

Research and Development SOP026 eNotes in Research Standard Operating Procedure

V1.0

July 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

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1. Introduction

- 1.1. The Medicines for Human Use (Clinical Trials) Regulations 2004 Sch 1 Part 2 (9) states that 'All clinical information shall be recorded, handled and stored in such a way that it can be accurately reported, interpreted and verified, while the confidentiality of records of the trial subjects remains protected'.
<https://www.legislation.gov.uk/ukxi/2004/1031/schedule/1/paragraph/9>
- 1.2. Source Data is defined in the International Council of Harmonisation of Good Clinical Practice (ICH GCP) (E2) paragraph 1.51 as: 'All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).'
- 1.3. ICH GCP (E2) paragraph 5.15.1 states: The sponsor should ensure that it is specified in the protocol or other written agreement that the investigator(s)/institution(s) provide direct access to source data/documents for trial-related monitoring, audits, Institutional Review Boards (IRBs) or Independent Ethics Committees (IEC) review, and regulatory inspection.'
- 1.4. The Medicines in Healthcare Products Regulatory (MHRA) Inspectorate provides guidance around ensuring that use of Electronic Health Records meet the requirements of Good Clinical Practice.
<https://mhrainspectorate.blog.gov.uk/2019/07/23/electronic-health-records/>
- 1.5. NHS England Records Management Code of Practice for Health and Social Care provides a framework for consistent and effective records management based on established standards. <https://transform.england.nhs.uk/information-governance/guidance/records-management-code/records-management-code-of-practice/>

1.6. Scope

This Standard Operating Procedure (SOP) relates to the use of the Cito eNotes system (known as eNotes) in research studies and clinical trials, providing guidance for all research staff on the procedures for using the Trust's Electronic Document Management System (EDMS).

1.7. Definitions / Acronyms

- 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. **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.

- 1.7.3. **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.
- 1.7.4. **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).
- 1.7.5. **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.
- 1.7.6. **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.
- 1.7.7. **Source Data** is defined in ICH GCP (Glossary 1.51) as 'All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies)'.
- 1.7.8. **Contract Research Organisations (CROs)** is defined as an organisation or company who is formally delegated one or more of the functions of sponsorship, this may include performing monitoring activities for a study.
- 1.7.9. **Clinical Research Associates (CRAs)** are appointed by the sponsor and/or vendor to undertake monitoring actively for a research study.
- 1.7.10. **Standard Operating Procedure (SOP)** is a procedure document detailing a specific sequence of events that must be followed for an activity.
- 1.7.11. **Glossary of Terms (RD and I AD 07)** is a glossary of the terms and the definition of the acronyms and can be found in the Associated Documents folder in Edge.
- 1.7.12. **EDGE** is a dedicated, web-based, research database which is used within, and managed by, the R and D department at RCHT.
- 1.7.13. **Acronyms**
- **CI:** Chief Investigator.
 - **CITS:** Cornwall IT Service.

- **CRA:** Clinical Research Associate.
- **CRO:** Contract Research Organisations.
- **EDMS:** Electronic Document Management System.
- **EHR:** Electronic Health Records.
- **GCP:** Good Clinical Practice.
- **GDPR:** General Data Protection Regulation.
- **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.
- **QMS:** Quality Management System.
- **PI:** Principal Investigator.
- **R and D:** Research and Development.
- **RCHT:** Royal Cornwall Hospitals NHS Trust.
- **SMT:** Senior Management Team.
- **SOP:** Standard Operating Procedure.
- **WI:** Work Instruction.

2. Purpose of this Standard Operating Procedure

- 2.1. The Royal Cornwall Hospitals NHS Trust (RCHT) has implemented the replacement of patients' paper medical records with a new Electronic Document Management Solution (EDMS), known as eNotes (or Cito eNotes).
- 2.2. The deployment of eNotes has resulted in changes to the preparation and management of health records and any associated clinical documentation for participants of research studies and clinical trials.
- 2.3. The purpose of this document is to describe the processes for uploading and viewing source data and relevant documentation for research studies and clinical trials, via the eNotes system used by the RCHT.
- 2.4. This document is for all staff working on research studies at RCHT, where eNotes is being used to upload patients' paper medical records. The eNotes system is not used in all specialties across the Trust.

