SOP number	**51.025**	Version	**2.0**
Title	**Archiving Essential Documents for Non-CTIMP Research Studies Sponsored or Co-Sponsored by NHS Greater Glasgow & Clyde and the University of Glasgow**		

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SOP category	NHS GG&C Sponsor R&I

Staff category

Staff Category	**R**	**A**	**C**	**I**
Research Governance Manager		X		
Research & Innovation Systems Manager			X	
Sponsor R&I Co-coordinator	X			
Sponsor Research Facilitator	X			
Senior Research Administrator	X			
Research Information Officer	X			
Project Management	X			
Chief Investigator	X			
Pharmacovigilance and Safety Manager	X			
University of Glasgow Research Regulation and Compliance Team	X			
Principal Investigator			X	
Quality Assurance Manager			X	
Sponsor Pharmacy			X	
Monitoring Team			X	
Data Management			X	

1. Scope

This process applies to the NHS Greater Glasgow & Clyde (NHSGGC) Research and Innovation (R&I) department and all individuals involved in NHSGGC Sponsored or Co-Sponsored clinical research of non-regulated research studies.

2. Purpose

The purpose of this SOP is to describe the requirements and procedures for archiving essential documents i.e. the Trial Master File (TMF), Investigator Site Files (ISFs,) and medical records for research studies sponsored by NHSGGC, or Co-Sponsored by NHSGGC and the University of Glasgow (UoG). For clarification this does not apply to Clinical Trials of Investigational Medicinal Products (CTIMPs) or Clinical Investigations of Medical Devices (CIMDs) Sponsored by NHSGGC or Co-Sponsored by NHSGGC and UoG, this process is addressed in SOP 51.024.

3. Procedures

3.1. Background

For CTIMPs, it is a legal requirement to archive essential trial documents and participant medical records to enable trial reconstruction and inspection by the MHRA, in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended. While there is no explicit legal requirement in the UK to archive documentation for non-regulated research studies (referred to as non-CTIMPs), it is good practice to apply the same principles used for CTIMPs. For non-CTIMP studies, essential documents must be retained for a minimum of five years from the end of the study, which in turn must be defined in the protocol (see SOP 51.001). If the end of study is not defined, retention should be calculated from either the last patient's last visit or database lock, depending on the study.

For studies Sponsored by NHSGGC, all TMFs will be held electronically within the R&I team, and as such, an electronic Trial Master File (eTMF) will be archived in a secure, password-protected, backed-up section of the R&I Common Drive, hosted on an NHSGGC server. Sections of the TMF managed by those external to R&I may retain their documentation in electronic or paper format depending on local practice. The specific arrangements for archiving these materials will be discussed during study set-up, and formally documented within the contract, in accordance with SOP 51.039. These responsibilities must be clearly defined and agreed upon during the contract negotiation phase to ensure consistency and compliance with Sponsor expectations.

Arrangements for Investigator Site Files (ISFs) will be agreed between the Chief Investigator (CI) and the Sponsor during the initial Sponsor review, with associated costs identified and included in the grant application (see SOP 51.010). The ISF for NHSGGC sites must be stored securely, and identifiable data should not be held on University of Glasgow (UoG) servers, except where hosted by the Robertson Centre for Biostatistics (RCB) or on a cloud platform that complies with an approved Cloud System Security Policy (CSSP). All individuals involved in creating or maintaining an ISF must adhere to the UK General Data Protection Regulation (GDPR). If held separately, there must be a clear reference within the ISF to the location of any identifiable data to ensure it can be appropriately archived and destroyed when required. Medical notes generated as part of the research must also be archived and appropriately marked as being for research purposes.

3.2. Responsibilities

The Sponsor R&I Co-ordinator or Research Facilitator is responsible for costing archiving activities at the grant stage of a study (see SOP 51.010) and archiving arrangements should be described in the protocol (as per SOP 51.001) as well as the R&I Study Strategic Plan (Form 51.010E).

The Sponsor holds overall responsibility for ensuring the archiving of the TMF and ISFs. A designated individual will be appointed to manage the archiving process within NHSGGC, this role is typically undertaken by the Project Manager (PM), R&I Information Officer (IO), or their delegate. The IO or delegate will maintain a log of archived and destroyed files and will control access to archived materials. This log will be held centrally within the R&I common drive.

