Schedule - Day 2: Tuesday, 5 April 2022

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
11:15-13:00	Hands-on training and assistance to generate a Data Management Plan (DMP)

Legal Requirements for RDM of human data

Nazeefa Fatima
Data Steward | Computational Biologist
ELIXIR Norway (University of Oslo)

Disclaimer

This is not a legal advice

Important Relevant Legislation

- 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 Legislation

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.

Research Ethics Act: https://lovdata.no/dokument/NL/lov/2017-04-28-23

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

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)

REK
REGIONAL COMMITTEES FOR MEDICAL AND HEALTH RESEARCH ETHICS

Health Research Act: https://lovdata.no/dokument/LTI/lov/2008-06-20-44

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: Up to 20 million Euros, ... up to 4 % of their total global turnover of the preceding fiscal year

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

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.

Further reading: https://ec.europa.eu/info/law/law-topic/data-protection/reform/what-personal-data_en

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.

Further reading: https://ec.europa.eu/info/law/law-topic/data-protection/reform/what-personal-data_en

What personal data is considered special?

- ➔ 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

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

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

Further reading: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN#d1e1489-1-1

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

Further reading: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN#d1e1807-1-1

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://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
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  - ☐ Integrity and Confidentiality
  - ☐ 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 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://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

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://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://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

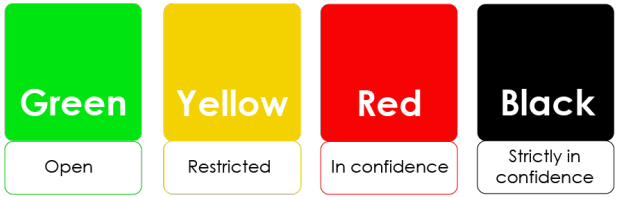
Further readings:

- 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://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

System for Risk and compliance. Processing of personal data in research and student projects at UiB: https://rette.app.uib.no

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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://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN#d1e3546-1-1

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

Further reading: Chapter 5, The EU's General Data Protection Regulation (GDPR) in a Research Context - Mondschein, C. F. & Monda, C. Springer 2019 https://www.ncbi.nlm.nih.gov/books/NBK543521/

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
- 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
- gov.uk/government/news/eu-adopts-adequacy-decisions-allowing-data-to-continue-flowing-freely-to-the-uk

International Data Transfers

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Additional safeguards - e.g. Pseudonymization

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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
- 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
- gov.uk/government/news/eu-adopts-adequacy-decisions-allowing-data-to-continue-flowing-freely-to-the-uk

Responsible Authorities

Data Privacy Assessments

Since 2020:

~~NSD~~ SIKT carries out privacy assessments on behalf of Norwegian university DPOs.
Processing personal data in project → Apply to SIKT

Sikt

earlier:

NSD NORSK SENTER FOR FORSKNINGSDATA

Data Privacy Assessments

Since 2020:

~~NSD~~ SIKT carries out privacy assessments on behalf of Norwegian university DPOs.
Processing personal data in project → Apply to SIKT

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

Sikt

earlier:

NSD NORSK SENTER FOR FORSKNINGSDATA

REK
REGIONAL COMMITTEES FOR MEDICAL AND HEALTH RESEARCH ETHICS

Approval/Reporting

Type of project	Approving authority	Advisory authority
Research on personal data which are not health-related?	DPO	Datatilsynet/Privacy Protection ombud
Human biological material?	REK + DPO (+SIKT)	REK
Health data?	REK + DPO (+SIKT)	Datatilsynet + REK
Involving test persons?	REK + DPO (+SIKT)	REK
Radiation on humans?	REK + DPO(+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 +DPO (+SIKT)	The Norwegian Directorate of Health

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Health data?	REK + DPO (+SIKT)	Datatilsynet + REK
Involving test persons?	REK + DPO (+SIKT)	REK
Radiation on humans?	REK + DPO(+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?	DPO	Datatilsynet/Privacy Protection ombud
Human biological material?	REK + DPO (+SIKT)	REK
Health data?	REK + DPO (+SIKT)	Datatilsynet + REK
Involving test persons?	REK + DPO (+SIKT)	REK
Radiation on humans?	REK + DPO(+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 +DPO (+SIKT)	The Norwegian Directorate of Health

Contact Information

Data Protection Officers

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rek-sorost@medisin.uio.no

Datatilsynet - datatilsynet.no

SIKT - sikt.no

Datatilsynet

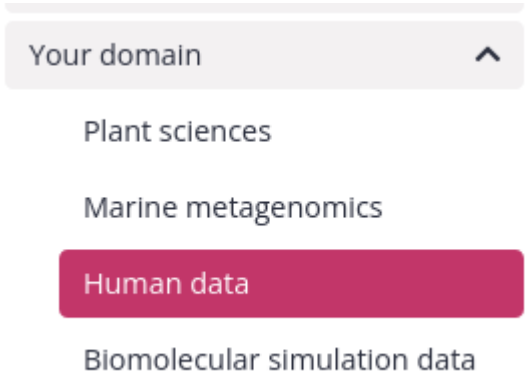
REK
REGIONAL COMMITTEES FOR MEDICAL AND HEALTH RESEARCH ETHICS

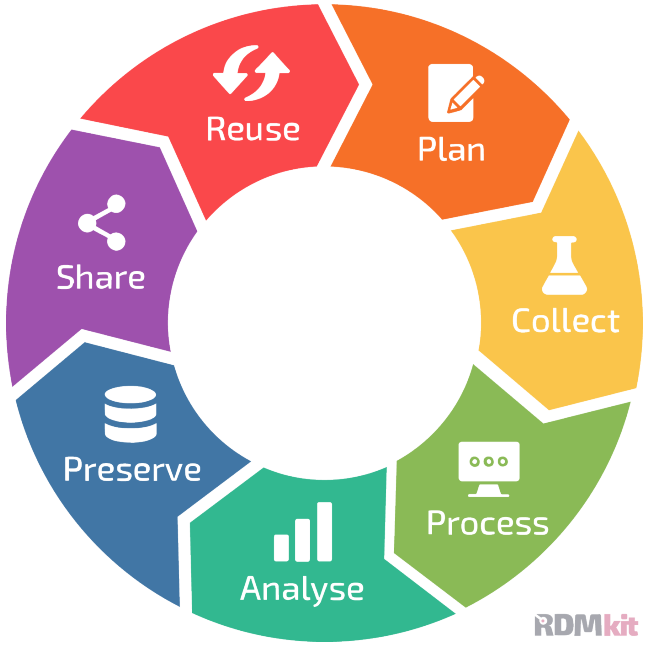
rekportalen.no/#home/REK

Sikt

sikt.no

RDMkit





Data Management Life Cycle

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

https://rdmkit.elixir-europe.org/human_data.html