

Research and Development SOP002 – Monitoring Studies Sponsored by RCHT

V1.0

September 2025

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Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation.

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

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

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

1. Introduction

- 1.1. The Medicines for Human Use (Clinical Trials) Regulations 2004 (“the Clinical Trials Regulations”) as amended by the Medicines in Human Use (Clinical Trials) (Amendment) Regulations 2025 (referred to as the “amended Clinical Trials Regulations”), Part 12, Section 37 states “Clinical trials must be conducted in accordance with the principles of good clinical practice set out in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice, as amended from time to time”
<https://www.legislation.gov.uk/ukxi/2025/538/regulation/37>
- 1.2. International Council for Harmonisation (ICH) Good Clinical Practice (GCP) E6 (R3) Guideline, paragraph 3.11 states ‘The sponsor is responsible for establishing, implementing and maintaining appropriate quality assurance and quality control processes and documented procedures to ensure that trials are conducted, and data are generated, recorded and reported in compliance with the protocol, GCP and the applicable regulatory requirement(s).’
https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf
- 1.3. ICH GCP E6 (R3) Guideline paragraph 3.11.4 state ‘The aim of monitoring is to ensure the participants’ rights, safety and well-being and the reliability of trial results as the trial progresses. Monitoring is one of the principal quality control activities.’
https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf
- 1.4. The National Institute for Health and Care Research (NIHR) Clinical Trials Toolkit trial planning phase emphasises that ‘Appropriate planning before the trial and adequate oversight and monitoring during the trial will help ensure trial subject safety is maintained throughout the trial and there is accurate reporting of results at its conclusion’. <https://www.ct-toolkit.ac.uk/routemap/trial-management-and-monitoring>
- 1.5. Monitoring is a quality control function designed to ensure that a clinical trial or study is run to a high standard and that all trial or study related activities are fulfilled. It is the act of overseeing the progress of a clinical trial or study, ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).
- 1.6. **Scope**
 - 1.6.1. This Standard Operating Procedure (SOP) applies to clinical trials and studies sponsored by the Royal Cornwall Hospitals NHS Trust (RCHT), that have a requirement for monitoring.
 - 1.6.2. This SOP is designed to be used by the members of the RCHT Research and Development (R and D) Governance Team or their designated monitors and the study teams, whether internal or external, who are delivering RCHT sponsored research.

1.7. Definitions and Glossary

- 1.7.1. **Good Clinical Practice (GCP)** is an international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials that provides assurance that the rights, safety and well-being of trial participants are protected and that the data and reported results are credible and accurate.
- 1.7.2. **Medicines and Healthcare products Regulatory Agency (MHRA)** is the executive agency of the Department of Health and Social Care in the UK which is responsible for regulating the use of medicines, medical devices and blood components for transfusion in the UK.
- 1.7.3. **International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, Good Clinical Practice (GCP or ICH GCP)** is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve human participants.
- 1.7.4. **Research Ethics Committee (REC)** is a group of people appointed to review research proposals to formally assess whether the research is ethical. This means the research must conform to recognised ethical standards, which includes respecting the dignity, rights, safety and well-being of the people who take part.
- 1.7.5. **Sponsor** is an individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial. A group of individuals and/or organisations may take on sponsorship responsibilities and distribute them by agreement among the members of the group, provided that, collectively, they make arrangements to allocate all the responsibilities that are relevant to the study in line with the UK Policy Framework for Health and Social Care Research.
- 1.7.6. **Chief Investigator (CI)** is the authorised health care professional who takes primary responsibility for the conduct of the study. The CI must be a senior individual, with appropriate experience, expertise, and training to undertake the design, conduct and analysis of the study to meet the requirements set out in legislation.

They must also lead and manage others who have been delegated responsibilities as part of the research project.
- 1.7.7. **Principal Investigator (PI)** is the person who takes responsibility for the initiation and conduct of the study at site. There is one Principal Investigator at each site participating in a research study. For a single site study, the Chief Investigator (CI) may also take on the role of Principal Investigator (PI).
- 1.7.8. **Sponsored studies** are studies for which RCHT has ultimate responsibility for the initiation, management and financing. RCHT R and D takes responsibility for ensuring that the design of the study meets

relevant standards and that arrangements are in place to ensure appropriate conduct and reporting.

