Standard Operating Procedure			**53.009**
Preparation and Maintenance of a Clinical Trial Monitoring File			
Version	2.0		
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1. SOP Category
NHS GG&C Sponsor Governance

2. Staff Category
- Sponsor Research Co-ordinators
- Clinical Trials Monitors
- Lead Clinical Trial Monitor
- Research Governance Manager
- R&I Project Managers
- Glasgow University Project Managers

3. Scope
This procedure applies to NHS Greater Glasgow and Clyde Research Governance.

4. 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 will be stored, prepared and maintained by the Clinical Trials Monitoring team.

5. Procedures
5.1. 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 51.016F) should be followed when preparing the initial file and also when preparing any additional folders for multi-site trials throughout the duration of the study. The monitoring file should be securely stored and kept within the Sponsor Clinical Trials Governance office at all times. Along with the hard file, a mirrored electronic copy should also be prepared and stored within the appropriate study folders of the R&I shared drive.

5.2. Maintenance of the Monitoring File
The assigned Clinical Trial Monitor will be responsible for the continuous maintenance of the Monitoring File and should follow the guidelines detailed in FORM 51.016F at all times. All study documents should be filed in sequential order as per index within each section with the most recent at the top. The fully executed/most up to date version of a document should be stored in the monitoring file, all superseded or partially executed documents should be stored electronically in the R&I shared drive and associated TMF section for the purposes of an audit trail.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 and uploaded on to Q-Pulse.

Hard copies of completed protocol deviations will be filed in section 4 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 closing, as well as sent back to site for storage in their ISF. A hard copy of the protocol deviation log (FORM 51.008C) will also be filed in section 4, reviewed and signed-off by the CI on a monthly basis. Only the most recent log will be held in the

monitoring file as a hard copy, superseded versions will be removed and stored electronically in the shared drive.

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 file. 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.

5.3. 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.

5.4. Archiving of Monitoring File

The Monitoring file will be archived according to SOPs 50.014 and 51.006

6. Referenced documents

- SOP 50.014 - Archiving Completed Study Documentation
- SOP 51.006 - Archiving Essential Documents from Clinical Research – Process for Sponsored and Hosted Research
- SOP 53.006 - Handover Checklist Process
- Form 51.016F - Clinical Trial Monitoring File Index
- Form 51.008C - Protocol Deviation Log
- Form 53.006A - Handover Checklist Form

7. Related documents

- SOP 51.016 - Preparation and Maintenance of a Trial Master File
- SOP 53.004 - Monitoring Clinical Trials

8. 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