

Research and Development SOP021 Preparation and Maintenance of an Investigator Site File (ISF)

V5.0

February 2024

Table of Contents

1. Introduction	4
1.7. Scope	4
1.8. Definitions/Glossary	4
2. Purpose of this Standard Operating Procedure	6
3. Ownership and Responsibilities	6
3.1. Role of the R and D Clinical Director	6
3.2. Role of the Senior Management Team (SMT)	6
3.3. Role of the Principal Investigator (PI)	7
3.4. Role of the Team Leader	8
3.5. Role of the Research Nurse	9
3.6. Role of the Research Administration Team	10
3.7. Role of the supporting service Lead	11
3.8. Role of the Study Set-Up Team (SST)	12
4. Standards and Practice	12
4.6. Before the study commences	13
4.7. During the conduct of the study	13
4.8. After completion or termination of the study	14
5. Dissemination and Implementation	14
6. Monitoring compliance and effectiveness	16
7. Updating and Review	16
8. Equality and Diversity	16
Appendix 1. Governance Information	17
Appendix 2. Equality Impact Assessment	21

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 are applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

1. Introduction

- 1.1. The Investigator Site File (ISF) is a collection of essential documents, that individually and collectively create an audit trail for all research **hosted** by the Royal Cornwall Hospital NHS Trust (RCHT), facilitating the evaluation of the conduct of the study and the quality of the data produced.
- 1.2. The essential documents demonstrate compliance with the standards of the International Council for Harmonisation of Good Clinical Practice (ICH GCP), and applicable UK regulations.
- 1.3. Clinical Trials Regulation (EU) No 536/2014 (Article 56) states; 'All clinical trial information shall be recorded, processed, handled, and stored by the sponsor or investigator, as applicable, in such a way that it can be accurately reported, interpreted and verified while the confidentiality of records and the personal data of the subjects remain protected in accordance with the applicable law on personal data protection.'
- 1.4. The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031 Sch 1 Part 2) 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 the trial subjects remains protected.'
- 1.5. ICH GCP E6 (R2) Part 8 Addendum defines the essential documents for the conduct of a clinical study
(https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf)
- 1.6. This version supersedes any previous versions of this document.
- 1.7. **Scope**
 - 1.7.1. This Standard Operating Procedure (SOP) applies to all staff conducting research where the study is **hosted** by RCHT.
 - 1.7.2. The procedures outlined in this SOP apply for all ISFs, whether paper-based, digital or a combination of both.
- 1.8. **Definitions/Glossary**
 - 1.8.1. **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.
 - 1.8.2. **Sponsor** is an individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial. A group of individuals and/or organisations may take on sponsorship responsibilities and distribute them by agreement among the members of the group, provided that, collectively, they make arrangements to allocate all the responsibilities that are relevant to the study in line with the UK Policy Framework for Health and Social Care Research.

- 1.8.3. **Principal Investigator (PI)** is the person who takes responsibility for the initiation and conduct of the study at site. There is one Principal Investigator at each site participating in a research study. For a single site study, the Chief Investigator (CI) may also take on the role of Principal Investigator (PI).
- 1.8.4. **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 research study and the quality of the data produced to be evaluated and demonstrate the study has been conducted in accordance with the legislation.
- 1.8.5. **Investigator Site File (ISF)** contains the essential documents which show that the investigator and the conduct of the study are following the regulatory requirements. The ISF can be held in paper or digital formats, or a combination of both.
- 1.8.6. **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.
- 1.8.7. **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.
- 1.8.8. **Hosted** refers to an externally sponsored study for which the RCHT is acting as a research site.
- 1.8.9. **EDGE** is a dedicated, web-based, research database which is used within, and managed by, the R and D department at RCHT.
- 1.8.10. **Standard Operating Procedure (SOP)** is a procedure document detailing a specific sequence of events that must be followed for an activity.
- 1.8.11. **Glossary of Terms (RD and I AD 07)** is a glossary of the terms, and the definition of the acronyms can be found in the Associated Documents folder in Edge.
- 1.8.12. **Acronyms**
- **CI:** Chief Investigator.
 - **CTIMP:** Clinical Trial of an Investigational Medicinal Product.
 - **EOI:** Expression of Interest.
 - **GCP:** Good Clinical Practice.
 - **HRA:** Health Research Authority.
 - **ICH GCP:** International Council for Harmonisation of Good Clinical Practice.

