UNIVERSITY OF COPENHAGEN
FACULTY OF HEALTH AND MEDICAL SCIENCES

Policy for Research Data Management

Approved by the Faculty Leadership Team on 19 April 2016

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Preface

This policy was written in response to the Danish Code of Conduct for Research Integrity[1], published in 2014. In the Code, the Danish Government prompts research institutions to develop data management policies in order to increase data openness and maximize transparency as well as accountability of the research results derived from those data.

The objective of the policy below is explaining what is expected of researchers (including students, affiliates and data managers) working at the Faculty of Health and Medical Sciences at the University of Copenhagen, in terms of managing both primary material and research data. The policy adheres to the University of Copenhagen's policy for data management, published in 2014[2].

This policy is based on knowledge available in February 2016. As the field of research data management is moving fast with numerous activities at central UCPH and national levels, the task force recommends regular revisions as needed.

What is research data management and why is it important?

Research data management is a collective term for the planning, collecting, processing, sharing, storing and archiving of research data.

Good research data management has become increasingly important as

- Governments in Denmark and abroad are demanding transparency in research,
- More scientific journals and research funders are asking for open access to data,
- The need to reuse data increases,
- Fear of data loss leads to demands for more robust data security practices,
- More research funders ask for data management plans to be included in funding proposals.

Data management plans (DMPs) are documents that provide an overview of intended data management actions that will be taken from project initiation to project conclusion. DMPs represent useful tools for good research data management as they help train researchers to think about data handling as well as rules and regulations relevant to their data, before initiating data collections.

Contact

For any questions regarding this policy, please contact researchdata@sund.ku.dk

[1] http://ufm.dk/en/publications/2014/files-2014-1/the-danish-code-of-conduct-for-research-integrity.pdf
[2] https://intranet.ku.dk/research/rcr/data-storage-and-sharing/Documents/University%20of%20Copenhagen's%20policy%20on%20research%20data.pdf

Policy for research data management

The policy is structured to follow the research data lifecycle described in Figure 1. Definitions are explained in the appendix.

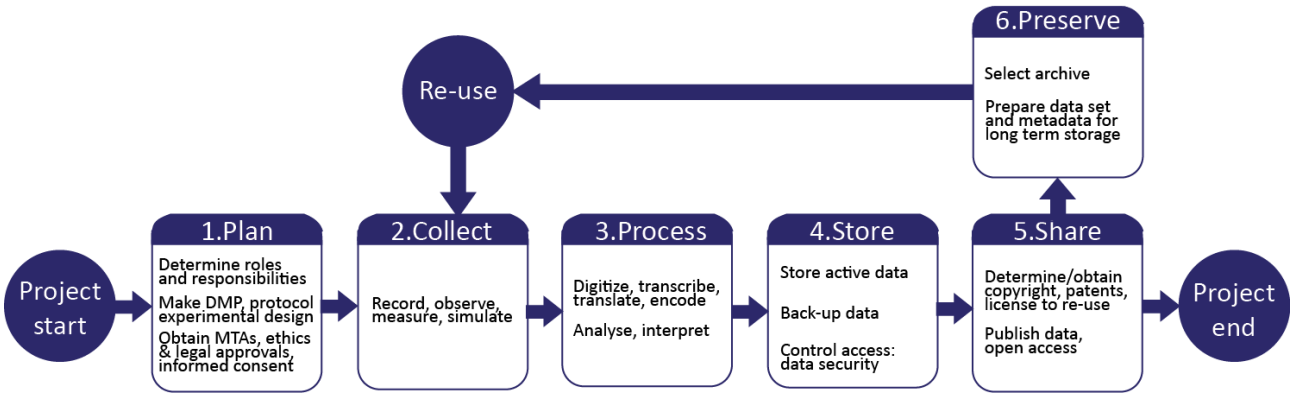

Figure 1. *The research data lifecycle. DMP: Data Management Plan, MTA: Material Transfer Agreements*

1. Planning the research project

(1.1) **Researchers** should design a data management plan (DMP) for the data they will create or collect in their research projects, describing most of the features of the research data lifecycle (Figure 1) and this policy. Information should include as a minimum:

- The origin and type of data to be collected
- Where data will be stored, both during and after the project, and for how long
- Who is responsible for the data collected, both during and after the project
- How and to whom access to data is given, both during and after the project

Researchers should keep DMPs updated throughout the research project or replace a DMP on initiating a new project with the same dataset thus making the old DMP obsolete. Researchers should keep a copy of the DMP with the data as long as the data exist.