Responsibility for ensuring that the ISF (including documentation from local departments such as pharmacy) is complete and ready for archiving is delegated to the Principal Investigator (PI) and site via the Site Agreement (model Non-Commercial Agreement (mNCA)/ Organisation Information Document (OID)). Archiving of the ISF should follow local procedures, for NHSGGC sites, SOP 52.014 must be followed. In the absence of a PM, the IO will inform sites when the

ISF can be archived and/or destroyed, with support from Senior Research Administrators (SRAs) if the study involves more than 10 sites.

The Sponsor recommends that sites follow their local policies when documenting patient participation in non-CTIMP studies within medical records. The responsibility for archiving study data lies with the CI, although can be delegated to an accredited clinical trials unit.

3.3. Archiving Sponsor R&I TMF/eTMF

Archiving of the Sponsor's TMF/eTMF begins once the Sponsor R&I Co-ordinator or Research Facilitator receives formal acknowledgement of the End of Study Declaration from the Research Ethics Committee (REC), or Health Research Authority (HRA) for studies not requiring REC review (see SOP 51.005). The retention period for the study will begin from the date of this acknowledgement, unless otherwise specified in the protocol, and documents will be archived for the duration stated in the protocol, with a minimum of five years.

The Sponsor R&I Co-ordinator or Research Facilitator is responsible for ensuring that all essential documents are saved in the study's eTMF, using REC approvals and the Project e-File Checklist (Form 52.009D). For studies involving imaging beyond standard protocols, an Imaging Manual must be included in the eTMF (see SOP 51.034). The Sponsor R&I Co-ordinator or Research Facilitator must also complete the Sponsor Archiving Checklist for non-CTIMPs (Form 51.025A) and notify the SRA. The SRA will then update the study record in SReDA with the 'Actual End Date (Board)' and 'Location End Date' for each location within NHSGGC on SReDA as well as 'Archiving Proposed Destruction Date' (in the Pharmacy/custom tab on SReDA).

Once the study is ready for electronic archiving, the SRA will inform the IO and forward the completed checklist (Form 51.025A). The IO will verify that the checklist on Form 51.025A has been completed before transferring the Sponsor R&I eTMF and associated email folder into the designated 'Sponsor Archiving' folder. Following this, the IO will update the study record in SReDA by entering the 'Archiving Date' on the Project Information tab, thereby archiving the study entry within the database. The IO will maintain a log of archived files and will control access to archived materials. The Quality Assurance (QA) Manager may audit the 'Sponsor Archiving' folder and log of archived studies from time to time and will be given access to do so.

3.3.1. Archiving Collaborators and Supporting Departments TMF Sections

Additional departments may be involved in the study including Pharmacy, Pharmacovigilance, Monitoring, Project Management, Imaging, Data Management (e.g. RCB), collaborators or services. The SRA will contact each relevant department specified on Form 51.025A, using the template email on Form 51.025A, to initiate their respective archiving procedures. For internal NHSGGC departments such as Sponsor Pharmacy, PV and PMs, these files, or a copy where appropriate, will also be sent to the IO to archive along with the main R&I file. Archiving and retention of associated study documents held by external collaborators or services will be addressed within the contract with the with each respective organisation. These files must be stored securely and remain accessible for audit or inspection if required. Where documents are being archived separately to the Sponsor eTMF, the location should be documented on Form 51.025A by the Sponsor R&I Co-ordinator or Research Facilitator.

3.3.2. Access to Archived eTMF

Access to the password-protected archived eTMF will be granted to the IO and Sponsor R&I Co-ordinators and Research Facilitator. Any requests to review or obtain copies of archived files or specific documents within the eTMF must be directed to the relevant Sponsor R&I Co-ordinators or Research Facilitator. The Sponsor R&I Co-ordinator or Research Facilitator will assess the nature and purpose of the request to ensure it is appropriate. All reasonable requests will be accommodated, in line with Sponsor responsibilities and data governance standards.

