STANDARD OPERATING PROCEDURE

S01 – Preparation of Standard Operating Procedures in Research and Development

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Controlled document

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It is the responsibility of all users of this SOP to ensure that the correct version is being used. If you are reading this in a paper format please go on-line to confirm you have the latest version.

DISCLAIMER

This generic R&D Standard Operating Procedure (SOP) must be followed unless a study specific SOP exists.

Once printed this is an uncontrolled document

Full History			
Version	**Date**	**Author**	**Reason**
1.0	25/02/2011	Research Manager and Governance Manager	New SOP
2.0	13/02/2014	Quality Assurance Coordinator	Document updated to reflect revised processes and procedures
3.0	12/09/2014	Quality Assurance Coordinator	Document updated to reflect revised processes and procedures
3.1	22/10/2015	Quality Assurance Coordinator	Updated reference number
3.2	22/09/2016	Quality Assurance Coordinator	Updated to reflect revised job titles and changes to hyperlinks
4.0	22/11/2017	Research Governance & Quality Manager	Document updated to reflect revised processes and procedures; Revised into Trust template
5.0	26/06/2019	Research Governance & Quality Manager	Updated to incorporate study specific SOPs. Revised into current SOP template.
6	13/05/2020	Quality Assurance Coordinator	Updated to include CRF SOPs, R&D numbering convention, SOP ratification changes and Work Instruction guidance.

Associated Trust Policies/ Procedural documents:	S26 - Providing and Documenting Training for Researchers
Key Words:	R&D SOP Template Work Instruction

In consultation with:

- Quality Assurance Group (September 2017)
- Divisional Governance Group (October 2017)
- Quality Assurance Group (June 2019)
- Quality Assurance Group (January 2020)

Contents

1 INTRODUCTION

The purpose of a standard operating procedure (SOP) is to describe what needs to be done in order for a process to be conducted in compliance with the applicable standards and to ensure uniformity in the performance of a specific procedure. Research and Development (R&D) SOPs are designed to ensure that clinical research and its supporting activities are conducted to the principles of Good Clinical Practice (GCP) and the applicable regulations. Within R&D, SOPs are supported by Work Instructions (WIs) and other guidance documents which provide the detail on how to perform the specific task.

2. PURPOSE

This document describes the procedure for preparing, approving and distributing SOPs.

3. SCOPE

This SOP is applicable to all R&D staff who are involved in writing, reviewing, approving and implementing SOPs relating to Trust-wide systems and processes for research.

For all research studies sponsored by R&D on behalf of the Trust, R&D SOPs will apply.

For all research studies hosted by RDE, R&D SOPs should be considered the default procedures to be used except where study-specific procedures are specified in the protocol.

The Clinical Research Facility will also have generic administration, clinical, study specific, laboratory and HTA specific SOPs.

4. DEFINITIONS

CI	Chief Investigator
CRF	Clinical Research Facility
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTU	Clinical Trials Unit
CTG	Clinical Trials Group
DGG	Divisional Governance Group
GCP	Good Clinical Practice
GOG	Governance and Oversight Group
QA	Quality Assurance
R&D	Research & Development
SOP	Standard Operating Procedure
Sponsor	An individual, company, institution or organisation which takes responsibility for the initiation, management and financing of a clinical trial. Sponsorship activities may be delegated to the Investigator, CTU and/ or other organisations as appropriate
TMF	Trial Master File
WI	Work Instruction

5. DUTIES AND RESPONSIBILITIES OF STAFF

The **Governance and Oversight Group (GOG)** will provide oversight of the SOP library, confirming the need for new procedural documents and those documents which need to be superseded or retired.

The **QA Coordinator** is responsible for the day to day management of the SOP library to ensure that up to date versions of documents are made available,

superseded versions are archived and to prompt document authors to undertake timely reviews.

All **R&D personnel and research active staff** involved in writing, reviewing, approving and/ or implementing R&D SOPs must read and apply this document when writing or reviewing SOPs.

All **R&D personnel and research active staff** are responsible for ensuring that they have read, understood and documented training (if applicable) for all relevant SOPs.

All **R&D personnel and research active staff** have a responsibility to identify changes in policy, legislation and procedures that affect R&D SOPs and for bringing this to the attention of R&D.

Chief Investigators are responsible for signing off study specific SOPs.

6. PROCEDURES

6.1 SOP layout and format

6.1.1 All R&D SOPs must be written in the standard R&D SOP template. The SOP template is a controlled document and as such access is restricted to the QA Coordinator.

