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SOP 900 Archiving, retrieval and destruction of Research Documents

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
Division responsible for document:	Research & Development
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Version No:	Date of update	QPulse Change Request reference (CR no.)	Change Description	Author
4	November 2023	CR118 CR192	- Revised procedure for archive retrieval at 10 - Return of NNUH Study Records to a Sponsor and destruction of archived study records. Addition of requirement to review retention period, prior to destruction. Clarification of when the retention period starts. Clarification re offsite archiving. - Additional information for studies sponsored by UEA	J Orford

This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

Copies downloaded from the website are only valid on the day of downloading.

SOP 900 Archiving, retrieval and destruction of Research Documents

1. Contents

2. Definitions of Terms Used / Glossary

CI	Chief Investigator
CTIMP	Clinical Trials of Investigational Medicinal Products
FMH	Faculty of Medicine and Health
ICH GCP	International Conference on the Harmonisation of Good Clinical Practice
IMP	Investigational Medicinal Products
IRAS	Integrated Research Application System
PI	Principal Investigator
QC	Quality Control
R&D	Research and Development
RIN	Research and Innovation
SOP	Standard Operating Procedure
TMF	Trial Master File

3. Objectives

To describe the process for archiving, retrieval and destruction of research documentation for all research activities within the UEA and NNUH

4. Scope

ICH GCP E6, as amended in article 58 (2020)/SI 2004/1031, as amended 31a (8) and (9), schedule 1, part 2/ 2003/63/EC

5. Purpose

This SOP describes the process to be followed to ensure that essential study documents, working files, electronic data and records pertaining to the conduct of clinical research at NNUH and UEA are archived at the end of a study in accordance with ICH GCP, where relevant.

All essential documents must be stored and archived in a way that allows accurate reporting, interpretation and verification and the period of retention should be agreed by Sponsor (identified in the IRAS application for each non MHRA regulated study).

Data collected in the course of the study must be retained for a period in line with current legislation (see table below) or locally approved records retention periods. The Sponsor may specify greater periods of record retention as described within the study protocol or IRAS application.

The study retention period will commence from the date of the end of the study (as declared to the regulatory/review bodies).

For studies which have been discontinued, the retention period will commence after completion of discontinuation as defined by the Sponsor. Where NNUH has withdrawn from a study prior to recruitment/set-up, records may be destroyed following approval from the Research Governance Co-ordinator/Sponsor.

Type of study	Period of retention
Trials not used for regulatory submission	5 years from study conclusion
CTIMP & Device trials	25 years after completion or discontinuation
For trials relating to full traceability of the IMP for advanced therapies	30 years

6. Rules

The Sponsor / Chief Investigator (CI) / Principal Investigator (PI)

- The CI has overall responsibility for all records generated during the course of the study and the contents of the TMF
- Depending on the organisation involved and the type of trial, the Sponsor may be required to give permission for archiving of the TMF
- The site PI is responsible for archiving all data at their site/s

7. NNUH Archivist

The Research Governance Coordinator will assume the role of named Archivist. During times of absence this will pass to the Research Services Manager. It is acceptable that tasks can be delegated to other members of the Research & Development (R&D) Team.

The Archivist is responsible for ensuring that systems are in place for tracking, retrieval and disposal of archived documents as well as ensuring that regulatory requirements for archiving are met.

The Archivist will ensure compliance of external archiving facility by periodic assessment and inspection of the facility and its processes.

8. Archiving Procedure for NNUH

- Request for archiving sent to rdoffice@nnuh.nhs.uk using heading "Request for Archiving and IRAS/R&D study number''
- Evidence to be provided that permission to archive has been approved by Sponsor (for sponsored and hosted studies) (R&D to retain copy in R&D Registered Projects folder). If after 2 documented attempts no response is received then the NNUH Archivist can approve the request. For UEA sponsored studies NNUH R&D contact the study CI for permission.
- If specific requirements are stipulated for a hosted study the PI/delegated other should ensure R&D have received a copy of this information particularly if there is a request for off-site archiving. Studies should **not** be sent for offsite archiving without notification to R&D and opportunity for R&D to check the records.
- R&D forwards **SOP 900 App 3** R&D Archiving Inventory Form and **SOP 900 App 4** R&D Archiving Chain of Custody Form to the requester.

Research Delivery Team, PI or delegated other:

- Prepares documentation for archiving in accordance with this SOP
- Populates the Archiving Inventory and the Chain of Custody form as far as possible
- Requests R&D to complete a QC check

- Once QC is complete the Archiving Inventory form is placed in the box

- R&D complete the forms, archive records and Edge database with all required information for the study
- R&D label the box with the study, reference number, box number and number of boxes for the study and then seal with a numbered security tag

- R&D log collection detail on the Archive Vault Portal
- Chain of Custody form signed / dated by collection driver
  R&D retains a copy of the completed Chain of Custody form in the Registered Project folder and forwards a scanned copy to the PI/Research Team with confirmation of completion of archiving

- Where a study has a database / other records, stored electronically, advice should be sought from R&D regarding their storage.

