

Research and Development SOP044 - Archiving of Essential Documents Standard Operating Procedure

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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. Archiving is the long-term storage of the essential documents which are held in the Trial Master File (TMF) and/or Investigator Site File (ISF), following the completion of a clinical trial or study. The media used to store essential documents must ensure documents remain complete and legible throughout the retention period and must be made available to regulatory authorities and for internal/external auditing purposes upon request.
- 1.2. The International Council for Harmonisation guidelines for Good Clinical Practice (ICH GCP) Section 8, defines the essential documents for the conduct of a clinical trial. The ICH GCP guidelines state that the storage system used during the trial and for archiving should provide for document identification, version history, search, and retrieval.
https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf
- 1.3. 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>
- 1.4. The Medicines for Human Use (Clinical Trials) Regulations 2004 (Regulation 31A of SI 2004/1031) specify that it is a legal requirement to retain the Trial Master File (TMF) for at least 5 years after the conclusion of the trial.
- 1.5. NHS England Records Management Code of Practice for Health and Social Care provides a framework for the 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. The NHS England Records Retention and Disposal Schedule identifies the main classifications of corporate records held by the organisation and provides appropriate retention rules for each.
<https://www.england.nhs.uk/publication/corporate-records-retention-disposal-schedule-guidance/>
- 1.7. The requirement for archiving extends to electronic data such as databases and copies of site-specific trial data and participant medical records. Electronic data must be retained using a media that will preserve the integrity and readability of the data for the duration of the required archiving period.
- 1.8. This version supersedes any previous versions of this document.
- 1.9. **Scope**
 - 1.9.1. This Standard Operating Procedure (SOP) describes the requirements and procedures for archiving essential documents for clinical trials and studies conducted at RCHT.

- 1.9.2. This SOP applies to clinical trials and studies, both sponsored and hosted by RCHT.

1.10. Definitions/Glossary

- 1.10.1. **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.

- 1.10.2. **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.

- 1.10.3. **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.

- 1.10.4. **Investigational Medicinal Product (IMP)** - Directive 2001/20/EC (Article 2) defines an IMP as a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorisation but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form.

- 1.10.5. **Clinical Trial of Investigational Medicinal Product (CTIMP)** – ICH GCP E6 (E2) Section 1.12 defines a clinical trial as any investigation in

human participants intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal products(s) and/or study absorption, distribution, metabolism and excretion of one or more investigational product(s) with the object of ascertaining its (their) safety and/or efficacy.

1.10.6. **Advanced Therapy Medicinal Product (ATMP)** The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (Part 2 Section 4 Regulation 2A) defines an ATMP as any of the following:

- a gene therapy medicinal product,
- a somatic cell therapy medicinal product, or
- a tissue engineered product.

1.10.7. **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.

1.10.8. **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.

They must also lead and manage others who have delegated responsibilities as part of the research project.

1.10.9. **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).

1.10.10. **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.

1.10.11. **Trial Master File (TMF)** is the collection of the files and documentation at all sites and organisations and those held by the sponsor that enable the conduct of the clinical trial or study, and the quality of the data produced to be evaluated and demonstrate the study has been conducted in accordance with the legislation.

- 1.10.12. **Investigator Site File (ISF)** contains the essential documents which show that the investigator and the conduct of the study are following the regulatory requirements. The ISF can be held in paper or electronic formats, or a combination of both.
- 1.10.13. **Essential documents** are those documents which individually or collectively enable both the conduct of the clinical trial or study, and the quality of the data produced to be evaluated. The International Council for Harmonisation guidelines for Good Clinical Practice (ICH GCP) Section 8, defines the essential documents for the conduct of a clinical trial.
- 1.10.14. **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.
- 1.10.15. **Hosted** refers to an externally sponsored study for which the RCHT is acting as a research site.
- 1.10.16. **Sponsored studies** refer to studies which are sponsored by RCHT.
- 1.10.17. **Iron Mountain** is the records management company contracted to store the archived files and documentation for RCHT R and D.
- 1.10.18. **EDGE** is a dedicated, web-based, research database which is used within, and managed by, the R and D department at RCHT.
- 1.10.19. **Standard Operating Procedure (SOP)** is a procedure document detailing a specific sequence of events that must be followed for an activity.
- 1.10.20. **Glossary of Terms** (R and D AD07) is a glossary of the terms, and the definition of the acronyms which can be found in the Associated Documents folder on EDGE.

