| SOP number | 50.023 | Version | 2.0 |
|---|---|---|---|
| Title | Management of SOPs within NHSGGC R&I | | |

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|---|---|
| Prepared by | Paul Gribbon |
| Approved by | Caroline Watson |
| Released by | Jesse Dawson |

| SOP category | NHS GG&C General |
|---|---|
| Staff category: | |

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

## 1. Scope

This procedure applies to all staff within NHSGGC R&I.

## 2. Purpose

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

## 3. 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).

### 3.1. SOP Management Structure

SOPs, Forms, Guidelines and Work Instructions within Research and Innovation are managed through the Q-Pulse application. Several Chapters make up the structure of the Quality Management System (QMS) within R&I and the ownership and responsibility for them all sit with different groups. The Quality Assurance Manager is responsible for the management and oversight of all Chapters relevant to R&I, but the day to day operations, management and update of certain Chapters sit with individual groups. Chapter 17, 57 and 58 are relevant to the GCRF, as such the Quality Lead for the GCRF has direct responsibility for maintaining, reviewing and updating these documents on Q-Pulse. Similarly, Chapter 60 is the responsibility of the Bio-Repository and this is managed by Bio-Repository Staff. All remaining Chapters will be managed and reviewed by the Quality Assurance Manager and the R&I QA team.

### 3.2. QMS Document Templates and Their Contents

Templates are in place for all of the Document Types to be held in the QMS: SOPs, Forms, Guidelines and Work Instructions. R&I have developed their own templates based off the templates set out for the Glasgow CTU in SOP 01.005. The content and structure of these templates are aligned but with some key additions relevant to R&I. Biorepository will make use of a variant of these templates due to requirements of ISO accreditation. These templates are available in both Q-Pulse and on the R&I website:

*SOP Template:* https://www.nhsggc.scot/downloads/sop-template/
*Form Template:* https://www.nhsggc.scot/downloads/Form-template/
*Guideline Template:* https://www.nhsggc.scot/downloads/Guideline-template/
*Work Instruction Template:* https://www.nhsggc.scot/downloads/WI-template/

#### 3.2.1. Composition of the QMS

The QMS is solely the documents held within Q-Pulse, although they are made available through websites for ease of access, the master documents are held in Q-Pulse. As copies of the documents are held in multiple locations, the QA team controls the update of the R&I website and relays the information to RCB to ensure they remain aligned. A small period of time during the update of documents will exist when Q-Pulse has been updated and the GCTU website may lag behind but this is brief. The R&I website is updated at the same time. Routine automated checks are performed weekly to compare the version numbers held for all documents across the 3 platforms to ensure alignment.

#### 3.2.2. QMS Document Signatories

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. The sign off of an SOP can be completed through the use of electronic signatures 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, Guidelines and Work Instructions only require sign off by the "Prepared By" and "Approved By" signatories.

##### 3.2.2.1. 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 3.2.2.1.1. 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. 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 Author field in Q-Pulse can be changed to the new individual. 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 be 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.

The Author is signing the SOP to confirm their position as the Author of the document and to agree to its contents, by signing they are confirming they have reviewed the final document and it is reflective or what they have prepared.
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.

#### 3.2.2.1.1. Owner

Generally the Owner will be the same name as the Author, however, it may be required to assign the ownership of the document to another individual for a number of circumstances. For example, the head of the functional area who acts as the approver of the document, in the event there are multiple authors, etc. This is simply an additional mechanism to highlight those involved with the document.

#### 3.2.2.2. 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 will generally appear in the "Accountable" section of the staff category table and will have been consulted as part of the SOP development.

#### 3.2.2.3. 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.

### 3.2.3. Staff Categories

All staff that are required to be trained in the content of the SOP must be detailed within the Staff Category section, 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 NHSGGC 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 within 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. If a staff group are listed within an SOP as responsible for completing an action they will generally appear under Responsible. However, typically with the Investigators an SOP may call for an R&I staff member to send the Investigator a document for them to complete which would only mean they are Consulted rather than Responsible.

**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. Those accountable for an SOP are a key stakeholder in the review process and must be consulted.

**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. As mentioned previously, a common example may be that they are sent documentation to complete but will not be solely responsible for initiating and completing the activity independently.

**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.

#### 3.2.4. Retrospective Implementation

By default, most updates to a QMS document will only apply to activity carried out going forward from the release date of the document. However, on some occasions it may be required to implement the changes retrospectively by updating older documents into the new format. This may be the case as a result of non-compliance or to correct a known issue. In these circumstances, the Document History will be marked to identify this requirement and an implementation plan must be documented to control this activity.

### 3.3. 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 Author/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. Change Requests can result from a number of different scenarios, i.e. audit, Non-Compliance, etc.

### 3.4. Review of SOPs

The review of all SOPs and associated Forms, Guidelines and Work Instructions must be carried out on a recurring basis. As standard, 3 years between reviews is the typical time frame, however, 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. 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, the Review Date will be moved to the end date of the relevant year.

The decision on whether to update a document or not can be made by the author by reviewing the content of the document themselves, consideration of any outstanding Change Requests and also by sending out a request for comments to the relevant stakeholders. In the event the feedback from the stakeholders results in the determination that no update is required, a review record can be created and then 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, a document review record in Q-Pulse will not be required, the new version is sufficient evidence of the review having taken place. 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 any other appropriate means.

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.

The review of a document must take the considerations set out in Guideline 50.023B into account and authors should read this ahead of carrying out a review. This explains a number of considerations that will be considered by QA when the document is reviewed ahead of adding to Q-Pulse for sign off.