- 1.7.9. **Trial Master File (TMF)** is the collection of 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.
- 1.7.10. **Investigator Site File (ISF)** contains the essential documents which show that the investigator and the conduct of the study are following the regulatory requirements.
- 1.7.11. **Monitoring** is the act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).
- 1.7.12. **Monitoring Report** is a written report from the monitor after each site visit and/or other trial or study-related communication in line with the requirements of this SOP.
- 1.7.13. **Corrective and Preventative Action (CAPA)** is a systematic approach to identifying, addressing, and preventing issues or non-compliance that may arise during the conduct of a clinical trial or study.
- 1.7.14. **Non-compliance** is non-adherence to trial or study-related requirements, GCP and all applicable regulatory requirements. A non-compliance may be categorised as a deviation, violation or serious breach.
- 1.7.15. **Standard Operating Procedure (SOP)** is a procedure document detailing a specific sequence of events that must be followed for an activity.
- 1.7.16. **Source documentation** is defined as the original documents, data and records which provide information of clinical findings, observations, and any activities in a clinical study necessary for the reconstruction and evaluation of the study.
- 1.7.17. **EDGE** is a dedicated, web-based research database which is used within, and managed by, the R and D Department at RCHT. EDGE maintains a robust audit trail to meet MHRA inspection expectations.
- 1.7.18. **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 in EDGE.
- 1.7.19. **Acronyms**
 - **CAPA:** Corrective and Preventative Action.
 - **CI:** Chief Investigator.

- **EHR:** Electronic Health Records
- **GCP:** Good Clinical Practice.
- **ICH GCP:** International Council for Harmonisation (ICH) of Good Clinical Practice (GCP)
- **ISF:** Investigator Site File.
- **MHRA:** Medicines and Healthcare products Regulatory Agency.
- **PI:** Principal Investigator.
- **QMS:** Quality Management System.
- **QA:** Quality Assurance.
- **QC:** Quality Checks.
- **R and D:** Research and Development.
- **RCHT:** Royal Cornwall Hospitals NHS Trust.
- **REC:** Research Ethics Committee.
- **SMT:** Senior Management Team.
- **SOC:** Sponsorship Oversight Committee.
- **TMF:** Trial Master File.

2. Purpose of this Standard Operating Procedure

This Standard Operating Procedure (SOP) describes the procedures for carrying out risk-based monitoring activities of clinical trials and studies sponsored by the Royal Cornwall Hospitals NHS Trust (RCHT). It describes the process of preparing, conducting and reporting monitoring activities.

3. Ownership and Responsibilities

3.1. Role of the R and D Director

The R and D Clinical Director is responsible for:

- Having oversight of the implementation of robust arrangements to ensure staff follow the processes described in Section 4, Standards and Practice.
- Gaining assurance from the Senior Management Team (SMT) to ensure compliance with the processes outlined in Section 4, Standards and Practice.

3.2. Role of the Senior Management Team (SMT)

The SMT is responsible for:

- Providing assurance to the R and D Clinical Director of the compliance with the processes outlined in Section 4, Standards and Practice.
- Ensuring adequate provision of training for staff to perform their roles and responsibilities in association with the processes described in Section 4, Standards and Practice.
- Gaining assurance from the Research Governance Manager of the delivery of the monitoring plan via the monthly Governance and Performance SMT meetings.
- Ensuring episodes of non-compliance of the systems and processes described in Section 4 are processed in accordance with R and D SOP004 Reporting and Managing Non-Compliance and Serious Breaches (See Documents Folder on EDGE).

3.3. Role of the Sponsorship Oversight Committee (SOC)

The SOC is responsible for:

- Having oversight of the monitoring plan, ensuring sponsored studies are monitored in line with the risks identified in the risk assessment for the study or trial.
- Arranging monitoring of RCHT sponsored studies, as required in the monitoring plan or when triggered by an event or concern.
- Supporting the CI/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 SOP004 Reporting and Managing Non-Compliance and Serious Breaches (See Documents Folder in EDGE).