Acronyms

- **CI:** Chief Investigator.
- **CTIMP:** Clinical Trial of an Investigational Medicinal Product.
- **ECG:** Electrocardiogram.
- **GCP:** Good Clinical Practice.
- **HRA:** Health Research Authority.
- **ISF:** Investigator Site File.
- **MHRA:** Medicines and Healthcare products Regulatory Agency.
- **PI:** Principal Investigator.

- **R and D:** Research and Development.
- **RCHT:** Royal Cornwall Hospitals NHS Trust.
- **SOC:** Sponsorship Oversight Committee.
- **SMT:** Senior Management Team.

2. Purpose of this Standard Operating Procedure (SOP)

The purpose of this Standard Operating Procedure (SOP) is to describe the required documentation and procedures for the filing and archiving of essential documentation, to ensure that the TMFs, ISFs and source documentation for clinical trials and studies are readily available within reasonable timescales for inspection by regulatory bodies or any person appointed by the sponsor or RCHT to conduct an audit.

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 monitoring and audit 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 SOP for Non-compliance Reporting (see SOP index guide).
- Directing the Named Archivist to make archived records available for inspection and audit as required.

3.3. Role of the Head of Research and Development

The Head of Research and Development is responsible for:

- Appointing a Named Archivist to ensure the management of the archived department files and documents in accordance with the regulations, Trust policies and principles of Good Clinical Practice (GCP). The R and D Archivist will be a member of staff in RCHT R and D.
- Ensuring adequate provision of training for the Archivist to perform the roles and responsibilities in association with the processes described in Section 4, Standards and Practice.
- Supporting the Archivist to fulfil the duties, responsibilities, and obligations in executing the processes described in Section 4, Standards and Practice.

3.4. Role of the Archivist

The Archivist is responsible for:

- Supporting all RCHT staff to fulfil the duties, responsibilities, and obligations in executing the processes described in Section 4, Standards and Practice in accordance with the regulations and principles of GCP.
- Managing the archive in accordance with the Standards and Practice described in Section 4 in accordance with the regulations and principles of GCP.
- Liaising with the sponsor of archived studies to ensure the processes are conducted in accordance with the processes described in Section 4, Standards and Practice.
- Ensuring the documents submitted for archive have an accurate log that corresponds with the location and identification of all essential documentation. (R and D AD23 Archive Box Label, available in the Associated Documents folder on EDGE)
- Formally acknowledging receipt of the documents and ensuring the documents are securely stored with access restricted to essential staff for the duration of the retention period.
- Making the records available for inspection or audit at the direction of the SMT.
- Ensuring a chain of custody in the movement of archived records and access to archived material is properly controlled. Thus, ensuring preservation of records held in the archive are clearly documented and alterations logged.
- To inform the sponsor in writing if the clinical trial or study-related documents/records are moved/any changes to the offsite archiving facility.

- Ensure that the sponsor is contacted when it has been determined that the trial or study related documents no longer need to be retained, to gain approval for the destruction of the essential documents.
- Ensuring the destruction of the documents is recorded and conducted in accordance with the Standards and Practice described in Section 4 and the Trust Waste Management Policy (available on the Trust Documents Library).
- Updating the status of the study on EDGE and providing the provisional date of destruction.
- Restricting access to EDGE archived studies to the Archivist, Research Governance Manager and essential staff involved in the maintenance of EDGE.

3.5. **Role of the Chief Investigator (CI) for RCHT Sponsored Studies**

The CI for RCHT sponsored studies is responsible for:

- Informing the Archivist when a study can be archived, following approval from the Sponsorship Oversight Committee (SOC).
- Ensuring that all essential documentation is filed, and the Trial Master File (TMF) is complete, in accordance with the R and D SOP033 Preparation and Maintenance of the Trial Master File (see Documents in EDGE).
- Notifying all staff involved in the clinical trial or study to prepare the files and documents for archive following approval from SOC, including all host sites.
- Agreeing that upon the end of the clinical trial or study the TMF is complete and can be archived in accordance with the processes described in Section 4, Standards and Practice.
- Liaising with the Archivist to arrange the transfer of all essential documentation.
- Ensuring duplicate files and documents are deleted following acknowledgement by the Archivist of receipt of the essential documentation.