#### 3.4.1. Identifying Stakeholders

The review of all documents must consider the appropriate stakeholders to be part of this review, by default the RACI matrix is a good place to start. All those listed under Responsible and Accountable must be included in the review and those under Consulted and Informed may also be included. However, it is worth considering that the RACI may not be complete and take into consideration the potential impact to other groups not mentioned. If the changes to an SOP are to be significant, it may be worth sending out to a wider distribution and include the relevant heads of the functional areas potentially impacted to offer the opportunity for input. It is not required to send the document to every member of staff within a group listed in the RACI, simply to an appropriate number of representatives for that group. For example, if Project Manager appear under Responsible it should be sent to a least one member of each Project Management group.

#### 3.4.2. 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.

##### 3.4.2.1. 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.

### 3.5. Release of New or Updated SOPs

The update of all SOPs, Forms, Guidelines and Work Instructions 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 and also updated on the R&I

website according to instructions in Guideline 50.023A. The release date on both websites 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 on the GCTU website and also updated on the R&I website. Note: Work Instructions are not released on either website.
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 Forms, Guidelines and Work Instructions 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.

#### 3.5.1. Trial of New Processes

In the event a new process or a change to an existing process is to be trialled 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.

#### 3.5.2. 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. 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, approver or the person accountable 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.

#### 3.5.3. Minor Corrections

In the event a minor correction is required to an SOP after approval and release, this can be completed without the need to up-revision. For example, if a typo has been identified, an incorrect email address or a minor mistake which does not impact on the actual details of the process outlined.

### 3.6. 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, Guidelines and Work Instructions will traditionally only be distributed to staff using the notify function, unless the Form, Guideline or Work Instruction 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.

The Read and Comprehend process is only required to evidence that staff are aware of the relevant process and have not previously identified any major issues. It is expected that staff will refer to the relevant SOPs when completing the required activity to ensure they remain compliant.

#### 3.6.1. Participating Site staff for Research Sponsored or Co-Sponsored by NHSGGC

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 GCRF 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.

#### 3.6.2. Glasgow University Staff Read and Comprehend

It may be required that staff who work for Glasgow University require to be trained in R&I SOPs, to this end key staff within Glasgow University are notified on a weekly basis of any changes to R&I SOPs to which they have access and they then have the responsibility of ensuring that relevant staff are trained and that this is documented through their training processes.

### 3.6.3. 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 | R&I Staff Action | Investigator Action |
|---|---|---|
| 30 Days from distribution | Weekly E-Mail Reminder | Monthly E-Mail Reminder |
| 90 days from distribution | Notification sent to functional head (repeated monthly) | List of Overdue actions sent to QA Manager |
| 180 days from distribution | Notification sent to Senior R&I Manager (repeated monthly) | List of Overdue actions sent to Research Governance Manager |
| 270 days from distribution | Notification sent R&I Director (repeated monthly) | List of Overdue actions sent to R&I Director and Senior Manager |

### 3.6.4. 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 Quality Assurance Manager or relevant designees must be notified to complete the relevant action of creating or disabling a Q-Pulse account as well as assigning the required SOPs. The list of Investigators will be maintained through the use of regular reporting from SReDA for the list of CIs and EDGE for the list of PIs.

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.

### 3.7. Deviation from SOPs

The processes outlined within the SOPs that make up the QMS for NHSGGC R&I must be complied with at all times, in the event an SOP is discovered to not have been complied with a Non-Compliance will be raised as per SOP 51.008.

In the circumstances a planned deviation from an SOP is to occur, permission must be granted in advance in order to not result in a non-compliance. A number of reasons may exist why it will not be possible to fully comply with an SOP, it must be reviewed in advance to determine if this is justifiable before staff may proceed. Form 50.023B must be completed and signed to provide this permission and provided to the Quality Assurance Manager to keep a record. Deviation from R&I SOPs must be authorised by the R&I Senior Manager or R&I Director.

### 3.8. Trial Specific Instructions

It may on occasion be required for a trial to produce their own set of instructions for an activity they must carry out that is unique to that trial. As a result, it may not be appropriate for the creation of an SOP as no other trials will make use of it.

The creation and management of such an Instruction document is the responsibility of the individual trial team and does not form part of the R&I QMS, therefore it will not be managed through Q-Pulse and fall under the oversight of the Quality Assurance Manager. In order to differentiate these documents from an R&I SOP they will make use of the appropriate template linked below. These document are not an SOP and must not be referred to as such to avoid confusion of it being considered part of the R&I QMS, some pre-existing documents are in place that are referred to as “Trial Specific SOPs” and used SOP templates similar to those used in the R&I QMS. There is no requirement to update or remove these documents and only future documents must be changed to the new template going forward.

Trial Specific Instruction Template: https://www.nhsggc.scot/downloads/trial-specific-instruction-template/

## 4. Referenced Documents

- Form 50.023B - Deviation from NHSGGC R&I SOPs Permission Request
- Guideline 50.023A – Management of SOPs through Q-Pulse Guide
- Guideline 50.023B - Review of QMS Documents
- 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
- R&I SOP Template - https://www.nhsggc.scot/downloads/sop-template/
- R&I Form Template - https://www.nhsggc.scot/downloads/Form-template/
- R&I Guideline Template - https://www.nhsggc.scot/downloads/Guideline-template/
- R&I Work Instruction Template - https://www.nhsggc.scot/downloads/WI-template/
- Trial Specific Instruction Template - https://www.nhsggc.scot/downloads/trial-specific-instruction-template/

## 5. Related Documents

- N/A

## 6. Document History

| Version | Date | Description | Retrospective Implementation |
|---|---|---|---|
| 1.0 | 25/08/2022 | First Release | No |
| 2.0 | 22/09/2025 | Several updates to content, introduction of new templates. | No |