6.1.2 All R&D SOPs should contain the following sections as a minimum:

- Introduction
- Purpose
- Scope
- Definitions
- Duties and responsibilities of staff
- Procedures
- Dissemination and training
- Monitoring compliance and effectiveness
- Archiving
- References

Additional sections may be added.

6.2 Creating a new SOP

6.2.1 Where a member of staff or researcher identifies the need for a new SOP, they should first check existing R&D SOPs and Trust Guidelines or Policies to ensure the topic is not already covered. Consideration should also be given as to the most appropriate format for the document, i.e. Work Instruction or SOP. A Work Instruction is a document that provides specific instructions on how to carry out an activity. A Work Instruction contains more detail than a Procedure and is only created if detailed step-by-step instructions are needed to support an associated SOP.

6.2.2 A request should then be made to GOG via the QA Coordinator. The Governance and Oversight Group will look to identify the most appropriate member(s) of staff to devise the new SOP and support the author in defining the scope of the SOP including supporting documentation such as WIs and/ or templates.

6.2.3 The QA Coordinator will provide the author with the current version of the R&D SOP template.

New R&D SOPs shall be allocated an SOP number by the QA Coordinator.

6.2.4 SOPs must be written in a concise, step-by-step and clear format so that someone with limited experience or knowledge of the procedure, but with a basic understanding, can successfully carry out the procedure with limited supervision. Titles should be used rather than names.

6.2.5

6.2.6 SOPs will be called 'Draft' until they have been submitted for approval. The word 'Draft' must be watermarked on each page of the document and added to the document name in the footer.

6.2.7 Where applicable, any associated WIs, forms and templates should also be drafted/ updated and referenced within the SOP. Such documentation should not be developed independent of a supporting SOP (or protocol in the case of study-specific SOPs).

6.2.8 On completion of a draft SOP, internal review by appropriate staff members will be undertaken. This review will consider readability, conciseness and accuracy of information. Any deficiencies should be addressed at this review stage.

6.2.9 The final draft SOP, together with any associated forms and templates should be sent to the QA Coordinator to coordinate review.

6.3 Study Specific SOPs

6.3.1 Study specific SOPs are likely to be rare as the study Protocol should provide adequate instructions. In relation to RDE sponsored research projects, SOPs concerned with study specific procedures appropriate for use across individual research project work but not already covered by existing R&D SOPs or Trust Policies will be written by the CI or delegated to an identified individual deemed to be best qualified by experience or competency.

6.3.2 Consideration should be given as to whether a Work Instruction would be more appropriate.

6.3.3 In relation to RDE sponsored research projects, study specific SOPs should be approved by the study CI. If the SOP relates to Pharmacy, Laboratory or Radiology issues, then the relevant staff members from that support department should also consulted on contents of the SOP before it is approved. If the SOP relates to a CRF study, the relevant CRF management staff should be consulted.

6.3.4 Where a study specific SOP is required for a hosted study, this should be written by the PI or delegated to an identified individual deemed to be best qualified by experience or competency and approved by the study PI. These SOPs will be maintained by the Trial Team and will not be managed within the R&D SOP library.

6.4 Reviewing an SOP

6.4.1 R&D SOPs will indicate on their front cover when they require a review. Each SOP will have an effective date (date of implementation following approval) and a review date which should be no more than three years from the effective date. The Author of the SOP is responsible for periodic review.

6.4.2 SOPs will also be reviewed on an ad hoc basis as a result of amendments to legislation, process or organisational change or following audit. It is the responsibility of any user to notify the R&D QA Coordinator if they believe an SOP needs reviewing before the review date.

6.4.3 R&D SOPs will be reviewed and agreed as described below. This may be done

electronically or via a full meeting. Comments will be documented and addressed as required. Where necessary, other stakeholders will be consulted to guarantee that the SOP is workable in practice.

New SOPs

New SOPs relating to aspects of research activity will be approved by GOG.

Existing SOPs

Updates to existing SOPs will be reviewed by GOG to determine whether the changes made are minor or major as follows:

Minor changes constitute an amendment to the document that does not substantially affect the main body of the document (e.g. changes to references and standard forms) and will be reviewed and agreed by the document author and GOG.

Major changes constitute an amendment to the document that will result in a change of practice and will be subject to consultation, reviewed and agreed by the document author and GOG.

6.5 Approval of SOPs

6.5.1 Once an R&D SOP has been satisfactorily reviewed and, if necessary, updated, it will be approved by GOG and notified to the QA Coordinator.

