NHS
Great Ormond Street Hospital for Children
Research and Innovation

DIRECTORATE OF RESEARCH AND INNOVATION

Document Number: GOSH/ICH/SOP/R/001	Version Number: 03
Title: Writing, Approval, Distribution, Control and Review of Written Procedures	
Effective Date:	*Same as implement by date.*

	Name	Position
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1. Scope

This Standard Operating Procedure (SOP) applies to written procedures created by the Research and Innovation (R&I) Directorate. It applies to all R&I Directorate staff.

This SOP does not apply to study specific written procedures; these are written by the study team in collaboration with the Sponsor (see SOP/R/006 Study Documentation and Monitoring, Audit and Inspection).

This SOP is not a tutorial on using the Q-Pulse system; please refer to 'Help' within Q-Pulse for instructions on performing the tasks listed.

2. Purpose

The purpose of this document is to define the procedure for the writing, approval, distribution, control and review of written procedures in the R&I Directorate.

3. Definitions/Abbreviations

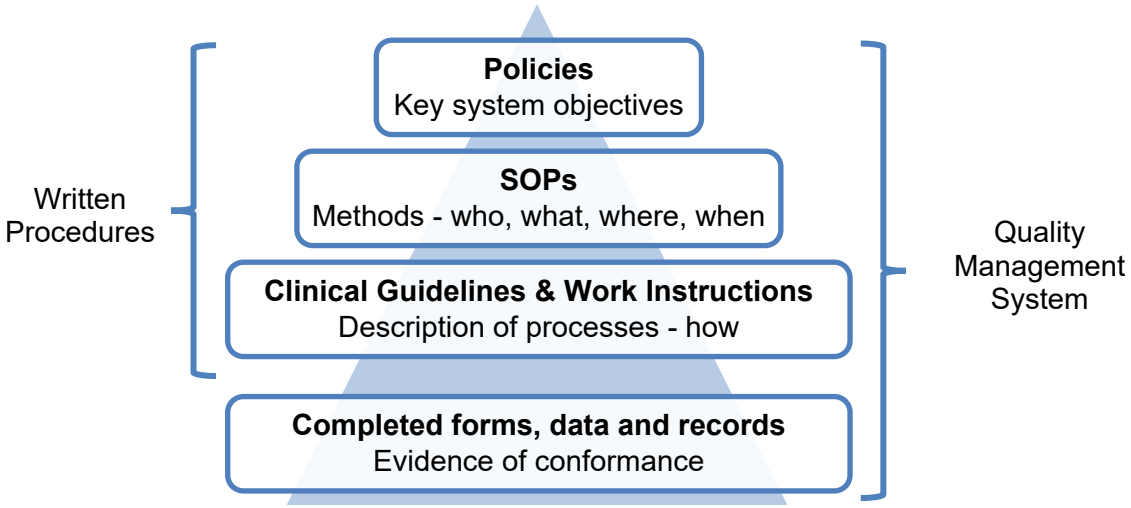
Clinical Research – As per UK Framework for Health and Social Care Research and HRA/MRC 'Is my study research?' tool.

CRF – Clinical Research Facility

Q-Pulse – An electronic document management system

Quality Management System (QMS) – A formalised system that documents processes, procedures, and responsibilities for ensuring the quality of clinical research.

Written Procedures – Policies, SOPs, clinical guidelines or work instructions. May be supported by related documents (such as blank forms or templates).



4. Responsibilities

The Head of Governance, Clinical Trials and Contracts, and the R&I QA Manager have overall responsibility for the maintenance of the R&I Quality Management System.

Duties may be delegated but the responsibility always remains with those listed.

4.1 The Document Owner is responsible for:

- Creating and maintaining the document record on the Q-Pulse System. This includes assigning; the Document 'Type' and 'Number' (for new written procedures), the version number, and the Document Author.
- Activating documents once they have been approved, adding them to the Written Procedure Matrix, and distributing them to applicable Q-Pulse users; ensuring that an appropriate communication and/or training plan is in place.

4.2 The Document Author is responsible for:

- Preparing the document for approval, including assigning Reviewers and Approvers, and managing the review and approval process.

4.3 A Document Approver is responsible for:

- Reviewing written procedures (and related documents) and approving or rejecting the document(s) as applicable.

4.4 All R&I staff are responsible for:

- Raising a request for a new or amended procedure if they identify a gap within the Quality System or a problem with a current procedure.

5. Procedure

Written procedures are an essential part of the R&I Directorate Quality Management System; they ensure roles, responsibilities and required tasks are clear to all parties.

