Standard Operating Procedure			***50.023***
Management of SOPs within NHS GG&C R&I			
Version	***1.0***		
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

Staff Category	R	A	C	I
All Research and Innovation Staff	X			
Quality Assurance Manager		X		

3. Scope
This procedure applies to all staff within NHS GG&C R&I.

4. Purpose
The purpose of this Standard Operating Procedure (SOP) is to detail the process by which SOPs owned by NHS GG&C R&I are produced and managed.

5. Procedures
The production, management and issuance of SOPs will be conducted in compliance with SOPs 01.005, 01.006 and 01.008 which are applicable to all of the Glasgow Clinical Trials Unit (GCTU). Deviation from GCTU SOPs will be managed in accordance with SOP 01.007.

5.1. SOP Signatories
In line with SOPs 01.005, 01.006 and 01.008, all SOPs must have 3 signatories to allow for their release. Each of these signatories have a specific role to play in the process of the development and release of the SOP in question which are detailed below and in SOP 01.006. The sign off of a SOP can be completed through the use of electronic sign off in Q-Pulse, the signatures must occur sequentially in the order designated on the SOP (e.g. 'approved by' date cannot occur before 'prepared by' date), and have a record of the date of each approval. Associated Forms and Guidelines only require sign off by the "Prepared By" and "Approved By" signatories as per SOP 01.006.

5.1.1. Prepared by
This signatory is the Author of the SOP, they are responsible for writing or updating the content of the SOP and must do this in co-operation with the relevant stakeholders for the SOP as detailed in the Staff Category section. The title of "Author" is reflective of the "Prepared By" name as it appears on the SOP, "Owner" is an additional field present in Q-Pulse to show who the document has been assigned to and is described in section 5.1.1.1. Any individual assigned as Author/Owner must be knowledgeable, experienced and appropriately trained in the relevant process area to take on ownership. There is no exclusion on updating the SOP solely for this purpose if it is preferred.

As this individual is responsible for writing the content of the SOP they must be suitably trained and experienced in relevant process. It is not necessary for the Author to be directly involved with the completion of the assigned activity, however they must include the input of those who are. Examples of this type of scenario relate largely to process areas for

Governance and Quality wherein the process will be owned by Governance or Quality but activities completed by other members of staff.

As an SOP can have associated Forms and Guidelines it will most commonly be the Author of the SOP that acts as the Author for the associated Forms and Guidelines as well. However, there may be occasional scenarios in which an associated document has a different Author, typically in the scenario described above relate to processes which involve Governance and or Quality activity. In this instance it is a requirement that there is agreement in the content of the associated document between both Authors.

5.1.1.1. Owner

Generally the Owner will be the same name as the Author, however, if the author of an SOP is required to be changed due to the original author no longer being in role for example, it is not required to release a new revision of an SOP in the absence of any other changes to the SOPs content to capture this. The Owner field in Q-Pulse can be changed to the new individual and the Author retained as the previous name until such a time that the content of the SOP is to also be updated. This mechanism can also be utilised if a member of staff is not available through a prolonged period of absence, i.e. long term sick or secondment. The Author field of the SOP can remain unchanged and the Ownership assigned to another appropriate member of staff to answer any questions or manage the responsibilities associated with the SOP while the original author is not available. If the SOP requires to be updated in this time period, the authorship can be changed to a new name while the original author is not available.

5.1.2. Approved By

This signatory will be the most appropriate functional head relevant to the content of the SOP, as some SOPs will cover more than one functional area there may be more than one appropriate option. The SOP will always be reviewed by a more senior individual with knowledge of the subject area, who will sign the 'approved by' section of the SOP.

The role of the approver is to act as a final reviewer of the content of the SOP relevant to the functional area and ensure it is appropriate. The Approved By signatory will review the final draft of the SOP, ensuring its content is accurate and appropriate before signing to show their approval of the content. Any named approver must appear in the "Accountable" section of the staff category table and will have been consulted as part of the SOP development.

5.1.3. Released By

This is the final signatory in the release of a SOP and is the responsibility of the Director of R&I or an appropriate designee, as determined by the Director. This is intended as a final control in the release of SOPs to ensure they are appropriate for release and in line with the requirements for the R & I Quality Management System. The Released By Signatory will review the SOP and its content to ensure they are satisfied the content is accurate and appropriate before signing to show their approval of the content.