3.4. Role of the Research Governance Manager

The Research Governance Manager is responsible for:

- Developing and managing a monitoring plan for each RCHT sponsored study or trial, in line with the risks identified in the risk assessment for that study or trial.
- Identifying staff with the appropriate skills and experience to conduct the monitoring visits, in line with the monitoring plan.
- Identifying training needs for the monitors and providing support to help them undertake their duties.

- Carrying out quality checks of the monitoring reports, ensuring quality and consistency of the procedures described in Section 4.
- Providing support to help all staff involved in the conduct of RCHT sponsored studies, to undertake their delegated duties in accordance with the principles of GCP.
- Ensuring episodes of non-compliance associated with the standards and practice described in Section 4 are processed in accordance with the R and D SOP004 Reporting and Managing Non-Compliance and Serious Breaches (See Documents Folder in EDGE).

3.5. Role of the Monitor

The monitor is responsible for:

- Providing assurance that the rights and safety of participants are protected throughout the clinical trial or study.
- Conducting monitoring visits of sponsored trials or studies, to provide assurance that they have been conducted in accordance with the relevant protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).
- Verifying that reported data is accurate, complete and verifiable against source documents.
- Producing a monitoring report and disseminating to the CI, PI and study team. The monitoring report should include timeframes for the resolution of the findings and Corrective and Preventative Action(s) (CAPA(s)).
- Documenting findings and communicating with the Sponsorship Oversight Committee (SOC) regarding any deviations, non-compliance and other concerns about the conduct of the study or trial, ensuring oversight of studies sponsored by RCHT.
- Supporting the Research Governance Manager by reviewing and maintaining a monitoring plan for RCHT sponsored studies, ensuring monitoring activities are conducted in line with the risks identified for the studies.
- Identifying any training requirements to ensure they have the appropriate skills and knowledge to conduct monitoring visits.
- Ensuring episodes of non-compliance of the systems and processes described in Section 4 are processed in accordance with R and D SOP004 Reporting and Managing Non-Compliance and Serious Breaches (See Documents Folder in EDGE).

3.6. Role of the Sponsorship Office

The Sponsorship Office is responsible for:

- Supporting the CI to fulfil the duties, responsibilities, and obligations in

executing the processes described in Section 4, Standards and Practice.

- Providing support to help all staff involved in the study to undertake their delegated duties in accordance with the principles of GCP.
- Ensuring all monitoring reports are filed in the Trial Master File (TMF).
- Ensuring episodes of non-compliance of the systems and processes described in Section 4 are processed in accordance with R and D SOP004 Reporting and Managing Non-Compliance and Serious Breaches (See Documents Folder in EDGE).

3.7. Role of the Chief Investigator (CI)

The CI is the overall lead researcher for the clinical trial or study. In addition to their responsibilities if they are members of a research team, CIs are responsible for the overall conduct of the clinical trial or study. The CI may delegate tasks; however, they retain primary responsibility for the conduct of the study or trial at all sites.

The CI is responsible for:

- Having oversight of the monitoring plan, ensuring the study or trial is monitored in line with the risks identified in the risk assessment. The CI should review and sign-off both the risk assessment and monitoring plan.
- Acting as the contact point for monitoring feedback and having CI oversight of all outstanding actions documented in the monitoring reports, providing support where needed with closing actions at RCHT and other sites, as appropriate.
- 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 episodes of non-compliance of the systems and processes described in Section 4 are processed in accordance with R and D SOP004 Reporting and Managing Non-Compliance and Serious Breaches (See Documents Folder in EDGE).

3.8. Role of the Principal Investigator (PI)

The PI is responsible for:

- Ensuring the conduct of the study is compliant with the study or trial specific protocol, the applicable regulatory requirements and adheres to the principles of Good Clinical Practice (GCP).
- Ensuring that all staff carrying out delegated duties are familiar with all aspects of the study, described in the latest version of the protocol, as approved by the sponsor, Health Research Authority (HRA), Research Ethics Committee (REC) and where applicable the Medicines and Healthcare products Regulatory Agency (MHRA).

