

Research and Development SOP023 Data Management and Processing for Hosted Studies

V5.0

October 2025

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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/ukxi/2025/538/regulation/37>
- 1.2. International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines E6 (R3) paragraph 9.2 states, “Systems and processes that aid in data capture, management and analyses, as well as those that help ensure the quality of the information generated from the trial, should be fit for purpose, should capture the data required by the protocol and should be implemented in a way that is proportionate to the risks to participants and the importance of acquired data.”
https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf
- 1.3. Personal and identifiable information should be processed in a way that is compliant with the principles of the Data Protection Act 2018 (DPA) and UK General Data Protection Regulation (UK GDPR) (Regulation 2016/679 of the European Parliament and of the Council). Confidential data must be handled in accordance with the Common Law Duty of Confidentiality to protect the rights and freedoms of research participants. The UK GDPR requires that appropriate security measures are in place to safeguard against unauthorised or unlawful access and processing of personal identifiable data.

1.4. Scope

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

1.5. Definitions and Glossary

- 1.5.1. **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 rights, safety and well-being of trial participants are protected and that the data and reported results are credible and accurate.
- 1.5.2. **Medicines and Healthcare products Regulatory Agency (MHRA)** is the executive agency of the Department of Health and Social Care in the UK which is responsible for regulating the use of medicines, medical devices and blood components for transfusion in the UK.
- 1.5.3. **International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, Good Clinical Practice (GCP or ICH GCP)** is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human participants.

- 1.5.4. **Research Ethics Committee (REC)** is a group of people appointed to review research proposals to assess formally if the research is ethical. This means the research must conform to recognised ethical standards, which includes respecting the dignity, rights, safety and well-being of the people who take part.
- 1.5.5. **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.
- 1.5.6. **Chief Investigator (CI)** is an authorised health care professional who takes primary responsibility for the conduct of the 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.
- They must also lead and manage others who have been delegated responsibilities as part of the research project.
- 1.5.7. **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).
- 1.5.8. **Sponsored Studies** are studies for which RCHT has ultimate responsibility for the initiation, management and financing. RCHT R and D take responsibility for ensuring that the design of the study meets relevant standards and that arrangements are in place to ensure appropriate conduct and reporting.
- 1.5.9. **Investigator Site File (ISF)** contains the essential documents which show that the investigator and the conduct of the study are following the regulatory requirements.
- 1.5.10. **Non-compliance** is non-adherence to study-related requirements, GCP and all applicable regulatory requirements. A non-compliance may be categorised as a deviation, violation or serious breach.
- 1.5.11. **Standard Operating Procedure (SOP)** is a procedure document detailing a specific sequence of events that must be followed for an activity.
- 1.5.12. **Case Report Form (CRF)** is a document used to record the required data as defined by the protocol for each participant throughout their participation in the trial or study.

- 1.5.13. **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.
- 1.5.14. **Electronic Data Capture (EDC)** systems are software platforms used to collect, manage and store research data electronically.
- 1.5.15. **Self-Evident Corrections (SECs)** is a list of corrections to the CRF or eCRF that can be made by the sponsor's data management staff without the requirement for case-by-case referral to the investigator. These should be agreed with investigators prior to implementation.
- 1.5.16. **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.
- 1.5.17. **Quality Assurance Database (QuAD)** is a dedicated R and D designed database which manages and tracks the resolution findings and actions from monitoring and audit reports. QuAD maintains a robust audit trail to meet MHRA inspection expectations.
- 1.5.18. **Glossary of Terms (R and D AD 07)** is a glossary of the terms, and the definition of the acronyms which can be found in the Associated Documents folder in EDGE.
- 1.5.19. **Acronyms**
- **CAPA:** Corrective and Preventative Actions.
 - **CI:** Chief Investigator.
 - **CRA:** Clinical Research Associate.
 - **CRF:** Case Report Form.
 - **CRO:** Contract Research Organisation.
 - **DMP:** Data Management Plan.
 - **DPA:** Data Protection Act 2018.
 - **EDC:** Electronic Data Capture.
 - **GCP:** Good Clinical Practice.
 - **ICH GCP:** International Council for Harmonisation of Good Clinical Practice.
 - **ISF:** Investigator Site File.
 - **MHRA:** Medicines and Healthcare products Regulatory Agency.
 - **PI:** Principal Investigator.

