

Guidelines on handling information that is created in research activities within Stockholm County Council

Contents

Background	3
Scope	3
Research documents	3
The research principal's responsibility for archiving	4
Are research documents official documents?	4
When does a research document become an official document?	4
Confidentiality of research documents	5
Registration	5
Granting access to research documents	6
Retention and disposal of research documents	7
Which research documents should be retained and how?	7
Which types of research information may be disposed of?	8
Long-term storage of research information	9
Contract research	9
Special provisions that apply to project documents	9
Further information	10
ANNEX 1: Research documents/information to be retained, examples	11
ANNEX 2: Documents/information that may be disposed of among research documents/information, examples	14
ANNEX 3: Form for documenting the retention or disposal of the research register	18

Glossary

<i>File (project file)</i>	Documents created or received during case handling and stored together, because they refer to the same case/object.
<i>Official document</i>	A document that has been created by or received by a public agency and is stored there. This applies regardless of the technical format of the document. All kinds of information can thus constitute an official document, including hard copies, films, audio tapes or electronic information in databases.
<i>Archive</i>	Safeguard information for long-term storage and retention in accordance with an established system.
<i>Data carrier</i>	Physical or logical storage site for documents/information. Examples are CDs, servers, USB memory sticks.
<i>Research project</i>	A research activity that can be delimited in terms of time and aim and that is often linked to a certain assignment and/or certain people.
<i>Research activity</i>	Basic research and applied R&D (research and development) work, along with analysis work.
<i>Disposal (after sorting)</i>	Disposal of official documents or data in official documents. Disposal of such documents or data in conjunction with transfer to a different data carrier is also classed as disposal if the transfer entails loss of information, loss of possible compilations of information, loss of search options or loss of the opportunity to verify the authenticity of the information.
<i>Retention period</i>	The time that must elapse before the document/information can be disposed of. If these are documents in which notes are made continually, the retention period applies after the final note has been made.
<i>Medium</i>	See data carrier.
<i>Document/information group (in archive inventory)</i>	Group of documents that must be accounted for in the same process as they are a requirement for or result of some activity within it. The process is their common denominator.

Background

Within Stockholm County Council information is created in research and development activities. Sometimes questions arise regarding to what extent this information should be saved and where long-term storage should take place. The answer is rarely simple, because the information may have been created in various kinds of research activities, which often include partners from other areas besides Stockholm County Council, such as Karolinska Institutet. The aim of these guidelines is to provide general advice on how different types of research information can be handled in your own activities. The guidelines often need to be supplemented by contact with the supervisory archivist at the County Council Archive and/or contact with the respective archival institutions for units not belonging to the Stockholm County Council.

Scope

The guidelines can be used by all Stockholm County Council operative units that have official documents that have been added in research activities. Records management and archive issues are the joint responsibility of the County Council; all professional categories that come into contact with research documents/information can therefore apply the guidelines.

The guidelines are in the form of recommendations, to be used for example when drawing up a proposal for disposal of information that applies to an entire operative unit or one type of information.

If the following exist:

- regulations about retention or disposal in laws or ordinances that differ to those stated here
- specific disposal plans for the operative unit, approved by the County Council Archive

they take precedence over these guidelines.

Official documents must not be disposed of until a decision to do so has been approved by the County Council Archive.

This guideline replaces Guideline 1 Version 1 and applies as of 1 September 2013.

Research documents

Research documents/information includes all the information – irrespective of medium – that is created in conjunction with a research activity. They can be roughly divided into information that concerns:

- administration, personnel and finances regarding the research

- working documents/information, i.e. primary or processed data that the researcher, project manager or analyst draws up and uses in the actual research work.
- documents/information that concern the report on the research, project or analysis.

All this information may constitute official documents, and as long as no decision to dispose of them applies, the information must be retained.

The research principal's responsibility for archiving

When research is conducted at university clinics, both the County Council and the university may be the research principal, if the researcher carrying out the study is employed by both the university and the County Council. If the responsibility for archiving is not regulated in a written agreement the research principal who is in charge of management of the research funding is responsible.

If there are additional principals – from the public sector – in the research, it is recommended that they initially solve the issue of long-term document archiving in a written agreement. If no such written agreements exist, the archiving responsibility falls on the research principal who is in charge of managing the research funding.

Are research documents official documents?