Q-Pulse is used to manage the R&I Directorate written procedures and helps ensure they are readily available, subject to version and document control and that there is only one final version of a written procedure in circulation at any given time.

5.1 Preparation of Document or Revision Record

If it is identified that a new or amended written procedure may be needed; staff should inform the Head of Governance, Clinical Trials and Contracts, and/or R&I QA Manager as soon as possible. If it is decided that a new or amended procedure is required; the Document Owner (usually the Head of Governance, Clinical Trials and Contracts, R&I QA Manager, or delegate) will create a draft document record (for new procedures) or draft revision record (for amendments).

The Document Owner will assign/confirm the Document Type and Number (see Appendix 2), and version number, and assign an appropriate Document Author.

5.2 Preparation and Review of Written Procedures

The Document Owner can provide support during preparation and review.

All written procedures must be written and reviewed by appropriately trained and experienced personnel (across different areas as required) and be reflective of the requirements in clinical trial legislation, applicable guidelines and Trust policies.

The Author is responsible for drafting the new or amended written procedure, and circulating the document to appropriate staff members for review.

The Author should use the appropriate template to ensure key sections or wording are included, and to ensure consistency between documents. Key sections are:

- Scope
- Purpose
- Definitions/Abbreviations
- Responsibilities
- Procedure (including Support and Escalation, and Compliance)
- Related documents
- References
- Appendices (if applicable)

The document should be clearly marked as a draft by using a ‘DRAFT’ watermark until the document is submitted for Approval.

For updates, the Author must review any Change Requests raised against the document to ensure they are incorporated. They must also ensure they review all ‘Related Documents’ to check if they are impacted and are updated as necessary.

Selection of appropriate Reviewers will vary depending on the written procedure but should always include appropriate senior R&I staff, and staff who will carry out

the activities listed in the procedure. Reviews may also include specialist staff or staff from other departments as necessary e.g. a representative from pharmacy must always review written procedures that relate to medicinal products.

Reviewers should use tracked changes and/or comments to ensure their feedback is clear, and should respond within the Author's specified timeframe.

Q-Pulse is not a document collaboration system. Reviewing should be managed outside of Q-Pulse. It may be necessary to cycle through review several times until there is a consensus on the final document.

Any Related Documents must be looked at as part of the review (even if they are not new or changing) to ensure the documents are consistent.

Once consensus is reached, and the document is final, the DRAFT watermark must be removed and the document sent for approval on the Q-Pulse system.

For updated documents, the Author must complete the Change Details for the Revision History on the Document Record.

5.3 Approval of Written Procedures

The Document Owner can provide support during approval.

The Author is responsible for assigning Approvers and any associated workflows (workflows can be used to set an approval order if required).

Written procedures must be approved by an appropriate multi-disciplinary group within the organisation (as per the Trust Policy on Policies, Procedures, Guidelines and Integrated Care Partnerships) and then Approved on Q-Pulse by individuals who have appropriate authority. Selection of appropriate Approvers will vary depending on the written procedure type and scope, see Appendix 2.

The final Approver must ensure that the necessary staff members have completed their review and approval prior to their approval.

5.4 Distribution of Written Procedures

Written procedures must be distributed and immediately available to all appropriate staff once they are effective. A period of time between approval of the procedure and the procedure becoming effective may be used to allow for training of relevant personnel if necessary.

The Document Owner will activate the document and will designate Q-Pulse users as 'Copy Holders' for the written procedures that are relevant to their role (based on the Written Procedure Matrix). As per the SOP 'Training Requirements for Staff Participating in Clinical Research', the relevant written procedures must be read, understood, and acknowledged by staff on Q-Pulse before they carry out the related activities, or within the designated timeframe, whichever is soonest.

5.5 Control of Written Procedures

Written procedures are held on the Research Q-Pulse database. They are protected from unauthorised access and unauthorised or accidental editing.

Any print-offs or downloads of written procedures from Q-Pulse are classed as uncontrolled and personnel are instructed to refer to Q-Pulse for the latest version of the procedure, this is to minimise individuals referring to a paper or saved versions that may be out of date. It is the responsibility of the individual to ensure the copy that they have is the current version.

All written procedures must have a document number and version number so that different versions of a particular document can be distinguished from each other.

5.6 Review and Update of Written Procedures

Written procedures must be reviewed on a periodic basis to check that they still accurately reflect current practice. The maximum review period is 3 years.

If written procedures are reviewed, but it is determined that they are still current and no changes are required, this should be documented on Q-Pulse.

It may be necessary to implement changes to a written procedure prior to the next routine review, e.g. if there is a significant change to legislation, or if a significant gap or error in the procedure is identified that could affect safety or data integrity.

