Dorset County Hospital NHS Foundation Trust

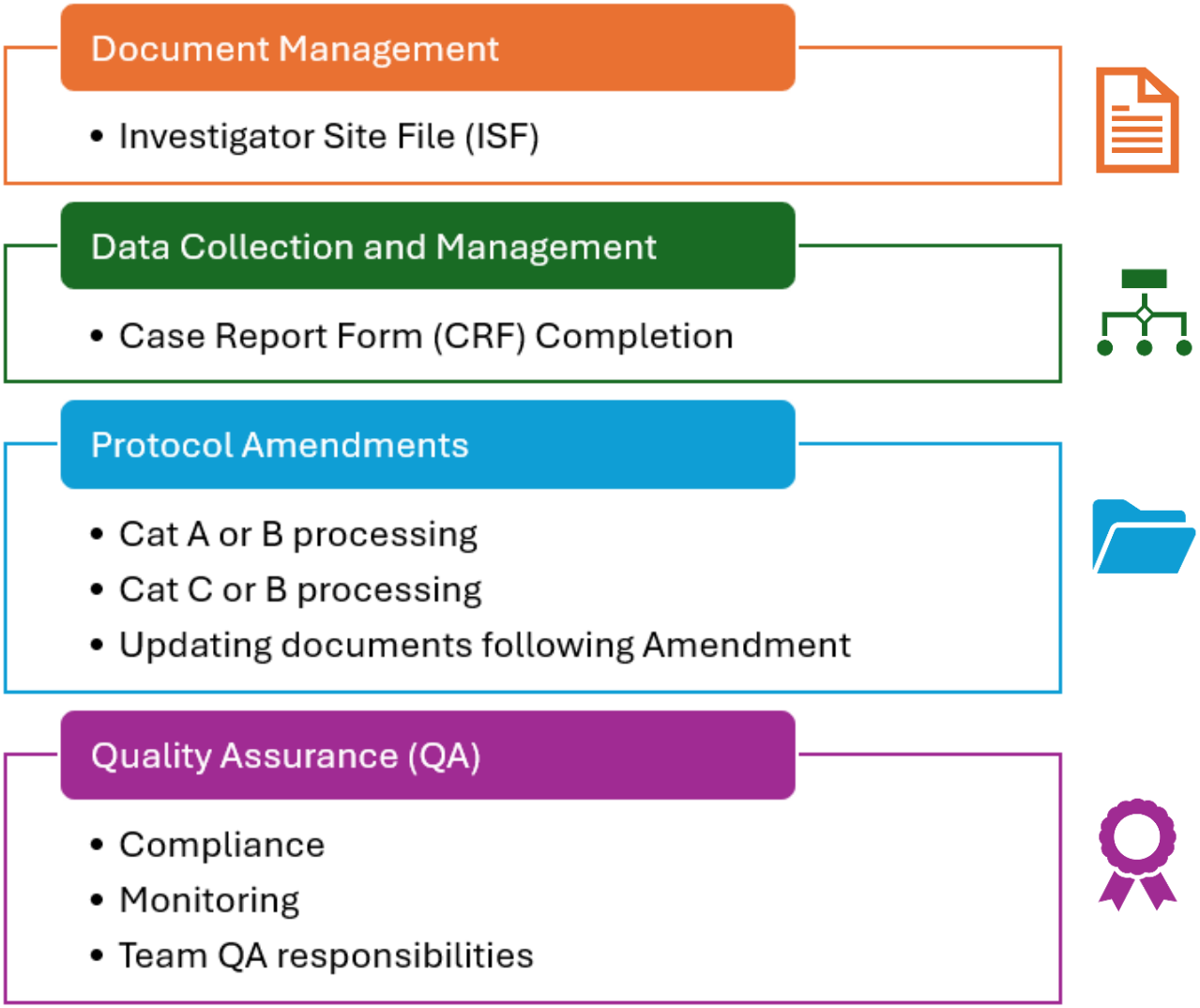
RESSOP004 - RESEARCH STUDY MAINTENANCE AND AMENDMENTS

SOP Title	RESSOP004 - Research Study Maintenance and Amendments		
SOP Number	**RESSOP004**	**Policy Version Number**	**1**
Applicable to	All research staff undertaking activity		
Aim of the Policy	To provide a structured and standardised approach to managing and documenting any changes or updates to an ongoing research study. This SOP will ensure that all modifications are systemically reviewed, approved and implemented.		
Next Review Due Date	**06/03/2026**		
Author/ Reviewer	Josie Goodsell- Research Project Manager		
Policy Sponsor	Sarah Doyle- Head of Research		
Responsible Executive	*Quality Group*		
Expert Group	Quality Group		
Date Approved	06/03/2025		
Ratified by	*Sarah Doyle – Head of Research*		
Date Ratified	*22/04/2025*		
Primary Specialty	Research Department		
Secondary Specialty	All department active in research		

Document Version Management			
Version	Date	Reviewer	Description of Change(s)

Content

Quick Reference Guide:



1. Introduction

1.1 This procedure outlines procedures for maintaining and organising study documentation and describes the process for implementing protocol amendments.