- Supporting monitors with access to the study files and documentation, relevant to the study or clinical trial being reviewed.
- Gaining assurance that any monitoring findings and actions in the Corrective and Preventative Action(s) (CAPA(s)) are actioned and resolved, in line with the timeframes agreed in the monitoring report.
- Ensuring episodes of non-compliance of the systems and processes described in Section 4 are processed in accordance with R and D SOP004 Reporting and Managing Non-Compliance and Serious Breaches (See Documents Folder in EDGE).

3.9. Role of the Study Team

The Study Team is responsible for:

- Supporting the PI to fulfil the duties, responsibilities, and obligations in executing the processes described in Section 4, Standards and Practice.
- Ensuring the fulfilment of the duties delegated by the PI regarding the standards and processes described in Section 4.
- Providing monitors with access to the study files and documentation, relevant to the study or clinical trial being reviewed
- Supporting the PI with investigating episodes of non-compliance with the standards and processes in accordance with R and D SOP004 Reporting and Managing Non-Compliance and Serious Breaches (See Documents Folder in EDGE).

4. Standards and Practice

4.1. Monitoring Overview

- 4.1.1. Monitoring is defined as ‘the act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).’ <https://ichgcp.net/1-glossary>
- 4.1.2. Monitoring is an ongoing integral part of quality control activities, fulfilling the role as the sponsor to have oversight of the conduct of the trial or study.
- 4.1.3. Monitoring may include on site or remote monitoring, depending on the monitoring strategy and the design of the clinical trial or study.

4.2. Monitoring Methods and types of monitoring

- 4.2.1. On-site monitoring is when the visit is performed at the sites where the research is being conducted, via a physical visit to the site by appropriately trained staff. Source data verification and other activities which require access to site documentation should be undertaken on

site, wherever possible.

- 4.2.2. Remote monitoring refers to the use of technology to monitor research activities, collect data and analyse results without the need for a face-to-face meeting. Methods for remote monitoring can include approved and validated online platforms, phone calls, video conferencing and emails.
- 4.2.3. Monitoring activities for a study are decided based on the study risk assessment and are put in place to mitigate any foreseen risks. Appendix 3 details the different types of monitoring.

4.3. Monitoring Strategies

- 4.3.1. Monitoring strategies should take a proportionate and risk-based approach to the management and monitoring of a study. Monitoring should focus on the aspects of the study that impact participant safety and the integrity of the data. The MHRA GCP guidance provides recommendations for risk assessment and monitoring approach, including the suggested monitoring activities before, during and at the end of the trials. (Refer to MHRA GCP Guidance Section 7.3.1)
- 4.3.2. Risk-based adaptations can be incorporated to build flexibility into the monitoring strategy. Monitoring activities may change during the lifecycle of the study or trial, for example there may be high intensity activity at the start of the study or trial and activity may decrease as the study or trial progresses, and compliance is evidenced.

4.4. Monitoring Plan

- 4.4.1. Monitoring method, frequency, focus and intensity of the monitoring activities for a study or trial will be based on factors identified in the risk assessment and any proposed control measures. Studies assessed as very low or low risk may not be monitored. Monitoring activities will focus on the studies assessed as moderate or high risk.
- 4.4.2. The monitoring plan describes the agreed monitoring activities that will take place and specifies the documentation and data to be reviewed, during the lifetime of the study. Monitoring activities for a study are decided based on the study risk assessment and are put in place to mitigate any foreseen risks.
- 4.4.3. Monitoring plans should be documented using R and D AD43 Monitoring Plan for Sponsored Studies (available in the Documents folder on EDGE). The Monitoring Plan should be reviewed by the Chief Investigator (CI) and a copy retained in the Trial Master File (TMF).

4.5. Preparing for Monitoring

- 4.5.1. A monitor will be identified and assigned by the Research Governance Manager. Monitoring visits should be conducted in line with the monitoring plan for the study.
- 4.5.2. Prior to the monitoring visit, the monitor should familiarise themselves with the study to be monitored, ensuring they have a full understanding

of the relevant versions of protocol and study documents in use, all the study procedures, monitoring plan, risk assessment, GCP and any relevant regulatory requirements.

