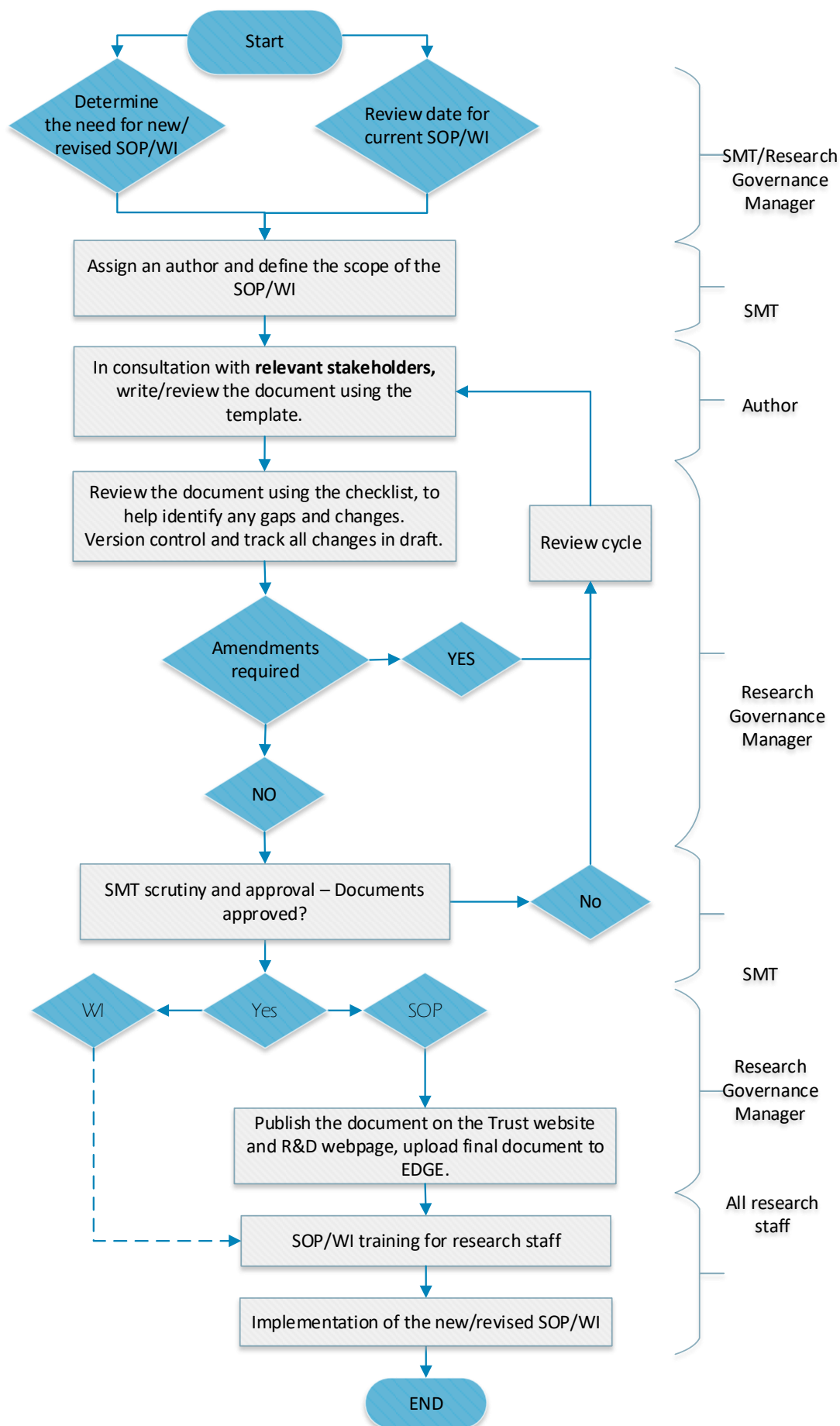


# **Research and Development SOP001 - Preparation, Approval and Review of Standard Operating Procedures and Work Instructions**

**V7.0**

**February 2026**

## Summary Process Map



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## **Data Protection Act 2018 (General Data Protection Regulation – UK GDPR) Legislation**

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team.

Royal Cornwall Hospital Trust      [rch-tr.infogov@nhs.net](mailto:rch-tr.infogov@nhs.net)

