

Research and Development SOP043 Closure Process for Hosted Studies

V5.0

October 2025

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 Research and Development Clinical Director	7
3.2. Role of the Senior Management Team (SMT)	8
3.3. Role of the Principal Investigator.....	8
3.4. Role of the Research Clinical Team.....	9
3.5. Role of the Research Administrator	9
3.6. Role of the Data Officer.....	10
3.7. Role of the Supporting Services.....	10
3.8. Role of the Pharmacy staff.....	11
3.9. Role of the EDGE Officer	11
4. Standards and Practice	12
4.1. End of Study Notification.....	12
4.2. Closure of Study.....	12
4.3. Investigational Products	13
4.4. Human Tissue	13
5. Dissemination and Implementation.....	13
6. Monitoring compliance and effectiveness	15
7. Updating and Review.....	15
8. Equality and Diversity	16
Appendix 1. Governance Information	17
Appendix 2. Equality Impact Assessment.....	20

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. International Conference on Harmonisation Good Clinical Practice (ICH GCP) E6 (R3) Annex 1 paragraph 2.12.11 states “The investigator/institution should have control of all essential records generated by the investigator/institution before and during the conduct of the trial.”
https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf
- 1.3. International Conference on Harmonisation Good Clinical Practice (ICH GCP) E6 (R3) Annex 1 paragraph 2.12.12 states “The investigator/institution should retain the essential records for the required retention period in accordance with applicable regulatory requirements or until the sponsor informs the investigator/institution that these records are no longer needed, whichever is the longest. The investigator/institution should take measures to ensure availability, accessibility and readability and to prevent unauthorised access and accidental or premature destruction of these records”.
https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf
- 1.4. The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research that take account of legal requirements and other standards. Principle 11 states that the findings from research must be accessible in a suitable format and timely manner after the study has finished.
<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/#principles>
- 1.5. Effective study closedown is essential to the overall quality management of the trial or study, ensuring data and documentation are up to date, approved, verified and complete, to facilitate potential future audit(s) and/or inspection(s).
- 1.6. **Scope**
 - 1.6.1. This Standard Operating Procedure (SOP) applies to all clinical trials and studies, hosted by Royal Cornwall Hospitals NHS Trust (RCHT).
 - 1.6.2. This SOP applies to all staff involved in research activities being conducted by 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 participants are protected.
- 1.7.2. **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.

- 1.7.3. **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.
- 1.7.4. **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.

- 1.7.5. **Chief Investigator (CI)** is the authorised health care professional who takes primary responsibility for the conduct of the clinical trial or study. The CI must be a senior individual, with appropriate experience, expertise, and training to undertake the design, conduct and analysis of the study to meet the requirements set out in legislation.
- 1.7.6. **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 clinical trial or study. For a single site study, the Chief Investigator (CI) may also take on the role of Principal Investigator (PI).
- 1.7.7. **The Research Team** is a group of people involved in the conduct of a research project at site. It may include care professionals, academics, patients and service users, members of the public, research professionals, students and/or scientists.
- 1.7.8. **Investigator Site File (ISF)** contains the essential records and documentation which show that the investigator and the conduct of the study are following the regulatory requirements. The ISF can be held in paper or electronic formats, or a combination of both.
- 1.7.9. **Pharmacy Site File (PSF)** contains documentation relating to the accountability, storage and prescribing of investigation product.
- 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 trial or study necessary for the reconstruction and evaluation of the study.
- 1.7.11. **Modifications** are changes made to a research project after the approval from a review body has been given. Medicines in Human use (Clinical Trials) (Amendment) Regulations 2025 (referred to as the “amended Clinical Trials Regulations”) Section 4 (3) (c) changes the terminology from “amendment” to “modification”.
- 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. EDGE maintains a robust audit trail to meet MHRA inspection expectations.
- 1.7.14. **Radico** is a dedicated web-based research finance database, used to capture research costs for trials and studies, and research activity for each participant, which is used for invoicing the sponsor and reconciling payments.
- 1.7.15. **Standard Operating Procedure (SOP)** is a procedure documents detailing a specific sequence of events that must be followed for an activity.