- 4.5.3. The monitor will review previous monitoring activities and relevant site correspondence to identify issues requiring follow-up or resolution during the monitoring visit.
- 4.5.4. The monitor should identify any participant records that need to be requested or accessed for monitoring. If participant records need to be randomly sampled for source data verification (SDV), the randomisation process does not need to be formal, however the participant selection must be made by the monitor, not the researcher.

4.6. Arranging the Monitoring Visit

- 4.6.1. The monitor will arrange the monitoring visit with the study team, giving adequate notice, and identify any attendance requirements. Usually at least one member of the core study team will be required to be available for an onsite monitoring visit.
- 4.6.2. For onsite visits the monitor and study team should identify an appropriate working space for the monitoring to take place.
- 4.6.3. The monitor should advise the study team of any medical notes, other study documentation or electronic systems access that will be required. Sufficient time should be allowed for the retrieval of medical notes. It will be the responsibility of the study team to ensure all requested documentation is made available for the monitoring visit.

4.7. Conducting the Monitoring Visit

- 4.7.1. During an onsite visit, the monitor will record their name, signature, the date and nature of the monitoring visit on the study R and D AD03 Monitoring and Audit Visit Log and ensure that an appropriate member of the study team also signs the log. The Monitoring and Audit Visit Log should be filed in the Investigator Site File (ISF).
- 4.7.2. The monitor will complete a monitoring form to evaluate and record the conduct and delivery of the study to date.
- 4.7.3. The monitor will verify that outstanding issues from any previous visits are addressed, documented and followed to resolution.
- 4.7.4. At the end of the monitoring visit the monitor will discuss any findings and expected next steps with the PI and/or study delivery team.
- 4.7.5. If non-compliance is identified, this will be recorded in the monitoring report and the monitor should ensure that appropriate corrective and preventative action(s) (CAPA(s)) are put in place, as required.

4.8. Remote Monitoring

- 4.8.1. Remote direct access to the electronic health records (EHR) of trial or study participants may be undertaken by the monitor by logging into

the EHR system remotely rather than onsite or via video calls. The decision to provide remote login access to the EHR will depend on the policies for the site.

- 4.8.2. If required, the monitor may meet virtually with the study team via telephone, Microsoft Teams or equivalent video-conferencing software. Identifiable participant records should not be shared or discussed using video-conference software. Redacted documentation can be shown on webcam for the monitor to review during these meetings. Screen shots must not be taken by the monitor in any circumstances.

4.9. Documenting the Monitoring Visit

- 4.9.1. All monitoring visits should be documented as evidence of study oversight. Monitoring activities will be documented in a manner appropriate to the nature of the monitoring visit and monitoring plan. Refer to R and D AD05 Sponsored Studies Monitoring Report Form (See Documents folder in EDGE).
- 4.9.2. Monitoring reports should make clear the nature of the monitoring activity, the personnel present, what was monitored, any findings and any required CAPA.
- 4.9.3. The monitoring visit will be reported promptly to the CI, PI and study team. Where possible, this should be sent within 10 working days of the visit taking place. The monitoring report will outline the timeframe for the resolution of findings and CAPA, as appropriate.
- 4.9.4. Monitoring findings may be categorised as deviations, breaches or serious breaches as per the definitions for non-compliance described in R and D SOP004 Reporting and Managing Non-Compliance and Serious Breaches (See Documents Folder in EDGE). In accordance with the SOP, all appropriate actions should be taken for all reported non-compliance and serious breaches.
- 4.9.5. Monitoring activities and a summary of any findings will be presented at the RCHT R and D Sponsorship Oversight Committee (SOC) meeting, to ensure the wider department is aware of all monitoring activity taking place. Any learning from the monitoring visits will be reviewed by SOC and actions taken as appropriate.
- 4.9.6. All monitoring documentation must be filed in the Trial Master File (TMF) held by the RCHT Sponsorship Team and the Investigator Site File (ISF) held by site visited by the monitor.

4.10. Monitoring Follow Up

- 4.10.1. The monitor and study team are both responsible for tracking the resolution of any monitoring findings and actions in the CAPA. Timeframes should be described in the monitoring report and the CAPA, as appropriate.
- 4.10.2. The timeframes for the resolution of findings and CAPA will consider the seriousness, and the risks associated with the non-compliance.