# 1. Introduction

- 1.1. The Medicines for Human Use (Clinical Trials) Regulations 2004 (“the Clinical Trials Regulations”) as amended by the Medicines in Human Use (Clinical Trials) (Amendment) Regulations 2025 (referred to as the “amended Clinical Trials Regulations”), Part 12, Section 37 states “Clinical trials must be conducted in accordance with the principles of good clinical practice set out in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice, as amended from time to time”.  
<https://www.legislation.gov.uk/uksi/2025/538/regulation/37>
- 1.2. International Council for Harmonisation (ICH) Good Clinical Practice (GCP) E6 (R3) Guideline, paragraph 3.10 states that ‘The sponsor should implement an appropriate system to manage quality throughout all stages of the trial process.’  
[ICH E6\(R3\) Step4 FinalGuideline 2025 0106.pdf](#)
- 1.3. Good Clinical Practice (GCP) Guide (Chapter 14 Section 14.1) states that ‘an essential element of any clinical trial system is that there are clear written procedures in place to ensure that the system functions properly, that the roles, responsibilities and required tasks are clear to all parties involved and that there is provision for proper control, review and, when needed, change to the system’.
- 1.4. Procedural documents are produced by Research and Development (R and D) to describe a system or process. These documents should be followed to ensure that procedures are standardised and are compliant with all applicable regulations and standards. The procedural documents collectively comprise the R and D Quality Management System (QMS). All procedural documents produced by R and D must be used in conjunction with the associated Trust policies and procedures.
- 1.5. This Standard Operating Procedure (SOP) sets out the framework for the development and management of the Research and Development (R and D) procedural documents in accordance with the Royal Cornwall Hospitals NHS Trust (RCHT) policy, [The Policy of Policies](#).
- 1.6. Procedural documents are the core of the R and D Quality Management System (QMS). Other QMS procedural documents include Work Instructions (WIs), Associated Documents (ADs) and other forms which fall outside of the requirement to use the trust-wide template. The mechanism for naming, version control and archiving these other documents will be managed by the Research Governance Manager or delegate, and the documents will be held on EDGE in the Documents folder.
- 1.7. An external sponsor can request that the research team follow the external sponsor’s own SOPs for their specific studies. These should not conflict with local SOPs without approval from R and D Senior Management Team (SMT) and, if applicable, the Trust. The format for SOPs written and developed by external organisations will be the responsibility of the organisation producing them. Research teams must only follow these if they are not in conflict with UK standards and regulations, and Trust policies and procedures.

- 1.8. For the purposes of RCHT sponsored research, all studies must follow RCHT SOPs for procedures conducted at RCHT. RCHT sponsored research conducted at other institutions and NHS organisations can follow their own SOPs provided they are not in conflict with GCP, and the regulatory requirements.
- 1.9. For research projects where management has been subcontracted to organisations such as clinical trial units (CTU), the other organisation's SOPs can be used by agreement before the research study or clinical trial is undertaken.
- 1.10. This version supersedes any previous versions of this document.

#### 1.11. **Scope**

- 1.11.1. This SOP will describe the process for the preparation, review, and approval of all new SOPs or WIs as well as the revision of existing SOPs or WIs that are produced by RCHT R and D for hosted and sponsored studies.
- 1.11.2. For all clinical trials and research studies hosted by RCHT, R and D and Trust SOPs should be considered the default procedures to be used, except where trial or study-specific procedures are specified in the protocol, and where agreement must be obtained from SMT and delegated Trust representative(s).
- 1.11.3. This SOP is applicable to all R and D staff who are involved in writing, reviewing, approving, and implementing SOPs relating to Trust-wide systems and processes for Research and Development.

#### 1.12. **Definitions / Glossary**

- 1.12.1. **Standard Operating Procedure (SOP)** is defined within the glossary of the ICH (The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) GCP E6 (R3) guideline as 'detailed, documented instructions to achieve uniformity of performance of a specific function'.  
[ICH E6\(R3\) Step4 FinalGuideline 2025 0106.pdf](#)
- 1.12.2. **Work Instruction (WI)** describes how to perform a task within a process, which is a more detailed portion of the standard operating procedure (SOP).
- 1.12.3. **Procedural Documents** are any documents that provide instructions on how to carry out certain tasks and can be strategies, protocols, policies, guidelines, work instructions or Standard Operating Procedures (SOPs).
- 1.12.4. **Trust-wide document** refers to documents which are kept in the Documents Library and can be on the RCHT intranet and RCHT internet.
- 1.12.5. **Local document** refers to a procedural document that is only applicable to a discrete element of the Trust.

- 1.12.6. **Quality Management System (QMS)** is a structured framework that integrates processes, policies and procedures to ensure that clinical research complies with regulatory requirements and standards, enhances data integrity and safeguards participant safety.
- 1.12.7. **EDGE** is a dedicated, web-based research database, which is used within, and managed by the R and D Department at RCHT. EDGE maintains a robust audit trail to meet MHRA inspection expectations.
- 1.12.8. **Key Stakeholders** are those people who are affected by the contents of a document.
- 1.12.9. **Documents Library** refers to RCHT's online repository for all procedural documents that need to be accessed via the intranet and internet.
- 1.12.10. **Acronyms**
- **AD:** Associated Document.
  - **CI:** Chief Investigator.
  - **GCP:** Good Clinical Practice.
  - **HRA:** Health Research Authority.
  - **ICH GCP:** International Council for Harmonisation of Good Clinical Practice.
  - **MHRA:** Medicines and Healthcare products Regulatory Agency.
  - **PI:** Principal Investigator.
  - **PRG:** Policy Review Group.
  - **QMS:** Quality Management System.
  - **R and D:** Research and Development.
  - **RCHT:** Royal Cornwall Hospitals NHS Trust.
  - **SOP:** Standard Operating Procedure.
  - **SMT:** Senior Management Team.
  - **WI:** Work Instructions.