3.6. **Role of the Principal Investigator (PI)**

The PI is responsible for:

- Informing the Archivist when a study can be archived following notification from the sponsor.
- Ensuring that all essential documentation is filed, and the Investigator Site File (ISF) is complete in accordance with the R and D SOP021 Preparation and Maintenance of an Investigator Site File (ISF) and the R and D SOP Study Closure (see SOP index guide).
- 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.

- Ensuring 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 as detailed in the R and D SOP for Study Closure (see SOP index guide).
- Notifying all staff involved in the clinical trial or study to prepare the files and documents for archive following notification from the sponsor.
- Agreeing that upon the end of the clinical trial or study the ISF is complete and can be archived in accordance with the processes described in Section 4, Standards and Practice.
- Ensuring episodes of non-compliance with the systems and processes described in Section 4 are processed in accordance with the R and D SOP Non-compliance Reporting (see SOP index guide).
- Liaising with the Archivist to arrange the transfer of all essential documentation.
- Ensuring duplicate files and documents are deleted following acknowledgement by the Archivist of receipt of the essential documentation.

3.7. Role of the Research Governance Manager

The Research Governance Manager is responsible for:

- Supporting the Head of R and D and the Archivist to fulfil the duties, responsibilities, and obligations in executing the processes described in Section 4, Standards and Practice.
- Undertaking an audit of the clinical trial or study documentation, if required after consultation with the SMT, sponsor, or member of the delivery team.

3.8. Role of the Team Leader

The Team Leader is responsible for:

- Supporting the Principal Investigator (PI) to ensure all staff involved in the study are adequately trained to fulfil the duties, responsibilities, and obligations in executing the processes described in Section 4, in accordance with the principles of GCP.
- Liaising with the Research Administrator to arrange for the transfer of all essential documents, both paper-based and electronic, prior to archiving.
- Supporting the PI with investigating episodes of non-compliance in line with the R and D SOP Non-compliance Reporting (See SOP index guide).
- Providing monitors, auditors and regulators supervised access to the study files and documentation for final checks in line with the R and D SOP Study Closure. (See SOP index guide).

- Deleting duplicate documentation of archived material following notification from the Archivist.

3.9. Role of the Research Nurse

The Research Nurse is 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 in a tidy state, with all paper-based and essential documentation filed in the appropriate sections.
- Liaising with the Research Administrator to arrange for the transfer of all essential documents, both paper-based and electronic, prior to archiving.
- Providing monitors, auditors and regulators supervised access to the study files and documentation for final check in line with the R and D SOP Study Closure (See SOP index guide).
- Supporting the PI with investigating episodes of non-compliance in accordance with R and D SOP Non-compliance Reporting (See SOP index guide).
- Deleting duplicate study files and documentation of archived material following notification from the Archivist.

3.10. Role of the Senior Research Administrator

The Senior Research Administrator is 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, Standards and Practice in accordance with the principles of GCP.
- Supporting the Research Administrator to ensure the ISF is in a tidy state, with all documentation filed in the appropriate sections.
- Carrying out quality checks to ensure that the ISF is complete, with all documentation filed in the appropriate sections and logged correctly.
- Supporting the PI with investigating episodes of non-compliance in accordance with R and D SOP Non-compliance Reporting (See SOP index guide).

3.11. Role of the Research Administrator

The Research Administrator is 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, Standards and Practice in accordance with the principles of GCP.
- Liaising with RCHT staff in all locations to ensure that all electronic and paper-based essential documentation are collated and logged prior to archiving.
- Ensuring the ISF is complete and in a tidy state, with all documentation filed in the appropriate sections.
- Supporting the PI with investigating episodes of non-compliance in accordance with R and D SOP Non-compliance Reporting, (See SOP index guide).
- Providing monitors, auditors and regulators supervised access to the study files and documentation for final check in line with the R and D SOP Study Closure (See SOP index guide).
- Logging the study files and documents in accordance with the processes described in Section 4, Standards and Practice.
- Liaising with the Archivist or their delegate to arrange the transfer of the study files and documentation for archiving and, where applicable, arranging the uploading of the electronic files onto EDGE.
- Establishing the provisional date for study destruction and agree with the sponsor.
- Liaising with all staff involved in the conduct of the study, to arrange for all duplicate electronic and paper-based files and documentation of archived material to be deleted following notification from the Archivist.
- Deleting duplicate study files and documentation of archived material following notification from the Archivist.

