

Research and Development SOP030 Delegation of Research Duties Standard Operating Procedure

V6.0

April 2026

Table of Contents

1. Introduction	4
1.6. Scope.....	4
1.7. Definitions and Glossary.....	5
2. Purpose of this Standard Operating Procedure.....	7
3. Ownership and Responsibilities	7
3.1. Role of the R and D Clinical Director	7
3.2. Role of the Senior Management Team (SMT)	7
3.3. Role of the Chief Investigator (CI).....	8
3.4. Role of the Principal Investigator (PI)	8
3.5. Role of the Team Leader	9
3.6. Role of the Research Clinical Study Lead	9
3.7. Role of the Research Administration Team.....	10
4. Standards and Practice.....	10
4.1. Approaching Staff	10
4.2. Staff not working in Research and Development	10
4.3. Education, training and experience	11
4.4. Documentation	11
4.5. EDGE Delegation Logs.....	12
5. Dissemination and Implementation.....	12
5.11. Training and Education	13
5.12. SOP Deviations.....	13
6. Monitoring compliance and effectiveness.....	13
7. Updating and Review	14
8. Equality and Diversity.....	14
Appendix 1. Governance Information	15
Appendix 2. Quality and Equality Impact Assessment (QEIA) Guidance Form.....	19

Data Protection Act 2018 (UK General Data Protection Regulation – 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

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”) 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. Section 9 of the UK Policy Framework for Health and Social Care Research (2017) outlines the roles and responsibilities of the various stakeholders involved in health and social care research. [UK Policy Framework for Health and Social Care Research - Health Research Authority](#)
- 1.3. International Conference on Harmonisation Good Clinical Practice (ICH GCP) E6 (R3) outlines specific responsibilities for various functions involved in clinical trials, including investigators, sponsors, and ethics committees, to ensure the integrity and quality of clinical research. ICH GCP E6 (R3) (II) Principle 10 states; “Roles and responsibilities in clinical trials should be clear and documented appropriately”.
https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf
- 1.4. ICH GCP E6 (R3) (III) Annex 1 paragraph 2.3.2 states; “The investigator should ensure that persons or parties to whom the investigator has delegated trial-related activities are appropriately qualified and are adequately informed about relevant aspects of the protocol, the investigational product(s) and their assigned trial activities (including activities conducted by staff provided by other parties in accordance with local regulatory requirements). Trial-related training to persons assisting in the trial should correspond to what is necessary to enable them to fulfil their delegated trial activities that go beyond their usual training and experience.” [ICH_E6\(R3\)_Step4_FinalGuideline_2025_0106.pdf](#)
- 1.5. The Principal Investigator (PI) is responsible for the local site in a study and may also be the Chief Investigator for the study. PIs may delegate tasks to appropriately trained and qualified members of their research team; however, they must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibilities. The delegation of duties from PI to staff working on clinical trials or research studies must be clearly and consistently defined and documented.

1.6. Scope

This Standard Operating Procedure (SOP) applies to all staff conducting research for the Royal Cornwall Hospitals NHS Trust (RCHT).

1.7. Definitions and Glossary

- 1.7.1. **Good Clinical Practice (GCP)** is an international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.
- 1.7.2. **Sponsor** is an individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial. A group of individuals and/or organisations may take on sponsorship responsibilities and distribute them by agreement among the members of the group, provided that, collectively, they make arrangements to allocate all the responsibilities that are relevant to the study in line with the UK Policy Framework for Health and Social Care Research.
- 1.7.3. **Principal Investigator (PI)** is the person who takes responsibility for the initiation and conduct of the study at site. There is one Principal Investigator at each site participating in a research study. For a single site study, the Chief Investigator (CI) may also take on the role of Principal Investigator (PI).
- 1.7.4. **Clinical Study** – Regulation (EU) no 536/2014 Chapter I, Article 2 differentiates between clinical studies and clinical trials. Regulation (EU) no 536/2014, Chapter I, Article 2 (2 (1 (a-c))) defines a clinical study as any investigation in relation to humans intended:
- To discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products.
 - To identify any adverse reactions to one or more medicinal products.
- Or,
- To study the absorption, distribution, metabolism and excretion of one or more medicinal products.
- With the objective of ascertaining the safety and/or efficacy of those medicinal products.
- 1.7.5. **Clinical Trial** - Regulation (EU) no 536/2014, Chapter I Article 2 (2 (a-c))) defines a clinical trial as any research which fulfills any of the following conditions:
- The assignment of the subject to a particular therapeutic strategy is decided in advance and does not fall within normal clinical practice in the Member State concerned.
 - The decision to prescribe the investigational medicinal products is taken together with the decision to include the subject in the clinical study or, diagnostic or monitoring procedures in addition to normal clinical practice are applied to the subjects.

