

SOP number	51.042	Version	1.0
Title	Preparation and Maintenance of a Non-CTIMP Sponsor e-File		

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SOP category	NHS GG&C Sponsor R&I			
Staff category				
Staff Category	R	A	C	I
Systems & Operations Manager		X		
Research Governance	X			
Sponsor R&I Co-ordinator	X			
Sponsor Research Facilitator	X			
Senior R&I Administrators	X			
R&I Sponsor Pharmacy	X			
Project Management	X			
University of Glasgow Research Regulation and Compliance team			X	
Data Management				X
Chief Investigator				X

1. Scope

This SOP applies to all non-CTIMP research studies sponsored by NHS Greater Glasgow & Clyde (NHSGGC) or co-sponsored with University of Glasgow (UoG). This SOP describes the process for creating, maintaining and quality-checking the Sponsor e-file, which serves as the Sponsor's official record of trial conduct. NHSGGC does not maintain the same paper Trial Master File (TMF) for non-CTIMPs as it does for CTIMPs (SOP 51.016). Instead, a proportionate Sponsor e-file is maintained to demonstrate compliance with governance, legal, and Sponsor oversight requirements in line with the UK Policy Framework for Health and Social Care Research and the HRA Non-CTIMP Standard Conditions.

2. Purpose

To ensure all NHSGGC-Sponsored non-CTIMP studies maintain a proportionate, accurate and complete Sponsor e-file that: demonstrates appropriate Sponsor oversight; supports transparency requirements (registration, reporting and end-of-study notifications), evidences contractual and governance compliance, including information governance (DPIA/DPAs) and vendor management and enables reconstruction of study conduct, oversight and decisions.

3. Procedures

3.1. Definitions

- **Non-CTIMP:** Research not falling under the Medicines for Human Use (Clinical Trials) Regulations.
- **Sponsor e-file:** The Sponsor's central electronic repository of essential governance and oversight documentation for non-CTIMP studies.
- **Essential documents:** Documents and records that enable evaluation of study conduct and data integrity.

3.2. Overview of the Sponsor e-File

The Sponsor e-file is an electronic-only file structure (unless specified otherwise) used for all non-CTIMP studies. It is located in the NHSGGC R&I secure common drive and accessible only to authorised personnel. The Sponsor e-file typically includes the following (exact content may vary depending on the study type as proportionality applies):

- Governance / Sponsorship Documents
- Contracts & Agreements
- Financial Documents
- Study Management & Oversight
- Modifications
- Safety Oversight (risk assessment, protocol deviations etc.)
- Information Governance (DPIA, SSP etc.)
- End of Study & Archiving

Communications and decision-making emails will be held in Sponsor shared email inbox.

3.3. Responsibilities

The Senior Research Administrator (SRA) is responsible for creating the Sponsor e-file when sponsorship is confirmed (as per SOP 51.007). They ensure that the appropriate folder structure is applied, correct naming system is used (as per SOP 50.009) and initial documents uploaded. The Sponsor Research Co-ordinator, Innovation Co-ordinator or Sponsor Research Facilitator (SRC/IC/SRF) ensures that all decisions, approvals and oversight activities are filed in a retrievable format and conducts periodic file checks throughout the lifecycle of a study. The Chief Investigator (CI) is responsible for providing up-to-date versions of the protocol and other study documents and any other documents required for Sponsor oversight.

3.3.1. Additional Teams (as applicable)

If a Monitor is involved in the study, all monitoring and safety-related documentation will be stored on the NHSGGC secure common drive, with access restricted to authorised personnel. Where R&I Pharmacy are involved, pharmacy-related documentation will likewise be maintained on a separate pharmacy section for non-CTIMPs in the NHSGGC secure common drive with controlled access. If a Project Manager is assigned, they will support the maintenance of project management and location-related documentation in accordance with SOP 56.002. External vendors including, but not limited to, data management services and laboratories, will maintain their own operational records. They are responsible for supplying any contractual or governance-related documentation required for inclusion in the Sponsor's e-file such as contracts or service agreements where applicable (see SOP 51.015). Vendors are expected to maintain their own study documentation unless the contract states otherwise.

3.4. Preparation of the Sponsor e-File

When preparing the Sponsor e-file, the SRA creates the file structure from the template saved in the common drive: "\\northnet-11\wg-research\common\SPONSOR PORTFOLIO\Template E-folder - Sponsor Non-CTIMPS" and uploads the initial set of documents, including draft funding application, Form 51.010A: Costs for Non-Commercial and Project File Checklist (Form 52.009D). The Project File Checklist must be completed by the SRA prior to local R&I Management Approval and SRC/SRF must complete the 'Extended Sponsor Process' prior to Sponsor Green Light. The CI and relevant project staff are notified by the SRC/SRF of the documentation required for the file including R&I Study Strategic Plan (Form 51.010E).