3.12. Role of the Sponsorship Facilitator

The Sponsorship Facilitator is responsible for:

- Supporting all staff involved in RCHT sponsored studies 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.
- Liaising with the CI following the closure of a clinical trial or study, to confirm that it can be archived.
- Requesting approval to archive from the Sponsorship Oversight Committee (SOC) for sponsored clinical trials and studies.
- Supporting all RCHT staff involved in the conduct of sponsored clinical trials and studies 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.

- Liaising with RCHT staff in all locations to ensure all paper-based and electronic essential documentation is collated and logged prior to archiving.
- Ensuring the TMF is complete and in a tidy state, with all documentation filed in the appropriate sections.
- Sending notification of the approval to archive the essential documents to host sites. Host sites should archive their ISF in accordance with their site SOPs, ensuring compliance with GCP and the relevant regulatory requirements.
- Liaising with the Archivist to arrange the transfer of the study files and documentation for archiving.

3.13. Role of the Supporting Services

The Supporting Services are responsible for:

- Supporting all staff involved in the 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.
- 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 arrange for the transfer of all essential documents, both paper-based and electronic, prior to archiving.
- Supporting the PI with investigating episodes of non-compliance in accordance with R and D SOP Non-compliance Reporting (See SOP index guide).
- Providing monitors, auditors and regulators supervised access to the study files and documentation for final check in line with the R and D SOP Study Closure (See SOP index guide).
- Deleting duplicate study files and documentation of archived material following notification from the Archivist.

3.14. Role of the Study Set-Up Team (SST)

The SST is 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, Standards and Practice in accordance with the principles of GCP.
- Supporting the PI with investigating episodes of non-compliance in accordance with R and D SOP 08 Non-compliance Reporting (See SOP

index guide). Liaising with the Research Administrator to arrange for the transfer of all essential documents, both paper-based and electronic, prior to archiving.

- Deleting duplicate study files and documentation of archived material following notification from the Archivist.

3.15. Role of the Research Clinical Team

The members of 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 in a tidy state, with all documentation filed in the appropriate sections.
- Liaising with the Research Administrator to arrange for the transfer of all essential documents, both paper-based and electronic, prior to archiving.
- Supporting the PI with investigating episodes of non-compliance in accordance with R and D SOP Non-compliance Reporting (See SOP index guide).

4. Standards and Practice

4.1. Sponsor notification of archive

- 4.1.1. For all hosted studies, the sponsor will notify the PI or RCHT R and D in writing that the study can be archived, the PI or delegate should immediately contact the R and D Archivist (the Named Archivist and contact details are available on the R and D webpages on the Trust website).
- 4.1.2. The Sponsorship Oversight Committee (SOC) will make the decisions to archive RCHT sponsored clinical trials and studies. The CI for the study to be notified of the SOC decision.
- 4.1.3. The Research Governance Manager will establish whether the study requires an internal audit prior to archiving and inform the PI accordingly (See R and D SOP Monitoring and Audit, see SOP index guide).
- 4.1.4. The PI or delegate will arrange for the study files and essential documentation to be transferred to the Research Administrator to prepare the study for archiving.

4.2. Preparing paper documents for archive

- 4.2.1. For hosted studies, the Research Administrator is responsible for collating and preparing the study files and essential documentation for archiving, including the ISF and participant identifiable data. Please refer to R and D SOP021 Preparation and maintenance of an Investigator Site

File (ISF) for guidance on the content of an ISF (see Documents folder in EDGE).

- 4.2.2. For sponsored studies, the Sponsorship Facilitator is responsible for collating and preparing the study files and essential documentation for archiving, including the TMF and participant identifiable data. Please refer to R and D SOP033 Preparation and Maintenance of a Trial Master File (TMF) for guidance on the content of a TMF (see Documents folder in EDGE).
- 4.2.3. Paper files should only be placed in R and D approved archived boxes (details available from the Archivist) and the boxes should not be overfilled and weigh no more than 15 kg.
- 4.2.4. All documents must be removed from plastic wallets as these can create humidity and degrade the quality of the file.
- 4.2.5. The contents of the ISF and other essential documents should be assessed:
 - Any records which are duplicates of an original document can be disposed.
 - Any documents which are subject to deterioration, for example, any documents which used thermal paper (ECGs) or photographic paper, should be copied to a more robust media, by photocopying, or copying to a pdf file and processed as electronic data (see paragraph 4.3). The copy should be certified as a copy of the original and signed and dated.
 - 'Post-it' notes should not be used to record data. Ensure that these are actioned appropriately and removed from documentation.
 - Remove staples and paper clips.
 - For any sellotaped documents or documents with degradable labels/attachments, the original should be photocopied, and the copy retained with the original. The copy should be certified as a copy of the original and signed and dated.
- 4.2.6. Before transferring to the Archivist, the essential documents should be checked by the Senior Research Administrator for hosted studies, or the Sponsorship Facilitator for sponsored studies. The checks should ensure that the essential documents are complete, and all necessary documents have been filed.
- 4.2.7. An Archive box label (R and D AD23 Archive Box Label, available in the Associated Documents folder on EDGE) should be fully completed and placed on the top of the documents inside the box before it is closed and sealed.
- 4.2.8. Where a box contains documents relating to more than one study, care must be taken to keep the documentation for each study together and clearly separated from other study documents, for example, by using a