- **ISF:** Investigator Site File.
- **MHRA:** Medicines and Healthcare products Regulatory Agency.
- **PI:** Principal Investigator.
- **QMS:** Quality Management System.
- **R and D:** Research and Development.
- **RCHT:** Royal Cornwall Hospitals NHS Trust.
- **REC:** Research Ethics Committee.
- **SMT:** Senior Management Team.

2. Purpose of this Standard Operating Procedure

- 2.1. This Standard Operating Procedure (SOP) describes the essential study documentation and procedures for preparing and maintaining the Investigator Site File (ISF) as evidence that the data generated is complete, accurate, verifiable, and traceable.
- 2.2. Maintenance of essential documentation demonstrates compliance with the Clinical Trial Regulations including the principles of ICH GCP and the UK Policy Framework for Health and Social Care Research.
- 2.3. This SOP applies to all studies **hosted** by RCHT.

3. Ownership and Responsibilities

3.1. Role of the R and D Clinical Director

The R and D Clinical Director is responsible for:

- Supporting the implementation of robust arrangements to ensure staff follow the processes described in Section 4 Standards and Practice.
- Checking the processes described in Section 4 Standards and Practice support the requirements of the regulators and appropriate standards.
- Checking the processes described in Section 4 Standards and Practice support the requirements of the Trust policies and procedures.

3.2. Role of the Senior Management Team (SMT)

The SMT is responsible for:

- Ensuring adequate provision of training for staff to perform their roles and responsibilities in association with the processes described in Section 4, Standards and Practice.

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

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

The PI is responsible for the oversight of:

- Ensuring the Investigator Site File (ISF) containing all the essential documentation required for the conduct of the study is in place prior to the start of the delivery/green light.
- Ensuring the ISF is stored in a secure location with restricted access.
- Ensuring all staff involved in the study have access to the appropriate files and documents to perform their function and undertake all the procedures in the protocol as delegated.
- Ensuring the ISF is maintained for the duration of the study.
- Ensuring a robust process is in place for good version control in accordance with the principles of Good Clinical Practice (GCP).
- Ensuring the essential documentation is updated in real time or as soon as practically possible.
- Ensuring staff with delegated duties related to the standards processes and processes described in Section 4 fulfil their duties in accordance with the principles of GCP.
- Ensuring monitors and sponsor representative have supervised access to the ISF in accordance with the Associated Documents, AD01a Code of Conduct for the Monitoring Visit (available in the Documents folder on EDGE).
- Informing the Head of R and D and the Research Governance Manager immediately upon notification of an audit or inspection from the regulators or an external audit arranged by the sponsor.
- Supporting the regulators and auditors with queries relating to the study files and documentation.
- Supporting research staff to expedite the implementation of amendments and raise objections within the time frames directed by the Health Research Authority (HRA) and in accordance with the R and D SOP Amendments (See SOP index guide) and Work Instruction W14 Amendment Process (located in the Documents Folder on EDGE).

- Ensuring episodes of non-compliance of the systems and processes described in Section 4 are processed in accordance with R and D SOP Non-compliance Reporting (See SOP index guide).
- Ensuring that upon notification of the study closure or termination from the sponsor, all essential documentation is filed and the ISF is complete prior to archiving in accordance with R and D SOP 44 Archiving Essential Documents (available in the Documents Folder on EDGE).