1.7.16. **Glossary of Terms (R and D AD07)** is a glossary of terms and definition of the acronyms can be found in the Associated Documents folder in EDGE.

1.7.17. **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.
- **IP:** Investigational Product.
- **ISF:** Investigator Site File.
- **MHRA:** Medicines and Healthcare products Regulatory Agency.
- **PI:** Principal Investigator.
- **PSF:** Pharmacy Site File.
- **R and D:** Research and Development.
- **RCHT:** Royal Cornwall Hospitals NHS Trust.
- **REC:** Research Ethics Committee.
- **SMT:** Senior Management Team.

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

2. Purpose of this Standard Operating Procedure

This Standard Operating Procedures (SOP) describes the procedure for the closure of trials and studies hosted by the Royal Cornwall Hospitals NHS Trust (RCHT).

3. Ownership and Responsibilities

3.1. Role of the Research and Development Clinical Director

The Research and Development (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 internal audits of the systems and processes associated with the standards and practice described in [Section 4](#).
- Supporting the Principal Investigator (PI) to fulfil the duties, responsibilities, and obligations in executing the processes described in [Section 4](#), Standards and Practice.
- Ensuring any 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 (available in the Documents Folder in EDGE).

3.3. Role of the Principal Investigator

The PI is responsible for:

- Gaining assurance from the Research Administrators that all essential records and documentation is complete and filed in the Investigator Site File (ISF) in accordance with the R and D SOP021 Preparation and Maintenance of an Investigator Site File (ISF).
- Ensuring staff with delegated duties related to the processes described in [Section 4](#) are adequately trained to fulfil their duties in accordance with the regulations and principles of GCP.
- Notifying all staff involved in the clinical trial or study to prepare the files and documents for closure following notification from the sponsor.
- Meet with the monitors, sponsor representatives and auditors, relevant to the clinical trial or study being reviewed and closed.
- Supporting the monitors, sponsor representatives and auditors with any queries relevant to the trial or study being reviewed and closed.
- Ensuring episodes of non-compliance 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 (available in the Documents Folder in EDGE).

3.4. Role of the Research Clinical Team

The Research Clinical Team are responsible for:

- Supporting all RCHT staff involved in the study to fulfil the duties, responsibilities, and obligations in executing the processes described in [Section 4](#), in accordance with the principles of GCP.
- Supporting the Research Administrator to ensure the ISF is complete, and documentation is filed in accordance with the R and D SOP021 Preparation and Maintenance of an Investigator Site File (ISF).
- Supporting the Data Officers, to ensure all CRFs and eCRFs are complete and all outstanding queries have been resolved to the sponsor's satisfaction.
- Supporting the Research Administrators and Data Officers to ensure relevant activities are recorded in Radico in accordance with R and D SOP012 Income from Clinical Trials (available in the Documents Folder in EDGE).
- Supporting monitors, sponsor representatives and auditors with access to the study files and documentation relevant to the clinical trial or study being reviewed and closed.
- Supporting the monitors, sponsor representatives and auditors with any queries relevant to the trial or study being reviewed and closed.
- Supporting the PI to ensure 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 (available in the Documents Folder in EDGE).

3.5. Role of the Research Administrator

The Research Administrator is responsible for:

- Supporting all RCHT staff involved in the trial or study to 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 ISF is complete, and documentation is filed in accordance with the R and D SOP021 Preparation and Maintenance of an Investigator Site File (ISF). Liaising with research staff in all locations to ensure essential records relating to the clinical trial or study are filed in the ISF.
- Ensuring relevant activities are documented in Radico in accordance with R and D SOP012 Income from Clinical Trials (available in the Documents Folder in EDGE).
- Notifying the EDGE Officer of changes required to trial or study status in EDGE.

- Supporting the PI and Research Clinical Team to ensure monitors, sponsor representatives and auditors have supervised access to the ISF in accordance with the R and D AD01 Code of Conduct for Monitoring Visits (available in the Associated Documents folder on EDGE) for a final document check.
- Supporting the monitors, sponsor representatives and auditors with any queries relevant to the trial or study being reviewed and closed.
- Supporting the PI to ensure 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 (available in the Documents Folder in EDGE).