- **PIS:** Patient Information Sheet.
- **QMS:** Quality Management System.
- **R and D:** Research and Development.
- **RCHT:** Royal Cornwall Hospitals NHS Trust.
- **REC:** Research Ethics Committee.
- **SDV:** Source Data Verification.
- **SEC:** Self Evident Correction.
- **SMT:** Senior Management Team.
- **UK GDPR:** UK General Data Protection Regulations.

1.6. 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 management and protection of data (both paper and electronic) for clinical trials and studies conducted for the Royal Cornwall Hospitals NHS Trust (RCHT), that ensures data is managed in a manner that preserves the scientific integrity of the research and complies with the relevant regulatory requirements.

3. Ownership and Responsibilities

3.1. Role of the 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 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 of the systems and processes described in [Section 4](#) are processed in accordance with 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 (PI)

The PI is responsible for:

- Gaining assurance that appropriate data management procedures are in place to preserve the integrity of the research data.
- Ensuring the conduct of the study is compliant with the study or trial specific protocol, the applicable regulatory requirements and adheres to the principles of GCP and the relevant SOPs.
- Complying with UK General Data Protection Regulations (UK GDPR), Data Protection Act 2018 (DPA), GCP guidance and any regulatory requirements for the maintenance of confidentiality of participant identity.
- Supporting monitors, regulators and auditors addressing queries relating to data management.
- Supporting the investigations into episodes of non-compliance of the systems and processes described in [Section 4](#) are processed in accordance with R and D SOP004 Reporting and Managing Non-Compliance and Serious Breaches (available in the Documents Folder in EDGE).

3.4. Role of the Clinical Research Team

The Study Team is responsible for:

- Supporting the PI to fulfil the duties, responsibilities, and obligations in executing the processes described in [Section 4](#), Standards and Practice.
- Ensuring the fulfilment of the duties delegated by the PI regarding the standards and processes described in [Section 4](#).
- Complying with UK GDPR, DPA, GCP guidance and any regulatory requirements for the maintenance of confidentiality for participant identity.
- Providing monitors, auditors and regulators with access to the study files and documentation, relevant to the clinical trial or study being reviewed.

- Supporting monitors, regulators and auditors addressing queries relating to data management.
- Supporting with investigations into episodes of non-compliance with the standards and processes in accordance with R and D SOP004 Reporting and Managing Non-Compliance and Serious Breaches (available in the Documents Folder in EDGE).

3.5. **Role of the Study Set Up Team**

The Study Set Up Team is responsible for:

- Facilitating the assessment of capability and capacity for trials and studies, which will include a review of the data management requirements.
- Ensuring compliance with UK GDPR, DPA, GCP guidance and any regulatory requirements for the maintenance of confidentiality of participant identifiable information.

3.6. **Role the Data Officer**

The Data Officer is responsible for:

- Supporting the PI to fulfil the duties, responsibilities, and obligations in executing the processes described in [Section 4](#), Standards and Practice.
- Ensuring the fulfilment of the data management duties delegated by the PI regarding the standards and processes described in [Section 4](#).
- Accurately transcribing the data for the trial or study into the sponsor's electronic data capture (EDC) or paper systems.
- Complying with UK GDPR, DPA, GCP guidance and any regulatory requirements for the maintenance of confidentiality for participant identity.
- Providing monitors, auditors and regulators with access to the study files and documentation, relevant to the clinical trial or study being reviewed.
- Supporting monitors, regulators and auditors addressing queries relating to data management.
- Supporting the investigations into episodes of non-compliance of the systems and processes described in [Section 4](#) are processed in accordance with R and D SOP004 Reporting and Managing Non-Compliance and Serious Breaches (See Documents Folder in EDGE).

4. Standards and Practice

4.1. Compliance with the UK GDPR, DPA and Common Law of Confidentiality

- 4.1.1. Depending on the nature of the study, consideration should be made for how personal identifiable and confidential data is handled, to ensure compliance with the UK General Data Protection Regulation (UK GDPR), Data Protection Act 2018 (DPA) and the Common Law of Confidentiality.
- 4.1.2. The trial or study protocol and Patient Information Sheet (PIS) should outline how personal and confidential data will be handled, and the data management procedures which will ensure compliance with regulatory requirements including anonymisation or pseudonymisation of data, who will have access to the data and how long the data will be retained.