## 2. Purpose of this Standard Operating Procedure

- 2.1. The purpose of this document is to describe the procedure for developing a new or reviewing an existing Standard Operating Procedure (SOP) or Work Instruction (WI).

- 2.2. SOPs are controlled documents of written methods (who, what, where and when) necessary to achieve a consistent approach to a process and provide a platform for training, monitoring compliance with applicable guidance and regulation, and assessing quality.
- 2.3. WIs describe the steps involved in the process, detailing the tasks outlined in the SOP.

### **3. Ownership and Responsibilities**

#### **3.1. Role of the R and D Clinical Director**

The R and D Clinical Director and their delegate are responsible for:

- Having oversight of the implementation of robust arrangements to ensure staff follow the processes described in [Section 4](#), Standards and Practice.
- Gaining assurance from the Senior Management Team (SMT) to ensure compliance with the processes outlined in [Section 4](#), Standards and Practice.

#### **3.2. Role of the Senior Management Team**

The Senior Management Team is responsible for:

- Providing assurance to the R and D Clinical Director of the compliance with the processes outlined in [Section 4](#), Standards and Practice.
- Providing initial approval or endorsement of relevant procedural documents as part of the document's pathway through to final approval.
- Gain assurance that the document is required, does not duplicate other local work, and that the need is confirmed by the relevant line management or working group.
- Ensuring that all procedural documents submitted for approval comply with the Trust's Policy on Policies and this Standard Operating Procedure (SOP).
- Ensuring that the new or updated procedural document(s) support the requirements of the regulatory bodies.
- Ensuring that responsibility for developing a procedural document within the R and D department is assigned to the most appropriate person or team to act as author(s).
- Ensuring local systems and processes comply with approved Trust and R and D documents, and applicable research regulations and standards where relevant.
- Providing a source of expertise and advice for staff developing R and D procedural documents.
- Embedding robust arrangements to ensure staff follow the contents of the department's procedural documents appropriately.

- Ensuring that any resource implications of procedural document implementation have been addressed; this must include personnel, documentation, equipment (purchase and maintenance), finance and training.
- Deciding whether to restrict publication to the Trust's Intranet webpage and ensuring that, as all procedural documents should be published via the Internet, any reason for restricting publication is prominently recorded on the document's front page.
- Assisting with identifying exceptions regarding use of the R and D Internet Webpage for publication of procedural documents, and which documents should be stored on EDGE.
- Ensuring all procedural documents comply with the RCHT NHS Trust's Equality and Diversity statement. Trust wide documents will require approval from an Executive Director or Care Group Directors/Governance Leads as appropriate and should be submitted for authorisation along with the appropriate governance coversheet.

### 3.3. **Role of the Research Governance Manager**

The Research Governance Manager and their delegate are responsible for:

- Ensuring that the development and approval of procedural documents follow the processes described in [Section 4](#), Standards and Practice.
- Providing advice to authors and other R and D staff regarding the development and management of procedural documents, including archiving arrangements.
- Ensuring the document is required and does not duplicate other local work, and for confirming the need with relevant line management, working group or SMT.
- Assisting the author to identify and consult with the key stakeholders in the development of the relevant procedural document.
- Ensuring that the content of R and D procedural documents is aligned with the relevant regulatory requirements, Good Clinical Practice (GCP) guidelines and Trust policies.
- Submitting the final drafts of all new and revised SOPs or WIs to SMT for ratification.
- Submitting SOPs to the Trust Policy Review Group (PRG) for approval to publish on the Trust's internet and intranet webpages.
- Allocating a unique identity number to each procedural document to enable appropriate recording of the document, version control and archiving within the R and D's document system.

- Maintain records to track the development and review dates for new and revised SOPs and WIs, ensuring the documents requiring a periodic review are sent to the author or other reviewer for assessment of any changes in legislation, procedures and GCP guidance.
- Ensuring information regarding new or revised procedural documents is disseminated to all relevant staff working on research studies across RCHT.
- Where appropriate, ensuring implementation is carried out whilst retaining evidence of the implementation.
- Ensure appropriate training is carried out for new and revised procedural documents, and training completion is recorded in EDGE.
- Providing assurance to the SMT of the programme for developing and reviewing SOPs and WIs, ensuring that the procedures and timeframes follow the processes described in [Section 4](#), Standards and Practice.
- Ensuring new and revised procedural documents are uploaded to the Documents folder in EDGE, following the ratification of the document by SMT and approval for publishing received from PRG.
- Ensuring procedural documents which are no longer required are superseded in the EDGE Documents folder, and access limited.
- Ensuring that the most up-to-date version of the SOP or WI is published in the Trust's Document Library, and available on the Trust's Intranet page and Internet page.
- Ensuring that where SMT have agreed that a SOP or WI is no longer required, that the document is removed from the Trust Document Library and appropriately archived in the Documents folder in EDGE.
- Maintaining R and D AD07 Glossary of Terms (see Documents folder in EDGE).