Independent of the type of research and who finances it, research documents/information in public-sector operative units are to be seen as official documents. Research documents in universities and university colleges of higher education, which are run as public agencies and/or in which a county council is the research principal, are official documents and thereby subject to the regulations of the public access principle that applies to official documents. The official documents/information of public agencies are mainly public. A document/ information is official if it is stored at a public agency and is regarded as having been received or drawn up by an agency regardless of the medium on which the document is stored.

When does a research document become an official document?

A document becomes an official document when it is received by or created by a public agency. The research documents that are received become official when they arrive. The research documents that are created and dispatched become official when they are sent. Regarding other created research documents (the ones that have not been dispatched) they can become official at different times depending on how you view them.

Research can either be seen as an activity that is equal to the handling of a case or as a concrete action (sampling, taking measurements and so on). If the research is considered to be equal to the handling of a case (c.f. Kammarrätten in Stockholm's verdict 2014.01-28 in case nr 6378-13) the

documents become official when the result of the research has been published or the research is in some other way ended. When on the other hand the research is considered to be a concrete action the documents that are produced during the research become official when they are completed. A request can then be made to make them available, which means that it may be necessary to hand them out before the research is concluded.

Confidentiality of research documents

Documents/information may only be confidential (classified) if they meet the criteria specified in the Swedish Public Access to Information and Secrecy Act. In a research operation, if the County Council cooperates with a private individual or a private company who demands some form of confidentiality, the parties may not enter into an agreement on additional confidentiality stipulations besides those in the Secrecy Act. Examples of research documents/information that may be covered by confidentiality are:

- documents that are classified on arrival
- data received from healthcare services about an individual's health or other personal circumstances
- data about an individual's personal circumstances from a social worker, an education advisor or a psychologist
- personal data in statistics or research¹
- documents/information pertaining to contract research

Classified documents/information should be stored separately from other documents/information. It may also be appropriate to label such documents as "Hemlig" and state the applicable section of law, date and who labelled the document. This labelling acts as a warning sign in case a request is made for access to an official document. Each time such a request is made; the document(s) must be reassessed to ascertain whether they are actually to be considered classified.

Registration

Official documents must be kept in order so that they are easy to find when requested, but research projects usually live a life of their own alongside the administration's more established procedures for case handling. It is therefore particularly important to establish procedures for these projects.

A case for the research project should be opened as soon as documents/information starts to be produced. In small projects, all documents should be registered. If the project is very extensive, there is an

¹ In its brochure, "Personuppgifter i forskningen – vilka regler gäller" [Personal data in research – the rules that apply], the Swedish Data Inspection Board has compiled a list of the applicable regulations. The brochure is available in Swedish on the Data Inspection Board's website. <http://www.datainspektionen.se/Documents/faktabroschyr-pul-forskning.pdf>

option of registering important documents in the case and in addition stating in the register where other project documents are stored.

When a public agency runs an extensive research activity with a large number of documents/amount of information, the register should be adapted to the circumstances. This can be done by using a separate data field for registration of the name or other reference of the research project. Another option is to register the project as a separate organisational unit in the register, and to class staff connected with the research as administrators in this unit. After completion of the project the data about the unit and administrators can be deactivated.

A minimum level of registration is required at the responsible operative unit. Besides the legally required data, at least certain basic facts must be entered into the register: the research project's name, appointed project manager (responsible for documentation) and "milestone" documents, i.e. those that are very significant in showing the progress of the project. Those documents/the information that is/are to be stored and is/are not registered, is archived either in a project file among those registered documents or in its own document/information group in the archive.

If the research includes several operative units, the operative units that are not responsible for the documentation must also enter the research project into their registers. In such cases, the information registered must include legally required data, the name of the research project, the name of the operative unit that is responsible for the documentation and the responsible operative unit's registration number for the research project. Not all documents must be registered in these cases, only a copy of the project plan and of the final report.

Granting access to research documents

The general public is entitled to have access to official documents. This right applies to both Swedish and foreign citizens, because people who request access to official documents are entitled to remain anonymous. We therefore do not have the right to ask for the person's name or purpose. In addition, we may not demand that the request to access information is made in writing. The exception to this is if the research documents/information are/is confidential. If a person requests access to research documents/information that may be confidential, an assessment of confidentiality must always be performed, preferably by the research principal. If someone is denied access to confidential information, the rejection of the request must be written and include information on how the person who requested the data can proceed to obtain a public agency decision and how to lodge an appeal against such a decision.

The research principal is responsible for ensuring that requests to access data are handled promptly.

