Guideline

Data management plan in Research

Joint documents - level 1 - OUS/Research, Innovation and Education

1. Changes since the previous version

This is the first version of the document.

2. Purpose and scope

The guideline describes the use of a data management plan for research and is part of ensuring good research practice and a good data management.

Oslo University Hospital HF (henceforth OUS) is responsible for ensuring that all research in which the company participates is carried out on a responsible and trust-building manner and that it is planned, implemented and concluded in line with statutory requirements and recognized research ethics norms. OUS wants to manage research data responsibly, in line with The FAIR-principles, Guide for use of the FAIR principles for health data sources - ehelse (ref. ALLEA 2.5), and according to international standards, which The CARE principles, and trough this supports the development of a global research community where research data is widely shared.

Research data management includes e.g. data documentation, organization, licensing, sharing, archiving and includes far more than data security and privacy considerations. Research data management increases the possibilities for reuse data, verifiability and can contribute to making the research more visible.

The guideline should contribute to **research data being**:

- accurate, complete, genuine and reliable
- retrievable, accessible, interoperable and reusable
- properly stored and/or archived, either centrally at the own institution or in national/international/domain-specific archives
- managed in accordance with legal and research ethics obligations

- shareable with others in line with relevant ethical principles for sharing research data

The guideline is a supplement to The research instructions - responsibility and authority in research. It must be made known for everyone involved in research, form the basis for training and are followed in planning, implementation and completion of research.

Other policy documents

University of Oslo - Research data management: Policy and guidelines

Research Council - Policy for open research

Eropean Research Council - Open Science Policy

3. Liability

***Managing Director*:** Has the overall responsibility for the research activities in OUS.

Director research, innovation and education: Responsible for the guideline.

Managers within the various units are responsible for ensuring that this guideline is made known and adhered to within their own area of responsibility.

The clinic's research manager (staff function for clinic manager): is responsible for keeping up-to-date continuously. Research leader will be a central point of contact in the dialogue/information flow between the health institution's research management and the clinics.

All employees who are employed by, or under the instructional authority of, OUS when it comes to research projects under.

The hospital's responsibility is responsible for familiarizing itself with and complying with the guideline.

4. Procedure

Most of the major financiers (The Research Council and EU) requires a data management plan (DHP, eng. data management plan, DMP) for projects they finance.

A DHP documents how to collect, organize, document, store, quality assurance, protect, share and archive your data during and after the research period. The plan describes how data is handled, documented and stored collection until the end of the project. The plan should be updated along the way, so that it always reflects the project. DHP is also a communication tool for the research group and must ensure that research data is managed in a responsible manner throughout the project period (and afterwards).

More specifically, one can say that a DHP:

- Describes how data will be handled during the research project and after it has ended
- Clarifies expectations and areas of responsibility for the various members of a research group.
- Makes it possible to discover and clarify potential challenges early in the process (e.g. storage and transfer of data across countries, documentation, verifiability, etc.)
- Makes it possible to detect additional costs or the need for additional resources (f. Ex. storage space needs, etc.)
- Makes it possible to handle and make data available in line with The FAIR-princeples
- Can be time-saving - by early identifying challenges, requirements for documentation and time-dependent factors
- Strengthens safety and quality of research
- Increases research visibility and impact by making the data reusable
- Encourages improvement and validation of research methods.
- Makes it easier to do data FAIR
- Makes it easier to update new participants in a project on current data handling practices.

Before initiating a DHP, the researcher should investigate whether the current funder recommends a specific template. If they do, it should be followed. For example, the EU's Horizon Europe program has a separate template they recommend for their projects.

- If there are no specific requirements for the plan, you can choose which DHP you want to use, see below. Text-based templates are often more flexible and can be adapted to the project. Web-based tools can provide the opportunity to choose between different templates, guide how the plan should be filled in, be machine-readable, most tools also allow this sharing with others.

4.1 Templates and tools for DHP

Text-based data management plan templates

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

DHP tool

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

The content of a DHP will vary according to which template is used and of course according to the subject area. One will stay asked to inform about the following:

- Brief description of the research project
- Role description and distribution of responsibilities in the research group when it comes to data handling
- Description of data sets to be used and/or generated in the project, for example:

-What type of security level does the data belong to?