5.2. Staff Categories

It is a requirement in SOP 01.005 that all staff which are required to be trained in the content of the SOP are detailed within the Staff Category, this may include staff external to R&I which must be considered during the development of the SOP. The list of titles to be used in the Staff Categories must be uniform and controlled centrally by the Quality Assurance Manager to ensure consistency as it relates to the use of Q-Pulse. The list of selectable titles or groups will be controlled by the managed list within Q-Pulse. SOPs prepared and managed by NHS GG&C R&I will further define relevant staff groups through the use of a RACI matrix to detail the relationship they hold with the SOP. When determining both the content of an SOP and the staff to be listed in a RACI, the consent and agreement of those mentioned should be achieved. It is good practice to have agreement from a group that the actions detailed with the SOP are fair and reflective of the work expected of them

and is achievable. Special care must be taken in this regard to groups external to R&I as they may have existing SOPs in place to govern their activity, this will be the responsibility of the author to consult with proposed groups to be represented in staff category to review the content and for these groups to then inform of any existing processes they follow.

The benefits of using the RACI format beyond its link to the Read and Comprehend and Notify activity is to detail the relationships and interactions between different groups of staff and the defined process, for example the additional granularity in detail between Consulted and Informed is the implication of the exchange of information between those consulted with those responsible as opposed to informed simply being aware the activity takes place.

Responsible
This descriptor is used to identify which staff category is involved in the conduct of the activity outlined within the SOP. As a result, if a staff category is identified as Responsible they must complete a Read and Comprehend record for the SOP, either through Q-Pulse or in appropriate paper records at the site level. As part of the stakeholder review process, any groups mentioned as responsible for completing an action must be in agreement that this action is appropriate.

Accountable
This descriptor is used to identify which staff category holds an ownership of the activity outlined within the SOP. This category may not be directly involved in the completion of the required activity however they will have objectives or deliverables which must be met as part of their role through the conduct of the activity. Some SOPs may cover several functional areas and as such may have several staff categories appropriate to be listed as Accountable, however, only one group can be listed as accountable and others reflected within another appropriate section of the RACI. As a result, if a staff category is identified as Accountable they must complete a Read and Comprehend record for the SOP, either through Q-Pulse or in appropriate paper records at the site level.

Consulted
This descriptor is used to identify which staff category may be consulted in the development of the procedure or through the completion of the associated activities. They will not be directly responsible for the completion of activities or named within the SOP, however their expertise may be sought by those who are required to do so. As a result, it is not required to complete a Read and Comprehend record for the SOP. Instead, a record of being notified of the SOP is all that is required.

Informed
This descriptor is used to identify which staff category must be kept informed of the progress or outcome of an activity. As a result, it is not required to complete a Read and Comprehend record for the SOP. Instead, a record of being notified of the SOP is all that is required.

5.2.1. Migration to new format

As all existing SOPs are currently released and do not contain a RACI matrix in section 2 – Staff Category, Form 50.023A will be used by the Quality Assurance Manager to store a live record in Q-Pulse showing the appropriate RACI for each SOP as the distribution records are updated on Q-Pulse, this will be used as SOPs are distributed avoid the need for mass update of SOPs. The RACI will be introduced through natural evolution of SOPs over time, at which point this section will be removed from this SOP and Form 50.023A made obsolete.

5.3. Change Requests

A functionality is available in Q-Pulse for individuals to raise a Change Request against a document, this can be for many different reasons and levels of severity. If an internal stakeholder of a document has a question about the content, a suggestion for an improvement or details of a relevant experience from the use of the document they are able to raise a Change Request. External stakeholders may also raise questions or suggestions by contacting the document Owner or the R&I Quality Assurance Manager who will raise the Change Request on their behalf. This Change Request will act as a record of this information and will then be utilised by the Author of the SOP for further development. If the Change Request is urgent, the Author is able to complete an update immediately and introduce the change in a timely fashion. However, if the Change Request is less urgent the author can leave the suggestion until the next natural review period of the document, at this time the information will be retained and made available to them to choose to incorporate or not. The author of an SOP is notified each time a change request is raised against an SOP. The individual raising can set a priority level of Low, Medium or High which the Author can then review and change if required and set an "Implement By" date.

