

GUIDELINES FOR THE NATIONAL INSTITUTE OF PUBLIC HEALTH AT SDU

Implementation of the Open Science Policy

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Purpose of this document

This document addresses topics and questions to be considered in the process of implementing the University of Southern Denmark Open Science Policy at the National Institute of Pulic Health. It is based on experiences from the work in the University of Southern Denmark Research Data Management Forum and similar policies, procedures and guidelines from other universities.

Open Science Policy document and GDPR

All recommendations in the Open Science Policy should be handled within the framework of the GDPR and the Danish supplementary legislation, including the issue of identifiability of individuals in anonymous data.

University of Southern Denmark Open Science Policy

Open science includes transparent methods and public access to results, including publications, data, codebooks related to the data sets, and syntaxes in statistics programs (e.g. SPSS and SAS syntaxes, STATA do-files, R code) for data management as well as statistical analyses.

Purposes

- Help researchers to increase their scientific impact by making publications open and data publicly available.
- Help researchers to find and use existing infrastructures, resources and tools in the most efficient way and leading them to the right support for data management.
- Ensure that all research data are managed in line with requirements from funding agencies and journals, and compliant with the Danish Code of Conduct for Research Integrity, current legislation and ethical protocols.
- To ensure that primary materials and research data are available to support research findings and to contribute to other research projects, where possible.
- To enable Open Science by making data Findable, Accessible, Interoperable (accessible and usable across disciplines and methods) and Reusable (FAIR, see: https://www.force11.org/group/fairgroup/fairgrinciples and https://www.na-ture.com/articles/sdata201618).
- To promote visibility of research from the University of Southern Denmark.

General principles

Research data should be:

- Acknowledged as valuable output of research that should be made openly available and reusable, where possible.
- Covered by a data management plan when commencing a new research project.
- Stored securely and appropriately.

- Findable, Accessible, Interoperable and Reusable (FAIR).
- Retained for a minimum of five years after publication of the research, as stated in the Danish Code of Conduct for Research Integrity.
- Archived in Danish National Archives (Rigsarkivet), if accepted, instead of deleted or anonymised at the end of the project, according to current legislation. If not accepted, data must still be deleted or anonymized.
- Managed in line with ethical protocols, including confidentiality.
- Managed in compliance with legal requirements for privacy and data protection.

Scope

These guidelines apply to all employed scientific staff.

Communication and implementation of the procedures

These guidelines are communicated to all scientific employees as part of their introduction to data safety policies at the institute.

In addition, implementation of the guidelines can be discussed at research group and/or institute meetings.

What is research data?

Research data refer to material, data, records, files, and other evidence underpinning the research projects' findings, or other outcomes, including (the list is not exhaustive):

- Experimental and observational data.
- Results of clinical investigations and RCT's
- Responses to questionnaires, tests, surveys and interviews.
- Biological material and records of such material.
- Audio and video recordings.
- Transcriptions of interviews and other audio recordings.
- Data, regardless of form of storage (paper, electronically) or storage media.

Research data is described by example categories. Staff and students are encouraged to propose a single, logical definition of research data for use with the Open Science Policy, based on their knowledge of their fields of research.

Please note that by and large, all data handled at the National Institute of Public Health is sensitive and not anonymised, thus data will never be freely available in the raw form but as metadata.

Data exempt from the Open Science Policy

- Administrative data.
- Studies included in systematic reviews and meta-analyses. The exemption does not apply to documentation of searches, selection of studies for review and analyses in tables, figures and similar supplementary material routinely published online with reviews.

FAIR research data handling

All research data such as data sets, codes, empirical analyses, experimental and observational data, transcriptions of interviews and other audio/video recordings, responses to questionnaires/surveys, collections of images etc. must be prepared in as FAIR a way as possible, where FAIR is defined as findable, accessible, interoperable and reusable according to the FAIR principles¹.

The National Institute of Public Health is committed to practicing and promoting data handling in a FAIR manner and therefore supports the Sorbonne Declaration on Research Data Rights²

Research assessment

The National Institute of Public Health supports the general recommendation of the San Francisco Declaration on Research Assessment (DORA)³, thus will not use journal-based metrics, such as Journal Impact Factors, as a surrogate measure of the quality of research articles, to assess a researcher's contribution, or in hiring/promotion. For the purposes of research assessment, NIPH considers the value and impact of all research outputs (including datasets and software) in addition to research publications, and considers qualitative indicators of research impact, such as communication outreach, influence on policy and practice.