3.6. Role of the Data Officer

The Data Officer is responsible for:

- Supporting the PI to ensure all data related activities are processed in accordance with [Section 4](#), Standards and Practice and the principles of GCP.
- Ensuring all CRFs and eCRFs are complete and all outstanding queries have been resolved to the sponsor's satisfaction.
- Ensuring relevant activities are recorded in Radico in accordance with R and D SOP012 Income from Clinical Trials (See Documents Folder in EDGE).
- Supporting the PI and Research Clinical Team to ensure monitors, sponsor representatives and auditors have supervised access to documentation in accordance with the R and D AD01 Code of Conduct for Monitoring Visits (available in the Associated Documents folder on EDGE) for a final document check.
- Supporting the monitors, sponsor representatives and auditors with any data queries relevant to the trial or study being reviewed and closed.
- Supporting the PI to ensure 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 (available in the Documents Folder in EDGE).

3.7. Role of the Supporting Services

Supporting Services staff are responsible for:

- Ensuring that they fulfil the duties, responsibilities and obligations for the processes described in [Section 4](#), Standards and Practices, in accordance with the principles of GCP.

- Identifying staff with appropriate skills and experience to support the PI to undertake delegated duties in respect of the processes described in [Section 4](#), Standards and Practice.
- Liaising with the Research Administrator to ensure relevant essential records and documentation are filed in the ISF, in accordance with the R and D SOP021 Preparation and Maintenance of an Investigator Site File (ISF).
- Supporting the monitors, sponsor representatives and auditors with any queries relevant to the trial or study being reviewed and closed.
- Supporting the PI to ensure 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 (available in the Documents Folder in EDGE).

3.8. Role of the Pharmacy staff

Pharmacy staff are responsible for:

- Identifying staff with appropriate skills and experience to support the PI to undertake delegated duties in respect of the processes described in [Section 4](#), Standards and Practice.
- Ensuring relevant activities are recorded in Radico in accordance with R and D SOP012 Income from Clinical Trials (See Documents Folder in EDGE).
- Supporting monitors, sponsor representatives and auditors with access to the study files and documentation relevant to the clinical trial or study being reviewed and closed.
- Supporting the monitors, sponsor representatives and auditors with any queries relevant to the trial or study being reviewed and closed.
- Supporting the PI to ensure 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 (available in the Documents Folder in EDGE).

3.9. Role of the EDGE Officer

The EDGE Officer is responsible for:

- Updating the RCHT local status (known as the 'Red Level') of the trial or study in EDGE using the information provided by the research admin team.
- Providing an audit trail in EDGE for the changes made to the trial or study.

4. Standards and Practice

4.1. End of Study Notification

- 4.1.1. The definition of the end of trial or study should be documented in the protocol. In most instances, this will be the date of the last visit of the last recruited participant, or the completion of any follow-up monitoring and data collection described in the study protocol. Any change to this definition after approval for the research has been granted should be processed as a modification.
- 4.1.2. It is the responsibility of the sponsor to notify the Principal Investigator (PI) when a study is closed or terminated prematurely.
- 4.1.3. When written confirmation of the end of trial or study is received from the sponsor, the PI or an appropriately delegated person should inform all members of staff involved in the conduct of the trial or study.
- 4.1.4. The research administrator should upload the end of trial or study notification to EDGE and file a copy of the documentation in the Investigator Site File (ISF), refer to R and D SOP021 Preparation and maintenance of an Investigator Site File (available in the Documents folder in EDGE).