(1.2) Before the start of the research project, **researchers** should clarify entitlements to primary materials and/or research data, cf. sections II.2 and II.5 of the Danish Code of Conduct for Research Integrity. These entitlements may depend on employment with the University and can thus differ for BSc/MSc students and affiliates. Adjustments to entitlements should be disclosed in an agreement.

Among other things, participating **researchers** have to clarify:

a. To what extent they have access to the primary materials and/or research data collected. For example, researchers working with personal data should clarify to what extent rules of data confidentiality impose limits on data access, and how these limits will be upheld.

b. To what extent they are entitled to obtain a copy of the project's primary materials and/or research data.
c. To what extent they may use primary materials and/or research data, including in other projects and other purposes. In this context, it should also be determined which rules apply if a researcher leaves the project and/or the institution at which the researcher is currently employed.
d. The terms governing the above, including whether there are special loyalty or confidentiality obligations.
e. All disciplinary measures should these terms be violated.
f. Intellectual property rights, including whether the research project makes use of material that interferes with the rights of others as well as who must secure the clearing of these rights.
g. All data management and sharing requirements (e.g. for Open Access) of funding bodies and partner organisations.

Researchers employed at the University of Copenhagen should be aware that primary materials in the shape of physical objects collected during their employment at the University of Copenhagen belong to the university and may not be removed without permission.

The University's Tech Transfer Office[3] may be contacted for guidance on all questions concerning intellectual property rights. All third party contracts containing regulations on intellectual property rights must be negotiated by the Tech Transfer Office, such as Non-Disclosure Agreements, Material Transfer Agreements and Collaboration Agreements, etc. Patentable inventions must be reported to the Tech Transfer Office in accordance with the Act on Inventions made at public Research institutions[4].

(1.3) **Researchers** must adhere to Danish and University legislation and regulations, and they must obtain the appropriate (e.g. ethical) approvals to be kept with the data as long as the data exist.

Strict legal requirements exist for projects involving personal data, and **researchers** must acquaint themselves with these requirements before the data collection starts. Researchers must register projects involving personal data with the Danish Data Protection Agency (Datatilsynet). This should take place via a central registration at the Faculty. For guidance, researchers should contact **datatilsyn@sund.ku.dk**.

2. Collecting data

(2.1) **Researchers** must record their research. This includes:

- Writing a clear and detailed description of the project methodology, recruitment plan, etc.

[3] http://fi.ku.dk/english/tech_trans/
[4] https://www.retsinformation.dk/Forms/R0710.aspx?id=6138

- To the extent possible, choosing data formats, hardware, and software solutions that are widely accepted within the discipline and deemed durable.
- Describing any software programs, scripts etc. used to generate the data set.
- Planning the validation and assessment of data quality.

In experimental research, this ensures that experiments can be repeated, and not only by the same person but also by others, potentially several years after the project has ended.

(2.2) **Researchers** must describe all data sets and primary materials with appropriate metadata to facilitate searching for, and identification of, the data or primary materials. Metadata should be linked to the data set or primary materials as long as they exist, unless Danish and/or University legislation and regulations determine otherwise.

3. Processing data

(3.1) **Researchers** should produce reports on the data collections as soon as possible after data collection has ended, and in sufficient detail, as this will enable others to reconstruct how the final results were obtained. Reports must clearly describe how the raw data or primary materials were processed to produce the final data set, including information on calculations and coding principles, and, if applicable, justifications for excluding data from the final data set according to the standards and best practice in the respective research discipline. These reports should be stored along with the data and the DMP must clarify where they are located.