If any member of staff identifies a problem with a written procedure or Related Document, they must raise a Change Request against the document. This will inform the Document Owner who will decide if the document should be updated.

If amendments to a written procedure are required, the process outlined in sections 5.1 – 5.4 must be followed.

5.7 Archiving of Retired or Superseded Written Procedures

A document should only be deleted from Q-Pulse if it was added in error, as deleted documents cannot be retrieved. Retired or superseded documents should be ‘Deactivated’ by marking them as ‘Obsolete’ (for superseded versions) or ‘Inactive’ (for retired versions). Documents can be reactivated if necessary.

Procedures retired or superseded prior to Q-Pulse document module implementation (02Nov2017), may be kept in paper form. Retention is for a minimum of 25 years from the superseded or retired date of the written procedure. The Master Copy will be clearly marked as superseded or retired so these documents are not inadvertently used.

5.8 Support and Escalation

If a staff member has questions or queries they can ask for support from a more experienced colleague or their line manager. If the query is related to a specific procedure, then the Document Author may also be able to help. If staff (or monitors) have a question regarding the Quality Management System or Q-Pulse

then they can contact the R&I QA Manager or the Head of Governance, Clinical Trials and Contracts.

If a staff member becomes aware of an issue or has any concerns then this must be escalated to the appropriate person(s) in a timely manner (see SOP/R/005 Reporting and Escalation for Research).

5.9 Compliance

Written procedures and compliance with this SOP will be reviewed during routine monitoring/audit.

Systematic or persistent failure to comply with the study procedures and/or this SOP will be seen as non-compliance to GCP and must be bought to the attention of the Head of Governance, Clinical Trials and Contracts who will decide the appropriate action.

6. Related Documents

- SOP/R/006: Study Documentation and Monitoring, Audit and Inspection
- Trust Policy on Policies, Procedures, Guidelines and Integrated Care Partnerships
- Trust Policy Template
- TMP/R/001: Written Procedure Template
- TMP/R/002: Supporting Document Template
- SD/R/001: Written Procedure Matrix
- SOP/R/002: Training Requirements for Staff Participating in Clinical Research

