual property rights

Publication of research data that might impact the reputation

Publication of research data that might impact security of society -> data classification module

World news

In Africa the Hoodia cactus keeps men alive. Now its secret is 'stolen' to make us thin

Pharmaceutical firms stand accused of once again plundering native lore to make fortunes from natural remedies, writes Antony Barnett

Antony Barnett

Sun 17 Jun 2001 11.41 BST

For thousands of years, African tribesmen have eaten the Hoodia cactus to stave off hunger and thirst on long hunting trips.

The Kung bushmen who live around the Kalahari desert in southern Africa used to cut off a stem of the cactus about the size of a cucumber and munch on it over a couple of days. According to tradition, they ate together so they brought back what they caught and did not eat while hunting.



CARE Principles for Indigenous Data Governance

Collective Benefit.

Data ecosystems shall be designed and function in ways that enable Indigenous Peoples to derive benefit from the data.

- C1. For inclusive development and innovation
- C2. For improved governance and citizen engagement
- C3. For equitable outcome

Responsibility.

Those working with Indigenous data have a responsibility to share how those data are used to support Indigenous Peoples' self determination and collective benefit.

- R1. For positive relationships
- R2. For expanding capability and capacity
- R3. For Indigenous languages and worldviews

Authority to Control.

Indigenous Peoples' rights and interests in Indigenous data must be recognized and their authority to control such data respected.

- A1. Recognizing rights and interests
- A2. Data for governance
- A3. Governance of data

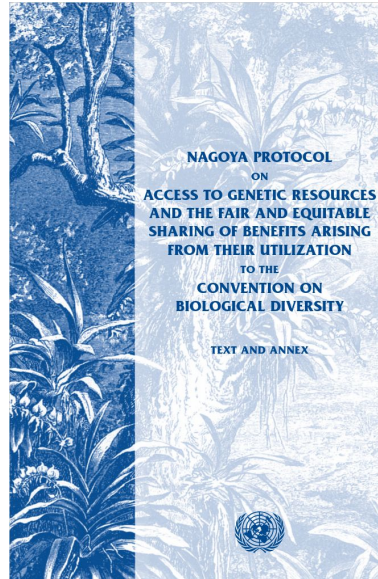
Ethics.

Indigenous Peoples' rights and wellbeing should be the primary concern at all stages of the data life cycle and across the data ecosystem.

- E1. For minimizing harm and maximizing benefit
- E2. For justice
- E3. For future use



1992



2010



[Marine Resources Act](#)
[Regulation on traditional knowledge associated with genetic material](#)
[Nature Diversity Act Chapter VII Access to genetic material](#)
[Traditional knowledge associated with genetic resources](#)

2013



Access obligations

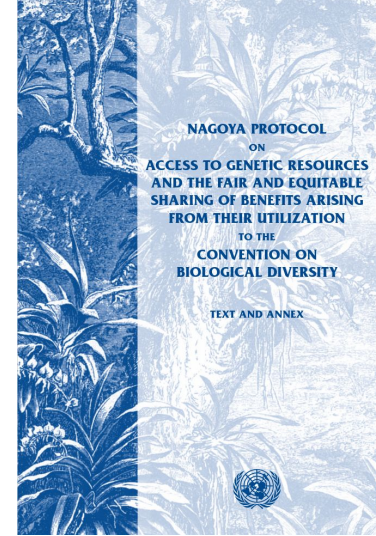
[conditions, legal clarity, consent]

Benefit-sharing obligations

Domestic-level benefit-sharing measures are to provide for the fair and equitable sharing of benefits arising from the utilization of genetic resources with the contracting party providing genetic resources. Utilization includes research and development on the genetic or biochemical composition of genetic resources, as well as subsequent applications and commercialization. Sharing is subject to mutually agreed terms. Benefits may be monetary or non-monetary such as royalties and the sharing of research results.

Compliance obligations

[monitoring, enforcement, justice]





Norway

Party to the Nagoya Protocol

1

ABS National Focal Point

1

Competent National Authority

8

Legislative, Administrative or Policy Measure

0

ABS Procedure

0

National Model Contractual Clause

0

Internationally Recognized Certificates of Compliance

0

National Websites or Databases

1

Checkpoint

0

Checkpoint Communiqué

1

Interim National Reports on the Implementation of the Nagoya Protocol



UN
environment
programme

CBD



Convention on Biological Diversity

Distr.
LIMITED

CBD/COP/15/L.30
18 December 2022

ORIGINAL: ENGLISH

Acknowledging the FAIR³ and CARE⁴ principles, the framework for data governance provided by the Organisation for Economic Co-operation and Development “Recommendation on Enhancing Access to and Sharing of Data”, and the recommendations set out in the United Nations Educational, Scientific and Cultural Organization “Recommendation on Open Science”,



General research ethics considerations reflecting on RDM



General research ethics considerations reflecting on

RDM

What are the reasons justifying the exclusion/inclusion of research data in a particular context?

Is the data source accurate and trustworthy?

How can bias in practices of research data management be identified and minimised/avoided?

Assessment of models and algorithms used with respect to possible bias

Can the research data be misinterpreted?

Prevention of withholding of research data

Prevention of manipulation and fraud of research data

Assessment of who is excluded or included to data access and why

How can harm to other beings and the environment be identified and mitigated in a timely manner?



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



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

Bodies on research ethics



**National
Research Ethics
Committees**



Thank you!



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