4.2. Closure of Study

- 4.2.1. Where applicable, the trial or study monitor will close out all data queries, perform a Study Close Out Visit and produce a Study Close Out Visit Report which should be filed in the ISF.
- 4.2.2. If the trial or study does not have a monitor, the research administrator will coordinate the close out of the trial or study, a close out checklist should be obtained from the sponsor. If the checklist is not available from the sponsor, R and D AD21 Study Close Out Checklist (available in the Documents folder in EDGE) should be used.
- 4.2.3. All staff involved in the conduct of the trial or study should ensure that all documentation is complete and up to date. The ISF should contain all essential records filed in the relevant sections and use the correct version control, as appropriate. Refer to R and D SOP021 Preparation and Maintenance of an Investigator Site File (available in the Documents folder in EDGE).
- 4.2.4. All financial matters should be resolved and all invoices completed, as agreed in the trial or study agreements and approvals. All outstanding invoices should be raised through Radico, including, but not limited to, study procedures, monitoring visits, modifications and archiving fees. Refer to R and D SOP012 Income from Clinical Trials (available in the Documents folder in EDGE) for further details regarding processing invoices.
- 4.2.5. Research Administrator should notify the EDGE Officer of the change of status for the clinical trial or study to closed at RCHT.

- 4.2.6. The sponsor should be notified when the ISF is ready for archiving and request email confirmation that the study can proceed to archiving. All staff should refer to R and D SOP044 Archiving Essential Documents (available in the Documents folder in EDGE) for further details regarding the archiving of the trial or study.

4.3. Investigational Products

- 4.3.1. The Pharmacy team will be notified of the end of trial by the sponsor or the PI or their delegate. Pharmacy should ensure that the Pharmacy Site File (PSF) is complete and up to date.
- 4.3.2. Unused investigational products should be returned to the sponsor or destroyed on site, in accordance with the agreements and arrangements made with the sponsor with details documented in the PSF. Destruction of the investigational products should be recorded in Radico for invoicing purposes.
- 4.3.3. In certain circumstances, it may be possible to use any remaining investigational products for non-trial patients, providing it is licenced for use in the UK, has not undergone modification, all additional labelling has been removed, and the sponsor has provided written agreement.

4.4. Human Tissue

- 4.4.1. For studies involving human tissue, the analysis of the samples should be undertaken as part of the data collection before the end of study is declared. Samples can be stored for a maximum of 12 months after this date to verify or check the quality of the research data, without needing a Human Tissue Authority (HTA) research license, where this is detailed in the protocol. <https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/>
- 4.4.2. For trials and studies that involve the collection of tissue for future use, steps should be taken to ensure these are used in line with the consent provided by participants. Where consent has not been obtained for future retention, only anonymised data and material that is not relevant material under the Human Tissue Act 2004 can be retained. <https://www.legislation.gov.uk/ukpga/2004/30/contents>
- 4.4.3. When notified of the end of trial, the research clinical team should identify any human tissue samples being stored by RCHT for the trial or study and action as appropriate, to meet the requirements of the protocol and the HTA. Documentation detailing sample shipping and/or sample destruction should be filed in the ISF.

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 will arrange for the documents to be sent to the EDGE Data Officer to publish a copy onto the EDGE system.
- 5.3. The EDGE Data Officer will record the date and version on the version control sheet in the sub-folder, storing the procedural document on the General Documents folder on EDGE. The EDGE Data Officer will ensure that any previous versions of the document are made inaccessible to general EDGE users, in accordance with the EDGE document archiving procedure (see SOP001 Preparation, Approval and Review of SOPs/WIs).
- 5.4. 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 training matrix (R and D AD 19).
- 5.5. Details of how to access EDGE is available by contacting the EDGE Data Officer via rch-tr.edge@nhs.net.
- 5.6. 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.
- 5.7. Consideration must be given during 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.
- 5.8. 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/WI.
- 5.9. Whilst SOPs may be printed, the electronic version maintained on the 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 of new and forthcoming SOPs via email.

5.11. Training and Education

- 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 whom the SOP is relevant, and this training documented in their training record.
- 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.

- Additional information is available by contacting the EDGE Data Officer via rch-tr.edge@nhs.net .

5.12. SOP Deviations

- 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.