- 4.10.3. The study team must inform the monitor of steps taken to resolve any findings and actions in the CAPA, as appropriate. When the CAPA(s) have reached a resolution, the details should be documented and filed in the ISF and TMF.

5. Dissemination and Implementation

- 5.1. Trust-wide R and D procedural documents will be stored on the Trust's Document Library, and a working copy will be accessible through EDGE providing alternative access for research staff.
- 5.2. The Research Governance Manager will arrange for the documents to be sent to the EDGE Data Officer to publish a copy onto the EDGE system.
- 5.3. The EDGE Data Officer will record the date and version on the version control sheet in the sub-folder, storing the procedural document on the General Documents folder on EDGE. The EDGE Data Officer will ensure that any previous versions of the document are made inaccessible to general EDGE users, in accordance with the EDGE document archiving procedure (see SOP001 Preparation, Approval and Review of SOPs/WIs).
- 5.4. Relevant research staff registered on EDGE will be notified by email of the new or reviewed document. Relevant staff will be identified from the ownership and responsibilities (Section 3) of this procedural document and the R and D Training Matrix (R and D AD 19).
- 5.5. Details of how to access EDGE is available by contacting the EDGE Data Officer via rch-tr.edge@nhs.net.
- 5.6. It is the responsibility of all staff to check the website regularly, in order to see if SOPs have been added or amended. R and D will endeavour to notify research staff of any SOP developments that may be relevant to them via staff communications e.g., R and D Newsletters, Leadership Huddle and Workstream Huddles. A list of any new or updated SOPs will be reviewed and ratified at the R and D Senior Management Team Governance and Performance monthly meetings.
- 5.7. Consideration must be given during study set up as to which SOPs will not apply to a specific study, with agreement from SMT. Full details must be included as a written statement in the study site file.
- 5.8. R and D SMT to define any training requirements prior to the implementation of any procedural documentation. There will be appropriate time allowed for such training prior to the publishing of the SOP/WI.
- 5.9. Whilst SOPs may be printed, the electronic version maintained on the R and D internet page is the controlled copy. Any printed copies are not controlled documents.
- 5.10. Chief and Principal Investigators will be notified of new and forthcoming SOPs via email.

5.11. Training and Education

- When a new SOP is authorised, or when an existing SOP is revised, self-directed training as specified and detailed by the SMT must be carried out by all staff to whom the SOP is relevant, and this training documented in their training record.
- Staff should take time to read and fully understand the SOP and relevant documents, ensuring that they are able to implement the SOP as required. If clarification is needed, the staff member should approach the Research Governance Manager, or another member of the SMT, who will arrange additional training. All staff are responsible for maintaining their own training logs and copies must be made available to study monitors on request.
- Additional information is available by contacting the EDGE Data Officer via rch-tr.edge@nhs.net.

5.12. SOP Deviations

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

6. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Successful implementation of the procedures described in this SOP ensures that there is a clear understanding of the roles and responsibilities and associated training requirements for staff conducting research studies and clinical trials.
Lead	Research Governance Manager
Tool	Internal auditing of sponsored the monitoring of research studies and clinical trials will provide assurance for 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 SMT Governance Meetings.
Reporting arrangements	The Research Governance Manager will provide monthly reports to the R and D Governance SMT.
Acting on recommendations and Lead(s)	The R and D Governance SMT will provide effective oversight and corrective actions.

Information Category	Detail of process and methodology for monitoring compliance
Change in practice and lessons to be shared	The R and D Governance SMT will identify non-compliance and appoint a member of the SMT to provide support and advice to identify training needs and improve practice. Required changes to practice will be implemented as soon as practically possible.

7. Updating and Review

This R and D procedural document will be reviewed no less than every three years by the R and D SMT unless an earlier review is required and in accordance with Section 9 of the Trust Policy for the Development and Management of Knowledge, Procedural and Web Documents (The Policy on Policies).

8. Equality and Diversity

8.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the [Equality Diversity And Inclusion Policy](#) or the [Equality and Diversity website](#).