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.
- Identifying secure space for the storage of essential study documentation and restricting access.
- 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.
- Liaising with RCHT staff in all locations to ensure the essential documentation is filed in real time or as soon as practically possible.
- Supporting research staff to expedite the implementation of amendments (see R and D SOP Amendment Process (see SOP index guide) and Work Instruction WI14 Amendments Process, located in Documents Folder on EDGE).
- 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 supervised access to the study files and documentation.
- Informing the Head of R and D and the Research Governance Manager immediately upon notification of an audit or inspection from the regulators or an external audit arranged by the sponsor.
- Supporting the regulators and auditors with queries relating to the study files and documentation.

- Supporting the PI and Archivist with collating the files for final audit prior to archiving in accordance with the processes described in R and D SOP 44 Archiving Essential Documents (available in the Documents folder on EDGE).

3.5. **Role of the Research Nurse**

The Research Nurse is responsible for:

- Supporting the PI and Team Leader 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 in accordance with the principles of Good Clinical Practice.
- Providing support to help all staff involved in the study to undertake their delegated duties in accordance with the principles of GCP.
- Ensuring study files and documents are filed in real time or as soon as practically possible.
- Liaising with RCHT staff in all locations to ensure the essential documentation is filed in real time or as soon as practically possible.
- Supporting the Research Administration Team to ensure that the ISF is maintained in a tidy state, with all documentation filed in the appropriate sections.
- Supporting research staff to expedite the implementation of amendments (see R and D SOP Amendments (see SOP index guide) and Work Instruction WI14 Amendments Process located in Documents folder on EDGE).
- 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, available in the Documents folder on EDGE).
- Supporting the PI and Team Leader to ensure monitors, auditors and regulators have supervised access to the study files and documentation as directed.
- Informing the Head of R and D and the Research Governance Manager immediately upon notification of an audit or inspection from the regulators or an external audit arranged by the sponsor.
- Supporting the regulators and auditors with queries relating to the study files and documentation.
- Supporting the PI, Team leader and Archivist with collating the files for final audit prior to archiving in accordance with the processes described in R and D SOP 44 Archiving Essential Documents (available in the Documents Folder on Edge).

3.6. Role of the Research Administration Team

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 processes described in Section 4 in accordance with the principles of Good Clinical Practice.
- Liaising with the Sponsor to identify the requirements for the ISF.
- Providing support to help all staff involved in the study to undertake their delegated duties in accordance with the principles of Good Clinical Practice.
- Liaising with the PI and RCHT staff involved in the study in all locations to ensure the essential documentation is filed in real time or as soon as practically possible.
- Ensuring the ISF is maintained in a tidy state, with all documentation filed in the appropriate sections.
- Supporting research staff to expedite the implementation of amendments (see R and D SOP Amendments and Work Instruction WI14Amendment Process located in Documents Folder on EDGE).
- Supporting the PI to ensure all staff involved in the study are made aware of amendments.
- 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), available in the Documents folder on EDGE).
- Supporting the PI and Team Leader to ensure monitors, auditors and regulators have supervised access to the study files and documentation as directed.
- Informing the Head of R and D and the Research Governance Manager immediately upon notification of an audit or inspection from the regulators or an external audit arranged by the sponsor.
- Supporting the regulators and auditors with queries relating to the study files and documentation.
- Supporting the PI, Team Leader, and Archivist with collating the files for final audit prior to archiving in accordance with the processes described in R and D SOP Archiving Essential Documents (available in the Documents folder on EDGE).

