SOP number	**53.006**	Version	**3.0**
Title	**Monitoring Handover Checklist Process**		

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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	
R&I Co-ordinators				X
Project Managers				X

1. Scope

This procedure applies to NHSGGC Research Governance Clinical Trial Monitors (CTM).

2. Purpose

The purpose of this SOP is to describe the process the monitoring department will comply with when a trial is transferred from one CTM to another, for example, when a person leaves the department or workload challenges. The process should ensure the team member receiving the new trial is fully informed on the history and ongoing information as detailed in the associated checklist.

3. Procedures

When a trial responsibility is reassigned from one CTM to another there must be a transfer of the knowledge and history of the trial, if feasible, this handover should take place when the previous CTM is still available (e.g. prior to retirement etc.). If a CTM needs to cover work during a long term sickness then it is not expected the handover process will be completed, unless this is a maternity leave where the length of time is known for absence. If it is not feasible to carry out a handover with the previous CTM present then the Lead CTM/RGM must complete the handover documentation to ensure that trial background is provided and the current CTM must ensure they are trained (e.g. Protocol and SIV slides) and document this training. The handover checklist Form 53.006A must be completed and a meeting must be set up to discuss the checklist. A checklist should be completed for each trial, if multiple trials are being transferred.

The previous CTM, or Lead CTM if required, will complete the handover checklist with the following to be covered:

- Monitoring plan – versions and locations
- Sites information – number and location
- Trial overview – monitoring process, CRF type, IMP information, data centre
- Data reports available and frequency
- TMG information
- Ongoing trial and site issues
- Trial contacts and essential document version(s)
- Visit tracker/status
- ISF tracker
- Protocol Deviations in progress
- Q-Pulse actions in follow up/status (contact QA to re-assign)
- TMF status i.e. is filing up to date and timeline
- Any relevant documents used in monitoring the trial

A meeting will be conducted between both team members to facilitate the handover of the trial(s) utilising the checklist. The Lead CTM/RGM should be present and both CTMs must sign the checklist off once the handover has been fully completed. The checklist must be filed in section 12.5 of the Monitoring TMF.

The previous CTM, or Lead CTM if required, will send an email to all stakeholders on the trial (one for each trial) to notify the team that a handover has taken place and copy the new CTM into the email to introduce them and help facilitate required training for the new CTM (e.g eCRF training and access to the database). This will be filed in the TMF correspondence alongside the handover documentation.

4. Referenced documents

- Form 53.006A - Handover Checklist Form

5. Related documents

- SOP 53.004 - Monitoring Clinical Research – Site Monitoring visit

6. Document History

Version	Date	Description
1.0	11/12/2018	Release of first Version
2.0	25/08/2022	Update of author as per the Process development SOP, formatting, filing location and addition of Form reference.
3.0	08/09/2025	Update of terms, RACI added and TMF location.