King's College London
Human Tissue Authority Licensed Laboratories

Standard Operating Procedure

Title: **Creation, Retention and Destruction of Research Documents**

Purpose
The purpose of this SOP is to describe the creation and retention of research documents associated the collection of HTA relevant material. It also details the procedure for document destruction.

Scope
The SOP describes the procedures to be followed for research documents. It does not apply to documents associated with clinical trials of investigational medicinal products (CTIMPs).

Document Detail	
Reference Number	KCL HTA108/ Creation, Retention & Destruction of records
Version	3.0
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Approved By	KCL HTA Governance Committee [30-Sep-2024]

Revision status

Each document has an individual record of amendments. The current amendments are listed below. The amendment history is available from the document control system

On issue of revised or new pages each controlled document should be updated by the copyholder.

Amendment Number: Date	Version no. Discarded	Insert Version no	Page	Section(s) involved	Amendment
1. 8/6/15	1.0	2.0	4	3.4, 4.1, 4.4. & 4.5	Updated departmental names
2. 11/9/2017	2.0	2.1	3	2.h	Update GSTT R&D role
3. 18/11/2019	2.1	2.2	3 3-4	2 2-4	Updated ethics terminology. Exchanged term 'College' for KCL or University
4. 12/09/2022	Review Only				No Changes
5. 30/09/2024	2.2	2.3	4	4.2	Updated link
6.					

Any minor amendment must be handwritten on the SOP without obscuring existing text. An asterisk should be placed in the adjacent margin to highlight the alteration. Alterations should be signed and dated by either the person designated or nominated individuals and then forwarded to the document controller. The SOP must be retyped, authorised and reissued as soon as possible. Amendments requiring immediate action should be dealt with in the same way but highlighted as high priority. Major changes must result in the immediate review of the procedure Document amendment does not replace the review process.

1 Responsibilities

It is the responsibility of personnel working under a KCL HTA Research licence to ensure that:

a) They create and maintain accurate and reliable records associated with the collection, storage or use of human 'relevant material'.
b) They ensure that all records are stored in a secure environment and accessed only by authorised staff.
c) Records containing personal or participant identifiers are stored under strict access conditions
d) Electronic data are regularly backed-up to a secure location.
e) All records are stored in such a way to minimise risk of loss, corruption or unauthorised destruction.

It is the responsibility of the Principle Investigator to ensure that:

a) Key documents from one study are linked by study name/number.
b) Copies of key documents are readily available when the study is active.
c) Arrangements are made to archive documents upon completion of the study.
d) Arrangements are made for the disposal of documents after the minimum retention period (see sections 4 & 5).
e) Responsibility for document retention and disposal are handed to someone else within KCL if they leave the University.

It is the responsibility of the Designated Individual and Persons Designated to:

a) Ensure that personnel working under the KCL HTA Research licence are aware of compliances associated with record creation, retention and destruction.
b) To regularly audit the accessibility, legibility and storage facilities of records.

2 Definition of Research Documents

Research –associated documents include but are not limited to the following:

a. Signed consent forms
b. Patient information sheet
c. Study-associated protocol/SOP
d. Service-level agreements
e. Material transfer agreements
f. Research ethics committee application form
g. Research ethics committee favourable opinion correspondence
h. Trust R&D capacity and capability correspondence
i. Participant/Sample registration record
j. Participant identification code list
k. Sample disposal record
l. Participant data
m. Experimental data

3 Creation of Documents

3.1 Documents should clearly state the title of the study, type of document and the date of creation.

3.2 Amended documents should be distinguishable as an altered, current version.

3.3 Paper printouts and images should be labelled with study name and date of analysis. These should be filed in such a way to remain accessible during the active study.

3.4 Records must comply with the KCL research data management policy (https://www.kcl.ac.uk/policyhub/research-data-management-policy)

4 Retention of Documents

4.1 Retention of documents and data associated with clinical trials of an interventional and medicinal product (CTIMP) is distinct from non-interventional or observational study. Information about clinical trials can be found from the King's Health Partners Clinical Trials Office www.khpcto.co.uk .

4.2 Documents and data associated with funded or sponsored non-interventional studies should be retained according to funder/sponsor guidelines. Further guidance related to specific types of study can be obtained from the Schedule of retention period for research data https://www.kcl.ac.uk/assets/aboutkings/business-assets/pdf/retention/research-data.pdf

4.3 Advice should be sought from KCL Research Grants & Contracts for retention of documents and data, which may have a commercial value and from Records Management, when data may have historical value.

4.6 When participants have consented to use of surplus relevant material in future (unspecified) studies, signed consent forms, patient information sheet and ethics committee application and approval letter for the initial study must be made available to the new custodian.

4.7 Documents associated with non-interventional studies can be scanned and stored in digital format.

4.8 Further advice on document retention and destruction can be obtained from the KCL Information Management and Compliance team [mailto:records-management@kcl.ac.uk]

5 Destruction of Documents and Data

5.1 Documents and data must remain secure with only authorised access until the point of destruction. This includes during transportation to the site of disposal.

5.2 Documents and data should be destroyed in such a way that data cannot be recovered. Electronic devices must be fully erased or physically destroyed.

5.3 Paper documents and electronic data recording devices should be destroyed in such a way to support the KCL Environment and Sustainability Policy.