5.4. Review of SOPs

The review of all SOPs and associated forms or guidelines must be carried out on a recurring basis. At a maximum, 3 years between reviews may elapse. As some SOPs may be more critical than others, it is possible to set a more stringent review period for individual SOPs, this will be the decision of the Author of the SOP. The review period of associated documents for a SOP (Forms and Guidelines) will also take place at the same time as any review of the SOP. **SOPS, Forms and Guidelines must remain aligned at all times**

The review periods for SOPs will be managed through Q-Pulse and an "Active Date" and "Review Date" will be held in each Document record. A review of the document will be created in the document record, as detailed in Guideline 50.023A, this will allow the Author to assign all the relevant stakeholders as detailed in the RACI matrix of the SOP as well as any others deemed necessary. Their review and feedback of the document can then be captured and utilised by the Author to determine if an update to the SOP is required.

In the event the feedback from the stakeholders results in the determination that no update is required, the review can be completed with the outcome of "No Change". This will result in the document retaining its current version number and the review period being extended, the review of the document captured in Q-Pulse will act as evidence that the document has been reviewed.

If however a review of the document results in the decision that the document requires an update, the review outcome will be set to "Update Required". Following this, the author of the document will make the required updates by taking into consideration the feedback from the stakeholders as well as any Change Requests registered against the document. The appropriate steps will then be taken to give stakeholders the opportunity to review the updated document and make any further comments, it is essential to secure the consent of the relevant stakeholder group if the changes to the document have an impact on the work they must conduct.

The method for collecting the feedback from stakeholders may be determined by the individual author, this can be completed in person during a meeting to review the documents, remotely by sharing track change copies of the document or through the use of SOP 50.019 - Independent Stakeholder Assessment (Glasgow Clinical Trials Unit).

Timelines must be set for both internal and external stakeholders to provide their feedback, all efforts must be taken to ensure stakeholders have sufficient opportunity to give input to updates to SOPs. However, in the event a stakeholder is not able to provide feedback within a reasonable time period the relevant updates may continue to ensure there are no undue delays.

5.4.1. Updates outside of review period

It may at times be necessary to update a SOP before its designated review period, this may be for a number of reasons such as change in operational requirement, as a result of non-compliances or just through the opportunity for efficiencies. In this instance, it is still the responsibility of the author to complete or sign off on the updates required, changes may be submitted to the author by a relevant stakeholder and if deemed of sufficient need the document can be updated early.

5.4.1.1. Urgent updates

In the event an urgent update is required for a SOP it is possible to set a deadline for the review and update. This turnaround time must be agreed with the relevant author and the relevant groups marked as accountable for the SOP.

5.5. Release of New or Updated SOPs

The update of all SOPs, Forms and Guidelines will be managed through the use of Q-Pulse which is the software to manage the Quality Management System for R&I. Q-Pulse will record the review process and sign off for all SOPs and associated documents. The document will be made live and distributed on Q-Pulse once signed off, the document will then sent to RCB for release on the CTU website. The release date on the CTU website will be updated to reflect the active date assigned on Q-Pulse. Q-Pulse will store the master copy of all documents which must be used to make any future updates. This will be manged by the Quality Assurance Manager for all of R&I, or an appropriate representative within some functional areas where previously agreed, i.e. Bio-Repository, GCRF. The relevant authors will have the responsibility to update the content and seek the input from the relevant stakeholders, following this the completed document will be sent to the Quality Assurance Manager or appropriate representative of the functional area to upload to Q-Pulse for sign off and liaise with RCB for release.

As with the review of existing processes, reasonable timelines must be set for stakeholders to provide their feedback. If a stakeholder is not able to meet this timeline the process may continue without their input to insure no undue delays to the process.

SOPs and their associated Guidelines and forms must remain aligned at all times. It is not appropriate to update a SOP without also updating the referenced documents or vice versa.

During this process, standard Quality Control checks will be completed by the Quality Assurance Manager or designated authority within a functional area to ensure compliance with processes, Form 01.006D will also be completed by the author at this time to ensure the required steps have been taken. If specific face to face training in an SOP is required, this must be recorded on Form 01.006D and records of this training procured and retained.

5.5.1. Training

As part of the role of the Author of an SOP, a determination must be made about the requirements to convey the information contained within a new or updated SOP. Form 01.006D captures the decision of whether or not face to face training is required as well as evidence of Read and Comprehend.

This determination comes down to the complexity of the nature of the content of the SOP, if the content is routine and procedural it may be appropriate for staff to simply read the content to understand the process. If, however, an SOP is complex and multifaceted in nature which requires a high degree of interaction or compliance by members of staff it may be appropriate to prepare training material to further clarify the content to the appropriate staff.

