SOP number	**53.009**	Version	**3.0**
Title	**Preparation and Maintenance of a Clinical Trial Monitoring File**		

Prepared by Signature	Sheila M^{c}Gowan Date
Approved by Signature	Caroline Watson Date
Released by Signature	Jesse Dawson Date

SOP category	NHS GG&C Sponsor Governance

Staff category

Staff Category	**R**	**A**	**C**	**I**
Clinical Trial Monitor	X			
Lead Clinical Trial Monitor		X		
Research Governance Manager			X	
Project managers				X
R&I co-ordinators				X
Governance Facilitator		X		

1. Scope

This procedure applies to NHSGCC Research Governance Clinical Trial Monitors.

2. Purpose

The purpose of this SOP is to describe the process for preparation and maintenance of a Clinical Trial Monitoring file. The monitoring file is a main component of the Trial Master File (TMF) and makes up Section 12 of Form 51.016A. This will be stored, prepared and maintained by the Clinical Trial Monitoring team.

3. Procedures

3.1. Monitoring File Preparation and Storage

The assigned Clinical Trial Monitor will be primarily responsible for the preparation and storage of the monitoring file. The Clinical Trial Monitoring File Index (Form 51.016A – Section 12) will be followed when preparing the file and also when preparing any additional folders for multi-site trials throughout the duration of the study. In case of the monitoring file being spread across multiple folders, they must be labelled to ensure no loss of documents e.g. 1 of 12. The monitoring file must be securely stored and kept within the Governance cabinet within the locked storage at all times. Along with the hard file, a mirrored electronic copy will also be prepared and stored within the appropriate study folders of the R&I shared drive.

3.2. Maintenance of the Monitoring File

The assigned Clinical Trial Monitor will be responsible for the continuous maintenance of the Monitoring File and must follow the guidance detailed in SOP 51.016 and 50.017 at all times. All monitoring related documents must be filed in sequential order as per the index within each section with the most recent at the top. The fully executed/current version of a document must be stored in the monitoring file alongside all superseded documents, and all partially executed versions will be stored electronically in the R&I shared drive for the purposes of an audit trail. Monitoring visit reports will not be kept as hard copies in the monitoring file as they are held electronically on Q-Pulse.

Hard copies of completed Protocol Deviations will be filed in section 12.3.1.2. IV of the monitoring file according to site. Electronic copies will be held in the shared drive and uploaded to their corresponding Q-Pulse file when closed. A hard copy of the Protocol Deviation log (Form 51.008C) will also be filed in section 12.3.1.2. V, Trial deviations/Non-Compliances triaged by the CTM and/or involving monitoring will also be stored in section 12.4, refer to SOP 51.008.

All relevant email correspondence will be stored in the 'Monitoring Group, RandD' mailbox and filed in appropriately titled folders to ensure they are easily accessible and archived. If a piece of correspondence is particularly relevant to a specific document (i.e. CI opinion for a Protocol Deviation classification), it may be attached to the document and stored in the monitoring section of the TMF. However, whenever possible any additional or late information provided by study personnel should be recorded on the original document and replaced as either the fully executed or most up to date version of the document in the monitoring file.

3.3. Handover of Responsibilities

In the event that the assigned Clinical Trial Monitor changes, the responsibilities will be handed over according to SOP 53.006 and Form 53.006A and this will be filed in section 12.5.

3.4. Archiving of Monitoring File

The Monitoring file will be archived according to SOP 51.024.

4. Referenced documents

- 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 50.017 – Research & Innovation Document Management
- SOP 51.016 - Preparation and Maintenance of a Trial Master File
- 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 53.006 - Handover Checklist Process
- Form 51.008C - Protocol Deviation Log
- Form 51.016A – Sponsor TMF Index
- Form 53.006A - Handover Checklist Form

5. Related documents

- SOP 53.004 - Monitoring Clinical Trials

6. Document history

Version	Date	Description
1.0	11/12/2018	Release of first version
2.0	25/08/2022	Formatting and R&I name update
3.0	08/09/2025	Periodic review and RACI added

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