- 1.7.6. **Clinical Study Lead** – is the person taking responsibility for the delivery of the trial or study on behalf of and with instruction from the Principal Investigator (PI). This person has oversight of the day-to-day running of the study. This role could be a Research Nurse, Allied Health Professional (AHP) or other clinical specialist delegated by the PI.
- 1.7.7. **Trial Master File (TMF)** is the collection of files and documentation at all sites and organisations and those held by the sponsor that enable the conduct of the research study, and the quality of the data produced to be evaluated and demonstrate the study has been conducted in accordance with the legislation.
- 1.7.8. **Investigator Site File (ISF)** contains the essential documents which show that the investigator and the conduct of the study are following the regulatory requirements. The ISF can be held in paper or digital formats, or a combination of both.
- 1.7.9. **Essential Documents** are those documents which individually or collectively enable both the conduct of the research study, and the quality of the data produced to be evaluated.
- 1.7.10. **Source Documentation** is defined as the original documents, data and records which provide information of clinical findings, observations, and any activities in a clinical study necessary for the reconstruction and evaluation of the study.
- 1.7.11. **Delegation Log** is a regulatory document of study staff and the tasks or duties that have been delegated to them by the Principal Investigator (PI) for a clinical trial or clinical study.
- 1.7.12. **Hosted** refers to an externally sponsored study for which the RCHT is acting as a research site.
- 1.7.13. **EDGE** is a dedicated, web-based research database which is used within, and managed by, the R and D department at RCHT.
- 1.7.14. **Standard Operating Procedure (SOP)** is a procedure document detailing a specific sequence of events that must be followed for an activity.
- 1.7.15. **Glossary of Terms (R and D AD07)** is a glossary of the terms and definition of the acronyms frequently used within research and can be found in the Associated Documents folder in EDGE.
- 1.7.16. **Acronyms**
- **CI:** Chief Investigator.
 - **CTIMP:** Clinical Trial of an Investigational Medicinal Product.
 - **GCP:** Good Clinical Practice.
 - **HRA:** Health Research Authority.

- **ICH GCP:** International Council for Harmonisation of Good Clinical Practice.
- **ISF:** Investigator Site File.
- **MHRA:** Medicines and Healthcare products Regulatory Agency.
- **PI:** Principal Investigator.
- **QMS:** Quality Management System.
- **R and D:** Research and Development.
- **RCHT:** Royal Cornwall Hospitals NHS Trust.
- **REC:** Research Ethics Committee.
- **SMT:** Senior Management Team.
- **TMF:** Trial Master File.

1.8. This version supersedes any previous versions of this document.

2. Purpose of this Standard Operating Procedure

This Standard Operating Procedure (SOP) describes the procedures for the delegation of duties when setting up and delivering all research studies being conducted at RCHT.

3. Ownership and Responsibilities

3.1. Role of the R and D Clinical Director

The R and D Clinical Director is 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 (SMT)

The SMT 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.
- Ensuring adequate provision of training for staff to perform their roles and responsibilities in association with the processes described in [Section 4](#), Standards and Practice.

- Arranging monitoring and auditing of the systems and processes associated with the standards and practice described in [Section 4](#).
- Supporting the PI to fulfil the duties, responsibilities and obligations in executing the processes described in [Section 4](#), Standards and Practice.
- Ensuring episodes of non-compliance associated with the standards and practice described in [Section 4](#) are processed in accordance with the R and D SOP004 Reporting and Managing Non-Compliance and Serious Breaches (see SOP index guide).