Box Labelling Guide

Boxes must have the following information written on one end of the box:

- IRAS number, if applicable
- R&D study reference
- Short Study Name
- R&D Box number / number of boxes

9. Retrieval of Archived Study Records for NNUH

The retrieval process must be controlled to ensure the safety of the study documentation and integrity of the data

- Study retrieval requests must have a valid reason for removal from storage
- Retrievals must be authorised as follows:
  - The NNUH Archivist can authorise retrieval for minor reasons e.g. to add additional paperwork to the study files
  - The CI / PI / Sponsor should authorise all other requests e.g. to review data
- Retrieval shall be for no longer than 30 days, a return date must be specified on the request form, any extension must be justified
- Records of Retrieval will be retained by R&D, filed in the Registered Projects folder and logged on the R&D archive records/Edge

10. Retrieval Process for NNUH

- Email request is received for retrieval via rdoffice@nnuh.nhs.uk – subject line 'Retrieval request, IRAS/R&D Study reference number'
- R&D completes Retrieval Request form **SOP 900 App 6 Request for Archive Retrieval** and sends for authorisation

- R&D will identify the box and barcode numbers from the records and request retrieval via the Archive Vault Portal
- Once received the requester will be advised that the records are ready for collection. If the records are returned directly to the requester they will notify rdoffice@nnuh.nhs.uk once the records have arrived.

- If documentation is to be added, the documents should be prepared in accordance with this SOP
- The Archiving Inventory should be updated (and returned to the box)
- R&D complete a QC check

- R&D will ensure timely return

- R&D requests a collection from the Archive Vault Portal. Archive facility collection driver will sign/date the retrieval form
- Archive record/Edge is completed for return date and a copy of the form is retained in the Registered Project folder

- Where NNUH records are held at another storage facility (arranged by the Sponsor) the Sponsor's retrieval procedures should be followed and agreed by the NNUH Archivist.

11. Return of NNUH Study Records

If a request is made by the Sponsor for return of the study records to them

- Written confirmation of such requests shall be retained in the Registered Project folder
- R&D will arrange retrieval of the records from the archive facility, so that the records can be returned to a designated archiving facility (rather than directly to the Sponsor)
- It is the responsibility of the Sponsor to arrange collection from NNUH R&D
- R&D will retain a copy of the chain of custody form in the project folder
- The Sponsor shall advise R&D when the records have been received by email via rdoffice@nnuh.nhs.uk
- R&D will retain the confirmation email within the Research Project folder

12. Destruction of Archived Study Records

- Once the destruction date is reached R&D will review the date against current retention period and extend the date if necessary and amend archive records / Edge. If there are no changes to destruction date R&D will seek permission from the Sponsor and prepare the request for destruction (via the Archive Vault portal for records held in that facility). For hosted studies, the Sponsor should be given a deadline for response (no less than one month) if no response is received from the Sponsor, or if 'undeliverable' responses are received and no other identifiable contact can be found then the NNUH Archivist can approve the request

- Once permission is received R&D will request destruction via Archive Vault.
- Destruction confirmation will be retained within the Registered Projects folder

- The R&D archive records /Edge will be updated and the PI advised.

13. Archiving Procedure for studies sponsored by UEA

UEA does not sponsor MHRA regulated clinical trials and has no dedicated archivist. CIs are responsible for arranging archiving of all essential documents. Archiving shall be overseen by Research and Innovation, under the direction of the Contracts Manager.

UEA archiving procedures for research data collected during the project is described in UEA's Research Data Management Procedures Guidance available on the UEA portal.

Sites do not need permission from UEA as Sponsor to begin archiving. Archiving can commence once the end of study has been declared. The CI will circulate the end of study report to Sponsor and each site. CI shall ensure the TMF including all essential documentation is archived as appropriate and the period of archiving shall be in accordance with the protocol and IRAS application. All sites will ensure they commence archiving of their essential documentation in accordance with the protocol/IRAS application.

CI will ensure arrangements have been put into place for appropriate removal of any regulated human tissue at the end of study and appropriate storage of non regulated tissue, in accordance with the REC approval.

Destruction of the archived documents should commence by CI and all sites following the immediate end of the archiving period.

14. References and Related Documents

References (NNUH)	
ICH GCP E6 / SI 2004/1011	
SOP No.	**SOP Title**
SOP 900 App1	Archive Process Map
SOP 900 App2	Research Delivery Team Archiving Checklist
SOP 900 App 3	R&D Archiving Inventory
SOP 900 App 4	R&D Archiving Chain Of Custody Form
SOP 900 App 6	Archiving Retrieval Request Form
SOP 900 App 8	R&D Archive Process Map

15. Approval

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Date	09 April 2024 | 4:47 BST

16. Training Implication

Training Implication	**Yes**
Actions required	• Read and understand updated process • Matrix to be updated