(3.2) When applicable, **researchers** must be able to justify the choice of statistical tests used to analyse their data, and their choice should be based on standards and best practice within their research discipline.

4. Storing data

(4.1) **Researchers** must follow the University's policy and handbook on information security[5]. This includes, among other things:

a. Data storage

For data security reasons, **researchers** should store their active data on the University of Copenhagen's network drives, or on systems approved by the University of Copenhagen.

b. Back-up

If not stored on the network drives, **researchers** must ensure that their data are backed up on a regular basis. Data stored on network drives is backed up automatically.

[5] http://informationssikkerhed.ku.dk/is-haandbogen/

c. Data sharing in research project collaborations

If multiple people are involved in generating the data and/or have approval to access the data set, **researchers** must request folder sharing at SUND-IT or use a University approved repository. Should researchers consider it necessary to e-mail research data to others, this can only be done via the University's official e-mailing system.

d. Data security

Researchers must ensure that unauthorised persons (people other than those specified in the DMP) are denied access to their data.

For support in terms of security, sharing and storing research data, researchers should contact **SUND-IT**[6] and/or visit the **University's Information Security website**[7].

5. Sharing data

(5.1) **Researchers** are encouraged to facilitate open access to data that underpin their publications as soon as possible after publication. This should be done in agreement with demands by funding bodies or publishers as well as Danish and/or University legislation and regulations.

(5.2) When making primary material available for re-use, **researchers** must communicate the terms and conditions for re-use through a Material Transfer Agreement where and whenever appropriate.

(5.3) When sharing research data sets, **researchers** should communicate the terms and conditions for re-use in accordance with the original agreements on entitlements.

6. Preserving data and primary material

(6.1) When a research project ends, **researchers** should prepare all data sets (published and unpublished) for long-term storage. This includes:

a. Deciding on which data should be archived.

As a minimum, **researchers** should archive all data of high value (costly or difficult to replace) and those included in/forming the basis of publications, unless legislation states that it must be destroyed on project completion. Sufficient data should be stored to allow for a defence against possible challenges.

[6] https://intranet.ku.dk/sund/sund-it
[7] http://informationssikkerhed.ku.dk/english

b. Ensuring that archived data are legible and searchable.

To the extent possible, **researchers** should store raw data accompanied with metadata that describe the data set and render it searchable. Researchers must adhere to the archiving (metadata) requirements of the repository used for archiving.

c. Ensuring that data are still accessible when employment or enrolment at the University terminates.

Researchers should ensure that the project's principle investigator, and/or their supervisor, and/or their research group leader, if employed at the University, has access to the data set and relevant metadata upon project completion, unless Danish and/or University legislation and regulations determine otherwise.

(6.2) In accordance with the University's policy for data management, and the Danish Code of Conduct for Research Integrity, **researchers** must ensure that data selected for archiving (6.1.a) remain stored for a minimum of five years after project completion.

(6.3) **Researchers** working with personal data should be aware that their research data must be archived at the National Archives (Rigsarkivet)[8], unless legislation states that it must be destroyed on project completion.

(6.4) **Researchers** should store primary materials of high value (costly or difficult to replace) as long as the quality of the material or finances/funding allow for, unless legislation states that it must be destroyed on project completion.

(6.5) **Supervisors and/or group leaders** are advised to develop local guidelines for procedures relating to long-term storage of, and access to, research data and primary materials collected or generated by their research group at the Faculty of Health and Medical Sciences.

[8] https://www.sa.dk/aflevering-arkivet/private-og-forskere/aflevering-af-forskningsdata