3.3. Role of the Chief Investigator (CI)

The CI is responsible for:

- Ensuring all Sponsor responsibilities are met as agreed and recorded in the Trial Master File (TMF).
- Gaining assurance that everyone involved in the conduct of the research is qualified by education, training and experience.
- Ensuring episodes of non-compliance associated with the standards and practice described in [Section 4](#) are processed in accordance with the R and D SOP004 Reporting and Managing Non-Compliance and Serious Breaches (see Documents folder in EDGE).

3.4. Role of the Principal Investigator (PI)

The PI is responsible for:

- Having oversight for the appropriate delegation of duties for the research team conducting the study at RCHT.
- Ensuring each member of the research team, is qualified, trained and has the relevant experience to discharge their role within the study, and their qualifications are documented and evidenced in the Investigator Site File (ISF) in accordance with the R and D SOP021 Preparation and Maintenance of an Investigator Site File (see Documents folder in EDGE).
- Ensuring all delegated duties are appropriately recorded within the delegation log.
- Ensuring episodes of non-compliance with the standards and practice described in [Section 4](#) are investigated and processed in accordance with R and D SOP004 Reporting and Managing Non-Compliance and Serious Breaches (see Documents folder in EDGE).

3.5. Role of the Team Leader

The Team Leader is responsible for:

- Identifying staff with appropriate skills and experience to support the PI to undertake delegated duties in respect of the standards and processes described in [Section 4](#), in accordance with the principles of Good Clinical Practice (GCP).
- Supporting the PI to ensure all staff involved in the study fulfil the duties, responsibilities, and obligations in executing the processes described in [Section 4](#), Standards and Practice in accordance with the principles of GCP.
- Identifying training needs for RCHT staff involved in the standards and processes described in [Section 4](#).
- Ensuring the delegation logs and supporting documentation are maintained and filed appropriately.
- Supporting the PI with investigating episodes of non-compliance with the standards and processes described in [Section 4](#), in accordance with R and D SOP004 Reporting and Managing Non-Compliance and Serious Breaches (see Documents folder in EDGE).
- Providing monitors, auditors and regulators with access to the study files and documentation, relevant to the study or clinical trial being reviewed.
- Supporting monitors, regulators and auditors with addressing queries relating to the delegation of duties.

3.6. Role of the Research Clinical Study Lead

The Clinical Study Lead is responsible for:

- Supporting the PI to ensure all staff involved in the study fulfil the duties, responsibilities, and obligations in executing the processes described in [Section 4](#), Standards and Practice in accordance with the principles of GCP.
- Ensuring the delegation log is up to date with staff changes, records of staff training are maintained, for the duration of the trial or study for which they are the lead.
- Supporting the Research Administration Team with maintaining the delegation logs.
- Supporting the PI with investigating episodes of non-compliance with the standards and processes described in [Section 4](#), in accordance with R and D SOP004 Reporting and Managing Non-Compliance and Serious Breaches (see Documents folder in EDGE).
- Providing monitors, auditors and regulators with access to the study files and documentation, relevant to the study or clinical trial being reviewed.

- Supporting monitors, regulators and auditors addressing queries relating to the delegation of duties.

3.7. Role of the Research Administration Team

The Research Administration Team is responsible for:

- Providing administrative functions to support the PI with processing and management of documentation for the delegation of duties process.
- Supporting the PI and Research Clinical Study Lead to ensure all staff involved in the study are added to the delegation log before undertaking any research activity.
- Liaising with research staff, to ensure that delegation logs and EDGE are updated in a timely manner.
- Ensuring accurate version control of the delegation log.
- Ensuring the delegation log and supporting documentation are filed appropriately.
- Supporting the PI with documentation for episodes of non-compliance with the standards and processes described in [Section 4](#), in accordance with R and D SOP004 Reporting and Managing Non-Compliance and Serious Breaches (see SOP index guide).
- Supporting the PI to ensure monitors, auditors and regulators have access to the study files and documentation as directed.
- Supporting monitors, regulators and auditors with queries relating to the study files and documentation.

4. Standards and Practice

4.1. Approaching Staff

Any staff member approached should carefully consider if they have the time and suitable education, training and experience to undertake the duties. The staff member should inform the PI of any training requirements that are required to carry out their duties.