3.7. Role of the supporting service Lead

The Supporting Service Lead is responsible for:

- Supporting the PI to fulfil the duties, responsibilities, and obligations in executing the processes described in Section 4, Standards and Practice.
- Identifying secure space for the storage of essential study documentation with controlled access.
- 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 staff within the supporting service, and other staff involved in the study, and to provide support to help all staff to undertake their delegated duties.
- Liaising with the PI and RCHT staff involved in the study in all locations to ensure the essential documentation is filed in real time or as soon as practically possible.
- Supporting research staff to expedite the implementation of amendments (see R and D SOP Amendments (see SOP index guide) Work Instruction WI14 Amendment Process, located in Documents folder on EDGE).
- Supporting the PI to ensure all staff involved in the study are made aware of amendments.
- 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, available in the General Folder on Edge).
- Providing monitors, auditors and regulators supervised access to the study files and documentation within their service.
- Informing the Head of R and D and the Research Governance Manager immediately upon notification of an audit or inspection from the regulators or an external audit arranged by the sponsor.
- Supporting the regulators and auditors with queries relating to the study files and documentation within their service.
- Supporting the PI, Team Leader, and Archivist with collating the files for final audit prior to archiving in accordance with the processes described in R and D SOP 44 Archiving Essential Documents (available in the Documents folder on EDGE).

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

The SST is responsible for:

- Liaising with the sponsor, Health Research Authority (HRA), PI, Team Leader, Supporting Service Leads, and any other staff involved in the study, as required, during the set-up of any new studies.
- During study set-up, uploading the latest approved version of all study documents on EDGE and ensuring adequate version control of the documents in accordance with the principles of GCP.
- Supporting the PI to fulfil the duties, responsibilities, and obligations in executing the processes described in Section 4, Standards and Practice.
- During study set-up, liaising with the PI and RCHT staff involved in the study in all locations to ensure the essential documentation is filed in real time or as soon as practically possible.
- 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, available in the Documents folder on EDGE).
- Supporting the regulators and auditors with queries relating to the study files and documentation.
- Supporting the PI, Team Leader, and Archivist with collating the files for final audit prior to archiving in accordance with the processes described in R and D SOP 44 Archiving Essential Documents (available in the Documents folder on EDGE).

4. Standards and Practice

- 4.1. The Investigator Site File (ISF) consists of essential documents relating to the specific research study; before the study commences, during the study conduct and after the completion of the study.
- 4.2. It is the responsibility of the Principal Investigator (PI) to have oversight of the establishment and maintenance of the ISF for each study that they participate in. The PI may delegate this duty to a member of the study team, authorising this in the delegation log.
- 4.3. The format of the ISF can be paper, electronic or a combination of both, as agreed by the Sponsor and both formats must adhere to the requirements of ICH GCP guidelines.
- 4.4. The essential documents should be collected and stored in the agreed format, as soon as the sponsor makes them available to R and D.
- 4.5. The files and documents required for each study vary according to the phase of the study, the activity conducted at site, which staff and departments are involved and whether the study is a clinical trial of an investigatory medicinal product (CTIMP) or other type of study.

4.6. Before the study commences

- 4.6.1. The Admin Team will identify the Sponsor requirements for the format and content for the Investigator Site File (ISF) during the initiation and set-up of the study.
- 4.6.2. Each paper based ISF should contain an index at the beginning of the file which details of where essential documents should be filed.
- 4.6.3. The Sponsor may provide the ISF with all the relevant documents prior to the start of the study or the relevant template for the ISF indexes for the files that the study teams should use. If the templates are not provided by the Sponsor, RCHT will provide a template index using Work Instruction WI09 Study Folder Index and Filing.
- 4.6.4. Electronic ISF formats will be informed by the Sponsor and saved in a folder in the R and D shared drive, unless an alternative electronic platform is provided by the sponsor. Access to the electronic ISF will be restricted to those delegated to work on the study.
- 4.6.5. Before a study is opened at RCHT the PI will receive sponsor notification (Green Light) providing authority to start. At this stage, the ISF should be in place containing all essential documentation required for the conduct of the study.
- 4.6.6. Before a study is open at RCHT the PI must ensure that all supporting services involved in the study have access to the appropriate files and documentation required to perform the associated protocol procedures.