-How will the data be collected, or will data from other projects be reused?

-What file formats and sizes should be collected?

-How should the data be organized (ie folder structure and file names)

-Where will the data be stored?

-What type of documentation and metadata standards will be created?

-How should data quality be maintained?

-Storage solutions, data security and strategies for preserving the data

-How, when and where the data will be shared, published, and prepared so that they coincide with the FAIR principles

-Costs and resources related to data management

-Strategies to meet ethical and legal requirements (e.g. privacy, intellectual property law and licences)

5. Definitions

FAIR stands for Findable, Accessible, Interoperable and Re-usable, which in Norwegian is often translated to be retrievable, accessible, interoperable and reusable. It will often be the case that not all principles can be met, this will could vary with subject area and type of data.

Findability

(Meta)data is equipped with a unique and persistent identifier

The data is described with rich metadata

The identifier of the data is included in the metadata

(Meta)data is registered and indexed in a searchable resource

Accessible

(Meta) data is retrievable via the identifier via standardized protocols

The protocols are open, free and universally implementable, the protocol allows authentication when necessary

Metadata should be available even when the data is no longer available

Interoperable

(Meta)data use formal, accessible, shared and widely used languages for knowledge representation

(Meta)data uses vocabulary that follows the FAIR principles

(Meta)data includes qualified references to other (meta)data

(Meta)data is stored in open file formats that are suitable for long-term storage and archiving

Re-usable

(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 with detailed documentation/provenance

(Meta)data follow relevant subject-specific standards

The complete list of principles can be read at Go-Fairs webside, where they are also detailed and exemplified.

What is research data?

Research data are representations of observations, objects or other materials used as coating or foundation material in research.

- Observational data: Recordings or descriptions of phenomena. These can be collected manually or by using machines. Includes time and place, in some cases are longitudinal studies. The need for conservation is typically great because such data are difficult to reproduce.
- Calculation data: Data from models, simulations and other calculations. Whether it is input data and/or output data as well algorithm that should be preserved will depend on how complicated and costly it is to run the calculations again.
- Experimental data: Results from controlled trials. The need for archiving depends on how complicated and costly it is to repeat the experiment. If the conditions for the experiment cannot be reproduced, it can be necessary to preserve the data.
- Source data: Documents, recordings, registers and other sources become research data when they are used as basic material in research. Often these will be sufficiently well preserved elsewhere, and it is enough to document where they are located themselves. In cases where sources do not have a stable storage location or are difficult to access, it will make sense to store a copy.

6. References

Laws governing health research

- Act of 20 June 2008 No. 44 on medical and healthcare research (Health Research Act)
- Regulations on the organization of medical and healthcare research (the health research regulations)
- Act 2017-02-10 no 23: Act on the treatment of ethics and honesty in research (research ethics act)
- Act of 5 December 2003 no. 100 on human medical use of biotechnology, etc. (Biotechnology Act)
- Act 2014-06-20 no 43: Act on health registers and processing of health information (health registers act)
- Act 2018-06-15-38: Act on the processing of personal data (the Personal Data Act) **with associated regulations**
- Act 1999-07-02 no 64: Act on health personnel etc. (Health Personnel Act)
- Act 1999-07-02 no. 63: Patient Rights Act (Patient Rights Act)
- Act 1992-12-04 no 132: Act on medicinal products etc. (Pharmaceuticals Act)
- Regulation of 24 September 2003 no. 1202 on clinical trials of medicinal products for humans

Other eHandbook documents

- Research instructions - responsibility and authority in research
- Research procedure - health research projects REK
- Message to the Privacy Commissioner
- Possible violations of recognized research ethics norms - processing of cases
- Scientific publication
- Data sharing when publishing.
- Collaboration with industry in research, innovation and development projects
- Guidelines - Research groups
- Research strategy 2021-2025
- eHandbook - Research ethics and research integrity in medical and healthcare research projects (ous-hf.no)