### 3.4. **Role of the author**

The author is responsible for:

- Ensuring that the development and approval of procedural documents follow the processes described in [Section 4](#), Standards and Practice.
- Ensuring the SOP or WI document is written in accordance with the Trust's [Policy on Policies](#) and this SOP.
- Ensuring that the most up to date versions of the Trust's SOP templates are used, details provided in [Section 4.1](#), Standards and Practice.
- Ensuring that key stakeholders are consulted during the development and revision of procedural documents.

- Ensuring that the content of the R and D procedural document is aligned with the relevant regulatory requirements, Good Clinical Practice (GCP) guidelines and Trust policies.
- Ensuring the draft SOP or WI is reviewed by SMT and address comments until a final draft has been agreed.
- Submitting the final draft of the SOP or WI to the Research Governance Manager, who will follow the appropriate processes for the ratification of the document.
- Reviewing the document at the request of the Research Governance Manager and the SMT in response to any changes in legislation, Trust policy or when approaching the document review date.

### 3.5. **Role of Managers**

Line managers are responsible for:

- Ensuring staff are aware of, and act upon, the most up-to-date versions of Trust and R and D's procedural documents.
- Implementing the procedural documents for the areas in which they apply.
- Notifying all new and existing staff on how to access current R and D procedural documents.
- Ensuring that all staff members have access to the Trust Intranet site and/or EDGE to enable access to published documents.
- Ensuring that all staff members are aware of their responsibility in maintaining compliance with Trust and R and D policies and procedural documents.
- Escalating to the Research Governance Manager where the procedural document does not fit with practice or the current standards, following the processes described in [Section 4](#), Standards and Practice.

### 3.6. **Role of Research and Development Staff**

All research staff are responsible for:

- Participating in the development and consultation process for R and D procedural documents, where appropriate.
- Making themselves aware, remain fully conversant with and follow the published procedural documents that relate to their role and responsibilities.
- Complying with agreed Trust and R and D procedural documents where they apply.
- Raising any queries about implementation of R and D documents with their line manager.

- Contacting the CITS Service Desk (01209 881717) if experiencing difficulties accessing documents via the R and D intranet or internet webpage, or if unable to access EDGE, contact the Research Systems Administrator via the generic e-mail account ([rch-tr.edge@nhs.net](mailto:rch-tr.edge@nhs.net)).
- Ensuring that any anomalies or omissions within R and D procedural documents are highlighted to the Research Governance Manager, following the processes described in [Section 4](#), Standards and Practice.

## 4. Standards and Practice

### 4.1. Developing Standard Operating Procedures (SOP) and Working Instructions (WI)

- 4.1.1. R and D SOPs and WIs may be written when the need for a new or revised document is identified. The Research Governance Manager will ensure that a similar Trust or departmental document does not already exist and present the proposed document to SMT to gain initial approval to start the process and appoint an appropriate person(s) as author.
- 4.1.2. The author(s) should use the Trust SOP template, to ensure a comprehensive and consistent approach for published documents.
  - [Standard Operating Procedure \(SOP\) Template](#)
- 4.1.3. All documents must be compliant with relevant legislative requirements and aim to adopt any recommended national best practice or standards within that area of expertise. Where no national guidance exists, the document should reflect agreed local or regional practice and, where possible, be evidence-based and bench-marked.
- 4.1.4. For draft procedural documents, the version will be recorded as draft at the front of the title of the document, in the electronic filename and as a diagonal watermark.
- 4.1.5. The procedure shall be described in a logical, step-by-step order using unambiguous language.
- 4.1.6. Responsible people (referred to by job description or role rather than by name) or groups should be included in the description of specific steps of a procedure where applicable.

### 4.2. Style and Format

- 4.2.1. Please refer to the current Royal Cornwall Hospitals NHS Trust (RCHT) [The Policy of Policies](#) on the following issues:
  - Style and Format.
  - Mandatory elements of a procedural or web document.
  - Consultation, Approvals and Ratification.

- Extension of Document Validity.
  - Deletion and Archival of Documents.
- 4.2.2. When using RCHT templates, all mandatory headings should be included, as listed and detailed in the [Policy on Policies](#) document.
  - 4.2.3. SOPs may reference a generic form, checklist, template, or associated document (for example, 'using the current checklist template') to outline a step in a procedure, these should not be attached to the SOP document.
  - 4.2.4. A form, checklist or template may reference a SOP or WI which should be used (for example, 'refer to WIxx for further instruction'), but the document version should not be specified.

#### **4.3. Change Requests**

- 4.3.1. Where changes are required for R and D procedural documents, R and D AD18 New QMS Document or Change to existing QMS Document Request Form (see Documents folder on EDGE) should be emailed to the Research Governance Manager via [rcht.researchqualityassurance@nhs.net](mailto:rcht.researchqualityassurance@nhs.net).
- 4.3.2. The Research Governance Manager will assess the priority within which the change request should be treated and forward the form to the document author(s).
- 4.3.3. The document author(s) will review the procedural document and update with all relevant changes, the revised document should be submitted to the Research Governance Manager in line with any agreed timeframes.
- 4.3.4. For major amendments, such as changes to relevant regulations or standards and practice, the version number should increase in sequential increments of 1 (for example version 1.0, version 2.0, version 3.0).
- 4.3.5. For minor amendments, such as correction of typographical errors and clarifying ambiguous statements, the version number should increase in sequential increments of 0.1 (for example version 1.1, 1.2 or 3.1, 3.2).