Retention and disposal of research documents

Retention of documents/information means that the document must be preserved in a long-term perspective for at least 1000 years. Disposal of documents/information means destroying them as per an established decision to do so. Official documents/information may not be disposed of unless their disposal is authorised in law or public agency decisions. At Stockholm County Council no individual employee (e.g. researcher, project manager or analyst) may make decisions on disposal of official documents; such decisions must always be made at public agency level and in consultation with the County Council Archive. If no disposal decision has been made, all official documents must be retained.

Which research documents should be retained and how?

Documents/information, created or received, that are to be stored contain basic data on the research's

- *aim*
- *method*
- *result*

Nor should documents/information that reflects the economic conditions of the research or the research context be disposed of.

Documents/information must be created on durable material for archiving purposes, both in terms of the actual material and the way in which the document is drawn up. For example, a printer must maintain a certain standard regarding the technical equipment as well as the quality of the printout. More information on the durability of archiving material is available on www.sp.se, the website of SP – the Technical Research Institute of Sweden.

It must be borne in mind that documents and information that are produced digitally and must be retained must be created in a format that ensures their preservation for long-term storage. Individual digital documents that have not been linked to any case handling/document handling system cannot be archived digitally at the County Council Archive (e.g. such documents that are stored in a joint folder). For information on digital archiving and long-term storage, see the County Council Archive website:

www.landstingsarkivetstockholm.se

Official documents must be kept in good order so that it is easy to find them when they are requested. Confidential documents must be registered. The documents of a research activity can be archived in a choice of the following:

- in project files
- among registered documents

- as a document/information group in the operative unit's archive

It is usually difficult to place research documents/information in just one of the above groups, because they often overlap. When such overlap occurs it is important that they are clearly recorded in the archive documentation.

Annex 1 contains examples of documents/information to be retained and recommendations on how best to keep them together.

Which types of research information may be disposed of?

Research units in Stockholm County Council may choose to dispose of their documents/information as per general retention and disposal plans drawn up by the County Council Archive or specific disposal plans that the operative unit itself has drawn up in consultation with the County Council Archive. The main aim of such (sorting and) disposal is to obtain a simple and clear information structure for the material.

The Swedish Archives Act, Arkivlagen, stipulates that the public's right to transparency, the operative unit's need for information, the need for administration of justice and the needs of future research must be taken into consideration before a decision is made to dispose of documents. In terms of research information you should also consider whether:

- the results of the work have been reported and published or made public in any other way.
- a reasonable length of time has passed to enable assessment of the documents/information in order to verify the results.
- financial reporting has taken place
- a follow-up of the research is planned

As a labour-saving measure, avoid using an excessive number of different retention periods. Disposal is most suitable in these circumstances:

- the information is outdated/no longer relevant, i.e. when the activity no longer needs it,
- on completion of the research activity, or
- 10 years after completion. If the document/information concerns a clinical trial, this retention period is extended to 15 years, which is marked by an asterisk in Annex 2.

Annex 2 contains a list of examples of document/information types that may be disposed of and recommendations on how to dispose of them. The list should only be regarded as a guide and is not exhaustive. Each archive must

be disposed of on the basis of its unique conditions in a planned and controlled way so that no information gaps are created. It is important that the disposal decision is carefully prepared.

Long-term storage of research information

The fact that a document/information exists or is stored at Stockholm County Council does not determine where it must be kept in the long term. At Stockholm County Council there are/is often documents/information from research activities that have/has several research principals/stakeholders. An operative unit is usually responsible for its own archive until the operative unit is discontinued or reorganised, after which the documents/information are transferred to an archival institution such as the County Council Archive or the National Archives. The location in which a research document must be archived is determined by the answer to both these questions: Who is the principal of the research, project or analysis? Who manages the research funds? The person who is stated as the research principal has the ultimate responsibility for archiving the information and ensuring that it is transferred to the right archival institution.

In purely practical terms, this task should be administered by the researcher who has primary responsibility for the research, project or analysis. This researcher is also responsible for contacting the document manager and, where applicable, the registrar and informing them how to keep the research activity's information in order, and if they contain confidential information that must be stored separately and where. The primary researcher must also consider the retention and/or disposal in the research database/register (see Annex 3: Form for documenting the retention and disposal of the research database/register).