1.2 Roles and responsibilities will be outlined for each team member involved in maintaining the research study, including principal investigators, coordinators and research project managers.

1.3 Mechanisms ensuring the quality and integrity of study data, including regular reviews of procedures and documentation will be covered.

2. Aims and Objectives of this SOP

2.1 The main aim is to provide a structured and standardised approach to managing and documenting ongoing research studies.

Main objectives are:

a. Ensuring Compliance

b. Consistency and Accuracy

c. Transparency

d. Communication

e. Efficiency

3. Scope

All research staff who are involved in the coordination, management and facilitation of research studies.

3.1 This procedure will be reviewed and approved by the Research Quality Group. Once published it should be disseminated by the line manager for all research staff who are required to:

a. Maintain a study investigator site file.

b. Maintain, file and review the quality of source documentation and CRFs

c. Process Amendments for studies.

3.2 Once approved and disseminated, it is the responsibility of staff to stay informed of any changes thereon.

3.4 This approved policy will be uploaded to the Trust Policies and Clinical Guidance database and published via the Trust StaffNet.

4. Definitions

a. **CRF** – Case Report Form

b. **EDGE** – Clinical research management system

c. **GCP** – Good Clinical Practice.

d. **ISF** – Investigator Site File

e. **QA** – Quality Assurance

f. **SAE** – Serious Adverse Event

5. Equality Impact and Compliance Assessment

Equality has been considered, see Appendix 1.

6. Data Protection Impact Assessment

Data protection and confidentiality has been considered, see Appendix 2.

7. Stakeholders and Consultation

- Research Project Manager representatives at Dorset County Hospital.
- Research Quality Group at Dorset County Hospital.

8. Roles and Responsibilities

6.1 It is the responsibility of Research staff to ensure they receive, understand, and document all necessary training to fulfil the requirements of this SOP.

6.2 Delegation logs for research studies are often an essential requirement and should detail a person's responsibilities within that study.

9. Training and Implementation

7.1 All research personnel must have up to date training in GCP and appropriate training as required by the research study.

7.2 During the 'set-up' phase of a new clinical trial, induction training is provided to all staff associated with delivering the study.

10. Risk Management

- Risk Management for this SOP is conducted via three key processes;
    - The SOP approval process involves governance and risk subject matter experts identifying generalized risks and mitigations to be written into the draft SOP prior to approval.

- The delivery of this SOP will be monitored both by the review periods identified and the datix incident reporting system to implement corrective and preventative actions through this SOP.
- The study feasibility process (RESSOP009) identifies risks related to individual study delivery and their compliance with this SOP.

11. Approval

9.1 This SOP has been approved in accordance with the Policy and Procedure for the Development and Management of Policies and Clinical Guidance (Ref 1126).

12. Monitoring and Reviewing Arrangements

10.1 This SOP will be reviewed at least every three years, in accordance with the Policy and Procedure for the Development and Management of Policies and Clinical Guidance (Ref 1126).

13. Dissemination

11.1 This approved SOP will be uploaded to the Trust Policies and Clinical Guidance database and published and accessible via the Trust intranet, StaffNet.

14. Policy Content

This procedure will provide guidance with document management, data collection, monitoring and amendments in accordance with GCP guidelines and the individual requirements of the study as defined in the study protocol.

Documentation Management

12.1 Investigator Site File (ISF)

An Investigator Site File (ISF) should be prepared as soon as possible after the first contact by the study organising body or, for trials where there is no external study organising body, as soon as an outline protocol is available. The file should be actively maintained and updated from this time until the trial is formally closed.

1. A version log should be used to provide a clear accurate summary of the current versions of all study-related documents, ensuring superseded documents are removed, if necessary. The version log should be kept in the front of the Investigator Site File. Where a version log is not provided, a local one should be produced.
2. One copy of any superseded document should remain in the site file, with a line through it. The date the document was superseded, and the latest version of the document should be stated on the document. For example, “Protocol superseded on 24/07/2009 by Protocol version 2 dated 20/07/2009”.