4.2. Establishing process for transferring data

- 4.2.1. The data transfer process from Royal Cornwall Hospitals NHS Trust (RCHT) to the trial or study team should be clearly defined from the outset of a trial or study in a specific document, such as the protocol or Data Management Plan.
- 4.2.2. Data management procedures are required throughout the lifetime of the clinical trial or study, from the point of design up until the end of the retention period for the data. A plan for how data will be managed should be in place prior to study green light.
- 4.2.3. Data management activities should only be undertaken by appropriately trained members of staff who have been delegated by the Principal Investigator (PI).

4.3. Source data

- 4.3.1. Source data refers to the original documents and records where clinical data is first captured, such as hospital records, clinical charts, and laboratory reports. It is essential for the accurate reconstruction and evaluation of clinical trials and studies.
- 4.3.2. Source data should be defined in the trial or study protocol, including the location of where the information is held, such as the specific folders within RCHTs electronic systems.
- 4.3.3. The PI or their delegate should identify where the source data will be recorded and regularly updated. The sponsor should provide a source data log, which will identify the required source data, as well as the format and location. If the sponsor does not provide a template source data log, please refer to R and D AD58 Source Data Log (available in the Documents Folder in EDGE). The source data log should be filed in the Investigator Site File (ISF).

4.3.4. eNotes is the Electronic Document Management Solution (EDMS) used by RCHT to provide a document repository for the preparation and management of patient records and associated clinical documentation. All patients' legacy health records have been scanned and will be available to view electronically in the eNotes system. Refer to R and D SOP026 eNotes in Research (available in the Documents Folder in EDGE).

4.4. Documentation of Source Data

4.4.1. All forms of source data, whether paper-based or electronic, should adhere to the ALCOA plus principles:

- **Attributable.** Data entries should be easily traced back to the individual who performed the data collection, and the date and time that this was performed. Data entries should be signed and dated by the person making the entry. Electronic entries should have clear audit trails. Entries should also include details of staff involved and should be countersigned where decisions have been made by staff other than the person making the entry.
- **Legible.** Data should be easily readable and permanent, ensuring the records can be trusted and verified over time. This also applies to metadata that may be recorded to support an electronic record.
- **Contemporaneous.** Data should be recorded at the time the activity occurs, and not retrospectively. If retrospective entries or annotations are made then this should be obvious, and they should be signed and dated with the date the updated entries were added.
- **Original -** Records should be original as opposed to transcriptions or copies of the originals. All copies of original documentation must be formally verified as a true copy and the original must be preserved.
- **Accurate.** Data must reflect the true values or observations without errors or unauthorised changes. Changes should be documented clearly and concisely so tracing back to the original entry is possible. This requires the use of calibrated instruments and proper documentation practices to ensure data quality.
- **Complete.** All data, including changes and deletions, must be accounted for. This includes maintaining audit trails that track every modification made to the data.
- **Consistent.** Data should be consistent across all records and systems, ensuring that there are no discrepancies in the information recorded.
- **Enduring.** Data must be maintained in a durable format that ensures its longevity and accessibility over time.
- **Available.** Data should be readily accessible to authorised personnel when needed, ensuring that it can be retrieved for review or analysis.

- 4.4.2. For paper-based records, any changes to source data should be signed and dated with the date the entries were added. Any errors should be corrected by drawing a single line through the error, initialing and dating the change, and adding a reason for the error if necessary. Incorrect entries which have had a line marked through them must always be legible and never obliterated. Furthermore, all entries should include details of staff involved in the consultation and should be countersigned where decisions have been made by staff other than the person making the entry.
- 4.4.3. For electronic based records, secure, computer generated, time stamped audit trails (or alternative methods that fulfil audit trail requirements) should be used to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Audit trails need to be readable and changes to audit trail data should be prevented by the system. The relevant investigators, sponsor representatives and inspectors should be able to review the audit trail.

4.5. Case Report Forms

- 4.5.1. During the set-up phase of the clinical trial or study, the PI or delegate should undertake Case Report Forms (CRF) and protocol compatibility checks. This will ensure that all data detailed in the protocol is collected and enable assessment of the extent of the workload and costs involved.
- 4.5.2. Sponsors may use Electronic Case Report Forms (eCRFs), particularly for commercial trials and studies. If access to the eCRF is not available during the set-up of the study, the sponsor should be able to provide a draft of the CRF in a readable format. The sponsor may also provide guidance for the completion of the CRF.
- 4.5.3. Where paper-based data capture forms are provided by the sponsor, these should be completed and sent to the sponsor as per their instructions.