#### **4.4. New Procedural Documents**

A new procedural document can be requested by emailing R and D AD18 New QMS Document or Change to existing QMS Document Request Form (see Documents folder on EDGE) to the Research Governance Manager via [rcht.qualityassurance@nhs.net](mailto:rcht.qualityassurance@nhs.net).

#### **4.5. Ratification of SOPs**

- 4.5.1. All Standard Operating Procedures (SOPs) are controlled documents, which are published on the Trust intranet and internet pages. All controlled documentation must be ratified by the Senior Management Team (SMT).

- 4.5.2. The Research Governance Manager or delegate is responsible for submitting final drafts of SOPs to SMT for ratification at the SMT meetings. An audit trail for the ratification of SOP documents will be provided by the SMT minutes and the sign-off in the Admin Control system.
- 4.5.3. Once ratified by SMT, the Research Governance Manager or delegate must submit the SOP to the Trust's Policy Review Group (PRG) for approval to publish on the Trust intranet and internet webpages.

#### **4.6. Approval for other procedural documents**

- 4.6.1. All other procedural documents which include Work Instructions (WIs), Associated Documents (ADs) and other forms which fall outside of the Trust Policy of Policies, should be reviewed regularly to ensure they are fit-for-purpose.
- 4.6.2. Approval of procedural documents which align to relevant SOPs should be approved as part of the SOP ratification process, these documents should be submitted for review and approval by SMT.

#### **4.7. Use of EDGE for procedural documents**

- 4.7.1. The EDGE system is used as a repository for all R and D procedural documents. EDGE maintains a robust audit trail to meet MHRA inspection expectations.
- 4.7.2. All R and D procedural documents will be published in the Documents folder in EDGE by the Research Governance Manager or delegate.
- 4.7.3. SOPs should only be published on EDGE following receipt of the approval to publish from PRG, see process described in [Section 4.5](#).
- 4.7.4. When documents are superseded in EDGE, only the current version of the document will be accessible by R and D staff. Obsolete and superseded documents should only be accessed by the Research Governance Manager and delegate, and any staff with admin access for the EDGE system.

#### **4.8. Training**

- 4.8.1. SOPs will be disseminated to all R and D staff following approval to publish and will be available on the Trust intranet and internet webpages, and the Documents folder on EDGE.
- 4.8.2. All staff conducting research at RCHT should read and acknowledge each current version of a SOP, within one month of the release of the SOP or before they need to conduct activities in accordance with the relevant SOP.
- 4.8.3. The Research Governance Manager or delegate will add a training module to the Training Courses folder in EDGE, when each new or revised SOP is published. R and D staff will be responsible for recording the completion of training for SOPs in their profile on EDGE, to document that the content of the relevant SOP has been read and understood.

#### **4.9. Non-compliance**

There may be situations where unplanned or accidental deviations from procedural documents are discovered, these should be classified and processed in accordance with R and D SOP004 Reporting and Managing Non-Compliance and Serious Breaches Standard Operational Procedure (see Documents folder on EDGE).

#### **4.10. Document Withdrawal**

- 4.10.1. A procedural document may be withdrawn due to a major change in current practice, an incorporation of a process or task into another document, or for another reason. Any member of staff may recommend that a procedure should be withdrawn by emailing R and D AD18 New QMS Document or Change to existing QMS Document Request Form (see Documents folder on EDGE) to the Research Governance Manager via [rcht.qualityassurance@nhs.net](mailto:rcht.qualityassurance@nhs.net).
- 4.10.2. Requests for the withdrawal of a procedural document should be reviewed and approved by SMT.
- 4.10.3. Withdrawn procedural documents will be archived in accordance with the process described in [Section 4.11](#) Archiving.

#### **4.11. Archiving**

- 4.11.1. All obsolete R and D procedural documents uploaded onto the Trust's Document Library will be archived in accordance with the Policy on Policies.
- 4.11.2. All obsolete documentation uploaded on EDGE will remain in the Documents folder, but it will only be accessible for staff with appropriate admin access.

### **5. Dissemination and Implementation**

- 5.1. Trust-wide R and D procedural documents will be stored on the Trust's Document Library, and a working copy will be accessible through EDGE providing alternative access for research staff.
- 5.2. The Research Governance Manager or delegate will arrange for the documents to be published on the Trust Documents Library and EDGE.
- 5.3. The Research Governance Manager or delegate will ensure that any previous versions of the document are made inaccessible to general EDGE users, in accordance with the EDGE document archiving procedure.
- 5.4. R and D SMT to define any training requirements prior to the implementation of any procedural documentation. There will be appropriate time allowed for such training prior to the publishing of the SOP or WI.

