Region Stockholm

Arts and Culture Department
Regional Archive

Date
2022-12-14

ARK 2022–0158

Document type
Instruction

Decision made by
Culture Committee

Version number
2.0

Retention and Disposal Plan for Information from Research Activity

Applies within Region Stockholm

Document owner: Regional Archive – Supervisory and Investigative Unit

Table of contents

Document history

Rev. No.	Date	Comments	Responsibility
2.0	2022-12-14	This document replaces *Retention and Disposal Plan for Information from Research Activity 1.0*, ARK 2020-0101	Peder Fallenius Alva Magnusson

1. Scope and limitations

This is a general retention and disposal plan for information arising from research activity at Region Stockholm.

In some cases, documents from EU projects have longer retention periods than those given here. Nothing must be disposed of prior to audit and control procedures. Other rules on retention and disposal in legislation or ordinances take precedence over Regional Archive rules. The plan is not media specific, and so it should be used for both digital and analogue information.

If a particular type of document is not included in this plan, it may be included in another plan, for example the Retention and Disposal Plan for Administrative Documents or HR Documents. If a type of document is completely absent, a request for disposal must be made in consultation with the Regional Archive. A retention decision endorsed by the Regional Archive must always be in place before official documents can be disposed of.

This plan takes effect on 1 February 2023. It replaces Retention and Disposal Plan for Information from Research Activity. The plan can be used retroactively.

2. Application

The plan applies to all Region Stockholm authorities, including departments, companies and foundations (see Information Management and Archiving Guidelines, RS 2019-0549, p. 3).

As a general rule, official documents must be retained. Official documents may normally only be disposed of if a general retention and disposal plan provides for disposal or a decision on disposal by the authority has been endorsed by the Regional Archive.

Where this plan prescribes disposal, the relevant items must be disposed of without delay at the end of the given retention period. An authority with its own retention and disposal plan agreed in consultation with the Regional Archive should apply that plan in the first instance. However, plans specific to an authority may not include retention periods shorter than those for the equivalent types of document in the Regional Archive's general retention and disposal plans.

3. Scanned documents

Before an authority starts to scan and dispose of paper documentation, the person with archival responsibility must make the decision to apply the provisions on scanning in this retention and disposal plan. The decision must include a start date for the new handling procedure, which systems are involved and the types of documentation that may be exempt. The decision must be sent to the Regional Archive for information.

When the authority changes over to digital storage of the scanned official documents included in this retention and disposal plan, certain formatting and quality requirements must be met before the paper originals can be disposed of. The following applies:

- The system in which the scanned information is to be stored must comply with the Regional Archive's *Rules on Information Management and Archiving in IT Systems/Applications*.[1]
- It must be possible to convert the information retained in the system to a format approved for final archiving in accordance with the Regional Archive's format specification[2].
- The format requirements of the preceding stipulation do not apply to disposable information.
- The authority is responsible for ensuring that all documents are correctly scanned and that readability is good.
- The authority must have established procedures that guarantee fulfilment of the format and quality requirements for scanning It must be able to make these established procedures available for inspection.

Provided the authority complies with these requirements when scanning, the scanned original documents can be disposed of once they are no longer relevant. Some exempt documents will be preserved in paper format in line with the authority's own decisions.

4. How to read this plan

The plan is divided into sections corresponding to the processes of a research project: planning, implementation and reporting. The types of document are listed alphabetically within the relevant process section in the left-hand column of the plan. The middle column states whether the document must be retained or disposed of, and, where relevant, when

[1] LA 2017–0112
[2]See the Regional Archive's specification of approved formats for the delivery of digital files, LA 2018–0122.

disposal should take place. The notes column provides further explanation and any necessary cross-references.

There is further information about the disposal and handling of official documents on the Regional Archive's website. There is also a glossary of information management and archiving concepts.

5. Specific information about documentation from research activity

It is common for several stakeholders to participate in a research project. For example, an authority could be the commissioning body and another authority or a company could be the contractor. The application for an ethical review must designate the entity responsible for the research, and it is generally this party that has archival responsibility. If there is no ethical review, details of the entity responsible for the research should be provided in some other form of contractual document.

Archival responsibility must be regulated in an agreement before the research project starts in order to avoid uncertainty around the provenance of the documentation. If archival responsibility is not regulated in an agreement, responsibility will lie with the research entity that is managing the research funds. For further information, see the section on documentation from research activity on the Regional Archive's website.

5.1 Unique research data

If the research data is of a type that can easily be recreated, such as register data, it can be disposed of in accordance with the rules in the retention and disposal plan. However, if the research data is unique, difficult to recreate and expected to be of value to future research, the retention period can be extended following consultation with the Regional Archive.

5.2 Clinical studies of medical products

In the case of clinical studies of medical products, two sets of rules will apply in parallel throughout a transition period. This period will run from 1 February 2023 to 31 January 2025, during which time clinical trials on medical products will fall under two sets of rules.

A clinical trial on a medical product approved under the old directive 2001/20/EC and completed before the end of the transition period will fall under 2001/20/EC as regards archiving.