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 the closing of clinical trials and research studies at RCHT.
Lead	Research Governance Manager.
Tool	Quality checks will be carried out by the Senior Research Administrator, to ensure compliance with this SOP and Good Clinical Practice (GCP).
Frequency	Compliance with this procedural document will be monitored as part of the R and D Quality Management System and quality checks which have been built into key milestones of the procedure.
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. 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 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 SOP043 Closure process for Hosted Studies V5.0
This document replaces (exact title of previous version):	Closure Process for Hosted Studies 06 Research and Development Standard Operating Procedure V4.0
Date Issued / Approved:	September 2025.
Date Valid From:	October 2025.
Date Valid To:	October 2028.
Author / Owner:	Caroline Phillips – Research Governance Manager
Contact details:	rcht.researchqualityassurance@nhs.net
Brief summary of contents:	This SOP describes the procedure for the closure of trials and studies hosted by the Royal Cornwall Hospitals NHS Trust (RCHT).
Suggested Keywords:	Standard Operational Procedure (SOP). Research and Development (R and D). Good Clinical Practice (GCP).
Target Audience:	RCHT: Yes CFT: No CIOB ICB: No
Executive Director responsible for Policy:	Director of Research and Development
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
Links to key external standards:	Good Clinical Practice for Clinical Trials https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials

Information Category	Detailed Information
Related Documents:	The Medicines for Human Use (Clinical Trials) Regulations 2004 The Medicines for Human Use (Clinical Trials) Regulations 2004 The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 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/ Health Research Authority. Ending Your Project (Last updated 15 July 2025) https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/ Human Tissue Act 2004 https://www.legislation.gov.uk/ukpga/2004/30/content S SOP001 Preparation, Approval and Review of SOPs/WIs R and D SOP004 Reporting and Managing Non-Compliance and Serious Breaches R and D SOP012 Income from Clinical Trials. R and D SOP021 Preparation and Maintenance of an Investigator Site File (ISF). R and D SOP044 Archiving Essential Documents. R and D AD01 Code of Conduct for Monitoring Visits R and D AD07 Glossary of Terms. R and D AD 19 R and D training matrix R and D AD21 Study Close Out Checklist.
Training Need Identified:	Yes – Details provided in Section 5.
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet

Information Category	Detailed Information
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 Assistant Research Manager
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 merging SOPs to meet updated standards and process and align to Trust policies.	Dr N Morley, R and D Assistant Research Manager
01/06/2021	V4.0	Review and update in accordance with RCHT policies	Dr N Morley, R and D Assistant Research Manager
18/09/2025	V5.0	Changes to from RD and I to R and D. Review of SOP in line with updated regulatory requirements, GCP guidance, feedback from external monitoring and audits and changes to R and D procedures, including the changes to the Clinical Trials Regulations 2025 and ICH GCP E6(R3). 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 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. 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

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Research and Development SOP043 Closure process for Hosted Studies V5.0
Department and Service Area:	Research and Development. Corporate.
Is this a new or existing document?	Existing.
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Caroline Phillips, Research Governance.
Contact details:	rcht.researchqualityassurance@nhs.net

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	This Standard Operating Procedures (SOP) describes the process for the closure of trials and studies hosted by the Royal Cornwall Hospitals NHS Trust (RCHT).
2. Policy Objectives	This SOP ensures that R and D processes are consistent with the requirements of the appropriate legislation, Good Clinical Practice and Trust policies.
3. Policy Intended Outcomes	Compliance with the regulatory requirements and Good Clinical Practice (GCP).
4. How will you measure each outcome?	Risk-based internal auditing and monitoring programme to ensure that research studies are compliant with GCP. External monitoring and auditing carried out by the Sponsors and Clinical Research Associates (CRAs).

Information Category	Detailed Information
5. Who is intended to benefit from the policy?	All research participants. All staff involved in research and the Trust.
6a. Who did you consult with? (Please select Yes or No for each category)	- Workforce: Yes - Patients/ visitors: No - Local groups/ system partners: No - External organisations: No - Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	Please record specific names of individuals/ groups: Senior Management Team (SMT). Research staff.
6c. What was the outcome of the consultation?	Consultation ensured that R and D understood the best practice in the development of procedural documents, aligned to the requirements of GCP guidance.
6d. Have you used any of the following to assist your assessment?	National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys: 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 RCHT R and D.

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
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	

Protected Characteristic	(Yes or No)	Rationale
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	
Marriage and civil partnership	No	
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

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](#)