SOP number	**52.014**	Version	**2.0**
Title	**Archiving Essential Documents from Clinical Research – Process for Hosted Research**		

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SOP category	NHS GG&C Hosted R&I
Staff category	

Staff Category	**R**	**A**	**C**	**I**
Research Governance Manager		X		
Archiving Representative (Research Information Officer or designee)	X			
NHSGGC Site Research Teams and Designees	X			
NHSGGC Site Pharmacy Clinical Trials Teams	X			
Investigators and Local Study Teams	X			
R&I Research Administrators and Senior Research Administrators	X			
Research Facilitators and Co-ordinators	X			
Project Managers	X			
NHSGGC NRS Portfolio Performance Manager			X	

1. Scope

This procedure applies to the Research and Innovation Office within NHS Greater Glasgow and Clyde and NHSGGC teams involved in hosted clinical research.

2. Purpose

The purpose of this SOP is to describe the requirements and procedures relating to the archival of essential documents for studies Hosted by NHSGGC on behalf of external Sponsors. This SOP can be provided to Sponsors as evidence of the NHSGGC process for archiving hosted activity.

3. Procedures

NHSGGC processes for archiving will be discussed and documented at the contract stage with the Sponsor, prior to study start, by the R&I co-ordinator to ensure the costs of archiving have been agreed. Archiving is likely to occur following the end of a study or after the completion of actions at the site monitoring close out visit and according to direction from the sponsor.

NHSGGC arrangements for archiving will be requested by the Sponsor according to the Sponsor processes. This may be described at the SIV and verified by the sponsor monitoring team. The archive period will be described within the study protocol.

The archival of documents provides long term secure storage for essential study documents (paper study records). Any essential documents that have been held centrally during the study must be added to the file at the time of preparing to archive as it is essential to have a complete document set before undertaking the archival process.

The Sponsor will notify the NHSGGC site when they are permitted to archive.

However, information may be stored at a NHSGGC facility if arrangements have not been agreed with a sponsor.

3.1. Responsibilities

3.1.1. Sponsor

The Sponsor is responsible for:

- Notifying the Research and Innovation department and the Investigator sites that the study is ready to be archived, indicating the retention period.
- Deciding when the archived documents can be destroyed and notifying Investigator sites and the Research and Innovation departments of this date.
- Ensuring the funding is in place for the required archiving period

3.1.2. Research Administrators/Senior Research Administrators and Project Managers (if involved in a Hosted study)

The Research Administrators/Senior Research Administrators and Project Managers (if involved in a hosted study) are responsible for:

- Upon receipt of a confirmation from the Sponsor that a study is ready for archiving an email will be sent to the local study team and other departments involved e.g. pharmacy and Imaging. The email will have attached the Archiving Certificate (Form 52.014A) for completion, and will inform that a study is ready for archiving as confirmed by the Sponsor. The Glasgow CRF and the Beatson CRF will have their own archiving arrangements (SOP 57.005 and SOP CTU-PTS-TM-006) and will only indicate the date of archiving, which will be recorded under the 'Archiving Date' field on SReDA, and under 'Archive Comments' either GCRF or BCRF will be added.
- To check for studies that have not been archived, an annual report (in May) will be generated by the Research Information Officer (or designee) to identify studies potentially requiring archiving. The report will be forwarded to the Research Administrators/Senior Research Administrators and they will contact the local investigator to discuss the archiving arrangements

- All returned Archiving Certificates and confirmations from the local study teams that a study is ready to be sent to Iron Mountain will be forwarded onto the Research Information Officer (or designee). These will be stored on SREDA.

3.1.3. NHSGGC Site Teams, Investigators or designees

The Sponsor's archiving procedures will be followed. The Sponsor will provide the local site teams with details of what is to be archived off site and they will be responsible for:

- Preparing the information from the site file for archiving according to the procedures within the study agreement and arranging with the Research Information Officer (or designee) to organise a collection of the documentation with Iron Mountain.
- For studies where Glasgow CRF or Beatson CRF are involved, they will follow their own SOPs in terms of archiving and destruction.
- Ensuring that an Archiving Certificate (Form 52.014A) has been completed, indicating the retention period and proposed date of destruction, signed off by the Principal Investigator and returned to the R&I Research Administrator/Senior Research Administrator. The completed Archiving Certificate will be saved in the R&I common drive under the project specific folder as well as centrally under: \\northnet-11\wg-research\common\1. Systems\Archiving\Archiving Certificates.
- If other departments hold essential documentation relating to the trial, the site team designee is responsible for informing the NHSGGC Archiving Representative.

3.1.4. The Archiving Representative (Research Information Officer or designee)

The Archiving Representative is responsible for:

- Organising an Iron Mountain uplift of the study files.
- Ensuring that Archiving Certificates (Form 52.014A) have been completed by local site teams to confirm files are ready to be archived. The completed Archiving Certificate will be saved in the R&I common drive under the project specific folder.
- Ensuring that the Scottish Research Database (SReDA) has been updated with the 'Archiving Date' (date that the study has been sent to the archive) and recording the archiving box number (the barcode from the Iron Mountain label) in the 'Archive Reference field'.
- Ensuring the completion of the SReDA 'Archiving Destruction Date' with the proposed date of destruction from the Archiving Certificate.
- Updating SReDA 'Destroyed' checkbox once the study has been destroyed.
- To follow the process for destruction of files as stated at section 3.6.

