

GUIDELINES FOR THE CLINICAL DEPARTMENTS AT SDU

KI AND IRS

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 Department of Clinical Research and the Department of Regional Health Research. 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.

GDPR defines anonymised data as “data rendered anonymous in such a way that the data subject is not or no longer identifiable.” This emphasizes that anonymised data must be stripped of any identifiable information, so it is impossible to derive information on individuals, even by the person or organisation that is responsible for the anonymisation.

University of Southern Denmark Open Science Policy and Research Assessment

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 syntaxes, STATA do-files, R code) for data management as well as statistical analyses.

- 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 **F**indable, **A**ccessible, **I**nteroperable (accessible and usable across disciplines and methods) and **R**eusable (FAIR, see: <https://www.force11.org/group/fairgroup/fairprinciples> and <https://www.nature.com/articles/sdata201618>). The Departments of KI and IRS are committed to practicing and promoting data handling in a FAIR manner and therefore supports the [Sorbonne Declaration on Research Data Rights](#).
- 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.
- Archived in Danish National Archives ([Rigsarkivet](#)) if accepted (instead of deleted 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 scientific employees, PhD and MSc students.

Research Assessment

The Departments of KI and IRS support the general recommendation of the San Francisco Declaration on Research Assessment ([DORA](#)), and 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.

Communication and implementation of the procedures

These guidelines are communicated by the heads of the research groups (forskningslederne) to all employees as part of their introduction to the department, to PhD students by their supervisor, and to MSc students by their supervisor, prior to signing the contract on thesis supervision.

In addition, implementation of the guidelines can be discussed at departmental meetings and be included in courses in responsible conduct of research in the MSc and PhD programs.

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.

Data exempt from the Open Science Policy

- Administrative data.
- Data from third parties, data repositories and administrative registers with conditions limiting reuse, publication and dissemination.
- Publicly available 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.

Data Management Planning

When commencing a new research project

- Projects covered by the Open Science Policy **must have** a data management plan¹.
- 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.
- 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/>.

¹ Courses are offered by SUND PhD-school

- For other data management plans, a general University of Southern Denmark template should be used when it becomes available. See: <https://www.sdu.dk/da/bibliotek/forskere/rdm+support>.
- 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/forskning/for-forskere/anmeldelse-aflevering-forskningsdata/>.
- 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>

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 Danish Data Protection Agency, 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 possible.
- Guidelines of the Danish National Archives (Rigsarkivet) for documenting, reporting and archiving research data are available in Danish: <https://www.sa.dk/da/forskning/for-forskere/anmeldelse-aflevering-forskningsdata/>.

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 recalculated.
- 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/for-forskere/anmeldelse-aflevering-forskningsdata/>.
- Documentation is to be included in published data sets.

Department staff 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.
- 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/research/data-management-services/data-best-practices/best-practices-file-naming>
- Use of lab notebooks, preferably electronic, for experimental data.

Department staff 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/for-forskere/anmeldelse-aflevering-forskningsdata/>.

When someone leaves the department

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

- When a project is discontinued, and the person responsible for the data leaves the department 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 department when the person responsible for the data leaves the department, responsibility for the data must be transferred to another person at the department, 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 department, 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 department:
 - **If the project is discontinued:** Archived in the Danish National Archives (Rigsarkivet) or deleted/anonymized.
 - **If the project is to be continued at the department:** Transferred to a person at the department, 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 limitations.

If data cannot be made openly available, at least the metadata 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.
- To expose the department's research and 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 department.
- 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/Danish Data Archive (Rigsarkivet/Dansk Data Arkiv): <https://www.sa.dk/da/brug-arkivet/dda/>
- Data Journals (e.g. <https://openpsychologydata.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/datamanagement>

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.>²
- All datasets should receive a license for reuse, e.g. Creative Commons: <https://creativecommons.org/licenses/?lang=da>, (in Danish) <https://creativecommons.dk/>, <http://sciencecommons.org/projects/publishing> and (in Danish) <https://www.emu.dk/modul/creative-commons#>.³
- 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.

Data storage options for active projects

See the department'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.⁴

Open Access to publications and registering with ORCID

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. The Departments of KI and IRS strongly recommend that all researchers register with [ORCID](#) via [PURE](#) and create a public ORCID profile.

Information about open access publishing:

<https://www.sdu.dk/en/forskning/forskningspublicering>.

Type of Open Access 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

² It is therefore important to choose a repository which gives your datasets a DOI or equivalent. Contact [RDM-support@bib.sdu.dk](mailto:rdm-support@bib.sdu.dk) for assistance.

³ Data repositories should also be able to offer a variety of licenses to place on your data. Contact [RDM-support@bib.sdu.dk](mailto:rdm-support@bib.sdu.dk) for assistance.

⁴ See <https://syddanskuni.sharepoint.com/Sites/persondata/Pages/welcomepage.aspx>

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.⁵

- **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 departments.

Funding of Open Access publications

- It is **not possible** for the departments of IRS and KI to provide funding for publishing Open Access.
- It has previously been possible to apply for reimbursement of specific Open Access publications from the SDU library (only BFI journals (the Danish bibliometric research indicator, affecting government funding of universities). Please note that this fund is closed for time being and may be terminated.
- A national agreement has been made with Elsevier (one of the largest publishers). In the agreement it is possible for Danish authors (Danish corresponding author) to obtain free Open Access publication in Elsevier’s hybrid journals. The agreement also applies for University Hospitals. See: <https://www.sdu.dk/da/forskning/forskningspublicering/open+access/publiceringsaftaler> and <https://www.sdu.dk/da/forskning/forskningspublicering/open+access/publiceringsaftaler/elsevier>
- 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).

@Created April 2018 by the 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 – to be revised in May 2020. Adjusted to the Departments of IRS and KI by Rikke Leth-Larsen and Kirsten Kyvik June 2018.

This policy will be subject to bi-annual revisions. This is the latest revision March 2021.

⁵ Contact puresupport@bib.sdu.dk for further support