3.4. Archiving of Participating Study Location ISFs

Archiving of ISFs, including medical notes generated as part of the research, is delegated to the PI or site team via the Site Agreement; however, the Sponsor retains overall responsibility for ensuring that archiving is completed appropriately. Once confirmation of the End of Study declaration has been received, as outlined in Section 3.3, the IO (in the absence of a PM) will notify all participating sites, including NHSGGC sites, listed in the Sponsor Archiving Checklist (Form 51.025A). This notification will be sent using the email template provided in Form 51.025A, and will include a 'read receipt' request to confirm delivery. The email will contain the relevant REC or HRA acknowledgment of the End of Study, along with the Form 51.025B Non-CTIMP Archiving Checklist for Sites to support the site team in preparing and archiving the ISF.

When there is a PM for the study, they will follow SOP 56.004 and the PM will notify the sites when they can proceed to archiving following site close out using Form 56.004A and Form 56.004B.

For archiving ISFs for NHSGGC sites, SOP 52.014 must be followed.

3.5. Destruction of Archived TMF/eTMF

The IO will run annual reports from SReDA to identify non-CTIMP studies that have passed their proposed destruction date. Once identified, the IO will notify the CI and study team listed on Form 51.025A that the study documents are due for destruction. If no response is received after three contact attempts over a minimum period of one month, the decision to proceed with destruction will be escalated to the Sponsor Systems Team.

If the CI or study team advises that the retention period should be extended, the IO will update the revised destruction date in SReDA and amend Form 51.025A accordingly. If there are any paper documents being held, a discussion must be had with the relevant Sponsor R&I Co-ordinators or Research Facilitator regarding any cost implications before this is extended. Once confirmation is received either from the CI, a member of the study team, or via approval at the Sponsor Systems Team meeting that the documents can be destroyed, the IO will update the date on Form 51.025A, delete the study's eTMF folder and mark the study as 'Destroyed' in the Pharmacy/custom tab on SReDA by ticking the appropriate checkbox. The IO will also inform the SRA and relevant Sponsor R&I Co-ordinator or Research Facilitator of the destruction date.

The SRA will contact each relevant department specified on Form 51.025A to initiate their respective destruction procedures using the template email on Form 51.025A. Destruction of associated study documents held by collaborators or services will be addressed within the contract with the respective body (see SOP 51.039).

The IO will maintain a log of all destroyed files and forward Form 51.025A to the QA Manager upon completion. This form will be retained indefinitely by the R&I department within NHSGGC on Q-Pulse.

3.6. Destruction of Participating Site ISFs

Once confirmation of destruction has been received, as outlined in Section 3.5, the IO will notify all participating sites, including NHSGGC sites, listed in the Sponsor Archiving Checklist (Form 51.025A). This notification will be sent using the email template provided in Form 51.025A, and will include a 'read receipt' request to confirm delivery.

4. Referenced Documents

- Form 51.025A - Sponsor Archiving Checklist (for non-CTIMPs)
- Form 51.025B - Non-CTIMP Archiving Checklist for sites
- SOP 51.001 - Protocol Development
- SOP 51.005 - R&I End of Study Procedures
- SOP 51.010 - Preparation and Review of Grant Applications and Costs
- SOP 51.024 - Archiving Essential Documents from Clinical Research – Process for a GGC Sponsored/Co –Sponsored Clinical Trial of an Investigational Medicinal Product (CTIMP) and/or Clinical Investigation of a Medical Device (CIMD)
- SOP 51.034 - Writing a Trial Specific Research Imaging Manual for Sites Participating in Clinical Trials of an Investigative Medicinal Product (CTIMP) Sponsored by NHS GG&C or Co-sponsored by NHS GG&C and University of Glasgow (UoG)
- SOP 51.039 - Contracts Management for Research Sponsored by NHSGGC or Co-Sponsored by NHSGGC and the University of Glasgow
- SOP 52.014 - Archiving Essential Documents from Clinical Research – Process for Hosted Research
- SOP 56.004 - Project Management Trial Site Close-Out
- Form 51.010E - R&I Study Strategic Plan
- Form 52.009D - Project File Checklist
- Form 56.004A - Site Close Out Checklist Template
- Form 56.004B - Close Out Email Template

5. Related Documents

- https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/research-ethics-committee-review/applying-research-ethics-committee/sl-ar2/
- GUI 57.005B - GCRF Archiving Process
- PTS-TM-6: Archiving of Clinical Trial Documentation

6. Document history

Version	Date	Description	Retrospective Implementation
1.0	12/04/18	Release of First Version	No
2.0	28/11/2025	Update to SOP and Forms to clarify staff roles	No