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

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.
- Supporting the PI to fulfil the duties, responsibilities and obligations in relation to the processes outlined 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.
- Ensuring any non-compliance associated with the standards and practice described in Section 4 are processed in accordance with the R and D SOP for Non-compliance Reporting (see SOP index guide).

3.3. Role of the Principal Investigator (PI)

The PI is responsible for:

- Ensuring robust study specific systems and processes are in place for recording and reviewing source data in the Trust's eNotes system.
- Ensuring staff with delegated duties related to the standards and practices described in Section 4, fulfil their duties in accordance with the principles of GCP.
- Ensuring episodes of non-compliance with the systems and process described in Section 4 are processed in accordance with R and D SOP Non-compliance Reporting (See SOP index guide).
- Supporting the regulators and auditors with queries relating to the study files and documentation.

3.4. Role of the Team Leader

The Team Leader 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.
- 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.
- Identifying training needs for the study delivery team and other staff involved in the study, and to provide support to help all staff to undertake their delegated duties.
- Supporting the PI with investigating episodes of non-compliance with the standards and processes described in Section 4 (see R and D SOP Non-compliance Reporting, See SOP index guide).
- Providing monitors, auditors and regulators with access to the study files and documentation, relevant to the study or clinical trial being reviewed.
- Supporting the regulators and auditors with queries relating to the study files and documentation.

3.5. Role of the Research Clinical Teams

Staff working in the research teams are 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.
- Ensuring source data is updated in the eNotes system as soon as practicable and in line with the standards and processes described in Section 4.
- Supporting the PI with investigating episodes of non-compliance with the standards and processes described in Section 4 (see R and D SOP Non-compliance Reporting, See SOP index guide).
- Providing monitors, auditors and regulators with access to the study files and documentation, relevant to the study or clinical trial being reviewed.
- Supporting the regulators and auditors with queries relating to the study files and documentation.

3.6. Role of the Research Administration Teams

The Research Administration 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 practices described in Section 4.
- Supporting the PI with investigating episodes of non-compliance with the standards and processes described in Section 4 (see R and D SOP Non-compliance Reporting, See SOP index guide).
- Providing monitors, auditors and regulators with access to the study files and documentation, relevant to the study or clinical trial being reviewed.
- Providing monitors and sponsor representatives with time limited access to the eNotes system in accordance with standards and processes described in Section 4.
- Supporting the regulators and auditors with queries relating to the study files and documentation.

4. Standards and Practice

4.1. eNotes overview

- 4.1.1. The implementation of eNotes is the first stage of the transformation for RCHT to make patient records fully digital.
- 4.1.2. eNotes is the Trust's Electronic Document Management Solution (EDMS), providing a document repository for the preparation and management of patient records and associated clinical documentation.
- 4.1.3. All patients' legacy health records have been scanned and will be available to view electronically in the eNotes system. Once patients' health records have been scanned to eNotes, they can only be viewed electronically.
- 4.1.4. Scanning services for the eNotes system have been contracted by the Trust to Hugh Symons Information Management (HSIM).
- 4.1.5. The scanning and transfer process from paper records to eNotes meets the requirements outlined in MHRA guidance. MHRA Position Statement and Guidance Electronic Health Records.
- 4.1.6. A validated process is in place to confirm scanned documents are certified copies, quality checks are carried out (to include scan quality, legibility, completeness, page counts etc.) and an audit trail of this process is documented, which shows when and how the scanning took place and by whom (i.e. metadata). [MHRA GXP' Data Integrity Guidance and Definitions](#)

- 4.1.7. Written procedures are in place which provide details of the scanning and transfer process, this is available via [Cito Version 2.3 - User Guide.pdf \(cornwall.nhs.uk\)](#).

4.2. Trust user access to eNotes

- 4.2.1. All research staff who require access to the eNotes system must complete the CITS online training and assessment. CITS training is available via: [CITS IT Training Portal - Home \(cornwall.nhs.uk\)](#).
- 4.2.2. User access to the eNotes system is controlled by a password, in line with the Trust's Information Technology Security Policy. [Information Technology Security Policy \(cornwall.nhs.uk\)](#).
- 4.2.3. Any staff leaving employment with the Trust will have access to eNotes removed by CITS.