This determination is to be made by the Author of the SOP based on their knowledge of the subject matter and interaction with the stakeholders. If the processes defined within the SOP relate to a known area of common issue, be it delay, clarifications or non-compliance,

this may be an indication that training would be beneficial. Any training should be captured using Form 01.008C and completed copies sent to the QA Manager.

5.6. Read and Comprehend and Distribution of SOPs

It is vital that the appropriate members of staff are aware of the relevant SOPs that impact their job role. It is also vitally important that for the purposes of inspection R&I are able to prove that the correct members of staff are appropriately aware and trained in the relevant SOPs.

To meet this requirement, Q-Pulse will be utilised to record the distribution of SOPs, Forms and Guidelines to the relevant members of staff as well as have confirmation back from members of staff that they have read the document and understood its content if required. 'Read and Comprehend' will by default only be utilised for SOPs. Forms and Guidelines will traditionally only be distributed to staff using the notify function, unless the Form or Guideline is highlighted as requiring a Read and Comprehend record by the author.

The level of action to be taken by the member of staff will be linked to the RACI for the SOP as detailed previously. All staff categories registered as "Responsible" and "Accountable" are directly linked to the SOP and its content, therefore it is required to have a record that the SOP has been sent to the member of staff but also have the confirmation back from the individual that they have Read and Comprehended the SOP. The process for how this is achieved is detailed in Guideline 50.023A.

For all staff categories that are registered only as being "Consulted" or "Informed", it is only required to have evidence that they have been sent a copy of the relevant SOP. In this instance it is not required to have the confirmation back from the individual.

5.6.1. Participating Site staff for research Sponsored or Co-Sponsored by NHS GGC

As some of the stakeholders for SOPs may be those at participating sites it will not be feasible to manage the distribution of SOPs to them all individually, with the exception of GCRF staff. Instead, the approach to be taken will be to control and manage the distribution of SOPs to CIs and PIs who then have the responsibility to ensure site staff are trained on the relevant SOPs and Form 01.008B completed and retained for each member of staff and updated as required.

5.6.2. Reminders and Escalation

When a document has been distributed to a member of staff for them to acknowledge under Read and Comprehend, it is essential that the appropriate acknowledgement from the member of staff is received.

When a document is initially distributed to a member of staff to confirm they have read and comprehended, they will be given a period of 30 days to respond, after this period they will receive reminders of the action required in line with the table below:

Time Elapsed	Action
30 Days from distribution	1st E-Mail Reminder
30 Days + 1 week	2nd E-Mail Reminder CC'ing QA Manager or delegated authority
30 Days + 2 weeks	3rd E-Mail Reminder CC'ing QA Manager or delegated authority & Research Governance Manager and functional head (Approved by on the SOP)
30 Days + 3 weeks	4th E-Mail Reminder CC'ing QA Manager or delegated authority, Research Governance Manager and functional head (Approved by on the SOP)and Senior R&I Manager

**To save on E-Mail traffic, each individual will receive 1 E-mail with a summary report

5.6.3. Addition/Removal of staff

In order to operate this functionality, an accurate list of relevant members of staff must be maintained. In the event a new member of staff joins or an existing member of staff leaves, the QA Manager must be notified to complete the relevant action of creating or disabling a Q-Pulse account as well as assigning the required SOPs.

5.6.4. Development of New Processes

In the event a new process or a change to an existing process is to be developed prior to release of a new or updated SOP, SOP 50.016 must be followed which outlines the steps to be taken to document and control this process.

5.7. Reporting

Weekly reports will be prepared by the Quality Assurance Manager to review and manage the status of major activities as they relate to SOPs and their management. These reports will include the following:

- Progress of Sign off of documents
- The status of upcoming Review periods for documents
- The status of open Change requests
- The response to Read and Comprehend requests

These reports will then in turn be reported through the SOP Committee which is chaired by the Quality Assurance Manager and distributed to the relevant functional heads between SOP Committee Meetings.

6. Referenced documents

Form 50.023A - RACI Matrix for R&I SOPs
Guideline 50.023A – Management of SOPs through Q-Pulse Guide
SOP 01.005 - Format of Standard Operating Procedures and Related Documents
SOP 01.006 - Production and Maintenance of Standard Operating Procedures and Related Documents
SOP 01.008 - Standard Operating Procedures, Guidelines and Forms: Training and Issuance
Form 01.006D - SOP/Guideline/Form Review
Form 01.008C - SOP Training Attendance Form

7. Related documents

N/A

8. Document History

Version	Date	Description
1.0	25/08/2022	*First Release*