4.6. Access to systems

- 4.6.1. Access to systems involved in the processing of clinical trial or study data should only be granted when:
- There is a legitimate and justified purpose.
 - The level of access is outlined in the information provided to the participants.
 - Appropriate safeguards are in place to ensure the security of the data.
- 4.6.2. Research staff should only be granted the level of access necessary to carry out their roles and the delegated tasks. Access should be reviewed and amended to reflect any changes.
- 4.6.3. If for any reason a person no longer requires access to a system, access should be revoked as soon as possible.

4.7. Entry of Data into the Electronic Data Capture (EDC) systems

- 4.7.1. EDC systems are software platforms used to collect, manage and store research data electronically. This data is collected, uploaded and saved in an electronic case report form (eCRF).
- 4.7.2. Data entry into an EDC system should be completed by staff who have been appropriately trained in how to use the system.
- 4.7.3. All data items should be entered exactly as they appear in the paper-based CRF or as recorded in source data when entering directly into the EDC.
- 4.7.4. Any discrepancies arising from the data entry should be addressed as soon as possible.

4.8. Resolution of Data Queries

- 4.8.1. Data queries are raised by the sponsor when the data is inconsistent, missing or unclear. The sponsor cannot alter the original entry without the explicit permission of the PI or their delegate.
- 4.8.2. Any amendments made to the original or copies of the CRF in response to queries raised should be clear with regards to who made the change and when.
- 4.8.3. The Data Officer will make appropriate changes directly into the EDC system. The requirement for recording who made the change and when will be provided via the audit trail where systems are managed by the sponsor.
- 4.8.4. For paper-based data documentation, changes should be signed and dated with the date the updated entries were added. It is essential that the method of correction ensures that the original entry is still legible. An audit trail should be maintained by detailing the method, date and person obtaining the data next to the correction.
- 4.8.5. Self-Evident Corrections (SECs) are where changes can be made to the CRF or eCRF by the sponsor's data management staff without the requirement for item-by-item referral to the PI or their delegate. These changes can only be used in specific, limited circumstances which must be considered and defined on a trial-by-trial basis and should be agreed with the sponsor and PI prior to the start of the trial or study.

4.9. Database Lock

- 4.9.1. A database lock occurs at a specific point in a clinical trial or study, when the sponsor locks the database to any further changes. The process allows for an interim or final analysis of the data, to ensure the dataset is consistent, complete and reliable.
- 4.9.2. The PI or their delegate will be notified by the sponsor when a database lock is planned.

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 managing and processing data for clinical trials and studies 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).
Frequency	Compliance with this procedural document will be monitored as part of the R and D risk-based internal audit programme 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 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 SOP023 Data Management and Processing for Hosted Studies V5.0
This document replaces (exact title of previous version):	Research Data Management, Protection and Verification 09 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 01872 256428
Brief summary of contents:	The SOP describes the procedures for the management and protection of data (both paper and electronic) for clinical trials and studies conducted for 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
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 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/ Data Protection Act 2018 https://www.legislation.gov.uk/ukpga/2018/12/contents Regulation (EU) 2016/679 of the European Parliament and of the Council https://www.legislation.gov.uk/eur/2016/679/contents The UK GDPR https://ico.org.uk/for-organisations/data-protection-and-the-eu/data-protection-and-the-eu-in-detail/the-uk-gdpr/ R and D SOP001 Preparation, Approval and Review of Standard Operating Procedures (SOPs) and Work Instructions (WIs). R and D SOP004 Reporting and Managing Non-Compliance and Serious Breaches. R and D SOP026 eNotes in Research. R and D AD07 Glossary of Terms. R and D AD19 Training Matrix. R and D AD58 Source Data Log Template.
Training Need Identified:	Yes – Details provided in Section 5.
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 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 from RD and I to R and D. Review of SOP in line with changes to legislation, GCP guidance, feedback from external monitoring and audits, and changes to R and D procedures. Scope and title the SOP changed. 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 SOP023 Data Management and Processing 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 Manager.
Contact details:	rcht.researchqualityassurance@nhs.net 01872 256428

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 SOP aims to provide clear guidance for the management and processing of data for research studies conducted at RCHT, in line with the requirements of relevant legislation and GCP.
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 ensures that R and D understand 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?	The outcomes of 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	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	

Protected Characteristic	(Yes or No)	Rationale
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](#)