4.3. Scanning documents to eNotes

- 4.3.1. The management, preparation and administration of eNotes uses the following folder structure:
- Episodic folders for records of episodes of care or treatment, this will include ward folders for inpatients and outpatient folders.
 - Departmental records are records that are not merged with the health record and are typically stored and used within a localised department.
 - Loose filing is a single or a collection of document types which currently require to be filed into the legacy health record.
- 4.3.2. All written entries on paperwork contained in the eNotes folders must be legible and written in black ink. This ensures clear reproduction of the paper record to scanned images when viewing in eNotes.
- 4.3.3. It is important that all written entries are visible during the scanning process and when adding stickers/labels to clinical documentation they must not obstruct any written information. Stickers must not be secured or stuck over written information already recorded and must be secured fully (not just in strips) to discourage anyone from lifting the sticker to write underneath.
- 4.3.4. Scanning of documents will primarily be performed in black and white, with only selective colour scanning being agreed, with the following approach:
- Scanning in full duplex, allowing for scanning of both sides of a page.
 - Scanning resolution for black and white: 200 dpi (dots per inch).
 - Scanning resolution for colour: 200 dpi, 256-bit colour depth.

- 4.3.5. Physical paper records sent for scanning will be retained by the scanning partner HSIM for a period of one month after the transfer of images from HSIM to the Trust, electronic images and metadata will be retained for six months after scanning.
- 4.3.6. The Trust will undertake quality checks of returned scanned images. A fixed daily volume of boxes will be returned for validation by the Trust against the scanned images. The volume quality checked will be determined by the Trust, this will be reviewed and adjusted as required.

4.4. Using eNotes in Research

- 4.4.1. Instructions for the transition of the current health records processes to the new processes resulting from the implementation of the Trust's eNotes system are outlined in the Management and Administration of the Health Record for RCHT Patients Electronic Notes (eNotes) Standard Operating Procedure. [Management and Administration of the Health Record for RCHT Patients Electronic Notes \(eNotes\) Standard Operating Procedure \(cornwall.nhs.uk\)](http://cornwall.nhs.uk/Management%20and%20Administration%20of%20the%20Health%20Record%20for%20RCHT%20Patients%20Electronic%20Notes%20(eNotes)%20Standard%20Operating%20Procedure).
- 4.4.2. User guide for eNotes is available from CITS via: [Cito Version 2.3 - User Guide.pdf \(cornwall.nhs.uk\)](http://cornwall.nhs.uk/Cito%20Version%202.3%20-%20User%20Guide.pdf)
- 4.4.3. eNotes filing process for research participants will be as follows:

Details of Visit	eNotes filing
1. Participant being consented (including re-consent) to a research study	All documents for the consent process should be filed in the Specialty section using attachment type Consent Form
2. Participant seen on the ward (not consent process)	Notes filed under the Specialty section in the Ward Episodic Folder
3. Participant seen at a clinic or an unscheduled non-research visit (not consent process)	Notes filed under the Specialty section in the Outpatient Episodic Folder
4. Participant seen in a research clinic or an unscheduled research visit (not consent process)	Notes to be filed under Specialty in the Research Episodic Folder

- 4.4.4. For studies where participants are attending their next scheduled appointment within a short timeframe, the research team may retain a photocopy of the documents pending the scanning of the original to eNotes.

4.5. Recorded in error in eNotes

For misfiled attachments or misfiled pages within an attachment, video guidance around how to correct the errors is available on the CITS Training Portal [Cito eNotes - Introduction \(cornwall.nhs.uk\)](https://cornwall.nhs.uk/cits/eNotes/Introduction).

