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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
Key words:	Archiving, retrieval, destruction, research
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This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

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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

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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.

All essential documents must be stored and archived in a way that allows accurate reporting, interpretation and verification.

Data collected in the course of the study must be retained for an appropriate period.

Retention periods must be in line with current legislation. The Sponsor may specify greater periods of record retention as described within the study protocol.

Study retention period will commence from the date of all close out activities being completed and final report being provided to regulatory bodies.

For studies which have been discontinued, retention period will commence after completion of discontinuation as defined by the 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
- The Sponsor must give permission to archive once a study has closed and state period of archiving
- 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.

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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''
- Delivery Team to provide evidence that permission to archive has been approved by Sponsor (retained in R&D Registered Projects folder. If after 2 documented attempts no response is received then the Archivist can approve the request
- R&D forwards to Research Delivery Team **SOP 900 App 1** Research Delivery Team Archive Process Map, **SOP 900 App 2** Archiving Checklist, **SOP 900 App 3** R&D Archiving Inventory Form and **SOP 900 App 4** R&D Archiving Chain of Custody Form

- Research Delivery Team ensures supplies are available and prepares documentation for archiving using the process map and checklist (as per App 2)
- Populates the Archiving Inventory and the Chain of Custody form with the Integrated Research Application System (IRAS) / R&D study reference number, number of boxes and a destruction date
- Request R&D to complete a QC check

- Once QC is complete the Archiving Inventory form is placed in the box
- Chain of Custody form is signed and dated by the Research Delivery Team and R&D

- R&D allocate a box number
- R&D complete the archive records/Edge attribute with all required information for the study, this acts as a record for the archive status
- Box is sealed with a numbered security tag

- R&D to log collection detail on the Archive Vault Portal, alternatively email the request to Storage@archive-vault.co.uk
- 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 Research Team
- Research Delivery Team will receive confirmation of completion of archiving via email from R&D confirming the barcode.

Box Labelling Guide
Boxes must have the following information written on the top and one end of the box: • IRAS number, if applicable • R&D study reference • Short Study Name • R&D Box number • Destruction Date

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
• Retrieval must be authorised by the CI / PI / Sponsor • If after two documented attempts for authorisation, authorisation cannot be confirmed then the Archivist can approve the request • Study retrieval requests must have a valid reason for removal from the Archive • 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 attribute

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 sends Retrieval Request form **SOP 900 App 6 Request for Archive Retrieval** for completion • Research Delivery Team return authorised retrieval form to rdoffice@nnuh.nhs.uk
	• R&D will identify the box and barcode numbers from the Archive records and request retrieval from the Archive Vault Portal or storage@archive-vault.co.uk • Once received the Research Delivery Team will be advised that the records are ready for collection

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- Research Delivery Team prepares documentation for archiving using the process map and checklist
- Populates the Archiving Inventory (placing it in the box) and Chain of Custody form with the IRAS / R&D study reference number, number of boxes and a destruction date
- Request R&D to complete a QC check
- R&D will check against the archiving inventory to ensure all data is present

- Chain of Custody form is signed and dated by the Research Delivery Team and R&D

- Return date shall be tracked to ensure timely return

- R&D requests a collection from the Archive Vault Portal or storage@archive-vault.co.uk
- Archive facility collection driver will sign/date the chain of custody form
- Archive record/Edge attribute is completed for return date and a copy of the form is retained in the Registered Project folder

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 as stated in SOP 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 to destruct on the Archive Vault portal. For hosted studies, if after 2 documented attempts no response is received from the Sponsor then the Archivist can approve the request

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- Once approved by the Archivist R&D will send confirmation to destroy to Archive Vault.
- Once the destruction is complete, electronic confirmation will be issued.
- Destruction confirmation will be retained within the Registered Projects folder
- The R&D archive records /Edge attribute will be updated to state that the data has been destroyed and a date of destruction

13. Archiving Procedure for UEA

The RIN Contracts Manager will assume the role of named Archivist. During times of absence this will pass to the FMH Research Manager. It is acceptable that tasks can be delegated to other members of the RIN Team.

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

14. References and Related Documents

References
ICH GCP E6 / SI 2004/1011

SOP No.	**SOP Title**
SOP 900 App1	Research Delivery Team 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

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15. Approval

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Date	26 November 2021

16. Reason for new version and Training Implication

This SOP replaces the previous version number V3

Changes made	
Reason	• Updated to include CR30: return of NNUH Study Records to a Sponsor and destruction of archived study records. Addition to of requirement to review of retention period, prior to destruction. Clarification of understanding of when the retention period starts
Training Implication	**Yes**
Actions required	• Read and understand updated process • Matrix to be updated