large envelope or divider. An Archive Box Label should be completed for each study within the box.

- 4.2.9. When the physical files have been boxed and checked the Archivist should be informed. The Archivist will liaise with the Research Administrator (hosted studies) or Sponsorship Facilitator (sponsored studies) to arrange for the boxes to be transferred to the Research Archiving Team.
- 4.2.10. For hosted studies, the PI must not release the ISF to the sponsor without a formal agreement in place approved by the Archivist.
- 4.2.11. If errors are identified, the Archivist or the delegate will alert the PI or delegate and provide guidance on correcting these before the Archivist can acknowledge receipt (R and D AD25 Rejection of Physical and Digital Files). Damaged or overfilled boxes will not be accepted by the Archivist.
- 4.2.12. The ISF will remain the responsibility of the PI until the Archivist has received the physical and electronic files, checked that the study has been prepared in accordance with this SOP and acknowledged the documents. (R and D AD26 Acceptance of Physical and Digital Files).

4.3. Electronic documents

- 4.3.1. Electronic documents must be uploaded onto EDGE and available for checking and archiving prior to the transfer of the physical boxes to the Archivist.
- 4.3.2. All electronic essential documents and files stored outside of EDGE (including from servers, emails, delivery teams, PIs, the Study Set-Up Team, Pharmacy Trials Team, and other supporting services) must be uploaded onto EDGE.
- 4.3.3. Electronic documents and files including from servers, emails (preferably in PDF(A) format), delivery teams, PIs, Study Set-Up Team, Pharmacy Trials Team and other supporting services, should be filed into the relevant folder within the Project Site Documents on EDGE. These may need to be uploaded in several files/folders depending on the file/folder size (currently limited to a maximum of 28MB (EDGE limitation)).
- 4.3.4. Any electronic data sent by the sponsor, including data contained on a flash drive/CD/DVD, should also be uploaded to the relevant folder on EDGE. Where information and data are held on CDs, USB drives or floppy discs, contact CITS to establish a secure method for the information to be downloaded and processed as electronic data, in line with the Trust's Acceptable Use Policy.
- 4.3.5. Password protected files/documents must have the password added into the comments section when uploaded to EDGE and commentary to alert the Research Archiving Team that a password protected file for restricted access has been added should be included in the Archiving Workflow.

- 4.3.6. The electronic files and folders will remain the responsibility of the PI until the Archivist has accepted and acknowledged receipt of the documents. If errors are identified, the Archivist will alert the PI or delegate and provide guidance on correcting these before acknowledging receipt.
- 4.3.7. The Archivist or their delegate will restrict access to the files to a limited number of individuals, which will include the Archivist, Head of R and D, Research Governance Manager, Governance Officers, and staff involved in the maintenance of EDGE.
- 4.3.8. After the Archivist has acknowledged receipt of the electronic files and access has been restricted the Senior Research Administrator will liaise with the PI and staff working on the study and instruct them to delete all electronic data outside of EDGE related to the study. (R and D AD26 Acceptance of Physical and Digital Files).

4.4. Claiming Archiving Fees

- 4.4.1. The provisional arrangements and costings (if applicable) for archiving the ISF will be agreed between the PI and the sponsor during the site selection process.
- 4.4.2. Upon notification from the sponsor that the study can be archived, the Research Administrator must check the contract or financial arrangements to ensure all archiving fees are claimed. If this is per box, the R and D accountant should be informed of the number of boxes in which the physical files have been collated. Please note this should be done at as part of study closure (see the Study Closure SOP in the SOP index guide) to ensure all fees are collected.