3.5. Maintenance of the Sponsor e-File

Throughout the study, the Sponsor e-file must be maintained in real time. All study documents must be stored as controlled versions and uploaded as soon as they become available. This includes, but is not limited to, the protocol, Participant Information Sheet (PIS), Informed Consent Form (ICF), and all other supporting documentation. Only one version of the document must be present in the folder with a clear naming convention to allow for its easy identification. When a document is updated, the previous version must be moved to a dedicated 'Superseded' sub-folder.

The e-file must also include all Sponsor oversight documentation, such as the risk assessment (Form 51.004B) and all required approvals (e.g. REC favourable opinion, HRA, ARSAC, Caldicott, PBPP or CAG). Where applicable, the Clinical Research Imaging Support Form (Form 58.004A), Laboratory Categorisation Form (Form 51.028A), deviations and serious breach assessments (as per SOP 51.008) must also be filed.

Where required, the Sponsor e-file must also contain evidence of study registration (per SOP 51.017), evidence of peer review (as per SOP 51.003), modification documentation (per SOP 51.021), safety communications, and end-of-study notifications (per SOP 51.019). For information governance, this includes DPIAs, IT risk assessments (such as SSPs or CSSPs), data processor contracts, and data-sharing agreements, where applicable.

All contracts and agreements (as outlined in SOP 51.039), along with financial documentation including the submitted application, award confirmation, SoECAT or Schedule of Events, Form 51.010A, and NHS costings must be stored in the Sponsor e-file, where applicable.

When additional clarification or context is required, a file note is added to the Sponsor e-file using the file-note template (Form 51.016M). File notes may be used to explain missing documentation, describe decision-making or clarify events, but they cannot replace non-compliance reports or grant protocol waivers.

3.6. Investigator Site File (ISF)

Although non-CTIMPs do not require a full Investigator Site File (ISF) equivalent to a CTIMP, the CI and study locations are advised to maintain an ISF under their own institutional procedures. Principal Investigator Site File Index (non-CTIMP): Template (Form 56.001H) can be supplied and tailored as appropriate.

3.7. Quality control

Quality Control of the Sponsor e-file will be conducted at study setup, periodically while the study is open and at study close-out, before archiving. QC reviews check that required sections are complete, documents are version controlled, decisions are traceable and file access remains appropriate. Issues identified during QC reviews or audits must be addressed promptly and escalated to the Sponsor Governance Manager when required.

3.8. Archiving

Essential Documents in Sponsor e-File will be archived according to SOP 51.025. As local policy, the minimum retention period is 5 years unless stated otherwise in the IRAS form or protocol.

4. Referenced documents

- SOP 50.009 - Project Numbering
- SOP 51.003 - Peer Review
- SOP 51.008 - Handling non-compliance with Good Clinical Practice (GCP) and/or the trial protocol in clinical research sponsored, co-sponsored or hosted by NHS Greater Glasgow and Clyde
- SOP 51.007 - Identifying a Sponsor Organisation
- SOP 51.015 - Assessment of Vendors
- SOP 51.017 - Registration of research projects on public databases
- SOP 51.019 - Sponsor – End of Study Procedures
- SOP 51.021 - Review and Approval of Amendments for Research Sponsored by NHSGGC or Co-Sponsored by NHSGGC and the University of Glasgow
- SOP 51.025 - Archiving Essential Documents for Non-CTIMP Research Studies Sponsored or Co-Sponsored by NHS Greater Glasgow & Clyde and the University of Glasgow
- SOP 56.002 - Project Management Trial Set-up
- Form 51.004B - Risk Assessment for Research Studies sponsored by NHS GG&C
- Form 51.010A - NHS Project Costs for Non-Commercial Research
- Form 51.010E - R&I Study Strategic Plan
- Form 51.016M - TMF/ISF File Note
- Form 51.028A - Categorising Laboratory Tests undertaken within Research Projects Sponsored by NHS GG&C or Co-Sponsored by NHS GG&C and University of Glasgow
- SOP 51.039 - Contracts Management for Research Sponsored by NHSGGC or Co-Sponsored by NHSGGC and the University of Glasgow
- Form 52.009 - Project File Checklist
- Form 56.001H - Principal Investigator Site File Index (non-CTIMP): Template
- Form 58.004A - Clinical Research Imaging Support Form

5. Related documents

- None

6. Document history

Version	Date	Description	Retrospective Implementation
1.0	08/04/2026	Release of first version	No

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