- 5.5. Relevant research staff registered on EDGE will be notified by email of the new or reviewed document. Relevant staff will be identified from the ownership and responsibilities ([Section 3](#)) of the procedural document and the R and D AD19 Training Matrix (see Documents folder in EDGE).
- 5.6. Details of how to access EDGE is available by contacting the Research Systems Officer via [rch-tr.edge@nhs.net](mailto:rch-tr.edge@nhs.net).
- 5.7. It is the responsibility of all staff to check the website regularly, in order to see if SOPs have been added or amended. R and D will endeavour to notify research staff of any SOP developments that may be relevant to them via staff communications e.g., R and D Newsletters, Leadership Huddle and Workstream Huddles. A list of any new or updated SOPs will be reviewed and ratified at the R and D Senior Management Team Governance and Performance monthly meetings.
- 5.8. Consideration must be given at the study set up as to which SOPs will not apply to a specific study, with agreement from SMT. Full details must be included as a written statement in the study site file.
- 5.9. Whilst SOPs may be printed, the electronic version maintained on R and D internet page is the controlled copy. Any printed copies are not controlled documents.
- 5.10. Chief and Principal Investigators will be notified as per the Trust's process for notifying all staff of new procedural documents.

#### **5.11. Training and Education**

- 5.11.1. When a new SOP is authorised, or when an existing SOP is revised, self-directed training as specified and detailed by the SMT must be carried out by all staff to which the SOP is relevant, and this training documented in their training record.
- 5.11.2. Staff should take time to read and fully understand the SOP and relevant documents, ensuring that they are able to implement the SOP as required. If clarification is needed, the staff member should approach the Research Governance Manager, or another member of the SMT, 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.

#### **5.12. SOP Deviations**

- 5.12.1. 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 need(s) to be taken. It may also be appropriate to submit an incident report via the Datix system.
- 5.12.2. The author of the risk assessment must submit the risk assessment to SMT.

## 6. Monitoring compliance and effectiveness

| Information Category                               | Detail of process and methodology for monitoring compliance                                                                                                                                                                                                                                                                                                                                                                           |
|----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Element to be monitored</b>                     | <p>Successful implementation of the processes described in this SOP culminates in a properly approved and formatted R and D Procedural Document. Only documents approved by the Clinical Director of R and D or delegate are published via the Trust's Documents Library and R and D Internet Pages.</p> <p>The Research Governance Manager will be responsible for the assessment of compliance of R and D Procedural Documents.</p> |
| <b>Lead</b>                                        | Research Governance Manager                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Tool</b>                                        | The preparation, approval, review and issue of R and D procedural documents will be under the control of the Research Governance Manager who will check that each document conforms to the requirements of the Trust Policy on Policies.                                                                                                                                                                                              |
| <b>Frequency</b>                                   | Compliance with this procedural document will be monitored as part of the R and D risk-based, audit and monitoring process directed through the SMT Governance and Performance Meetings.                                                                                                                                                                                                                                              |
| <b>Reporting arrangements</b>                      | <p>The Research Governance Manager will inform the SMT when aware of the following:</p> <ul style="list-style-type: none"> <li>• Changes in legislation and standards.</li> <li>• New requests for procedural documents.</li> <li>• Current documents due for review within next 6 months.</li> <li>• Change requests.</li> <li>• Findings from system audits.</li> </ul>                                                             |
| <b>Acting on recommendations and Lead(s)</b>       | The SMT will provide an effective oversight and ensure corrective actions are undertaken where applicable.                                                                                                                                                                                                                                                                                                                            |
| <b>Change in practice and lessons to be shared</b> | <p>The SMT will identify non-compliance and appoint a member of the SMT to provide support and advice to identify training needs and improve practice.</p> <p>Required changes to practice will be implemented as soon as practically possible.</p>                                                                                                                                                                                   |

## 7. Updating and Review

The R and D procedural documents will be reviewed no less than every three years by the SMT, unless an earlier review is required and in accordance with Section 6.16 of the Trust's Policy for the Development and Management of Knowledge, Procedural and Web Documents (The Policy on Policies).

## 8. Equality and Diversity

8.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the ['Equality, Inclusion and Human Rights Policy'](#) or the Trust's [Equality and Diversity website](#).

