SOP number	**50.016**	Version	**5.0**
Title	**Trial of New Processes Within NHSGGC R&I**		

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Approved by Signature	Caroline Watson	Date
Released by Signature	Jesse Dawson	Date

SOP category	NHS GG&C General
Staff category	

Staff Category	**R**	**A**	**C**	**I**
R&I Quality Manager		X		
All Clinical Research & Innovation Staff				X

1. Scope

This procedure applies to NHS Greater Glasgow and Clyde (NHSGGC) R&I Department

2. Purpose

The purpose of this SOP is to describe how to manage the trial of new processes in advance of official release of the new or updated process within the QMS. This can be used with SOPs, Forms, Guidelines or any other form of controlled documentation or process.

In the event a new process is to be trialled which requires a variation of activity currently detailed in an SOP or for an entirely new process, the steps outlined in this SOP must be followed. The benefit of the trial is to establish effectiveness and suitability of the process in a controlled manner ahead of official release in an SOP.

3. Procedures

3.1. When a New Process Is Needed

An update to an existing process or introduction of a new process does not require the use of a trial period as outlined in this SOP. If sufficient information or experience is available to directly update an existing process or introduce a new one it is possible to release this within the QMS with no trial period. However, in the event there is insufficient information available to be sure of what the final process will be, a trial period can be used to gather real world information to better inform the process.

The creation of a new process or update to an existing one may be required when instructions do not currently exist to sufficiently describe or control a required activity. This can be identified in a number of different ways e.g. Changes to regulations, introduction of a new activity, through Non-Compliances and the subsequent investigations into root cause or as highlighted through audit or from feedback of stakeholders involved in the process. These trigger points may then lead to development of new or updated processes which require a trial period.

3.2. Process Development Cycle

The process development lifecycle used within R&I follows the Plan Do Check Act methodology which will be described within this SOP, this allows for refinement of processes before official release within an SOP which leads to a more efficient process.

3.3. Process Development Plan

3.3.1. Process Development Plan Creation

The creation of a Process Development Plan is the first step in developing the new or updated process. This is documented using the Process Development Plan template, Form 50.016A. Detailed instructions on how to complete this can be found in the Guidelines for this process, Guideline 50.016A.

The form includes a table at the beginning which asks for some defining details relating to the plan to be completed, each plan will be submitted to QA to be recorded on Q-Pulse to track progress and assign a unique identification number. Once this number is assigned, a copy will then be returned to the Author.

The Author will have to give basic details relating to the plan. They will be asked for the following details:

Author	Who is the assigned Author for the Plan?
Title	What is the Title of the Process?
New or Updated	Is this a new Process or an Update to an existing one?
Submission Date	The date at which the plan is being submitted
Target End Date	When is the plan to end the trial?
Scope	Scope: How wide will the trial be followed, will this be followed by everyone in R&I or on a more limited scale?
Type	This allows the Author to identify if the intention is to produce an SOP, Form, Guideline, Other or a mixture of each.

3.3.1. Engaging Stakeholders

During the development of a new process, the appropriate list of stakeholders must be identified and sufficiently engaged and consulted through the development lifecycle by the author. Stakeholders can be identified by considering areas impacted or consulted through the process activity. If in doubt about an areas involvement, the author should share with relevant senior managers and organisational representatives to determine impact to them. Those involved in the aspects of the process under development must be provided with an opportunity to be involved with its creation for the purpose of giving factual input to requirements and limitations of activities involved. Stakeholders must remain engaged during development, trial and completion of the process. Stakeholders will have the opportunity to provide information and content to the process with the ultimate authority remaining with the Author, although the aim will always be to try achieve consensus.

3.3.2. Deviation from Existing Process

In the event the New or Updated Process requires a deviation from an existing SOP, an Exception Form will be required, the process for which is detailed in SOP 50.023. For R&I, Form 50.023B is filed centrally with the R&I QA Manager in Q-Pulse.

3.3.3. Management of Timescales

The timescales stated within the plan will be managed through Q-Pulse, a reminder that the end of the trial phase is approaching will be sent to the Author and QA Manager within 1 month of the final date. If the trial phase goes beyond the stated timescale, reminders will be sent.

3.3.4. Review and Approval of Plans

The Process Development plan will be reviewed by the relevant senior R&I Manager, who may consult other relevant members of R&I staff before giving their approval. The plans will then be electronically signed in Q-Pulse by the Author and the approving R&I Manager prior to the commencement of the trial phase of the process.

3.3.5. Process Development Plan Completion

On completion of the trial phase of the New or Updated process, if the outcome of the trial is found to be favourable then a new SOP can be created, or an existing SOP updated by following SOP 50.023. If however further work is required in the development of the process, Form 50.016A can be updated to reflect this and the relevant changes applied and the duration of the trial period extended accordingly. This will be subject to further management approval.

4. Referenced documents

- Form 50.016A - Process Development Plan Template
- Guideline 50.016A -
- SOP 50.023 - Management of SOPs within NHS GG&CNHSGGC R&I
- Form 50.023B - Deviation from NHSGGC R&I SOPs Permission Request

5. Related documents

None

6. Document History

Version	Date	Description
1.0	29/6/15	First version
2.0	14/07/16	Renumbered SOP
3.0	09/10/2019	Minor clarifications to process and changed author
4.0	31/03/2022	Update to process to include Q-Pulse and change of Author.
5.0	09/09/2025	Minor updates, clarification of when this process is to be followed.

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