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¹ FAIR guiding principles for research data. See https://www.force11.org/group/fairgroup/fairprinciples and https://www.nature.com/articles/sdata2

² https://www.leru.org/files/Sorbonne-declaration.pdf

³ https://sfdora.org/read/.

Data Management Planning

When commencing a new research project

- Projects covered by the Open Science Policy <u>must have</u> a data management plan⁴.
- The data management plan must be written at the beginning of the project.
- The data management plan must be updated when necessary.
- The data management plan is stored along with other documentation of the project.

Responsibilities and scope

- The person responsible for the project is responsible for writing and updating the data management plan. Support can be obtained by the datamanager at the institute.
- PhD and master's thesis supervisors are responsible for supervising the student's writing and updating the data management plan.
- Literature searches for studies, public databases, available data and funding, and similar exploratory data searches and collections, in preparation for a research project or proposal, do not require a data management plan. At this stage, protection of confidentiality, untested ideas, possibility of access to data and funding, hypothesised results and possible patents is important for innovation, creativity and output of the research process.

What should be covered in the data management plan?

- For data management plans required from funding agencies, the respective funding agency's template should be used. See: https://dmponline.deic.dk/.
- For other data management plans use the NIPH template available at https://sdunet.dk/da/enheder/institutter/sif/forskning+og+data/forskningspro-jekter+datahaandtering+fra+a+til+z/opstart+og+planlaegning+af+projekt/data-managementplan
- Description of the data to be collected in the project is required, using guidelines from the Danish National Archives (Rigsarkivet). See (in Danish): https://www.sa.dk/da/for-skning-rigsarkivet/anmeldogafleverforskningsdata/
- Estimation of the value of the data for long-term preservation or reuse, using the researcher's or student's best judgement and knowledge of the data and subject area. This general requirement is of specific relevance for the decision of the Danish National Archives as to whether the data can be archived under the proposed ministerial order of mandatory data reporting. See (in Danish): https://hoeringsportalen.dk/Hearing/Details/60866.

Guidelines and support for writing data management plans are available at: https://www.deic.dk/da/DMPOnline

⁴ Courses are offered by SUND PhD-school

How to preserve the data after the project has ended (particularly relevant for PhDs)

- Document the data, using guidelines from the Danish National Archives (Rigsarkivet).
- According to the permission from the University of Southern Denmark, personal and sensitive data should either be archived in the Danish National Archives (Rigsarkivet) or permanently deleted or anonymised before the permission expires.
- Data is required to be offered to the Danish National Archives (Rigsarkivet) with the least restrictive conditions for access possible⁵.
- Guidelines of the Danish National Archives (Rigsarkivet) for documenting, reporting and archiving research data are available in Danish: https://www.sa.dk/da/forskning-rigsarkivet/anmeldogafleverforskningsdata/

Documentation

Minimum requirements

- Data underlying a publication should be stored in a folder with documentation that allows graphs to be reproduced and model results to be recalculated⁶.
- Make sure there are backups of your work in a safe place where storage complies with the General Data Protection Regulation (GDPR) and Danish legislation.

Minimum requirements for documentation of published data

- Documented according to guidelines from the Danish National Archives (Rigsarkivet).
 See: https://www.sa.dk/da/forskning-rigsarkivet/anmeldogafleverforskningsdata/
- Documentation is to be included in published data sets.

The staff at the institute is encouraged to develop additional recommendations for documentation of published data, based on experience with implementation of the Open Science Policy.

Best practices

- Use of predefined file structures.
- Use of file versioning systems.
- Sample labelling and tracking.
- Discipline-specific metadata standards.

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⁵ Due to the type of data the National Institute of Public Health archives in the Danish National Archives and in order to ensure the quality of research projects who are reusing archived data, the least restrictive conditions are seldomly used by the National Institute of Public Health.

⁶ Applies only to anonymous data

- File naming, dating and versioning according to best available methods and practices. The university library can advise on this, contact Research Data Management Support at rdm-support@bib.sdu.dk. See also: http://library.stanford.edu/re-search/data-management-services/data-best-practices/best-practices-file-naming
- Use of lab notebooks, preferably electronic, for experimental data.