The new EU regulation 536/2014 will apply to clinical trials on medical products approved after 1 February 2023.

5.2.1 For clinical trials on medical products conducted under national legislation and EU Directive 2001/20/EC

Applies to applications submitted prior to 1 February 2023.

Under this set of rules, research documentation must be archived for ten years after the trial has been completed and the final report has been prepared. Should they wish, the entity responsible for the research and the contractor can also agree to retain the documentation for longer than ten years.

From 1 February 2025

Trials initiated under EU Directive 2001/20/EC and not yet completed are retained in compliance with the new rules, EU regulation 536/2014, i.e. for 25 years.

5.2.2 For clinical trials on medical products conducted under EU regulation 536/2014

Applies to trials conducted after 1 February 2023.

Under this set of rules, the entity responsible for the research and the contractor must retain the documentation for at least 25 years after completion of the clinical trial, unless other EU legislation stipulates a longer retention period.

5.3 Retention periods

A retention period given as 10 years means 10 years after completion of the project, once the findings of the research have been reported. In the case of clinical trials, see section 5.2.

6. Rules for retention and disposal

6.1 Research projects – planning

Document	**Retain/ Retention period**	**Notes**
Applications, successful	Retain	E.g. relating to research grants. Application documents and contracts, decisions and reports for successful applications.
Applications, unsuccessful	Must be disposed of on completion of the project.	E.g. relating to research grants. Successful applications must be retained.
Agreements, contracts, decisions	Retain	E.g. relating to: • research funds granted, financing • biobank agreements, Material Transfer Agreements, Data Transfer Agreements • purchase of register data • consortium agreements, partnership agreements • commissioned research contracts • third party agreements • data processing agreements: retain if the authority is the commissioning body and thus the data controller. If the authority is the contractor, agreements must be disposed of 2 years after the expiry date • confidentiality agreements • clinical investigation of medical devices Amendments and addenda to contracts and agreements must also be retained.
Questionnaire templates/ data collection forms	Retain	Blank template only. One copy must be retained.
Research descriptions Project descriptions	Retain	Includes research plans.

Document	**Retain/ Retention period**	**Notes**
Documents relating to the granting of permits/licences	Retain	Applications and decisions/permits/licences, e.g. for ethical screening/reviews, animal testing, clinical trials and similar, including all appendices. To and from organisations such as: • Etikprövningsmyndigheten (Swedish Ethical Review Authority) • Djurförsöksetisk nämnd (Animal Testing Ethics Committee) • Strålssäkerhetsmyndigheten (Swedish Radiation Safety Authority) • Läkemedelsverket (Swedish Medical Products Agency)> • Socialstyrelsen (Swedish National Board of Health and Welfare) • Jordbruksverket (Swedish Board of Agriculture) • Arbetsmiljöverket (Swedish Work Environment Authority)
Documents relating to the transfer of research material	Retain	Material Transfer Agreements, Data Transfer Agreements and similar.
Methodology documents	Retain	
Staff lists, partnerships	When no longer relevant	
Project plans Research plans	Retain	First and final project plans must be retained; interim plans must be disposed of 10 years after completion of project.
Permits/licences	Retain	*See Documents relating to the granting of permits/licences.*

6.2 Research projects – implementation

Document	**Retain/ Retention period**	**Notes**
Analysis/documentation of analysis		Retention/disposal must align with the corresponding retention periods for *Findings*; see below.
Analysis/syntax for statistical analysis		Retention/disposal must align with the corresponding retention periods for *Findings*; see below.

Document	**Retain/ Retention period**	**Notes**
Processing/working materials Primary data Raw data Databases, register data	10 years after completion of project	All types of raw data such as study reports, interviews, surveys, register data, patient records, biobank information, quality control documents, changes in primary data, unpublished results and similar. Calculations can be disposed of when no longer relevant. Raw data that is unique or is of value to future research must be retained. Justification must be provided for retention. Scanned or otherwise digitalised raw data can be disposed of provided the research can still be verified. Databases that can easily be recreated or that are felt not to be of value to further research must be disposed of 10 years after completion of the project. If the database is very valuable for future research, it can be retained for a longer period at the institution that conducted the research. Justification must be provided for extended retention periods. If consent has been obtained for data collection, the retention period must agree with the wording of the consents. Imported register data, e.g. from national registers, must be disposed of on completion of the project. The registers themselves must be preserved by the relevant manager. See also *Findings*.
Requests for erasure of data	Retain	
Biobank data	10 years after completion of project	See also *Listings of used biobank samples*.
Survey materials (completed)	10 years after completion of project	If the survey results are entered into a database, the materials must be disposed of on completion of the project. Survey materials deemed to be very valuable for future research can be retained; justification must be provided. See also *Processing/working materials…*
Excerpts	When no longer relevant	Includes other types of duplicates/copies.