6.5.2 The QA Coordinator shall prepare the SOP for publishing as follows:

- Each SOP will be issued with a unique reference number (using the format R&D/SOP title/S#), an effective date and a review date.
- Each document associated with a SOP will be coded with the same reference number as the relevant SOP. So if the reference number of a SOP is R&D/Archiving of Essential Documents/S03, an associated work instruction would be R&D/Archiving of Essential Documents/WI03.
- Only whole numbers shall be used for SOP version number increments.
- CRF SOPs will be numbered in accordance with the CRF numbering convention.
- The version history table on the front page of the SOP will be updated.
- References to draft versions will be removed from the watermark and footer.
- An electronic copy of the final SOP will be uploaded to the R&D Quality Management System and RDE Research website.
- A master copy will be signed (wet ink or electronic) by the Author and by the Approver and stored in the SOPs Master File.
- Copies of superseded SOPs will be destroyed and only the master copy will be retained electronically and archived to facilitate review by regulatory bodies (as required).

6.6 Distribution of SOPs

6.6.1 R&D SOPs will be uploaded to the RDE Research website as read-only documents. Where applicable, any associated templates and forms will be uploaded as separate documents for ease of use.

6.6.2 It is the responsibility of all staff to check the website regularly to see if SOPs have been added or amended. R&D will endeavour to notify research staff of any SOP developments that may be relevant to them via staff communications e.g.

newsletters, Comms Cell.

6.6.3 A list of any new or updated SOPs will be provided to GOG at their regular meetings.

6.7 Training

6.7.1 Careful consideration must be given at study set up as to which SOPs will apply to a specific study. Full details must be included as a written statement in the study site file.

6.7.2 When a new SOP is authorised, or when an existing SOP is revised, self-directed training must be carried out by all staff to which the SOP is relevant and this training documented in their training record.

6.7.3 Staff should take time to read and fully understand the SOP and relevant documents, ensuring that they are able to implement the SOP when required. If clarification is needed, the staff member should approach R&D who will arrange additional training. All staff are responsible for maintaining their own training logs and copies must be made available to study monitors on request. See S26 - Providing and Documenting Training for Researchers for further information on training.

6.8 SOP deviations

6.8.1 If a process deviates from an approved SOP, a risk assessment should be undertaken to determine the consequences and identify any remedial action(s) that needs to be taken. It may also be appropriate to submit an incident report via the Datix system.

6.8.2 The author of the risk assessment must submit the risk assessment to GOG.

6.9 Withdrawing SOPs

6.9.1 An SOP may be withdrawn if it describes a process that is obsolete. All withdrawn and/ or superseded SOPs will be retained on the Quality Management System.

6.9.2 Any decisions made by GOG to suspend or withdraw a document will be communicated to staff via staff communications e.g. newsletters, Comms Cell.

7. DISSEMINATION AND TRAINING FOR THIS DOCUMENT

7.1 This SOP and associated templates and forms will be uploaded to the RDE Research website shortly after having been released.

7.2 All staff whose activities are subject to this SOP should ensure that they take time to read and understand the content of this SOP.

8. MONITORING COMPLIANCE AND EFFECTIVESS OF THIS SOP

8.1 In order to monitor compliance with this SOP, the auditable standards will be monitored as follows:

No	Minimum Requirements	Evidenced by
1.	GOG should approve requests for new SOPs.	Consideration of new SOP minuted in GOG minutes or SOP tracker
2.	SOPs should be reviewed in a timely manner.	Check of current SOPs and renewal dates.
3.	When a new SOP is authorised, or when an existing SOP is revised, self-directed training must be carried out by all staff to which the SOP is relevant and this training documented in their training record.	Relevant staff training record checks.
4.	All withdrawn and/or superseded SOPs will be retained on the Quality Management System. GOG will provide notification of a suspended or withdrawn document to staff members.	Check Q-Pulse for records of withdrawn and superseded SOPs and check for evidence of notification to staff members.

8.2 Outcomes from audit will be presented to GOG which will monitor any resulting action plans until all issues have been addressed to satisfaction.

8.3 Issues identified via the audit process which require escalation will be referred to GOG.

9. ARCHIVING ARRANGEMENTS FOR THIS DOCUMENT

9.1 The original of this document will remain with the R&D Quality Assurance Coordinator. An electronic copy will be maintained on the R&D section of the Q-Pulse document management system and a pdf copy on the RDE Research website

9.2 Archive copies must be maintained for any documents which have been superseded. Archive copies in electronic format should be retained indefinitely.

10. REFERENCES

ICH Guidelines for Good Clinical Practice (E6 (R2) Step 5. Dec 2016)