The staff at the institute is encouraged to develop additional recommendations for best practices, based on experience with implementation of the open science policy.

Long-term preservation/archiving

All data should be stored for a minimum of five years after publication of the research (required permissions/ registrations should be extended). Beyond this minimum requirement, several types of research data should be preserved for long term access and reuse, including (the list is not exhaustive):

- If it would be unethical to subject humans or animals to unnecessary repetition of experiments, trials, observations or other research activities.
- If it would be unethical or indefensible to waste research funds and human resources that could be put to better use (i.e. prevention and cure of disease) on unnecessary repetition of experiments, clinical trials and observational research.
- Data and materials that is impossible or hard to reproduce.
- Data and materials that is costly to produce, in terms of funding, time or human resources.
- Data and materials that can be reused in new projects, serve as benchmarks, as reference or are of public interest.
- Data and materials underlying publications.

Archiving as an alternative to deletion

Valuable data and materials should be preserved by archiving in the Danish National Archives (Rigsarkivet). Preserving your data and materials in this archive fulfils legal requirements of deletion when a data processing permission expires.

Documentation of archived data is required, using guidelines from the Danish National Archives (Rigsarkivet) (in Danish). See: https://www.sa.dk/da/forskning-rigsarkivet/anmeldogafleverforskningsdata/

When someone leaves the institute

Rules for maintaining access to data when someone leaves the institute:

- When a project is discontinued, and the person responsible for the data leaves the institute or PhD project, the data is required to be offered to the Danish National Archives (Rigsarkivet) for archiving.
- If the Danish National Archives (Rigsarkivet) declines to archive the data, the person responsible for the data is responsible for deleting the data if the data can be linked to an individual.
- If a project is to continue at the institute when the person responsible for the data leaves the institute, responsibility for the data must be transferred to another person at the institute, after obtaining the necessary permissions (e.g. from one of the Danish Health Ethics Committees or the SDU Institutional Review Board (SDU-IRB)).
- When a person leaves the institute, as a routine part of the termination procedure, the person must confirm that the data the person is responsible for is taken care of in one of the following ways, if a project using this data is either discontinued or to be continued at the institute:
 - **If the project is discontinued:** Archived in the Danish National Archives (Rigsarkivet) or deleted.
 - If the project is to be continued at the institute: Transferred to a person at the institute, who will be responsible for the data once it has been transferred, after the necessary permissions have been obtained.

Publication of research data

Research data should be **F**indable, **A**ccessible, **I**nteroperable and **R**eusable (FAIR). The University of Southern Denmark encourages that research data are made freely accessible, respecting ethical regulations, legal and contractual obligations, data protection legislation, and intellectual property rights.

Data underpinning publications should be made openly accessible in appropriate data repositories, respecting any legal, ethical or commercial limitations⁷.

If data cannot be made openly available, at least the metadata along with the e-mail of the principal investigator should be published. Access to anonymised original data can be given upon request.

Examples of why research data should be made publicly available

- Required by funders or publishers (e.g. Horizon 2020).
- An obligation towards collaborators.

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⁷ Data from third parties, data repositories and administrative registers with conditions limiting reuse, publication and disseminstion as well as publicly available data do NOT have to be published. However, a data management plan is still recommended for such data. Publicly available data which have been combined with other data, and which have cost time and money, should also be published even though the source data is publicly available

- To expose the research of the institute as well as the individual researcher and to increase the impact.
- To enable new research and collaborations.
- For public interest.
- For secondary data analysis in other projects.
- For use in teaching and student projects.
- To heighten credibility and accountability of research at the institute.
- To improve transparency and reproducibility.
- To prevent or detect research fraud, biased and selective analyses and publication.
- To make replication of statistical and psychometric analyses possible.

Examples of where to publish research data

- Danish National Archives (Rigsarkivet): https://www.sa.dk/da/forskning-rigsarkivet/anmeldogafleverforskningsdata/
- Data Journals (e.g. https://openhealthdata.metajnl.com/)
- A data repository (see e.g., https://www.re3data.org/)
- The university library offers guidance and links to a directory of academic open access repositories: https://www.sdu.dk/en/bibliotek/forskere/rdm+support

Recommendations on how to publish research data

- All datasets should receive a permanent identifier, e.g. DOI (in Danish): https://www.deic.dk/da/news/2017-12-20/DataCite.⁸
- All datasets should receive a license for reuse, e.g. Creative Commons: https://creativecommons.ing/licenses/?lang=da, (in Danish) https://creativecommons.org/projects/publishing and (in Danish) https://www.emu.dk/modul/creative-commons#.
- All data should include all necessary documentation and metadata.
- Use open and long-lived file formats such as .csv alongside R, SPSS, STATA, SAS or other files for statistical or data management software.

