Standard Operating Procedure			**50.016**
Development of new processes within NHS GG&C R&I			
Version	4.0		
Prepared by	Paul Gribbon	Signature	Date
Approved by	Caroline Watson	Signature	Date
Released by	Julie Brittenden	Signature	Date

1. SOP Category
NHS GG&C General

2. Staff Category
All Clinical Research & Innovation Staff

3. Scope
This procedure applies to NHS Greater Glasgow and Clyde (NHS GG&C) R&I Department

4. Purpose
The purpose of this SOP is to describe the implementation of new processes with a trial period in advance of a formal process or update being available. This trial period allows for practical implementation of a process in a controlled format to get real world information relating to the effectiveness of the process. This can be used with SOPs, Forms, Guidelines or any other form of controlled documentation or process. The trial period of a process is not a requirement in all instances, a new process may be developed and released without the need for an initial trial period as detailed in SOP 01.006. In the event a new process is to be trialed 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.

5. Procedures
5.1. 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.

5.2. When a New Process Is Needed
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. 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.

5.3. Process Development Plan
5.3.1. 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, GUI 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.

5.3.1. 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 organizational 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, this may be recorded through the use of SOP 50.019. 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.

5.3.2. 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 01.007. For R&I, Form 01.007A is filed centrally with the R&I QA Manager in Q-Pulse.

5.3.3. 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 until an appropriate version of Form 50.016B is received and escalated as required to reach a conclusion.

5.3.4. 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.

5.3.5. Process Development plan completion

On completion of the trial phase of the New or Updated process, Form 50.016B should be completed with the relevant findings and evidence of the effectiveness of the process. If the outcome of the trial is found to be favorable then a new SOP can be created, or an existing SOP updated by following SOP 01.006. If however further work is required in the

development of the process, Form 50.016B can be completed 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.

6. Referenced documents

FORM 50.016A Process Development Plan Template
FORM 50.016B Process Development Plan Appraisal Template
SOP 01.006 Production and Maintenance of Standard operating Procedures, Guidelines and Forms
SOP 01.007 Deviation from Standard Operating Procedures (SOPs)
SOP 50.019 Independent Stakeholder Assessment

7. Related documents

None

8. 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.