3.2. NHS GGC Site Pharmacy Clinical Trials Team

- If the Sponsor permits, Pharmacy site files may be archived when pharmacy has been closed out (which may be in advance of the full study closing) and only when all IMP visits are complete.

3.3. Uplift/Retrieval of Archiving

- The Research Information Officer (or designee) will arrange for Iron Mountain to collect the archiving material, and can organise the supply of archive boxes and labels via Iron Mountain.
- Only one study may be archived in a single archive box.
- One Iron Mountain barcode/label is attached to the box prior to being sent to the storage facility and the other one is attached to the transmittal sheet. The barcode will be used to identify the box if and when it is required to be returned from the storage facility.
- The barcode from the label is also entered on SReDA under 'Archive Reference' by The Research Information Officer (or designee).

- The Research Information Officer (or designee) will ensure that the data held by Iron Mountain has been completed at www.ironmountainconnect.com and arrange for the physical archiving of the boxes to their secure archiving facility.
- Any requested retrievals will be delivered by Iron Mountain to the indicated site/hospital, and will later be returned to Iron Mountain from the same place.

3.4. Archiving Process for Electronic Files and SReDA

Requirements for the archiving of electronic records are the same as those for other record types. Electronic records will be held on a password protected area on the NHSGGC system.
All trial electronic files that cannot be printed will be copied on a USB drive or external hard disk and archived along with the trial paper files using Iron Mountain boxes as stated at section 3.3.

3.5. Retention Period

The retention period should be discussed between the Sponsor and the Investigators and agreed at the start of the study. It should also be outlined within the Protocol and/or Contracts with what is detailed in the Protocol being seen as the overriding time period. Extensions to agreed archival periods must be agreed with the Sponsor and appropriately funded if required. Retention period should be entered on the Archiving Certificate (Form 52.014A) by NHSGGC Site Teams, Investigators or designees as stated at section 3.1.3.

A number of scenarios where the legal minimum requirement is longer than the 5 year minimum and this must be considered when determining the retention period:

- Essential documents from Clinical Trials of Investigational Medicinal Products (CTIMPs) or Clinical Investigations of Medical Device (CIMDs) that will not be used in support of a marketing authorisation, will be archived for a minimum of 5 years. If the study will support a marketing authorisation this period will extend to a minimum of 15 years.
- Commercial studies will be archived for a minimum of 15 years.
- Advanced Therapy Investigation Medicinal Product (ATIMP) studies will be archived for a minimum of 30 years.
- Paediatric studies: 3 years after the youngest participant turns 18 or 5 years after conclusion of trial (whichever is longest).

3.6. Destruction of Archived Files

The study files archived at Iron Mountain will be destroyed following the receipt of authorisation from the Sponsor and a confirmation from the Research Facilitator/Co-ordinator dealing with the study, this process will also apply to any material held for trials that were not retained at Iron Mountain for whom the archiving period has elapsed. This can then be brought to the weekly R&I committee for ratification. However if no authorisation email has been received from the Sponsor within 6 months of the end date recorded in SReDA and upon chasing for reply once a month for 3 months, the study/studies will also be destroyed. The Archiving Representative or designee will contact Iron Mountain regarding destruction of documents at the end of their retention period. If files are not held at Iron Mountain they must be appropriately located and destroyed.

If the Sponsor does not wish to authorise destruction or to take receipt of the documents, then negotiations (facilitators, co-ordinators) will take place regarding extension of retention periods and for appropriate payment in support of these. Any change to the contractual archival agreement may necessitate amendment to the study contract.

The Research Information Officer will run annual reports from SReDA (which will be available for all users) in May. The first report titled “Date of Destruction Report” on studies passed the proposed destruction date, excluding studies that have already been destroyed following either the Sponsor or the Chief Investigator confirmation to destroy the files. The second report titled “Projects Missing Destruction dates” on studies missing destruction dates on SReDA. The reports will be forwarded onto the Research Administrators/Senior Research Administrators (and Project Managers if involved in a hosted study) indicating which sponsors they need to contact informing them that the destruction date has passed.

Form 52.014A will be held indefinitely by the R&I department within NHS Greater Glasgow and Clyde along with evidence of the consent from Sponsor to destroy. Those will be saved under the project specific folder in the common drive.

4. Referenced documents

- Form 52.014A - Archiving Certificate
- SOP 57.005 - GCRF Archiving Process
- SOP CTU-PTS-TM-006 - Archiving of Clinical Trial Documentation

5. Related documents

- SOP 53.004 - Monitoring Clinical Research – Site Monitoring Visit

6. Document history

Version	Date	Description
1.0	07/04/2017	Release of First Version
2.0	10/06/2025	Re-written process of archiving and destruction. Addition of new staff involved. Admin updates, R&D change to R&I, new author. Removal of some referenced and related documents - made obsolete in the past. Addition of new referenced documents.