⁸ It is therefore important to choose a repository which gives your datasets a DOI or equivalent. Contact <u>RDM-sup-port@bib.sdu,dk</u> for assistance.

⁹ Data repositories should also be able to offer a variety of licenses to place on your data. Contact <u>RDM-sup-port@bib.sdu,dk</u> for assistance.

Data storage options for active projects

See the institute's General Data Protection Regulation (GDPR) guidelines. Research Data Management support (rdm-support@bib.sdu.dk) and system administrator Erik B. Madsen (erikm@sdu.dk) can advise on options. 10

Open Access to publications

Information about open access publishing: https://www.sdu.dk/en/forskning/forskningspublicering.

Open access to publications

SDU PURE must be used to record all research publications. To support the national goal of having open and free access to all publications, researchers are encouraged to obtain open access (OA) from their publication outlet of choice.

Registering with ORCID

NIPH strongly recommends that all researchers register with ORCID¹¹ via PURE¹² and create a public ORCID profile.

Type of Open Access recommended

Research data at the National Institute of Public Health include data obtained/collected through research-based consultancy services for the public sector. Reports made by the National Institute of Public Health on the basis of such data are always accessible by the public as it is published on the webpage of the institute. As for scientific articles following is recommended:

- All members of staff are encouraged to publish all their articles as Green Open Access if permitted by the journal. The green way to Open Access includes articles published in traditional subscription journals that are not Open Access but allow a version of the article ("final author version approved"), after publication, to be placed in an Open Access institutional repository, which at SDU is PURE. This is also referred to as 'self-archiving', which is done by the author him- or herself as soon as allowed by the publisher after publication.¹³
- Provided that funding is procured externally, publishing in Full or Gold Open Access
 publications is recommended, as readers have access to these publications immediately
 and without restrictions (i.e., no subscriptions, no fees, etc.). This type of publication is
 typically funded via 'article processing charges' paid by the author.
- Provided that funding is procured externally, there is a variant of Gold Open Access
 called Hybrid Open Access, where the authors publish in traditional subscription journals
 but offer Gold Open Access to articles by paying the 'article processing charges'. This
 option is not recommended by the institute.

¹² How to register via PURE see https://www.sdu.dk/da/forskning/forskningspublicering/orcid

¹⁰ See https://syddanskuni.sharepoint.com/Sites/persondata/Pages/welcomepage.aspx

¹¹ See https://orcid.org/

¹³ Contact puresupport@bib.sdu.dk for further support

Funding of Open Access publications

The institute does not have possibilities to provide funding for publishing Open Access.

- Researchers from SDU publish open access free of charge in a number of Elsevier journals. Instead, open access costs are covered by an agreement between Danish research institutions and Elsevier. The agreement is in effect from January 1st 2021 up to and including 2024. See
 https://www.sdu.dk/en/forskning/forskningspublicering/open+access/publiceringsaftaler/elsevier
- See also this website for a list of other publishers which have Open Access agreements with SDU: https://www.sdu.dk/en/forskning/forskningspublicering/open+access/publiceringsaft aler"
- Open Access publications can be funded via external grants, provided that this was applied for in the budget and is supported by the funding agency.

Where can we publish with open access?

• See: Directory of Open Access Journals (www.doaj.org).

GUIDELINES FOR THE NATIONAL INSTITUTE OF PUBLIC HEALTH AT SDU is an adjusted version of the guidelines for the Departments of IRS and KI by Rikke Leth-Larsen and Kirsten Kyvik June 2018. Their guidelines are adjusted versions from the original version of Department of Psychology (Robin Kok, Malcolm Bang, Susanne S. Pedersen (sspedersen@health.sdu.dk)) in collaboration with Asger Væring Larsen and Evgenios Vlachos and approved by the SDU Research and Innovation (RI) council – Created 2018.

This policy will be subject to bi-annual revisions. First revision September 2020. Second revision to take place in the fall of 2022 at the latest.