4.2. Staff not working in Research and Development

- 4.2.1. External staff with delegated duties must have the appropriate contract to be on site and, where applicable, see patients. This could be through an honorary contract, a letter of access or a research passport.
- 4.2.2. Supporting Services and specialist roles will provide assurance that the relevant delegated staff have the required education, training and experience to carry out their delegated duties.

4.3. Education, training and experience

- 4.3.1. It is the responsibility of the PI to check that all staff members involved in the conduct of the clinical trials or research studies, are qualified by education, training or experience, to carry out their delegated tasks and responsibilities.
- 4.3.2. All delegated research staff must provide evidence of education, training and relevant experience.
- 4.3.3. All delegated staff working on clinical trials or research studies should undertake Good Clinical Practice (GCP) training. GCP training should be completed prior to commencing work on the trial or study and GCP Refresher training should be subsequently updated, in accordance with R and D SOP011 Research Training (see Documents folder in EDGE).

4.4. Documentation

- 4.4.1. A delegation log must be kept for all clinical trials and is recommended for all research studies, to record the delegation of duties and responsibilities.
- 4.4.2. The sponsor will define what documentation should be used for each trial or study, and whether it is paper-based or electronic. For sponsored studies or for hosted studies where the sponsor has not provided a delegation log, R and D AD57 Delegation Log template (available in the Documents folder on EDGE) should be used.
- 4.4.3. All staff involved in the conduct of the clinical trial or research study are responsible for completing and signing the relevant delegation log prior to working on the trial or study, ensuring they are delegated tasks and responsibilities appropriately.
- 4.4.4. The PI should review each staff member's tasks and responsibilities and countersign the delegation log as confirmation that the PI is delegating the listed tasks to that research team member. The PI's countersignature must be completed prior to a staff member commencing any trial or study activities.
- 4.4.5. The delegation log should be reviewed and updated on a continuous basis by the research clinical study lead throughout the life of the trial or study, to maintain its accuracy should new research team members start, delegated staff leave, or delegated staff change roles from their current post.
- 4.4.6. The delegation log should be kept in the Investigator Site File (ISF) and archived with the essential documentation at the end of the trial or study (See R and D SOP044 Archiving Essential Documents available in the Documents folders on EDGE).

4.5. EDGE Delegation Logs

- 4.5.1. The delegation log can be held electronically for research studies only, using the EDGE system. Guidance on how to manage delegation logs in EDGE is available in the EDGE Knowledge Base, Section 5.6 Delegation Log <https://www.edge.nhs.uk/#/help/group/10/sections/50>.
- 4.5.2. Agreement must be obtained from the sponsor for the use of EDGE delegation logs.
- 4.5.3. Once a PI has been added to the Project Site in EDGE, members of the research team will be able to add themselves to the delegation log. The start date and study role should be added, along with the applicable responsibilities.
- 4.5.4. Adding a new member of the research team to the EDGE delegation log will automatically send an approval request to the PI. The PI should review the requests and authorise as applicable. Authorised staff will receive an email and a notification on EDGE when the request has been approved by the PI. The PI's authorisation must be completed prior to a staff member commencing any study activities.

5. Dissemination and Implementation

- 5.1. Trust-wide Research and Development (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 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 this 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.
- 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 endeavor to notify research staff of any SOP developments that may be relevant to them via staff communications, for example, 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 study set up as to which SOPs will not apply to a specific study, with agreement from the R and D Senior Management Team (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 will 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.
- 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
Element to be monitored	Successful implementation of the procedures described in this SOP ensures that there is a clear understanding of the roles and responsibilities for staff conducting research studies and clinical trials at RCHT.
Lead	Research Governance Manager.
Tool	Internal and external monitoring of research studies and clinical trials will monitor the implementation of this SOP and compliance with Good Clinical Practice (GCP).

Information Category	Detail of process and methodology for monitoring compliance
Frequency	Compliance with this procedural document will be monitored as part of the R and D risk-based, audit and monitoring process directed through the R and D SMT Governance and Performance meetings.
Reporting arrangements	The Research Governance Manager will provide monthly reports at the R and D SMT Governance and Performance meetings.
Acting on recommendations and Lead(s)	The Governance and Performance SMT meetings will provide effective oversight and ensure corrective actions are undertaken .
Change in practice and lessons to be shared	The Governance and Performance SMT meetings will identify non-compliance and appoint a member of the SMT to provide support and advice to identify training needs and improve practice. The required changes to practice will be implemented as soon as practically possible.

