1. Changes from previous version

This is the first version of the document.

2. Purpose and scope

The guideline describes the use of data management plans for research and is part of ensuring good research practices and data management.

Oslo University Hospital (hereafter OUS) is responsible for ensuring that all research where the the enterprise is involved is conducted in a responsible and trustworthy manner and that it is planned, carried out and concluded in accordance with legal requirements and recognized research ethical norms. OUS wants to manage research data responsibly, in accordance with FAIR principles, cf. Guidelines for the use of FAIR principles for health data sources - e-health (ref. ALLEA 2.5), and according to international standards, such as CARE principles, and through this support the development of a global research community where research data is shared widely.

Research data management includes data documentation, organization, licensing, sharing, archiving and covers much more than data security and privacy considerations. Research data management increases opportunities for data reuse, reproducibility and can contribute to greater visibility of research.

The guideline aims to ensure that **research data** are:

- accurate, complete, authentic, and reliable
- findable, accessible, interoperable, and reusable
- safely stored and/or archived, either centrally at one's own institution or in national/international/domain-specific archives
- managed in accordance with legal and research ethical obligations
- shareable with others in accordance with relevant ethical principles for sharing research data.

The guideline supplements the Research Instruction – responsibilities and authorities in research. It should be made known to all those involved in research, provide a basis for training and be followed in the planning, implementation and completion of research.

Other policy documents:
Universitetet i Oslo - Forskningsdatahåndtering: Politikk og retningslinjer
Forskningsrådet - Policy for åpen forskning
European Research Council - Open Science Policy

3. Responsibilities

Chief Executive Officer: Has overall responsibility for research activities in OUS.
Director of Research, Innovation and Education: Is responsible for the guideline.
Managers in the various units are responsible for ensuring that this guideline is disseminated and adhered to within their area of responsibility.
Clinic Research Leader (staff function for clinic director): Is responsible for staying continuously updated. The research leader will be a central point of contact in the dialogue/information flow between the hospital's research leadership and the clinics.
All employees employed by, or under the authority of, OUS with respect to research projects under the hospital's responsibility: are responsible for familiarizing themselves with and adhering to the guideline.

4. Procedure

Most major funders (Research Council and EU) require a data management plan (DMP) for projects they finance.

A DMP documents how you will collect, organize, document, store, quality control, protect, share, and archive your data during and after the research period. The plan describes how data will be managed, documented and stored from collection to project completion. The plan should be updated as necessary, to reflect the project. The DMP is also a communication tool for the research team and ensures that research data is managed in a responsible manner throughout the project and beyond.

More specifically, a DMP:

- Describes how data will be managed during the research project and after it is completed
- Clarifies expectations and responsibilities between different team members.
- Enables potential challenges to be identified and resolved early in the process (e.g. storing and transferring data across borders, documentation, reproducibility, etc.)
- Enables additional costs or resource needs (e.g. storage space) to be identified
- Enables data to be managed and made available according to FAIR principles.
- Can save time – by identifying challenges, documentation requirements and time-dependent factors early on
- Strengthens the safety and quality of research
- Increases the visibility and impact of research by making data reusable
- Encourages improvement and validation of research methods
- Makes it easier to make data FAIR
- Makes it easier to update new participants in a project on current data management practices.

Before starting a DMP, researchers should check if the relevant funder recommends a specific template. If they do, it should be followed. For example, the EU's Horizon Europe program has its own recommended template for its projects.

- If there are no specific requirements for the plan, researchers can choose the DMP they want to use, see below. Text-based templates are generally more flexible and can be adapted to the project. Web-based tools can provide the ability to choose between different templates, guide how to fill out the plan, be machine-readable, and most tools allow for sharing with others.

4.1 Templates and tools for DMP

Text-based templates for data management plan

- UiOs template - Norwegian - English – a simple Word-based template with links to UiOs resource pages
- EU's Horizon Europe template - Horizon Europe template – recommended for use in connection with Horizon Europe projects
- Science Europe DMP template – a generic template, consisting of six core questions, often used as a starting point for other templates.

DMP tools

- Sikt (formerly NSD) - tailored for the Norwegian context, suitable for data involving people and society.
- EasyDMP - a tool with various templates, some tailored to the Sigma2 infrastructure.
- Data Stewardship Wizard - a tool developed with machine-readability and FAIR principles in mind. Recommended for those using the ELIXIR infrastructure.
- DMPonline is a tool that supports various templates.