Document	**Retain/ Retention period**	**Notes**
Photographs, data from measuring instruments, etc.	10 years after completion of project	
Research diaries Project diaries Logbooks Lab books	10 years after completion of project	Refers to laboratory notebooks or other project diaries, as well as protocols of trials/experiments. May only be disposed of if the associated raw data is disposed of, no earlier than 10 years after the research findings have been reported. If the raw data is retained, the log book must also be retained.
Listings of used patient records	10 years after completion of project	They must be sufficiently detailed as to enable the original data to be reconstructed if necessary. See *Code and variables lists*.
Listings of used biobank samples	10 years after completion of project	They must be sufficiently detailed as to enable the original data to be reconstructed if necessary.
Code and variables lists		To aid understanding of codes, abbreviations and similar for register data and other databases. May also be called field descriptions, data documentation or variable descriptions. The retention period must correspond with the retention period for the database; see also the stipulation on databases under *Processing/working materials…* above.
Consortium agreements	Retain	See also *Agreements, contracts, decisions*.

Document	**Retain/ Retention period**	**Notes**
Correspondence		Significant correspondence must be retained, e.g. correspondence of fundamental importance to the evaluation of methods and findings or that reports on the research process must be retained. Internal correspondence must be disposed of when no longer relevant, including correspondence with periodicals and publishers. Other correspondence must be disposed of on completion of the project, e.g. any relating to permits/licences and external funding with a Research Ethics Committee, an Animal Testing Ethics Committee, a Radiation Protection Committee, the Medical Products Agency or the IVO (Swedish Health and Social Care Inspectorate).
Sound and image recordings	10 years after completion of project	
Clinical studies of medical products	10/25 years after completion of project	Concerns: Processing/working materials Primary data Raw data Databases, register data, Biobank data Survey materials (completed) Photographs, data from measuring instruments, etc. Research diaries Project diaries Logbooks Lab books Listings of used patient records Listings of used biobank samples Sound and image recordings Findings, Measurement results, Test results Consents Permissions Congress reports See sections 5.2.1 and 5.2.2
Patient records, data from	On completion of project	Original patient records must be retained by the relevant care provider.

Document	**Retain/ Retention period**	**Notes**
Protocols	Retain	Protocols from major national/international collaborative projects or projects of major scientific significance must be retained. Also includes research protocols, trial/experiment protocols, investigation protocols, notes of project meetings.
Register data, in-house/original data		See also *Processing/working materials…* above.
Register data, imported		See also *Processing/working materials…* above.
Findings, Measurement results, Test results	10 years after completion of project	The findings referred to in the research. Also final versions of compilations, tables, diagrams, etc. Other documents must be disposed of on completion of the project.
Findings, compilations	On completion of project	
Consents Permissions	10 years after completion of project	The consents are linked to the collection of register data and samples; the retention periods must correspond. Scanned or otherwise digitalised raw data can be disposed of provided the research can still be verified.
Websites for research projects	Retain	Includes internal websites. The website must be archived if Region Stockholm is the entity responsible for the project. The website must be archived digitally in the first instance. Otherwise, screen dumps must be retained with documentation about the website's functionality, along with other research project documents that are to be preserved. See also *Retention and disposal plan for data on websites* (LA 2017-0035)

6.3 Research projects – reporting

Document	**Retain/ Retention period**	**Notes**
Abstracts	When no longer relevant	
Articles, scientific publications	Retain	
Theses/dissertations, Licentiate theses, Doctoral theses		Retain at the Higher Education institution where the thesis/dissertation was presented.
Interim reports, financial and scientific	Retain	
Documentation relating to the retention and disposal of research registers	Retain	
EU audit, documents relating to	Retain	Announcement letter, annex, draft audit report, final audit report and significant correspondence.
Research reports for the commissioning body	Retain	Including unpublished reports. Must be kept together with the relevant contract.
Conferences/seminars, documents relating to	Retain	Documents relating to conferences organised by Region Stockholm must be retained, i.e., documents relating to dissemination of the findings, e.g. invitations, programmes, delegate lists, researcher's presentation, abstracts. Documents from conferences attended that were organised by other parties must be disposed of once they are no longer relevant.
Conference reports	Retain	From conferences organised by Region Stockholm.
Congress reports	10 years after completion of project	Reports from in-house conferences are to be disposed of 10 years after completion of the project. Documents from attendance at other organised congresses, conferences, seminars and similar events can be disposed of once they are no longer relevant.
Manuscripts, ready-to-print	When no longer relevant	
Suspected misconduct during the research, documents relating to	Retain	E.g., reports, decisions, investigations and official written communications to and from other authorities.
Posters, printed items	Retain	2 archive copies; 1 copy must be kept with other research project documents, and 1 in the office of origin's collection of printed documents.

Document	**Retain/ Retention period**	**Notes**
Presentations from meetings and conferences	When no longer relevant	Ad hoc presentations at meetings during the course of the study must be disposed of when no longer relevant. See also *Conferences/seminars, documents relating to*.
Publications list, final	Retain	Ongoing lists of publication must be disposed of on completion of the project.
Publications, final version	Retain	
Reports	Retain	1 copy of in-house reports, e.g., evaluations, final reports, overviews.
Referee assessments, documents relating to	2 years	Also known as peer reviews.
Final reports, final statements, financial and scientific	Retain	
Working papers	Retain	