4.7. During the conduct of the study

- 4.7.1. During the conduct of the study, it is the responsibility of the PI or a delegated person to maintain the ISF.
- 4.7.2. Throughout the duration of the study, amendments and updates to study conduct and documentation may occur. New and superseded documents must be stored in the ISF.
- 4.7.3. All documents should be filed chronologically within each section to allow the most recent versions of the documents to be easily accessed.
- 4.7.4. All documents must be version controlled, signed, and dated where appropriate. All previous versions of the documents must be retained and marked as superseded. For paper version of the documents, this will be done by striking through the front page of the document with a single line in pen marking as superseded by the later version, signed, and dated.
- 4.7.5. Any documents identified as missing must be obtained by the PI or the person to whom this task has been delegated.

- 4.7.6. Documents should adhere to ALCOA CEEA (MHRA GXP Data Integrity Guidance and Definitions) and ALCOA ++ (European Medicines Agency (EMA) Guidelines on computerised systems and electronic data in clinical trials) principles; Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Corroborated, Enduring and Available when needed and Traceable. All documents should be signed and dated as appropriate in line with these principles.

4.8. After completion or termination of the study

- 4.8.1. Closure and archiving of the ISF and all associated essential documents must be undertaken as per the arrangements made with the Sponsor. Archiving provisions should be agreed with the Sponsor at the beginning of the study and will be documented in the protocol and/or contract.
- 4.8.2. For studies where the Sponsor will archive the essential documentation, all necessary arrangements including the location and required timescale should be agreed with the Sponsor when RCHT's involvement with the study has ended.
- 4.8.3. Archiving of the study should be carried out in accordance with SOP44 Archiving of Essential Documents (see Documents folder on EDGE).

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 SOP001 Preparation, Approval and Review of SOPs/WIs).
- 5.4. Relevant research staff registered on EDGE will be notified by email of the new or reviewed document. Relevant staff will be identified from the ownership and responsibilities (Section 3) of this procedural document and the R and D training matrix (R and D AD 19).
- 5.5. Details of how to access EDGE is available by contacting the EDGE Data Officer via rch-tr.edge@nhs.net.
- 5.6. It is the responsibility of all staff to check the website regularly, in order to see if SOPs have been added or amended. R and D will endeavour to notify research staff of any SOP developments that may be relevant to them via staff communications e.g., R and D Newsletters, Leadership Huddle and Workstream Huddles. A list of any new or updated SOPs will be reviewed and ratified 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 research studies and clinical trials at RCHT.
Lead	Research Governance Manager
Tool	Internal and external monitoring of research studies and clinical trials will monitor the implementation of this SOP and compliance with Good Clinical Practice (GCP).
Frequency	Compliance with this procedural document will be monitored as part of the R and D risk-based, audit and monitoring process directed through the R and D SMT Governance and Performance meetings.
Reporting arrangements	The Research Governance Manager will provide monthly reports at the R and D SMT Governance and Performance meetings.
Acting on recommendations and Lead(s)	The Governance and Performance SMT meetings will provide effective oversight and ensure corrective actions are undertaken.
Change in practice and lessons to be shared	The Governance and Performance SMT meetings will identify non-compliance and appoint a member of the SMT to provide support and advice to identify training needs and improve practice. 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 SOP021 Preparation and Maintenance of an Investigator Site File (ISF) V5.0
This document replaces (exact title of previous version):	Research Development and Innovation (RD and I) Study Files and Filing for Hosted Research Procedure V4.0
Date Issued / Approved:	December 2023
Date Valid From:	February 2024
Date Valid To:	February 2027
Author / Owner:	Caroline Phillips, Research Governance Manager
Contact details:	richt.researchqualityassurance@nhs.net 01872 256429
Brief summary of contents:	The SOP describes the essential study documentation and procedures for preparing and maintaining the Investigator Site File (ISF) as evidence that the data generated is complete, accurate, verifiable, and traceable.
Suggested Keywords:	Standard Operational Procedure (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:	Research and Development Senior Management Team (SMT)
Manager confirming approval processes:	Jaya Shrivastava – Interim 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:	Clinical Trails Regulation (EU) No 536/2014 https://www.legislation.gov.uk/eur/2014/536/article/56 Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. https://www.legislation.gov.uk/uksi/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/ Good Clinical Practice – HRA Guidance https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/good-clinical-practice/ Medicines and Healthcare products Regulatory Agency (MHRA) ‘GXP’ Data Integrity Guidance and Definitions https://www.gov.uk/government/publications/guidance-on-gxp-data-integrity European Medicines Agency (EMA) Guidelines on computerised systems and electronic data in clinical trials https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-computerised-systems-electronic-data-clinical-trials_en.pdf 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 ICH GCP Essential documents for the conduct of a clinical trial: ICH E6 (R2) Good clinical practice - https://ichgcp.net/8-essential-documents-for-the-conduct-of-a-clinical-trial