4.5. Offsite Archiving Facility

- 4.5.1. After the Archivist acknowledges receipt (R and D AD26 Acceptance of Physical and Digital Files) and effectively taking responsibility for the essential documents, the Archivist or delegate will ensure the study reference and details of the contents of the boxed physical files are recorded.
- 4.5.2. Unless alternative archiving storage arrangements have been agreed with the sponsor, the Archivist will arrange for the boxes to be sealed and transferred to RCHT's off-site, archiving facility. The Archivist will carry out routine /random checks on the process for sealing, logging the contents and transfer to the off-site archiving facility. For details on how to prepare the boxes, please see R and D WI 21 Iron Mountain Training Guides.

Contact address for the archiving facility supplier is:

Iron Mountain, Ground Floor, 4 More London Riverside, SE1 2AU.

Location of the archive:

Integra, Harrison Way, Leamington Spa, Warwickshire, CV31 3HJ.

- 4.5.3. The archiving facility is to be inspected in accordance with the requirements of GCP following the award of contract by the Archivist or a delegate, at a minimum of two yearly to ensure that they continue to meet regulatory requirements for archiving clinical research studies and outcomes to be presented to the SMT.
- 4.5.4. All clinical trials and studies should be archived in the same manner, but the retention period for the essential documents differs as per the regulatory requirements, sponsor and R and D retention policies, funder retention policies or third-party retention requirements:
- Commission Directive 2005/28/EC Chapter 4, Article 17 requires that essential documents relating to a clinical trial are retained for at least 5 years after its completion.
 - Under Regulation (EU) No 536/2014, applies for all clinical trials, it does not apply to non-interventional studies. Article 58 of the Regulation states that clinical trial master files must be archived for at least 25 years after the end of the trial.
 - The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 Section 87 (Regulation 78B (c)) and EC Guidelines on Good Clinical Practice (GCP) specific to Advanced Therapy Medicinal Products (2019)(Section 7) requires that clinical research data and documentation be kept for 30 years after the expiry date of the product (for traceability documentation only), or longer if required in the clinical trial authorisation. Under Regulation (EU) 2017/745 (Annex XV, Chapter III (3)) on medical devices, requires that documentation shall be kept for a period of at least 10 years after the clinical investigation with the device in question has ended, or, in the event that the device is subsequently placed on the market, at least 10 years after the last device has been placed on the market. In the case of implantable devices, the period shall be at least 15 years.

4.6. Access to archived material

- 4.6.1. If the PI or delegate should require access to archived material a Retrieval Request Form (R and D AD30 Archiving Retrieval Request Form, available in Associated Documents folder on EDGE) providing specific details of the study, the files and/or documents required and the reason why, should be submitted. Alternatively, the request could come directly to the Archivist from the sponsor. All requests should be addressed to the Named Archivist.
- 4.6.2. Providing the request does not breach regulations and Trust policies, the Archivist will arrange access to the archived material, as appropriate.
- Documents stored with RCHT's offsite archiving facility will be retrieved on the next scheduled collection date.
 - Retrieval of documents following urgent requests will be as soon as practicably possible.

- The requester should escalate concerns to the Head of R and D if experiencing a delay in the retrieval of documents.
- 4.6.3. The Archivist will control access to the archived documents, setting timeframes and limitations to the documents accessed, based on requirements. If the documents involved are electronic, the Archivist can provide access to EDGE or a copy of the required documents, as appropriate.
 - 4.6.4. Any alteration to archived files must be clear without any obliteration of the original record. Details of the alterations should be confirmed to the Archivist with the reason for the alteration made clear. For paper-based documentation, the changes should be initialed and dated.
 - 4.6.5. The Archivist will arrange for the records to be made available for regulatory inspection or internal audit upon request from the Senior Management Team (SMT).
 - 4.6.6. The Archivist will record the transport or transfer of any archived material recalled from archive, to provide a clear chain of custody for the documentation.