3. When it becomes available, the final report should be filed in the study file.
4. Specific space will be allocated for the filing of prospective studies, where protocols, investigator brochures and early correspondence can be stored when they are first produced or received by the department.
5. Should the investigator or the department decide not to participate in the study, the protocol and investigator's brochure should be destroyed or returned to the external study organising body (if applicable).
6. Each trial will have an individual Site File common items contained in an ISF can be found in Work Instruction: WE-36 – Investigator Site File.doc.
7. A study file may consist of more than one volume and should be labelled as such i.e. File 1, File 2, etc.
8. If any documents are filed separately then a note should be made in the study file detailing where the document is stored. (File Notes may be printed on hospital headed paper, with the full protocol title, name of PI and the title of the documents e.g. CRFs. The exact location of the documents is then typed in. The location could be just next to the site file, on another shelf, or in a different department. (For example, the Drug Accountability Log is stored in the Pharmacy Department. The File Note is then signed and dated).

12.2 Data Collection and Management

A. Case Report Form (CRF) Completion

ICH Good Clinical Practice Guidelines define a Case Report form (CRF) as:

"A printed, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject"

CRFs hold all the necessary information about:

- The patient
- Administration of the study drug
- Study Procedures
- Outcome of the assessments
- Adverse Events

This list is not exhaustive and will be dictated by the study protocol

CRFs are the official documentation of the study for the authorities and together, with the source documents, will be closely examined during audits and inspections.

The data collected in CRFs is therefore used directly as the basis for the study report and any publications, as well as supporting an application for marketing authority approval of a new or existing drug.

Detailed guidance surrounding procedures for completing CRFs can be found in the following work Instruction – WE37 – CRF Completion.doc

B. Data Queries

Data queries are communicated within a study process to clarify or resolve any discrepancies or inconsistencies found in the data provided from a CRF.

These are normally filed in the participant's file however more commonly they are held within an electronic data capture system provided by the study.

For multiple queries relating to different participants, which are printed on one sheet, the irrelevant data must have a single strike through along with initials and date of the person completing this, and filed with the accompanying letter in the Investigator Site File (ISF).

Data queries must be logged locally via the data queries log spreadsheet (located on the Portfolio Review Sheet).

12.3 Protocol Amendments

Amendments to a research project occur on the instigation of the sponsor. These should be processed according to the amendment workflow on the edge management system to ensure they have all appropriate approvals. Amendments should be assessed for their impact on the feasibility of continuing the study. For most amendments, this can be done informally, however where the amendment impacts study delivery locally, an updated feasibility assessment must be conducted.

The Sponsor decides on whether an amendment is substantial or non-substantial. A substantial amendment will go to a Research Ethics Committee for approval, whereas a non-substantial amendment does not need to.

The HRA will then categorize the amendment as A, B, or C - Category A is assessed as affecting all sites, Category B is assessed as affecting some sites, and Category C is assessed as not affecting any sites. There is a further category for addition of new sites only.

Any amendment which references '**Unexpected**', '**Serious**' and '**Reaction**' should be alerted to the R&D team within the Research Department at the earliest opportunity.

Guidance on the processing amendments according to their category can be found in Work Instruction: WI-38 – Amendment Procedure.doc

A. Updating documents for an amendment

The process for updating documents is covered in detail in the edge workflow, the following processes must be satisfied:

- All non-controlled copies of former documentation (i.e. outside of the ISF or electronic storage) should be destroyed.
- A notice should go out to all relevant parties (pharmacy, Principal Investigator) to notify them of the amendment and the need to destroy uncontrolled copies.
- Any pre-prepared patient packs should be updated with **immediate** effect from the point of implementation.

  **__Note__: immediate effect means that there should be no chance of a patient being recruited with the wrong documentation from the point of implementation.*
- Any superseded documents in the ISF should be marked as "Superseded" with the date and document superseded by, signed and dated (if the date marked is different to the date superseded).

12.4Quality Assurance

Quality Assurance (QA) in research at an NHS trust involves a variety of activities to ensure the highest quality of clinical trials and their data:

A. Compliance

Local, national and international guidance, as well as regulatory and legislative requirements must be adhered to. This includes following Good Clinical Practice (GCP) principles and study- specific Standard Operating Procedures (SOPs).

B. Monitoring

Research hosted or sponsored by a trust may be subject to audit and monitoring procedures. The frequency and method of these procedures is determined by a risk graded assessment.

C. Research team

All in the research team will be responsible for overseeing the entire research process, including patient safety, data quality and research integrity. This may involve reviewing and processing Serious Adverse events (SAEs), maintaining and overseeing documentation processes such as CRF completion, the archiving process and conducting audits.