Information Category	Detailed Information
	Records Management: Code of Practice for Health and Social Care https://www.gov.uk/government/publications/records-management-code-of-practice-for-health-and-social-care RCHT Management of Information, Records and Data Quality Policy - Management of Information, Records and Data Quality Policy (cornwall.nhs.uk) R and D SOP001 Preparation, approval and review of Standard Operating Procedures and Work Instructions. R and D SOP044 Archiving Essential Documents. R and D SOP Amendments (see SOP index guide). R and D Non-compliance (see SOP index guide). R and D WI14 Amendment Process. R and D AD01a Code of Conduct for the monitoring visits. R and D AD19 R and D Training Matrix.
Training Need Identified:	Yes – Details provided in Section 5
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Intranet Only
Document Library Folder/Sub Folder:	Research and Development

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
01/07/2014	V1.0	Complete revision to reflect current practice	Dr N Morley, RD and I ARM
27/04/2017	V2.1	'Policy Under review' label added.	Helen Holman, Data Quality and Project Monitoring Officer
01/08/2017	V3.0	Complete rewrite merging SOPs to meet updated standards and process and align to Trust policies	Dr N Morley, RD and I ARM

Date	Version Number	Summary of Changes	Changes Made by
06/08/2019	V4.0	The processing of amendments has been changed to reflect current practice	Dr N Morley, RD and I ARM
21/12/2023	V5.0	Change of the title of the SOP 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

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 SOP021 Preparation and Maintenance of an Investigator Site File (ISF) 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:	01872 256429 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 provides guidance for preparing and maintaining essential documents in the Investigator Site File (ISF) for studies hosted by RCHT.
2. Policy Objectives	This SOP ensures that essential study documentation is available within the Investigator Site File (ISF) as evidence that the data generated is complete, accurate, verifiable, and traceable.
3. Policy Intended Outcomes	Compliance with the regulatory requirements and Good Clinical Practice (GCP).
4. How will you measure each outcome?	Risk-based internal auditing and monitoring programme to ensure that research studies are compliant with GCP. External monitoring and auditing carried out by the sponsors and Clinical Research Associates (CRAs).

Information Category	Detailed Information
5. Who is intended to benefit from the policy?	All research participants. All staff involved in research and the Trust.
6a. Who did you consult with? (Please select Yes or No for each category)	- Workforce: Yes - Patients/ visitors: No - Local groups/ system partners: No - External organisations: 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 (SMT). 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 the best practice in the development of procedural documents, aligned to the requirements of GCP guidance.
6d. Have you used any of the following to assist your assessment?	National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys: The outcomes of internal and external monitoring and audits will inform the development of SOPs and WIs, ensuring that R and D has robust systems and processes in place which ensure patient safety and the quality and integrity of research studies carried out by RCHT R and D.

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

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

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

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

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

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

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
[Section 2. Full Equality Analysis](#)