4.7. Destruction

- 4.7.1. When the end of the retention period is reached, the Archivist or delegate will seek written approval to destroy the essential documents from the Sponsor or SOC where RCHT is the sponsor (please see R and D WI 22 Destruction Work Instruction). If the sponsor is no longer trading or in business every effort should be made to establish if a legacy for archived material has been made available. This could include a sponsor representative where a company has merged or been taken over, or written instruction for a company which has gone into liquidation.
- 4.7.2. R and D will make three separate attempts to contact the sponsor, documenting the details of the contact in EDGE. When the attempts made to contact the sponsor or person responsible for the study have been unsuccessful, the Head of R and D will decide if the archived material can be destroyed. In all instances the process must be recorded.
- 4.7.3. The Archivist or delegate should check that confirmation of destruction has been received and uploaded to EDGE into the Project Site Documents folder before proceeding further.
- 4.7.4. Once written approval for the destruction of archived material has been received, the Archivist or delegate will arrange for the physical files to be retrieved from the off-site storage facility. Checks will be carried out by the Archivist or delegate to ensure that this study details are correct, and the documentation relates only to the study for which authorisation has been given to destroy, before placing the documentation in confidential waste sacks and arranging for shredding in accordance with the Trust's Waste Management Policy (available on the Trust's intranet via the Documents Library).

- 4.7.5. The Archivist or delegate will delete the electronic folders and only brief details containing the study title and milestones for historical records will be kept on EDGE.
- 4.7.6. For RCHT sponsored studies, the Sponsorship Facilitator will contact the host sites, to confirm when approval has been given for essential documents to be destroyed.

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 any previous versions of the document are made inaccessible to general EDGE users, in accordance with the EDGE document archiving procedure (see R and D 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 AD19).
- 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 by at the R and D Senior Management Team Governance and Performance monthly meetings.
- 5.7. Consideration must be given at 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.
- 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 which 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.
- The author of the risk assessment must submit the risk assessment to SMT.

6. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Successful implementation of the procedures described in this SOP ensures that there is a clear understanding of the roles and responsibilities for staff conducting the archiving of clinical trials and research studies at RCHT.
Lead	Research Governance Manager.
Tool	Quality checks will be carried out by the Research Administrator and the Named Archivist, 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.

Information Category	Detail of process and methodology for monitoring compliance
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 SOP044 - Archiving of Essential Documents Standard Operating Procedure V6.0
This document replaces (exact title of previous version):	Research and Development SOP044 - Archiving of Essential Documents Standard Operating Procedure V5.0
Date Issued / Approved:	March 2025
Date Valid From:	June 2025
Date Valid To:	June 2028
Author / Owner:	Caroline Phillips – Research Governance Manager
Contact details:	rcht.researchqualityassurance@nhs.net 01872 256429
Brief summary of contents:	This SOP describes the required documentation and procedures for the filing and archiving of essential documentation for research studies and clinical trials.
Suggested Keywords:	Standard Operating Procedures (SOP). Good Clinical Practice (GCP). Research and Development (R and D).
Target Audience:	RCHT: Yes CFT: No CIOs 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
Links to key external standards:	Good Clinical Practice for Clinical Trials

Information Category	Detailed Information
	https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials [Accessed 28/01/2025]
Related Documents:	Medicines for Human Use (Clinical Trials) Regulations 2004 https://www.legislation.gov.uk/ukxi/2004/1031/contents/made [Accessed 28/01/2025] UK Policy Framework for Health and Social Care Research (29 March 2023) 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 28/01/2025] Good Clinical Practice – HRA Guidance https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/good-clinical-practice/ [Accessed 28/01/2025] Human Tissue Act 2004 https://www.legislation.gov.uk/ukpga/2004/30/contents [Accessed 28/01/2025] Commission Directive 2005/28/EC Chapter 4 Article 17 https://www.legislation.gov.uk/eudr/2005/28/article/17#:~:text=The%20sponsor%20and%20the%20investigator%20shall%20retain%20the,for%20at%20least%20five%20years%20after%20its%20completion. [Accessed 28/01/2025] Directive 2001/20/EC of the European Parliament and of the Council (Article 2) https://www.legislation.gov.uk/eudr/2001/20/article/2 [Accessed 04/03/2025] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use (Chapter I, Article 2) https://www.legislation.gov.uk/eur/2014/536/article/2 [Accessed 28/01/2025] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use (Article 58) https://www.legislation.gov.uk/eur/2014/536/article/58 [Accessed 28/01/2025] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on