4.6. External Monitoring by Sponsor appointed Clinical Research Associates (CRAs) or monitors

- 4.6.1. The data collected and analysed during research studies and clinical trials are verified and overseen by Sponsors via representatives such as CRAs or monitors.
- 4.6.2. CRAs or monitors may require direct access to the EDMS via the eNotes system when carrying out onsite monitoring visits, to enable verification of source data.
- 4.6.3. Access to the eNotes system is not available for CRAs or monitors to view when carrying out remote monitoring visits.
- 4.6.4. The Information Commissioner's Office (ICO) advice provided to the MHRA regarding data protection, confirmed that Trusts could ask sponsor representatives to sign an agreement to confirm they would only access records for study participants that they required and, provided the Trust has an audit trail and can verify what subjects the sponsor representative accessed, this would be acceptable.
<https://www.gov.uk/guidance/on-site-access-to-electronic-health-records-by-sponsor-representatives-in-clinical-trials>.
- 4.6.5. CRAs or monitors must complete training and mandatory assessment on how to access and view information in eNotes, prior to being given access to the system. Cito eNotes training is available via the following link: <https://elearning.cornwall.nhs.uk/entry>, this link can be accessed using an NHS email or non-NHS email address. The Admin Team will support the CRA or monitor to access the CITO eNotes training, as required.
- 4.6.6. Access to the eNotes system for CRAs and monitors must be controlled to ensure:
 - Access is limited to only those participant records being monitored during the visit.
 - Records of patients who are not a participant of the study being monitored, but maintained by the eNotes system, are not accessed by the CRA or monitor.
- 4.6.7. The Admin Team will contact the CRA or monitor prior to their onsite visit at RCHT, to identify the details of the study participants whose records will be viewed in eNotes during the monitoring visit.
- 4.6.8. The Admin Team raises a CITS call through the CITS Portal to request access to a Generic Monitor account and confirm date(s) required, where possible this should be within one working day before the CRA or monitor is due to attend RCHT.

- 4.6.9. The Admin Team will provide the following to CITS, who will record the following information in a spreadsheet, to track the access requests:
- Date of request.
 - Who requested eNotes access (Admin Team).
 - Date access to eNotes required.
 - Name of the CRA or monitor.
 - Access login number / Username assigned.
 - Names of patient records to be monitored.
- 4.6.10. The Admin Team will add a 'widget' to the eNotes access for the Generic Monitor account, for the participants records to be monitored at the visit by the CRA or monitor.
- 4.6.11. CRAs or monitors will be provided with access to eNotes only to the extent that it is deemed necessary to carry out their monitoring activities for a study and only for the participants' records to be monitored, as agreed prior to the visit.
- 4.6.12. When undertaking onsite monitoring visits, the CRAs or monitors will:
- Sign a Code of Conduct which clarifies the expectations of the CRA or monitor when carrying out onsite monitoring visits. Associated Documents, R and D AD01a Code of Conduct for the Monitoring Visit (available in the Documents folder on EDGE).
 - Be allocated a password for a generic monitor account to be reset by Cornwall IT Services (CITS) at the beginning of each visit.
 - Access is only permitted between 8am and 5pm each day.
- 4.6.13. eNotes can only be accessed by CRAs or monitors from a Trust laptop when on site at RCHT. CITS only allow access to the Generic Trust laptops for the extent of the monitoring visit, the access will terminate automatically at the end of the planned visit.

4.7. Auditing access to eNotes

- 4.7.1. CITS will carry out audits of eNotes user access in accordance with their policies and procedures, ensuring that there has been no unlawful access to patients' records, in line with the requirements of the UK General Data Protection Regulation (UK GDPR), further information around the monitoring and auditing processes for Trust systems is available via: [Information Technology Security Policy \(cornwall.nhs.uk\)](https://www.cornwall.nhs.uk/information-technology/security-policy)
- 4.7.2. CITS should run weekly reports for R and D Monitor accounts, to allow weekly audits to be conducted for the monitor access to eNotes. The Research Governance Team should carry out monthly quality checks to ensure that the audits of the Monitor accounts are taking place.

- 4.7.3. User guide for eNotes provides guidance on carrying out audits, this document is available via: [Cito Version 2.3 - User Guide.pdf](#)

5. Dissemination and Implementation

- 5.1. Trust-wide R and D procedural documents will be stored on the Trust's Document Library and a working copy will be accessible through EDGE providing alternative access for research staff.
- 5.2. The Research Governance Manager or delegate will arrange for the documents to be sent to the EDGE Data Officers to publish a copy on the EDGE system.
- 5.3. 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 the 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 Team 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 at the study set up as to which SOPs will not apply to a specific study, with agreement from SMT. Full details must be included as a written statement in the study site file.
- 5.8. 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 R and D internet page is the controlled copy. Any printed copies are not controlled.
- 5.10. Chief and Principal Investigators will be notified of new and forthcoming SOPs via email.

Training and Education

- 5.11. 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.

5.12. 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.