7. Updating and Review

The R and D procedural documents will be reviewed no less than every three years and by the R and D SMT unless an earlier review is required, in accordance with Section 9 of the Trust 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 Diversity And Inclusion Policy or the 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
Document Title:	Research and Development SOP030 Delegation of Research Duties Standard Operating Procedure V6.0
This document replaces (exact title of previous version):	Research and Development SOP030 Delegation of Research Duties Standard Operating Procedure V5.0
Date Issued / Approved:	March 2026
Date Valid From:	April 2026
Date Valid To:	April 2029
Author / Owner:	Caroline Phillips, Research Governance Manager.
Contact details:	richt.researchqualityassurance@nhs.net 01872 256428
Brief summary of contents:	The SOP describes the procedures for the delegation of duties when setting up and delivering all research studies being conducted at RCHT.
Suggested Keywords:	Standard Operational Procedure (SOP). Research and Development (R and D). Good Clinical Practice (GCP).
Target Audience:	RCHT: Yes CFT: No CIOs ICB: No
Executive Director responsible for Policy:	Chief Strategy Officer
Approval route for consultation and ratification:	Research and Development Senior Management Team (SMT)
Manager confirming approval processes:	Bianca Mills, Head of Research and Development
Name of Governance Lead confirming consultation and ratification:	Caroline Phillips, Research Governance Manager

Information Category	Detailed Information
Links to key external standards:	Good Clinical Practice for Clinical Trials https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials
Related Documents:	The Medicines for Human Use (Clinical Trials) Regulations 2004 https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/uk-policy-framework-health-and-social-care-research/ The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/uk-policy-framework-health-and-social-care-research/ International Council for Harmonisation (ICH) Guideline for Good Clinical Practice E6 (R3), (06 January 2025). https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf UK Policy Framework for Health and Social Care Research https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/uk-policy-framework-health-and-social-care-research/ EDGE Knowledge Base, Section 5.6 Delegation Log https://www.edge.nhs.uk/#/help/group/10/sections/50 [Accessed 25/02/2026]. R and D SOP004 Reporting and Managing Non-Compliance and Serious Breaches. R and D SOP011 Research Training. R and D SOP021 Preparation and Maintenance of an Investigator Site File. R and D SOP044 Archiving Essential Documents. R and D AD07 Glossary of Terms. R and D AD19 R and D Training Matrix. R and D AD57 Delegation Log Template.
Training Need Identified:	Yes – Details provided in Section 5

Information Category	Detailed Information
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Research and Development

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
01/07/2014	V1.0	Complete revision to reflect current practice	Dr N Morley, R and D ARM
27/04/2017	V2.1	'Policy Under review' label added.	Helen Holman, Data Quality and Project Monitoring Officer
01/08/2017	V3.0	Complete rewrite to align with Trust policies.	Dr N Morley, R and D ARM
01/06/2021	V4.0	Three-year review. Updated with policies and new details regarding electronic means of delegating duties	Dr N Morley, R and D ARM
29/05/2025	V5.0	Change of the title of the SOP. Changes from RD and I to R and D. Review of SOP in line with GCP guidance, feedback from external monitoring and audits and changes to R and D procedures. Review and update in accordance with Trust policies.	Caroline Phillips, Research Governance Manager
12/03/2026	V6.0	Review of SOP in line with the implementation of the amended by the Medicines in Human use (Clinical Trials) (Amendment) Regulations 2025 and International Conference on Harmonisation Good Clinical Practice (ICH GCP) E6 (R3).	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 6 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. Quality and Equality Impact Assessment (QEIA) Guidance Form

The QEIA process allows RCHT to monitor the impact of changes to its policies and services, ensuring that nobody is unduly disadvantaged.

Please ensure you have completed a Quality and Equality Impact Assessment (QEIA) using this link to complete the form:

[E11 QEIA Policy](#).

For guidance, please see the [QEIA Essentials – Quick Reference Guide](#) or contact as required below:

Equality, Diversity and Inclusion guidance, please contact: rcht.inclusion@nhs.net.

Quality Governance guidance, please contact Jillian Tozer: jillian.tozer3@nhs.net