Standard Operating Procedure			**53.006**
Monitoring Handover Checklist Process			
Version	**2.0**		
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Released by	Julie Brittenden	Signature	Date

1. SOP Category
NHS GG&C Sponsor Governance

2. Staff Category
Research Coordinators
Clinical Trials Monitors
Lead Clinical Trial Monitor
Research Governance Manager

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 the monitoring department will comply with when a trial is transferred from one team member to another, for example, when a person leaves the department. 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.

5. Procedures
When a trial responsibility is reassigned from one team member to another there should be transfer of the knowledge and history of the trial, if feasible this handover should take place when the old and new team members are still available. The handover checklist Form 53.006A must be completed and a meeting should be set up to discuss the checklist. A checklist should be completed for each trial, if multiple trials are being transferred. Alternatively, if a group of trials are aligned a single checklist may be used if appropriate.

The old monitor will complete the handover checklist with the following to be covered:

- Monitoring plan
- Sites information – number and location
- Trial overview – monitoring process, CRF type, IMP information
- Ongoing trial and site issues
- Trial contacts and essential document version(s)
- Protocol Deviations in progress
- Q-Pulse actions in follow up/status

A meeting will be conducted between both team members to facilitate the handover of the trial(s) utilising the checklist. The line manager for each team member should be present and both team members must sign the checklist off once the handover has been fully completed. The checklist must be filed in section 5 of the CTM TMF section.

The old monitor 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 monitor into the email to introduce them.

6. Referenced documents

FORM 53.006A: Handover Checklist Form

7. Related documents

SOP 53.004 Monitoring Clinical Research – Site Monitoring visit

8. 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.