SOP Deviations

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

5.14. 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 how Electronic Health Records (eNotes) are used in research studies and clinical trials, for staff conducting research studies and clinical trials.
Lead	Research Governance Manager.
Tool	Internal and external monitoring of research studies and clinical trial will monitor 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, audit and monitoring process directed through the SMT Governance Meetings.
Reporting arrangements	The Research Governance Manager will provide monthly reports to the R and D Governance SMT.
Acting on recommendations and Lead(s)	The R and D Governance SMT will provide effective oversight and corrective actions.
Change in practice and lessons to be shared	The governance SMT 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 and 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 SOP026 –eNotes in Research Standard Operating Procedure V1.0
This document replaces (exact title of previous version):	New document.
Date Issued / Approved:	February 2025
Date Valid From:	July 2025
Date Valid To:	July 2028
Author / Owner:	Caroline Phillips - Research Governance Manager.
Contact details:	rcht.researchqualityassurance@nhs.net 01872 256429
Brief summary of contents:	This document describes the processes for uploading and viewing source data and relevant documentation for research studies and clinical trials, using the eNotes system at the Royal Cornwall Hospitals NHS Trust (RCHT).
Suggested Keywords:	Standard Operating Procedures (SOP). Good Clinical Practice (GCP). Research and Development (R and D).
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:	R and D 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:	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. https://www.legislation.gov.uk/ukxi/2004/1031/contents/made 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/ [Accessed 20/08/2024] Good Clinical Practice for Clinical Trials https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials HRA Guidance – Good Clinical Practice https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/good-clinical-practice/ ICH Efficacy Guidelines Good Clinical Practice https://www.ich.org/page/efficacy-guidelines ICH GCP E6(R2) https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf Management and Administration of the Health Record for RCHT Patients Electronic Notes (eNotes) Standard Operating Procedure V1.1 August 2021 Management and Administration of the Health Record for RCHT Patients Electronic Notes (eNotes) Standard Operating Procedure (cornwall.nhs.uk) [Accessed 20/09/2024] MHRA Inspectorate Blog – Electronic Health Records https://mhrainspectorate.blog.gov.uk/2019/07/23/electronic-health-records/ [Accessed 20/09/2024] MHRA Position Statement and Guidance Electronic Health Records Electronic Health Records MHRA Position Statement.pdf

Information Category	Detailed Information
	Records Management: Code of Practice for Health and Social Care (Updated August 2023) https://transform.england.nhs.uk/information-governance/guidance/records-management-code/ [Accessed 28/01/2025] Access to Electronic Health Records by Sponsor Representatives in Clinical Trials (Updated 08/09/2021) https://www.gov.uk/guidance/on-site-access-to-electronic-health-records-by-sponsor-representatives-in-clinical-trials [Accessed 20/09/2024] Civica (eNotes) User Guide December 2018 - Civica Version 2.3 - User Guide.pdf (cornwall.nhs.uk) RCHT Information Technology Security Policy V4.0 January 2023 Information Technology Security Policy (cornwall.nhs.uk) R and D AD01a – Code of Conduct for the Monitoring Visit. R and D AD07 – Glossary of Terms. R and D AD19 – Training Matrix.
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 Innovation.

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
20/02/2025	V1.0	New Standard Operating Procedure (SOP) for the use of eNotes in research. Requirement for the SOP has been identified through feedback in monitoring visits and audits.	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 SOP026 – Use of eNotes in Research Standard Operating Procedure V1.0.
Department and Service Area:	Corporate. Research and Development.
Is this a new or existing document?	New Standard Operating Procedure.
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 256429

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 around the use of eNotes in research studies and clinical trials.
2. Policy Objectives	To ensure that there is a clear understanding of systems and processes for uploading and accessing source data in eNotes. To ensure there is a clear process for CRAs and monitors requiring access to eNotes when carrying out monitoring visits on site at RCHT.
3. Policy Intended Outcomes	Compliance with Good Clinical Practice (GCP).

Information Category	Detailed Information
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).
5. Who is intended to benefit from the policy?	Chief Investigators and Principal Investigators for sponsored and/or hosted studies at RCHT. 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: Yes - 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 Research staff Clinical Research Associates (CRAs) from vendor/monitoring companies.
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 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	For all staff members
Sex (male or female)	No	For all staff members

Protected Characteristic	(Yes or No)	Rationale
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	For all staff members
Race	No	For all staff members
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	For all staff members
Religion or belief	No	For all staff members
Marriage and civil partnership	No	For all staff members
Pregnancy and maternity	No	For all staff members
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	For all staff members

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

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

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

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:

[Section 2. Full Equality Analysis](#)