8.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Research and Development SOP002 – Monitoring Studies Sponsored by RCHT V1.0
This document replaces (exact title of previous version):	New document.
Date Issued / Approved:	August 2025.
Date Valid From:	September 2025.
Date Valid To:	September 2028.
Author / Owner:	Caroline Phillips – Research Governance Manager.
Contact details:	rcht.researchqualityassurance@nhs.net
Brief summary of contents:	This Standard Operating Procedure (SOP) describes the procedures for carrying out risk-based monitoring activities of clinical trials and studies sponsored by the Royal Cornwall Hospitals NHS Trust (RCHT). It describes the process of preparing, conducting and reporting monitoring activities.
Suggested Keywords:	Standard Operational Procedure (SOP). Research and Development (R and D). Good Clinical Practice (GCP). Quality Management System (QMS). Quality Assurance (QA.) Quality Checks (QC). Non-compliance.
Target Audience:	RCHT: Yes CFT: No CIOB ICB: No
Executive Director responsible for Policy:	Director of Research and Development.
Approval route for consultation and ratification:	Research and Development Senior Management Team (SMT).
Manager confirming approval processes:	Bianca Mills, Head of Research and Development.

Information Category	Detailed Information
Name of Governance Lead confirming consultation and ratification:	Caroline Phillips – Research Governance Manager.
Links to key external standards:	Good Clinical Practice for Clinical Trials. https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials
Related Documents:	The Medicines for Human Use (Clinical Trials) Regulations 2004 The Medicines for Human Use (Clinical Trials) Regulations 2004 The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 Internal Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guide for Good Clinical Practice E6 (R3) (6 January 2025) ICH E6(R3) Step4 FinalGuideline 2025 0106.pdf Internal Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guide for Good Clinical Practice Network, Glossary https://ichgcp.net/1-glossary National Institute for Health and Care Research (NIHR) Clinical Trials Toolkit, Trials and Monitoring https://www.ct-toolkit.ac.uk/routemap/trial-management-and-monitoring R and D SOP001 Preparation, Approval and Review of SOPs and WIs. R and D SOP004 Reporting and Managing Non-Compliance and Serious Breaches. R and D AD03 Monitor Log. R and D AD05 Sponsored Studies Monitoring Report Form. R and D AD07 Glossary of Terms. R and D AD19 Training Matrix. R and D AD43 Monitoring Plan for Sponsored Studies.
Training Need Identified:	Yes – Details provided in Section 5.

Information Category	Detailed Information
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
14/08/2025	V1.0	New document. RD and I SOP 10 Audit and Monitoring Standard Operating Procedure V2.0, replaced by new SOPs. - Research and Development SOP002 Monitoring of Research Studies Sponsored by RCHT V1.0. - Research and Development SOP003 Internal Audit Plan V1.0.	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 SOP002 – Monitoring Studies Sponsored by RCHT V1.0
Department and Service Area:	Research and Development.
Is this a new or existing document?	New.
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Caroline Phillips, Research Governance Manager.
Contact details:	rcht.researchqualityassurance@nhs.net 01872 256428

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	This Standard Operating Procedure (SOP) describes the procedures for carrying out risk-based monitoring activities of clinical trials and studies sponsored by the Royal Cornwall Hospitals NHS Trust (RCHT). It describes the process of preparing, conducting and reporting monitoring activities.
2. Policy Objectives	This SOP ensures that R and D processes are consistent with the requirements of the appropriate legislation, Good Clinical Practice and Trust policies.
3. Policy Intended Outcomes	Compliance with the regulatory requirements and Good Clinical Practice (GCP).
4. How will you measure each outcome?	Risk-based internal auditing programme to ensure that research studies are compliant with GCP.
5. Who is intended to benefit from the policy?	All RCHT sponsored research participants. All staff involved in sponsored research in 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: No - Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	Please record specific names of individuals/ groups: Senior Management Team (SMT). Research staff.
6c. What was the outcome of the consultation?	Consultation ensures that R and D understand 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	
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](#)

Appendix 3. Guidance on the different types of monitoring

The different types of monitoring visits would include the following:

1. Site Qualification Visits (SQV) and Site Initiation Visits (SIV)

Potential sites may be identified by contacting investigators who have previous experience in the therapeutic area, recommendations by colleagues, or via publications, professional groups, or research networks.