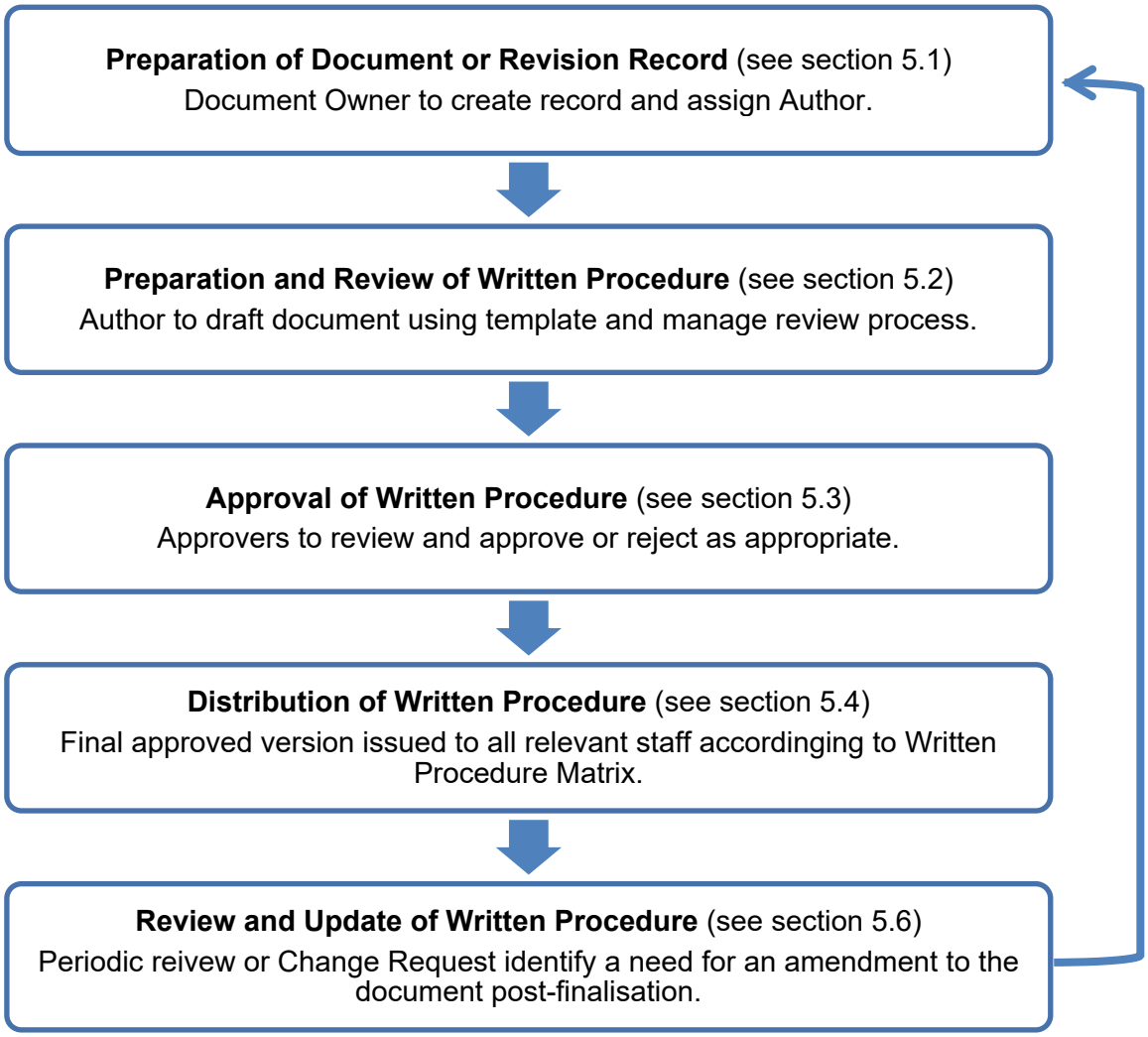
7. References

NA

8. Appendices

- Appendix 1 – Process Flow Chart
- Appendix 2 – Document Numbers and Approvers

Appendix 1 – Process Flow Chart



Appendix 2 – Document Numbers and Approvers

All new and revised written procedures are identified by code: GOSH/ICH/X/S/yyy

- GOSH ICH: identifies the origin of the document
- X: identifies the document type (e.g. policy (POL), SOP, work instruction (WI), form (FRM), template (TMP))
- S: identifies the document scope (e.g. All Research (R), Research and Development Office (R&D), Clinical Research Facility (CRF))
- yyy: identifies the list number of the document.

Approvers:

Document Type	Scope	Document Number GOSH/ICH/	Final Approvers*	
			Authorising Group	Q-Pulse Approver (select one)
Policy	Trust	POL/R/yyy	• Trust Policy Approval Group (PAG)	• Deputy Director of R&I
SOP	Research	SOP/R/yyy	• R&I Board (delegated to Risk Action Group – RAG)	• Head of Governance, Clinical Trials and Contracts • Head of Nursing for R&I • Head of Clinical Research Operations
	R&D	SOP/R&D/yyy	• RAG	• Head of Governance, Clinical Trials and Contracts • Senior Research Project Manager • Finance and Performance Manager
	CRF	SOP/CRF/yyy	• RAG	• Research Matron • Clinical Research Delivery Manager • QA Manager R&I
Work Instruction or Guideline	Research	WI/R/yyy	• R&I Board (delegated to Risk Action Group – RAG)	• Head of Governance, Clinical Trials and Contracts • Research Matron • Clinical Research Delivery Manager • QA Manager R&I
	R&D	WI/R&D/yyy	• RAG	• Head of Governance, Clinical Trials and Contracts • Senior Research Project Manager, or • Finance and Performance Manager
	CRF	WI/CRF/yyy	• RAG	• Research Matron • Clinical Research Delivery Manager • QA Manager R&I
Other Related	Research	FRM/R/yyy TMP/R/yyy	• Not Applicable	• Head of Governance, Clinical Trials and Contracts

Document (e.g. form, template, tip sheet)		TIP/R/yyy		• Research Matron • Clinical Research Delivery Manager • QA Manager R&I
	R&D	FRM/R&D/yyy TMP/R&D/yyy TIP/R&D/yyy	• Not Applicable	• Head of Governance, Clinical Trials and Contracts • Senior Research Project Manager, or • Finance and Performance Manager
	CRF	FRM/CRF/yyy TMP/CRF/yyy TIP/CRF/yyy	• Not Applicable	• Research Matron • Clinical Research Delivery Manager • QA Manager R&I

**Staff may not approve a written procedure they have themselves authored. The approver listed is the minimum level of approver required; a staff member higher in the organisation hierarchy may approve a written procedure if required.*

A Q-Pulse Administrator (such as the Head of Governance, Clinical Trials and Contracts, R&I QA Manager, or a delegate) must be additional approvers for all written procedures to maintain oversight of the Research Quality Management System.