Contract research

Contract research means when an external party (for example a private undertaking) is tasked by Stockholm County Council with performing a research task. Regardless of the form of the research, it is important to carefully regulate in agreements the conditions of the task. The agreement must also state who has right of ownership and use of the results. It should also be noted that no external party has the right to prevent Stockholm County Council from following applicable regulations, e.g. where the right of the public to access public official documents is concerned. If the client works in the private sector, the research principal is prohibited by law from transferring official documents to this client for archiving. The client may only receive copies of the documents/information. The extent to which the client shall have access to documents/information and on what media must be regulated by an agreement when a new research operation is initiated.

Special instructions that apply to project documents

If the research has been run as a project, the County Council Archive's instruction on handling project information must also be taken into

consideration, Föreskrift för hanteringen av allmänna handlingar i projekt inom SLL, (Instruction on handling official documents within projects at Stockholm County Council).

Further information

If you have questions not answered in these guidelines, please contact the supervisory archivist in your operative unit. Contact details are available on the website of the County Council Archive:
www.landstingsarkivetstockholm.se.

ANNEX 1: Research documents/information to be retained, examples

Examples of documents/information to be retained and recommendations on how best to keep them together.

Type of document/information	Recommendations
Applications for funding	Are registered. Preferably kept with contracts.
Application as per the Swedish Personal Data Act	Included in the project file.
Applications to and decisions from other public agencies or bodies	Included in the project file. For example from a research ethics committee or animal testing ethics committee, a radiation protection committee, the Medical Products Agency or the National Board of Health and Welfare.
Articles	Forms own document/information groups.
Theses/dissertations	Forms own document/information groups.
Decisions on granted funds/contracts	Are registered.
Form for documenting the retention and disposal of the research register	One copy in the project file and one copy along with code- and variable lists.
Sub-reports	Included in the project file.
Final financial reports	Are registered. Preferably kept with contracts.
Questionnaire forms	Forms own document/information groups. Applies to questionnaire material that is very valuable to future research. Less significant questionnaire material may be disposed of; only one copy of such questionnaire forms templates needs to be retained.
Research descriptions	Included in the project file.

Type of document/information	Recommendations
Research diaries	Forms own document/information groups.
Lists of codes and variables	Forms own document/information groups. Questionnaire forms templates and data collection forms for saved register data can also be included here.
Conference reports	Included in the project file.
Contracts	Are registered. For example regarding research funds or contract research.
Correspondence	Included in the project file. See also applications. Correspondence of principle significance to the evaluation of methods and results is retained. Other correspondence is disposed of when no longer relevant. See also Correspondence in Annex 2.
Template for questionnaires sent out.	One copy of each version needs to be retained.
Method descriptions	Included in the project file.
Non-printed research reports to clients	Are registered. Preferably kept with the respective contracts.
Plans, policies and programmes about the research	Are registered.
Project plans	Included in the project file. The first and last project plans are retained and those in between are disposed of.
Minutes of large national and/or international collaborative projects and/or of projects of major scientific significance.	Included in the project file. Minutes or notes from project meetings are disposed of on conclusion of the project. See also Minutes in Annex 2.

Type of document/information	Recommendations
Minutes/notes from steering group meetings and/or reference group meetings.	Included in the project file. Minutes or notes from project meetings are disposed of on conclusion of the project. See also Minutes in Annex 2.
List of publications, final	Included in the project file.
Register data, own	Forms own document/information groups. New register data that is difficult to recreate and that is judged valuable to further research.
Requests for pay-outs of grants	Are registered.
Final reports, financial and scientific	Are registered. Preferably kept with contracts.
Permits	Are registered.
Working papers	Included in the project file. Documents that describe working methods. Not to be confused with the types of working material that may be disposed of.

ANNEX 2: Documents/information that may be disposed of among research documents/information, examples

The list should only be regarded as a guide and is not exhaustive. The documents/information in each archive must be sorted out, retained or disposed of on the basis of its unique conditions in a planned and controlled way so that no information gaps are created.

Type of document/information	Recommendations
Abstracts	Disposed of if no longer relevant.
Rejected applications for financial assistance	Disposed of on completion of the project. Approved applications RETAINED .
Processing material	Disposed of if no longer relevant. This applies to calculations etc. However, it is recommended that processing material such as test reports, quality checks, changes to primary data, unpublished results etc. be disposed of 10 years* after completion of the project.
Data files	Disposed of if no longer relevant. Data files that are non-independent stages in on-going data processing.
Questionnaire material	Disposed of on completion of the project. Disposed of on completion of the project, provided that one printout of raw data that the project manager has attested is retained for 10 years*. Exceptions may be made for questionnaire material that is considered very valuable to future research and that MUST THEREFORE BE RETAINED .
Excerpts	Disposed of if no longer relevant along with other types of transcripts.
Photographs, printouts from measuring apparatus, etc.	Disposed of 10 years* after project completion.