The content of a DHP will vary depending on the template used and, of course, the field of study. Generally, you will be asked to provide information on the following:

- Brief description of the research project
- Role description and distribution of responsibilities in the research group regarding data management
- Description of datasets to be used and/or generated in the project, such as:
    - What level of security do the data belong to?
    - How will data be collected, or will data from other projects be reused?
    - What file formats and sizes are to be collected? ◦ How will the data be organized (i.e., folder structure and file names)?
    - Where will the data be stored?
    - What type of documentation and metadata standards will be created?
    - How will data quality be maintained?
- Storage solutions, data security, and preservation strategies • How, when, and where data will be shared, published, and made FAIR-compliant
- Costs and resources associated with data management
- Strategies for meeting ethical and legal requirements (e.g., privacy, copyright law, and licenses)
- Sikt (tidligere NSD) – tilpasset norsk kontekst, passer for data som omfatter mennesker og samfunn.
- EasyDMP – verktøy med ulike maler, noe tilpasset Sigma2 -infrastruktur
- Data Stewardship Wizard – verktøy utviklet med tanke på maskinlesbarhet og FAIR-prinsippene. Anbefalt å bruke for de som benytter seg av ELIXIR - infrastruktur
- DMPonline er et verktøy som støtter ulike maler.

5. Definitions

FAIR stands for Findable, Accessible, Interoperable, and Reusable. It is often the case that not all principles can be fulfilled, and this may vary depending on the field of study and type of data.

Findable: (Meta)data is assigned a unique and persistent identifier. Data is described with rich metadata. The identifier for the data is included in the metadata. (Meta)data is registered and indexed in a searchable resource.

Accessible: (Meta)data is findable through the identifier via standardized protocols. The protocols are open, free, and universally implementable, and authentication is allowed when necessary. Metadata should be accessible even when the data is no longer available.

Interoperable: (Meta)data uses formal, accessible, shared, and widely used language for knowledge representation. (Meta)data uses vocabularies that adhere to the FAIR principles. (Meta)data includes qualified references to other (meta)data. (Meta)data is stored in open file formats suitable for long-term preservation and archiving.

Reusable: (Meta)data is richly described with a diverse, precise, and relevant set of attributes. (Meta)data is shared with a clear license for reuse. (Meta)data is linked to detailed documentation/provenance. (Meta)data follows relevant domain-specific standards.

The complete list of principles can be found on the Go-Fair website, where they are also detailed and exemplified.

What are research data? Research data are representations of observations, objects, or other material used as evidence or foundational material in research.

- Observational data: Recordings or descriptions of phenomena. These can be collected manually or through machine methods. They include time and location and in some cases, longitudinal studies. The need for preservation is typically high because such data are difficult to recreate.
- Computational data: Data from models, simulations, and other computations. Whether input and/or output data, as well as the algorithm, should be preserved, depends on how complex and costly it is to rerun the calculations.
- Experimental data: Results from controlled experiments. The archival needs depend on how complex and costly it is to replicate the experiment. If the conditions for the experiment cannot be recreated, there may be a need to preserve the data.
- Source data: Documents, recordings, registries, and other sources become research data when used as foundational material in research. Often, these will be well-preserved elsewhere, and it is sufficient to document

their location. In cases where sources do not have a stable storage location or are difficult to access, it may be sensible to store a copy.

6. References

Laws governing health research

- Lov av 20. juni 2008 nr. 44 om medisinsk og helsefaglig forskning (helseforskningsloven)
- Forskrift om organisering av medisinsk og helsefaglig forskning (helseforskningsforskriften)
- Lov 2017-02-10 nr 23: Lov om behandling av etikk og redelighet i forskning (forskningsetikkloven)
- Lov av 5. desember 2003 nr. 100 om humanmedisinsk bruk av bioteknologi m.m. (bioteknologiloven)
- Lov 2014-06-20 nr 43: Lov om helseregistre og behandling av helseopplysninger (helseregisterloven)
- Lov 2018-06-15-38: Lov om behandling av personopplysninger (personopplysningsloven) med tilhørende forskrift
- Lov 1999-07-02 nr 64: Lov om helsepersonell m.v. (helsepersonelloven)
- Lov 1999-07-02 nr 63: Lov om pasientrettigheter (pasientrettighetsloven)
- Lov 1992-12-04 nr 132: Lov om legemidler m.v. (legemiddelloven)
- Forskrift av 24. september 2003 nr. 1202 om klinisk utprøving av legemidler til mennesker

Other documents from the eHandbooks

- Forskningsinstruksen - ansvars- og myndighetsforhold i forskning
- Forskningsprosedyre - helseforskningsprosjekter REK
- Melding til Personvernombudet
- Mulige brudd på anerkjente forskningsetiske normer - behandling av saker
- Vitenskapelig publisering
- Datadeling ved publisering.
- Samarbeid med industri i forsknings-, innovasjons- og utviklingsprosjekter
- Retningslinje - Forskningsgrupper
- Forskningsstrategi 2021-2025
- eHåndbok - Forskningsetikk og forskningsintegritet i medisinske og helsefaglige forskningsprosjekter (ous-hf.no)