Standard Operating Procedure		**52.014**	
Archiving Essential Documents from Clinical Research – Process for Hosted Research			
Version	1.0		
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1. SOP Category

NHS GG&C Hosted R&D

2. Staff Category

- Archivist (Research Information Officer)
- NHS GGC Site Research Teams and Designees
- NHS GGC Site Pharmacy Clinical Trials Teams
- Principal Investigators and Trial Team
- Laboratories (Involved in Primary and Secondary End Points)

3. Scope

This procedure applies to the Central Research and Development Office within NHS Greater Glasgow and Clyde (GG&C) and NHS GGC teams involved in hosted clinical research.

4. Purpose

The purpose of this SOP is to describe the requirements and procedures relating to the archival of essential documents for studies hosted by NHS GG&C on behalf of external sponsors. If the sponsor requests specific archiving this will be carried out. If the archiving is not detailed then this SOP will be followed.

5. Procedures

Archiving will occur following the end of a study, as defined in the protocol for each research study or during a study with the sponsor's permission, e.g. to improve space onsite by removing large files as appropriate.

The archive 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.

For studies sponsored by external organisations the archival procedures within the protocol and or contract will be followed. For hosted studies a study is deemed to have ended following receipt of a 'close-out' visit and report, and/or formal notification from the sponsor.

5.1 Responsibilities

5.1.1 The Archivists

The Archivist is responsible for:

- Facilitating the archival of the study files.
- Ensuring that Archiving Certificates (Form 50.014H) have been completed by local site teams to confirm files have been archived.
- 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 in the 'Archive Reference field'.
- Ensuring the completion of the SReDA 'Archiving Destruction Date' with the proposed date of destruction from Essential Document Checklist.
- Ensuring the 'Archive Project' checkbox is selected on SReDA to archive the entry on the database.
- Updating SReDA 'Archiving Destruction Date' and selecting the 'Destroyed' checkbox
- Review of studies nearing end of archival retention period to confirm that they can be destroyed at the end of the retention period. For all hosted studies the Named Archivist will contact the Sponsor on the agreed destruction date to obtain written authorisation for destruction.
- Destruction of documents at the end of their retention period.

5.1.2 NHS GGC Site Teams

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.

- Preparing the information from the site file for archiving according to the procedures within the study agreement and arranging with the Archivist to archive the documentation.
- Ensuring that an Archiving Certificate (Form 50.014H) has been completed.
- If other departments hold essential documentation relating to the trial, the site team designee is responsible for informing the NHS GG&C Archivist whether the information is to be archived by the sponsor or whether NHS GG&C has been contracted to archive this documentation. Other departments within/associated with NHS GG&C may include teams such as the Clinical Research Facility (CRF), the Robertson Centre for Biostatistics (RCB) and laboratories involved in primary and secondary end points. However, this list is not exhaustive.

5.2 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.

5.3 Archiving Process for Hard Copy Files

The Archivist will arrange for Iron Mountain to collect the archiving material.

Currently R&D archiving is at box level, with each archive boxes given a unique, sequential number from the list of R&D Archiving boxes. An Iron Mountain barcode is attached to the box by the Archivist prior to being sent to the storage facility, which is used to identify the box if and when it is required to be returned from the storage facility.

The Archivist 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.

5.4 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 NHS GG&C system.

5.5 Retention Period

Retention of study documents will be determined by the sponsor organisation.

5.6 Destruction of Archived Files

The Archivist will run quarterly reports titled "Date of Destruction Report" from SReDA (which will be available for all users) on studies nearing or passed their proposed destruction date. The Archivist will inform the sponsor that the destruction date is approaching.

Unless the sponsor advises that the retention period for their study should be extended, all studies that have been confirmed as passed their destruction date will be securely destroyed by Iron Mountain.

If the sponsor/client does not wish to authorise destruction or to take receipt of the documents, then negotiations 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.

Form 50.014H will be held indefinitely by the R&D department within NHS Greater Glasgow and Clyde.

6. Referenced Documents

- Good Clinical Practice Guide; 1st Edition 2012
- Form 50.014E Essential Documents for Archiving – Archiving Checklist (for CTIMPs)
- Form 50.014F Essential Documents for Archiving – Archiving Checklist (for non CTIMPs)
- Form 50.014G Agreement on Delegation of Responsibility for Archiving Study Documentation
- Form 50.014H Archiving Certificate
- SOP 53.004 Monitoring Clinical Trials

7. Related Documents

- Guideline 50.014A: Archiving Process Map

8. Document History

Version	Date	Description
1.0	07/04/2017	Release of First Version