Type of document/information	Recommendations
Lists of used samples in bio banks	Disposed of 10 years* after project completion. They must be sufficiently detailed to enable recreation of original data if required.
Lists of used patient records	Disposed of 10 years* after project completion. They must be sufficiently detailed to enable recreation of original data if required.
Testing, research or examination records	Disposed of 10 years* after project completion.
Code lists	Disposed of 10 years* after project completion. Lists of codes and variables etc. for register data that are simple to recreate.
Concepts	Disposed of if no longer relevant.
Congress reports	Disposed of 10 years* after project completion. Also includes congress reports from own events. If the documents refer to participation in congresses, conferences, seminars or similar events organised by others, the documents may be disposed of when no longer relevant.
Proofs	Disposed of if no longer relevant.
Correspondence, internal	Disposed of if no longer relevant. Also correspondence with e.g. journals, publishers and similar parties. HOWEVER , please note that correspondence of principle significance to evaluation of methods and results MUST BE RETAINED . See also Correspondence in Annex 1.

Type of document/information	Recommendations
Correspondence, other	<p>Disposed of on completion of the project. For example: correspondence about permits and external financing with a research ethics committee, animal testing ethics committee, a radiation protection committee, the Medical Products Agency or the National Board of Health and Welfare.</p> <p>See also Correspondence in Annex 1.</p>
Licentiate and doctoral theses/dissertations	<p>Disposed of if no longer relevant. As a rule, research institutes retain this type of document.</p>
Log books	<p>Disposed of 10 years* after project completion.</p>
Audio and visual recordings	<p>Disposed of 10 years* after project completion.</p>
Intermediate project plans	<p>Disposed of on completion of the project.</p>
Measuring and testing results	<p>Disposed of on completion of the project.</p>
Patient records, data from	<p>Disposed of on completion of the project. The authority responsible for healthcare keeps the original patient records.</p>
Minutes or notes from project meetings	<p>Disposed of on completion of the project. See also Minutes in Annex 1.</p>
Publication lists, on-going	<p>Disposed of if no longer relevant.</p>
Register data, original data	<p>Disposed of 10 years* after project completion. Applies to data that can be easily recreated or that is judged to lack value to further research.</p>
Register data, imported	<p>Disposed of on completion of the project. Data from e.g. national registers, County Council registers, etc. The registers themselves are retained by the respective principals.</p>
Compilations/Summaries	<p>Disposed of on completion of the project.</p>

Type of document/information	Recommendations
Consents	Disposed of 10 years* after project completion.
Print-ready copy	Disposed of if no longer relevant.
Data from bio banks	Disposed of on completion of the project. It is assumed that the healthcare authority owns and retains bio banks. If a department is the owner, a bio bank may not be disposed of until, at the earliest, 10 years* after testing unless it should be preserved for the future.
Printouts of raw data from questionnaire material	Disposed of 10 years* after project completion. This applies if the questionnaire material is disposed of on completion of the project. If the questionnaire material is retained for 10 years, the printouts may be disposed of earlier if no longer relevant.

*If the document/information is a medical trial, this retention period is extended to 15 years

ANNEX 3: Form for documenting the retention or disposal of the database/research register

Project heading:

Number of observations:

Number of variables:

The register is constantly expanded with new data:

Yes No

If yes, state the amount per year:

Collection method/source of original data (e.g. patient records, questionnaires, laboratory tests):

Will any category/categories of original data above be retained for the future:

Yes No

If yes, state which:

Can any category/categories of the original data above that is not being retained for the future easily be recreated through new collection of data of equally high quality:

Yes No

If yes, state which:

Can any category/categories of the original data above that is not being retained for the future be recreated with difficulty through new collection of data of equally high quality:

Yes No

If yes, state which:

Is the register currently used for research?

Yes No

Can the register be assumed to be of value to additional similar research?

Yes No

Can the register be assumed to be of value to other research that examines other issues?

Yes No

If yes, state which:

The research leader's/project manager's decision (check the appropriate option)

Retained Disposed of

Date
Signature Name (block capitals)