Standard Operating Procedure			**51.025**
Archiving Essential Documents from Clinical Research – Process for a Sponsored Non CTIMP.			
Version	1.0		
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1. SOP Category

NHS GG&C Sponsor R&D

2. Staff Category

- Archivist (Research Information Officer)
- Research Co-ordinators
- Co-ordinators Assistants
- R&D Trial Monitors
- Audit Facilitator
- Chief Investigators / study teams (Trial Manager etc)
- Principal Investigators

3. Scope

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

4. Purpose

The purpose of this SOP is to describe the requirements and procedures relating to the archival of essential documents and medical records for GG&C sponsored and co-sponsored studies that are non CTIMPs. For research studies sponsored by GG&C the procedures within this SOP will be followed, if not specified within the individual protocols.

5. Procedures

5.1 Background

The archive provides long term secure storage for essential study documents (paper study records). At the close of a study, the R&D department will ensure essential documents are archived in accordance with the retention agreement defined within the study contract, co-sponsorship agreement, protocol or agreed term within this SOP.

The process will begin when the Research Coordinator assigned to the study has confirmed that the study can be archived, the period of time between end of study and requirement for archiving may be defined within the protocol. For studies that do not have information within the protocol relating to end of trial or archiving procedures the following will apply:

- Within three years of the last patient visit (defined as end of trial) or
- If three years has lapsed then it will be archived as agreed between the Chief Investigator and Archivist. This will apply to research involving long term follow-up

5.2 Staff Group Involvement

5.2.1 Archivist Responsibilities

The Archivist will ensure that archiving is completed in accordance with this SOP and is responsible for:

- Facilitating the archival of the sponsor R&D study file*.
- Ensuring that Essential Documents for Archiving – Archiving Checklist (Non CTIMPs) (Form 51.025A) has been completed.
- Ensuring that an Archiving Certificate (Form 51.024C) has been completed.
- Completing of all paperwork to send the sponsor study file* to Iron Mountain and organising the uplift of archiving boxes and removal to the secure archiving facility.
- Updating SReDA 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
- Updating SReDA 'Archiving Destruction Date' with the proposed date of destruction from Essential Document Checklist.
- Changing the 'Archive Project' checkbox on SReDA to archive the entry on the database
- Updating SReDA 'Archiving Destruction Date' and selecting the 'Destroyed' checkbox when a study has been destroyed.

  *All Non CTIMP studies registered on SReDA after 25th April 2013 have an electronic R&D study file and no hard copy is kept by the R&D Department. There will be no file to send to the archive for non CTIMPS registered after this date.

Other Tasks

- Review of studies nearing end of archival retention period to confirm that they can be destroyed at the end of the retention period.
- Oversight of destruction of documents at the end of their retention period

5.2.2 Project Mangers/Research Coordinator or Designee Responsibilities

The Research Coordinators are responsible for:

- Oversight that a study is "Complete" and can be sent for archiving
- Approval for archiving
- The completion of Form 51.025A
- Inform the study team destruction of study documents is approaching.

5.2.3 Chief Investigator (CI) Principal Investigator (PI) or Designee Responsibilities

- The CI/PI (or a designee) is responsible for:
- Preparing the information from the site files for archiving according to the procedures within this SOP and arranging with the Archivist to archive the documentation.
- If other organisations hold essential documentation relating to the trial the Archivist will be informed whether the information is to be archived by the sponsor or whether the site has been contracted to archive separately.
- Ensuring that an Archiving Certificate (Form 51.024C) has been completed to confirm the CI/PI files have been archived independently

- The process for site archiving will be held in each site file and the individual at site responsible will be names on the delegation log.

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

Non CTIMPs should be retained for at least 5 years after the conclusion of the trial, or if longer, as documented within the study contract and protocol.

5.6 Medical Records

For medical records archived for Glasgow sites the policy of NHS greater Glasgow and Clyde for destruction will be followed.

For guidance on the retention of records consult the Scottish Government Records Management: NHS Code Of Practice (Scotland) Version 2.1 January 2012, Annex B - The management, retention and disposal of personal health records.

For the avoidance of doubt medical records of:

- Cancer patients involved in clinical trials within NHS Greater Glasgow and Clyde will be held indefinitely.
- Children and young people will be retained until the patients 25th birthday or 26th if the young person was 17 at conclusion of treatment. If the patient dies the records only need to be retained for the same time as for essential documents
- Adults will be retained for 5 years after the completion of the trial
- A mentally disordered adult will be retained for a minimum of 20 years after the last contact with the patient. . If the patient dies the records only need to be retained for the same time as for essential documents.

5.7 Multicentre Studies

The archiving of site study documentation for multicentre studies will be delegated to the hosting NHS organisation, as per the Site Agreement. During the Site Close Out Visit (please see SOP 53.004 Monitoring Clinical Trials for further information), the monitoring close-out process an Agreement on Delegation of Responsibility for Archiving Study Documentation form (Form 51.024B) will be completed by the PI and the Monitor.

The Delegation of Responsibility form should be completed to document the archiving agreement. The forms should include protocol name, site address, EudraCT number, the reason for requesting Board involvement with archiving, the Investigator's signature and date and also the monitor's signature and date. A copy should be placed in the Site File where possible and a copy placed in the Sponsor R&D study file.

An Archiving Certificate (Form 51.024C) will be completed by the Principal Investigator (PI) at the hosting site, to confirm PI site files have been archived.

5.8 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 Research Co-ordinator/Archivist will inform CI/PI that the destruction date for the TMF is approaching.

Unless the CI/PI 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 at the archivists' request.

Form 51.024C 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 51.025A Essential Documents for Archiving – Archiving Checklist (for non CTIMPs)
- Form 51.024B Agreement on Delegation of Responsibility for Archiving Study Documentation
- Form 51.024C Archiving Certificate
- SOP 53.004 Monitoring Clinical Trials

7. Related Documents

Guideline 51.024A: Archiving Process Map

8. Document History

Version	Date	Description
1.0	12/04/18	Release of First Version