Each Principal Investigator (PI) must be qualified in education, training, and experience, which is evidenced in the form of a Research CV, and each site must be adequately resourced to properly conduct the study.

Initial contact with a potential new site may be via an 'expression of interest' form. This is usually a brief document containing a short description of the study, participant population, and expectation of site requirements. The Chief Investigator (CI) will conduct a site selection assessment of all potential sites.

Details of any pre-initiation contact to assess site suitability should be documented and any issues raised must be addressed by the CI or delegate. Once information has been collected from the site, the CI should review and make a suitability decision. This process should be documented. If an assessment is deemed unnecessary, particularly if the site staff and facilities are already known to the CI or sponsor, the reason and decision for not performing an assessment must be documented in the Trial Master File (TMF).

The complexity and scope of the assessment should vary depending on the type of study or trial and the location of the sites. If detailed in the monitoring plan, an initiation visit will take place prior to any study activity commencing at site, either as a face-to-face or remote meeting. The visit may cover the follow:

- Overview of the protocol.
- Impact of study procedures on Standard of Care at the site.
- PI training, experience and availability.
- Staff training and experience.
- Recruitment plan, including availability of eligible participants, participant recruitment rate and details of any risks that could impact the recruitment process.
- Logistics of the participant visits throughout the study or trial.
- Informed consent process and if applicable, randomisation.
- Source data and maintenance of source data records and data protection.
- Data collection, including the Case Report Form (CRF) requirements and design.
- Sample processing and handling.

- Investigator Site File (ISF) maintenance.
- Safety reporting.
- Availability and adequacy of the site facilities, equipment and resources to conduct the study.
- Process for discontinuation or withdrawal of participants.
- Applicable SOPs.

2. Centralised Monitoring

Centralised Monitoring is a methodology used in clinical trials or studies to oversee and evaluate the data collected from multiple sites remotely. This approach allows for the identification of potential risks and anomalies in real-time, ensuring participant safety and data integrity are maintained throughout the study or trial.

3. Statistical Monitoring

Statistical monitoring is where the accumulating data, including the clinical data from the CRF or the performance data including the number of data queries, is examined using statistical approaches or modelling across the study or trial.

This method allows for trending and modelling with the aim of identifying any unusual patterns or variances within the data, and if any sites appear to be outliers. Outliers are values at the extreme end of the data sets; these should be investigated to assess whether the variances result from incorrect data entry, equipment malfunctions or other measurement errors.

4. Data Monitoring Committees (DMC) and Data Monitoring Boards (DMB)

A Data Monitoring Committee (DMC) or Data and Safety Monitoring Board (DSMB) is an independent group of experts who monitor participant safety and treatment efficacy data while a clinical trial or study is ongoing.

The DMC or DSMB should convene at predetermined intervals and may review unblinded results. The role of the DMC is to perform interim analyses and provide independent oversight and validation of decisions to continue with a trial. The DMC has the power to recommend termination of the study.

5. Trial Management Group (TMG) and Trial Steering Groups (TSC)

The TMG normally includes those individuals responsible for the day-to-day management of the trial, such as the Chief Investigator, statistician, trial manager, research nurse, data manager. The role of the group is to monitor all aspects of the conduct and progress of the trial, ensure that the protocol is adhered to and take appropriate action to safeguard participants and the quality of the trial itself.

The role of the Trial Steering Committee (TSC) is to provide overall supervision of the trial. Ideally, the TSC should include members who are independent of the investigators, their employing organisations, funders and sponsors. The TSC should monitor trial progress and conduct and advise on scientific credibility. The TSC will consider and act, as appropriate, upon the recommendations of the Data Monitoring

Committee (DMC) or equivalent. The need for a TSC will depend on the complexity of the study and will be identified by the risk assessment.

6. Close Out Monitoring

When a study ends, checks should be made to ensure the study documentation is complete and will be stored securely for the required time period. Close out checks can be carried out by on site or central monitoring.