Appendix 1: Definitions

Affiliate	A researcher not paid by the University, but engaged by the University or a research group to perform duties or functions.
Active data	Data produced and/or used in ongoing research projects.
Data Management Plan (DMP)	A plan describing the actions to be taken during various phases of the research data life cycle. Many funding bodies now require DMPs as part of research proposals.
Entitlements	Rights of access, disposal and use relating to primary material and/or research data as defined by law or contracts.
Intellectual Property Rights	Legal rights granted with the intention of safeguarding creations of the intellect. Among other things, this includes copyright, patent rights, design rights, and trademark rights.
Metadata	Information describing the attributes of an item or data set, which enables identification, retrieval and management of that item or data set in the future, e.g. sample name, units of measure, dates, contact information, etc. Metadata can take many forms, from free text to structured machine-readable content. Some disciplines or data repositories may have specific requirements for the format and content of metadata, possibly using a formal standard.
Personal data	Data relating to individuals, who can be identified directly or indirectly using those data. Examples are references to CPR numbers or economic, social, cultural, physical, physiological or mental characteristics.
Primary materials	All materials that form the basis of the research. By way of example, these could be physical objects (e.g. geological samples, non-human biological samples, and human tissue samples contained in materials purchased with funding from the university administration) or immaterial goods (e.g. interviews, texts, literature and recordings).
Principal Investigator (PI)	A researcher designated to head the research project. S/he will have primary responsibility for the design, execution and management of the research project and s/he will supervise the efforts of other researchers in that project.
Researcher	For the purpose of this policy, a researcher is defined as any individual engaged in research at the University of Copenhagen. This includes students, data managers and affiliates, unless specifically stated otherwise.
Research data	Detailed records of primary materials that comprise the basis of the analysis that generates the research results. For the purpose of this policy, research data (or simply 'data') comprise data sets either created in digital form (born digital) or converted from physical to digital form (digitised). Examples of such research data include (electronic) laboratory notebooks, documents (word, excel) and clinical records.

Research project	A project in which a researcher or a team of researchers pursue answers to research questions by collecting information after which they analyse the information and draw conclusions from the processed information. A research project might comprise subprojects that may be gathered in one DMP, if the materials to be included in a DMP are identical in all subprojects.
Research results	Conclusions made from primary materials and research data at the end of a research project.
Students	For the purpose of this policy, a student is defined as a BSc or MSc student.
Supervisor	An experienced researcher providing guidance for a less experienced researcher or student.
Third party	An individual, company, or other university etc. collaborating on a research project at the University of Copenhagen without being employed by the University of Copenhagen.

Appendix 2: Background and acknowledgements

SUND Task Force for Research Data Management

A task force for research data management was established at the Faculty of Health and Medical Sciences in March 2015, as a direct result of demands in the Danish Code of Conduct for Research Integrity. In the code, Danish institutions are, among others, asked to produce policies for RDM.

The task force members were:
Nicole Schmitt, Department of Biomedical Sciences (*chair*)
John Elmerdahl Olsen, Department of Veterinary Disease Biology
Harald S. Hansen, Department of Drug Design and Pharmacology
Klaus Lindgaard Høyer, Department of Public Health
Karin Moresco, Department of Cellular and Molecular Medicine
Allan Have Sørensen, SUND-IT
Susanne den Boer, Research and Innovation

The tasks set out in the task force's terms of reference were:
1. To create an overview of the relevant policies for the proper management of research planning and conduct and for the procedures regarding necessary approvals and permits existing at SUND.
2. To author a SUND policy for data management.
3. To explore the possibilities for common solutions for electronic laboratory notebooks (ELNs).

In February 2016, the taskforce delivered three documents:
1. A draft policy for research data management, which was approved by FLT on 19 April 2016.
2. A report on the possibility to introduce electronic laboratory notebooks at SUND.
3. A document outlining suggestions for the implementation of research data management infrastructure at SUND.

Acknowledgements

During their work on the policy, the task force consulted a number of persons with expertise in legal, ethical, administrative and information security aspects of research data management. We would like to thank the following persons for their valuable contributions:

- The research data management team at the University of Edinburgh, in particular Cuna Ekmekcioglu and Stuart Lewis
- Prof. Morten Rosenmeier
- Prof. Jens Schovsbo
- Poul Halkjær Nielsen
- The Committee for the Protection of Scientific and Scholarly Work (UBVA)
- The University of Copenhagen's Tech Transfer Office
- The University of Copenhagen's reference group for data management
- The team of Responsible Conduct of Research teachers
- The Danish National Archives (Rigsarkivet)