Information Category	Detailed Information
	medical devices, ((Annex XV, Chapter III (3))). https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745 [Accessed 28/01/2025] The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (Sections 4 and 87) https://www.legislation.gov.uk/ukxi/2019/775/data.pdf [Accessed 28/01/2025] EC Guidelines on Good Clinical Practice (GCP) specific to Advanced Therapy Medicinal Products (2019) https://health.ec.europa.eu/system/files/2019-10/atmp_guidelines_en_0.pdf [Accessed 28/01/2025] ICH Efficacy Guidelines Good Clinical Practice https://www.ich.org/page/efficacy-guidelines [Accessed 28/01/2025] ICH GCP E6(R2) https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf [Accessed 28/01/2025] Records Management Code of Practice for Health and Social Care (Updated 7 August 2023) https://transform.england.nhs.uk/information-governance/guidance/records-management-code/ [Accessed 28/01/2025] NHS England Corporate records retention and disposal schedule https://www.england.nhs.uk/publication/corporate-records-retention-disposal-schedule-guidance/ RCHT Management of Information, Records and Data Quality Policy v5.0 (May 2024) - http://doclibrary-rcht-intranet.cornwall.nhs.uk/DocumentsLibrary/RoyalCornwallHospitalsTrust/HealthInformatics/CorporateAndHealthRecords/ManagementOfInformationRecordsAndDataQualityPolicy.pdf [Accessed 28/01/2025] RCHT Waste Management Policy V3.0 November 2023 - http://doclibrary-rcht-intranet.cornwall.nhs.uk/DocumentsLibrary/RoyalCornwallHospitalsTrust/EstatesAndFacilities/Estates/WasteManagementPolicy.pdf [Accessed 28/01/2025] RCHT Acceptable Use Policy V4.0 (Approved July 2024) http://doclibrary-rcht-intranet.cornwall.nhs.uk/DocumentsLibrary/RoyalCornwallHospitalsTrust/HealthInformatics/Information

Information Category	Detailed Information
	Governance/AcceptableUsePolicy.pdf [Accessed 28/01/2025] R and D SOP001 Preparation, approval and review of Standard Operating Procedures and Work Instructions. R and D SOP Monitoring and Audit. R and D SOP Study Closure. R and D SOP Non-compliance. R and D AD01 Monitors Code of Conduct. R and D AD19 R and D Training Matrix. R and D AD23 Archive Box Label. R and D AD25 Rejection of Physical and Digital Files. R and D AD26 Acceptance of Physical and Digital Files. R and D AD30 Archiving Retrieval Request Form.
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
Date document created.	V1.0	Initial issue.	Not known.
Date partial revision completed.	V1.1	Partial Update (to be completed during the valid to dates). Details of sections which contains amendments to be included here.	Not known.
01/07/2014	V1.0	Complete revision to reflect current practice.	Dr N Morley, R D and I, Assistant Research Manager.
23/03/2017	V2.1	'Policy Under review' label added.	Helen Holman, Data Quality and Project Monitoring

Date	Version Number	Summary of Changes	Changes Made by
			Officer.
23/08/2017	V3.0	Complete rewrite to align with Trust policies	Dr N Morley, R D and I, Assistant Research Manager.
29/07/2019	V4.0	Full revision to update changes in procedures and updates following omissions in previous version	Dr N Morley, R D and I, Assistant Research Manager.
21/12/2023	V5.0	Changes to from RD and I to R and D. Review of SOP in line with GCP guidance, feedback from external monitoring and audits and changes to R and D procedures. Review and update in accordance with Trust policies.	Caroline Phillips, Research Governance Manager.
13/03/2025	V6.0	Review of document to reflect the regulatory definitions for clinical trials and clinical studies. Additional of the regulatory references in Section 4.5.4. Change to the off-site archiving supplier	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 SOP044 - Archiving of Essential Documents Standard Operating Procedure V5.0
Department and Service Area:	Corporate Group
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

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 archiving essential documents from research studies and clinical trials carried out at RCHT.
2. Policy Objectives	To ensure that there is a clear understanding of the roles and responsibilities, and procedures for archiving research studies and clinical trials, aligned to the regulatory requirements.
3. Policy Intended Outcomes	Compliance with the regulatory requirements and Good Clinical Practice (GCP).
4. How will you measure each outcome?	Regulatory Inspections will ensure compliance with regulatory requirements and GCP.
5. Who is intended to benefit from the policy?	All research participants. All staff involved in research and the Trust.

Information Category	Detailed Information
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 external audits have been used to inform the development of this SOP, ensuring that R and D has robust systems and processes in place which the quality and integrity of clinical research 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](#)