8.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

## Appendix 1. Governance Information

| Information Category                                             | Detailed Information                                                                                                                                                                                                            |
|------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Document Title:</b>                                           | Research and Development SOP001 - Preparation, Approval and Review of Standard Operating Procedures and Work Instructions<br>Standard Operating Procedure V7.0                                                                  |
| <b>This document replaces (exact title of previous version):</b> | Research and Development SOP001 - Preparation, Approval and Review of Standard Operating Procedures and Work Instructions<br>Standard Operating Procedure V6.1                                                                  |
| <b>Date Issued/Approved:</b>                                     | January 2026                                                                                                                                                                                                                    |
| <b>Date Valid From:</b>                                          | February 2026                                                                                                                                                                                                                   |
| <b>Date Valid To:</b>                                            | February 2029                                                                                                                                                                                                                   |
| <b>Directorate / Department responsible (author/owner):</b>      | Caroline Phillips - Research Governance Manager.                                                                                                                                                                                |
| <b>Contact details:</b>                                          | <a href="mailto:rcht.qualityassurance@nhs.net">rcht.qualityassurance@nhs.net</a>                                                                                                                                                |
| <b>Brief summary of contents:</b>                                | This standard operating procedure (SOP) details how R and D procedural documents, including SOPs, work instructions (WI) and associated documents relating to the trust-wide systems should be generated, updated and approved. |
| <b>Suggested Keywords:</b>                                       | Standard Operating Procedures (SOP).<br>Work Instructions (WI).<br>Good Clinical Practice (GCP).<br>Research and Development (R and D).                                                                                         |
| <b>Target Audience:</b>                                          | <b>RCHT:</b> Yes<br><b>CFT:</b> No<br><b>CIOs ICB:</b> No                                                                                                                                                                       |
| <b>Executive Director responsible for Policy:</b>                | Chief Strategy Officer                                                                                                                                                                                                          |
| <b>Approval route for consultation and ratification:</b>         | R and D Senior Management Team (SMT)                                                                                                                                                                                            |
| <b>General Manager confirming approval processes:</b>            | Bianca Mills, Head of Research and Development                                                                                                                                                                                  |

| Information Category                                                                                | Detailed Information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Name of Governance Lead confirming approval by specialty and care group management meetings:</b> | Caroline Phillips, Research Governance Manager                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Links to key external standards:</b>                                                             | Good Clinical Practice for Clinical Trials<br><a href="https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials">https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Related Documents:</b>                                                                           | <p>The Medicines for Human Use (Clinical Trials) Regulations 2004 <a href="#">The Medicines for Human Use (Clinical Trials) Regulations 2004</a></p> <p>The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 <a href="#">The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025</a></p> <p>Internal Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guide for Good Clinical Practice E6 (R3) (6 January 2025)<br/><a href="#">ICH E6(R3) Step4_FinalGuideline_2025_0106.pdf</a></p> <p>UK Policy Framework for Health and Social Care Research (2017) <a href="#">UK Policy Framework for Health and Social Care Research - Health Research Authority</a></p> <p>RCHT The Policy of Policies, Development and Management of Knowledge, Procedural and Web Documents). <a href="#">The Policy on Policies</a></p> <p>R and D SOP004 Reporting and Managing Non-compliance and Serious Breaches.</p> <p>R and D AD07 Glossary of Terms.</p> <p>R and D AD18 QMS Document Change Request Form.</p> <p>R and D AD19 Training Matrix.</p> |
| <b>Training Need Identified?</b>                                                                    | Yes – details provided in Section 5                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Publication Location (refer to Policy on Policies – Approvals and Ratification):</b>             | Internet and Intranet                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Document Library Folder/Sub Folder:</b>                                                          | Research and Innovation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

## Version Control Table

| Date       | Version Number | Summary of Changes                                                                                                                                                                                                                                                                                                                      | Changes Made by                                |
|------------|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| 01/07/2012 | V1.0           | Revision to reflect current practice                                                                                                                                                                                                                                                                                                    | Dr N Morley, R and D ARM                       |
| 22/12/2014 | V2.0           | Clarify introduction and apply change request                                                                                                                                                                                                                                                                                           | Dr N Morley, R and D ARM                       |
| 23/0/2015  | V2.1           | Update the change from Q-pulse to EDGE                                                                                                                                                                                                                                                                                                  | Dr N Morley, R and D ARM                       |
| 07/06/2016 | V3.0           | Review following new processes (HRA)                                                                                                                                                                                                                                                                                                    | Dr N Morley, R and D ARM                       |
| 09/08/2016 | V3.1           | Clarity on the change request process                                                                                                                                                                                                                                                                                                   | Dr N Morley, R and D ARM                       |
| 05/04/2017 | V4.0           | Change to Trust-wide Standard template format.                                                                                                                                                                                                                                                                                          | Dr N Morley, R and D ARM                       |
| 06/08/2019 | V5.0           | Minor change to 1.7 to state that SOPS must be followed unless in conflict with regulations                                                                                                                                                                                                                                             | Dr N Morley, R and D ARM                       |
| 02/03/2023 | V6.0           | Scope of the document amended to the development of Standard Operating Procedures and Working Instructions. Changes from Research, Development and Innovation (R D and I) to Research and Development (R and D). Minor changes made to content noted as tracked changes in draft. Document reformatted in line with the Trust's policy. | Caroline Phillips, Research Governance Manager |
| 16.06.2023 | V6.1           | Title updated to reflect the document is a Standard Operating procedure (SOP).<br>Section fore Scope and Definition moved to under Section 1 – to align with SOP Template.                                                                                                                                                              | Caroline Phillips, Research Governance Manager |
| 28/01/2026 | V7.0           | Review to reflect the changes to the clinical trials regulations and ICH GCP guidance.<br>Review of SOP in line with GCP guidance, feedback from external monitoring and audits and changes to R and D procedures.<br>Review and update in accordance with Trust policies.                                                              | Caroline Phillips, Research Governance Manager |

**All or part of this document can be released under the Freedom of Information Act 2000**

**All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus six years.**

**This document is only valid on the day of printing.**

### **Controlled Document**

This document has been created following the Royal Cornwall Hospitals NHS Trust [The Policy on Policies \(Development and Management of Knowledge Procedural and Web Documents Policy\)](#). It should not be altered in any way without the express permission of the author or their Line Manager.