13 Legislation, References, local Policies and Guidelines

No References

Dorset County Hospital NHS Foundation Trust

Appendix 1

EQUALITY IMPACT AND COMPLIANCE ASSESSMENT

1. General	
Title of Document	Research Study Maintenance and Amendments
Purpose of Document	Provision of a structured and standardised approach to managing and documenting ongoing research studies
Intended Scope	Outlines procedures for maintaining and organising study documentation and describes the process for implementing protocol amendments

2. Consultation	
Which groups/ associations/ bodies or individuals were consulted in the formulation of this document?	Circulated for review and comment by the Research Project Management Team prior to approval with the leadership and Quality group
What was the impact of any feedback on the document?	Feedback was considered and incorporated into the final document as appropriate
Who was involved in the approval of the final document?	The Research Quality Group
Any other comments to record?	None

3. Equality Impact Assessment/Analysis		
Reference: who it may impact		
Age **Disability** **Ethnicity** **Gender reassignment** **Marriage/ Civil Partnership** **Pregnancy/ Maternity** **Religion and Belief** **Sex** **Sexual Orientation**	**Patients** **Members of the local community** **Voluntary Sector Groups**	**Staff Groups** **Volunteers**

ED&I Considerations: (Access, Communications, Service delivery, Cultural competence).	
Does the document positively or negatively affect certain staff or groups of staff? If so, please state how this is justified.	No
Does the document positively or negatively affect certain patients or groups of patients? Please state how this is justified.	No
What measures are proposed to address any inequity?	Assessed at project level
Can the document be made available in alternative format or in translation?	No due to cost restrictions

4. Compliance Assessment	
Does the document comply with relevant employment/ equality legislation or Trust standards? Please specify.	Yes

5. Document assessed by:

Name	Anthony Homer
Post Title/ Position	Research Governance and Quality Lead
Date	22/04/2025

Appendix 2

Data Protection Impact Assessment (DPIA) Screening Questions

These screening questions should be used to inform whether a full DPIA is necessary - if you are uncertain, please talk to information.governance@dchft.nhs.uk. See the last page for information about why we must do this.

Please complete all sections

Title of Project	Research Study Maintenance and Amendments
Brief description	To provide a structured and standardised approach to managing and documenting any changes or updates to an ongoing research study. This SOP will ensure that all modifications are systemically reviewed, approved and implemented.
Completed by:	
Name	Anthony Homer
Title	Research Governance and Quality Lead
Department	Research
Email	Anthony.homer@dchft.nhs.uk
Date	22/04/2025

		Yes	No	Unknown
1.	Will the project involve the collection of new, person identifiable information[1], or potentially identifiable information, about individuals (patients and/or staff)?		☑	
2.	Will the project compel individuals to provide information about themselves, or involve the processing of personal data not obtained directly from the individual? *i.e., where they will have little awareness or choice, or it is impossible, or would involve disproportionate effort to inform the individuals that the processing is taking place.*		☑	
3.	Will identifiable information about individuals be shared with other organisations or people who have not previously had routine access to the information?		☑	
4.	Are you using information about individuals for a purpose it is not currently used for? *i.e., using data collected to provide care for an evaluation of service development, or data matching from multiple sources.*		☑	
5.	Where information about individuals is being used, would this be likely to raise privacy concerns or expectations? *i.e., will it include health records, criminal records, or other information that people may consider to be sensitive** and private, and may cause them concern or distress.*		☑	

1

6.	Will the project require you to contact individuals in ways which they may find intrusive? *i.e., telephoning or emailing them without their prior consent.*		☑	
7.	Will the project result in you making decisions in ways which could have a significant impact on individuals? *i.e., will it affect the care a person receives?*		☑	
8.	Does the project involve you using new technology which might be perceived as being privacy intrusive? *i.e., using biometrics, facial recognition, artificial intelligence, or automated decision making.*		☑	
9.	Is a service being transferred to a new supplier (re-contracted) and the end of an existing contract, or is the processing of identifiable/potentially identifiable data being moved to a new organisation?		☑	
10.	Will the project involve systematic monitoring of a publicly accessible area on a large scale? *i.e., use of CCTV.*		☑	
11.	Will the project involve the targeting of children or other vulnerable individuals? *i.e., for marketing purposes, profiling or other automated decision making*		☑	
12.	Will designated staff need approved access to this information, either by team membership or individual log-in? *i.e., shared file access, separate software username and password, information asset*		☑	
13.	What is the lawful basis for using this data? *√ all that apply*			
	A. Article 6(1)(e) - Public Task (direct healthcare)			
	B. Article 9(2)(h) (the processing is necessary for health or social care purposes)			
	C. Consent			☑
	D. Unknown			

- If all answers are **NO** then please file this with your project files to document that you have considered any possible risk to data.
- If any are **YES** or **UNKNOWN** please forward this document for review and next steps to informationgovernance@dchft.nhs.uk

OUTCOME

☑No Risk to data, or No data – file locally

Risk to data – forward to informationgovernance@dchft.nhs.uk

- ☐ Low Risk - approved by IG – file locally
- ☐ High Risk – complete full DPIA template and submit to IG

Name of Information Asset Owner: Anthony Homer

Name of Information Asset Administrator: Amy Thomson

Signed by Project Lead Date: 22.04.2025

Signed by Information Governance Date:
(if appropriate)