## Appendix 2. Equality Impact Assessment

### Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity and Inclusion Team  
[rcht.inclusion@nhs.net](mailto:rcht.inclusion@nhs.net)

| Information Category                                                                                                                | Detailed Information                                                                                                                                        |
|-------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Name of the strategy / policy / proposal / service function to be assessed:</b>                                                  | Research and Development SOP001 - Preparation, Approval and Review of Standard Operating Procedures and Work Instructions Standard Operating Procedure V7.0 |
| <b>Directorate and service area:</b>                                                                                                | Corporate.<br>Research and Development.                                                                                                                     |
| <b>Is this a new or existing Policy?</b>                                                                                            | Existing.                                                                                                                                                   |
| <b>Name of individual completing EIA</b><br>(Should be completed by an individual with a good understanding of the Service/Policy): | Caroline Phillips, Research Governance Manager.                                                                                                             |
| <b>Contact details:</b>                                                                                                             | <a href="mailto:rcht.qualityassurance@nhs.net">rcht.qualityassurance@nhs.net</a>                                                                            |

| Information Category                                                                                                                  | Detailed Information                                                                                                                                                                                                                                                                                 |
|---------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1. Policy Aim - Who is the Policy aimed at?</b><br>(The Policy is the Strategy, Policy, Proposal or Service Change to be assessed) | To ensure that R and D have robust procedures in place for the development of SOPs and WIs, in line with the requirements of Good Clinical Practice (GCP). The policy is aimed at all staff who work in research studies at RCHT.                                                                    |
| <b>2. Policy Objectives</b>                                                                                                           | To ensure that R and D procedural documents are consistent with Trust policies in terms of format, content, and dissemination, whilst being aligned to the requirements for GCP. This document ensures that governance processes are in place for consultation and ratification of all SOPS and WIs. |
| <b>3. Policy Intended Outcomes</b>                                                                                                    | Effective control of R and D procedural documents including version control and archiving arrangements. Documents are accessible via the Trust's Document Library and the web-based EDGE database.                                                                                                   |

| Information Category                                                                     | Detailed Information                                                                                                                                                                                                                                                                   |
|------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>4. How will you measure each outcome?</b>                                             | Risk-based internal auditing and monitoring programme to ensure that research studies are compliant with GCP.<br>External monitoring and auditing carried out by the sponsors and Clinical Research Associates (CRAs).                                                                 |
| <b>5. Who is intended to benefit from the policy?</b>                                    | All research participants.<br>All staff involved in research and the Trust.                                                                                                                                                                                                            |
| <b>6a. Who did you consult with?</b><br>(Please select Yes or No for each category)      | <ul style="list-style-type: none"> <li>Workforce: Yes</li> <li>Patients/ visitors: No</li> <li>Local groups/ system partners: No</li> <li>External organisations: No</li> <li>Other: No</li> </ul>                                                                                     |
| <b>6b. Please list the individuals/groups who have been consulted about this policy.</b> | <b>Please record specific names of individuals/ groups:</b><br>Senior Management Team.<br>Research staff.                                                                                                                                                                              |
| <b>6c. What was the outcome of the consultation?</b>                                     | Consultation ensures that R and D understand best practice in the development of procedural documents, aligned to the requirements of GCP guidance.                                                                                                                                    |
| <b>6d. Have you used any of the following to assist your assessment?</b>                 | The outcomes of internal and external monitoring and audits will inform the development of SOPs and WIs, ensuring that R and D has robust systems and processes in place which ensure patient safety and the quality and integrity of research studies carried out by R and D at RCHT. |

## 7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

| Protected Characteristic                                                   | (Yes or No) | Rationale             |
|----------------------------------------------------------------------------|-------------|-----------------------|
| <b>Age</b>                                                                 | No          | For all staff members |
| <b>Sex</b> (male or female)                                                | No          | For all staff members |
| <b>Gender reassignment</b><br>(Transgender, non-binary, gender fluid etc.) | No          | For all staff members |
| <b>Race</b>                                                                | No          | For all staff members |

| Protected Characteristic                                                                            | (Yes or No) | Rationale             |
|-----------------------------------------------------------------------------------------------------|-------------|-----------------------|
| <b>Disability</b> (e.g. physical or cognitive impairment, mental health, long term conditions etc.) | No          | For all staff members |
| <b>Religion or belief</b>                                                                           | No          | For all staff members |
| <b>Marriage and civil partnership</b>                                                               | No          | For all staff members |
| <b>Pregnancy and maternity</b>                                                                      | No          | For all staff members |
| <b>Sexual orientation</b> (e.g. gay, straight, bisexual, lesbian etc.)                              | No          | For all staff members |

**A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.**

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Caroline Phillips, Research Governance Manager.

**If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:**  
[Section 2. Full Equality Analysis](#)